



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 complicating factor is that most of the seafood consumed in the United States 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 (NMFS) in the Department of Commerce and the Food Safety and Inspection Service in the U.S. Department of Agriculture, also have notable responsibilities.

The Deepwater Horizon oil spill caused state and federal officials to close extensive areas of the Gulf of Mexico to commercial and recreational fishing. As areas have been reopened, concerns have been voiced by some fishermen and consumers regarding the safety of seafood from the Gulf. The FDA and NMFS have been testing areas before reopening them to fishing and no contaminated samples have been found in these areas.

In the 111th Congress, the food safety bills specific to seafood include S. 92 and S. 2934, 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. On July 30, 2009, the House approved H.R. 2749, a revised version of H.R. 759. H.R. 2749 takes a comprehensive approach to food safety, including seafood. On November 30, 2010, the Senate passed S. 510, another comprehensive approach to food safety. The Senate bill includes four provisions specific to seafood that focus on (1) establishing interagency agreements to improve seafood safety; (2) assessing changes to regulations for post-harvest processing of raw oysters; (3) sending inspectors to assess production of seafood imported into the United States; and (4) requiring FDA to update guidelines in *Fish and Fisheries Products Hazards and Controls Guidance* within 180 days.

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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. In 2007, the U.S. Centers for Disease Control and Prevention (CDC) reported 1,097 outbreaks,² which resulted in 21,244 cases of illness.³ Among the 235 outbreaks that could be attributed to a single commodity, seafood (finfish or shellfish) was reported as the cause for 57 outbreaks (24.2% of the total) and 318 illnesses.⁴ In comparison, red meats were reported in 54 outbreaks (23%), and poultry in about 40 outbreaks (17%). To put these data in context, annual U.S. per capita consumption of seafood was about 16 pounds in 2008, compared with 108 pounds for red meats and 73 pounds for poultry.⁵ Therefore, when compared to the consumption levels of beef and poultry, seafood is responsible for a disproportionate number of outbreaks. 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 the cause of most seafood-associated outbreaks in 2007. 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,

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; <http://www.health.gov/dietaryguidelines/default.htm>.

² An outbreak is an incident involving at least two persons (cases).

³ Centers for Disease Control and Prevention, "Surveillance for Foodborne Disease Outbreaks—United States, 2007," press release, August 13, 2010, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5931a1.htm?s_cid=mm5931a1_w.

⁴ Centers for Disease Control and Prevention, "Table 2. Number of reported foodborne disease outbreaks and outbreak-associated illnesses by etiology and food commodity—United States, 2007," press release, August 2010, http://www.cdc.gov/outbreaknet/pdf/2007MMWRSurveillanceOutbreaks_ExpandedTable2_WEB.pdf.

⁵ U.S. Department of Agriculture (USDA), Economic Research Service (ERS), *Food Availability (Per Capita) Data System*, 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.

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*, January 29, 2008, at <http://www.fda.gov/oc/opacom/hottopics/mercury/backgrounder.html>.

and the fact that certain health effects such as cancer develop over a much longer period than microbial illnesses.⁷ Recently concerns have been raised about potential contamination of seafood harvested from the Gulf of Mexico due to the Deepwater Horizon oil spill.

Worldwide, nearly one-half of all seafood consumed as food comes from aquaculture. Aquacultured (farm-raised) seafood also may contain 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 for the “Detention Without Physical Examination” of 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.”⁸ The import alert remains in effect except for firms that have provided evidence demonstrating that their products are free of unapproved animal drugs. As of September 30, 2010, eleven Chinese firms have been exempted from the alert for “Detention Without Physical Examination.”⁹

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 2008 they reached 83%.¹⁰ 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 from GMPs are establishments such as farms, including fish farms, that merely raise and/or harvest a raw commodity.

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

⁸ FDA Import Alert #16-13, January 23, 2008, at http://www.fda.gov/ora/riars/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.

⁹ E-mail communication from Phil Broadbent, FDA, October 20, 2010.

¹⁰ U.S. Department of Commerce, National Oceanic and Atmospheric Administration, *Fishwatch—U.S. Seafood Facts*, at http://www.nmfs.noaa.gov/fishwatch/trade_and_aquaculture.htm

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, find where they are likely to occur during processing, identify control points and how they will be monitored, and determine how hazards will be controlled. Importers of foreign seafood must take steps to verify that the products obtained from foreign processors are in compliance with the HACCP rules.¹¹

As the 2001 GAO report (see 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. The agency recently reported that there are approximately 11,848 domestic seafood processing establishments, and that it had inspected a total of 3,415 in 2007, 3,265 in 2008, and 3,013 in 2009.¹²

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. In FY2007, FDA processed approximately 868,000 entries of imported seafood and performed approximately 14,000 physical examinations.¹³

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.”¹⁴

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 2008.¹⁵ During Phase II, FDA is conducting onsite audits of programs by

¹¹ 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.

¹² E-mail communication from Phil Broadbent, FDA, October 20, 2010.

¹³ Don Kraemer, “Chinese Seafood Imports,” U.S. and China Economic and Security Review Commission, April 25, 2008, at <http://www.fda.gov/NewsEvents/Testimony/ucm115243.htm>.

¹⁴ *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.

¹⁵ “FDA Announces Participants of Pilot Program for Third-Party Certification of Imported Aquacultured Shrimp,” December 2, 2008, press release, March 31, 2009, at <http://www.fda.gov/bbs/topics/NEWS/2008/NEW01919.html>.

accompanying inspectors during certification inspections. FDA would use third parties to augment agency efforts, determine inspection priorities, and adjust “may proceed” rates (i.e., entry without FDA staff review) for imports of aquacultured shrimp or other food products.¹⁶ As of October 2010, FDA was still in the process of evaluating potential use of the pilot program.

NOAA Voluntary Inspection

Within the Department of Commerce, the National Marine Fisheries Service (NMFS) of the National Oceanic and Atmospheric Administration (NOAA) administers the 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. Exporters are often users of these services, in part because of foreign buyer requirements.

In 2009, NOAA reported active seafood inspection contracts with 282 firms and 40 foreign participants. The number of participating firms is a small fraction of all seafood facilities, but they produce a significant portion of the total volume: In 2009, the NOAA voluntary program inspected 1.6 billion pounds or 34% of the total seafood consumed in the United States.¹⁷

In January 2008, the Government Accountability Office (GAO) issued a report on federal oversight of food safety.¹⁸ The report included a recommendation for NOAA and FDA to develop an agreement to use NOAA’s inspection program resources to carry out inspections on FDA’s behalf and to augment FDA’s program for imported seafood with inspection training and product sampling services. On October 26, 2009, NOAA and FDA issued a memorandum of understanding to reinforce the agencies’ cooperative efforts. The agreement formalizes procedures for sharing information and for FDA to consider the results of NOAA inspections when determining the frequency of FDA seafood inspections.

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

¹⁶ 73 *Federal Register* 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 in the 111th Congress: H.R. 2749 and S. 510*.

¹⁷ National Marine Fisheries Service, *Fisheries of the United States, 2009*, Silver Spring, MD, September 2010, p. 83, http://www.st.nmfs.noaa.gov/st1/fus/fus09/fus_2009.pdf.

¹⁸ U.S. Government Accountability Office, *Federal Oversight of Food Safety: FDA’s Food Protection Plan Proposes Positive First Steps, but Capacity to Carry Them Out Is Critical*, GOA-08-435T, January 29, 2008, <http://www.gao.gov/new.items/d08435t.pdf>.

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.¹⁹

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.²⁰ 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.²¹

On October 17, 2009, at the biennial meeting of the ISSC, FDA announced its intention to implement new requirements for post-harvest processing of Gulf of Mexico oysters to reduce the number of illnesses resulting from *Vibrio vulnificus*.²² *V. vulnificus* is a species of pathogenic bacteria found naturally in marine environments. Infections are more likely to occur during warm months, when bacteria counts are higher. *V. vulnificus* causes disease in individuals who eat contaminated oysters that are raw or undercooked. In healthy people, *V. vulnificus* can cause diarrhea, vomiting, and abdominal pain, but usually without long-term consequences. However, in immunocompromised individuals, *V. vulnificus* can invade the bloodstream and cause life-threatening symptoms. According to FDA, 30 severe cases occur each year, with a 50% mortality rate.²³

Since 2001, collaborative efforts of the ISSC to reduce illness associated with *V. vulnificus* have included disseminating educational materials and refrigerating oysters after harvests. However, according to FDA, the program goal of a 60% reduction in severe illnesses and death has not been attained. During the 2009 biennial meeting of the ISSC, FDA announced that the changes to its policy on raw shellfish would be included in the update of *Fish and Fishery Products Hazards*

¹⁹ *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, March 31, 2009, at <http://www.gao.gov/highlights/d09258high.pdf>.

²⁰ 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.

²¹ See FDA, National Shellfish Sanitation Program, *Guide for the Control of Molluscan Shellfish*, 2005, at <http://www.cfsan.fda.gov/~ear/nss3-toc.html>.

²² Michael R. Taylor, “Remarks to the ISSC Biennial Meeting,” Manchester, NH, October 17, 2009, <http://www.fda.gov/NewsEvents/Speeches/ucm187012.htm>.

²³ FDA, “Questions and Answers about the Impact of FDA’s New Policy to Prevent *Vibrio vulnificus* in Gulf Coast Raw, Untreated Oysters,” press release, November 3, 2009, at <http://www.fda.gov/NewsEvents/Speeches/ucm188800.htm>. Hereinafter cited as FDA Questions and Answers 2009.

*and Controls Guidance.*²⁴ FDA would require the application of post-harvest processing (PHP) technologies such as individual quick freezing with frozen storage, high hydrostatic pressure, mild heat, and low-dose gamma irradiation. Although FDA plans to require PHP by the summer of 2011 for oysters harvested during April through October, as of October 2010 FDA had taken no action on this issue.

According to Gulf of Mexico seafood industry representatives, PHP infrastructure is not in place and the PHP requirements would be costly to implement and would threaten jobs.²⁵ The industry estimates that oyster prices could double or triple.²⁶ According to FDA, 40% of Gulf oysters are harvested during the warm months and about half are eaten raw.²⁷ The Gulf Coast oyster industry already subjects about 15% of oysters to PHP methods, and the cost of PHP has been estimated to be three to four cents per oyster.²⁸ Restaurant owners contend that PHP makes oysters less desirable to their customers because it changes the texture and flavor of the oyster. FDA counters that a study of oyster consumers has shown that most cannot recognize the difference between PHP-treated and raw oysters.

Several bills were introduced in response to this controversy, including identical House and Senate versions of the Gulf Oyster Protection Act of 2009 (S. 2735 and H.R. 4022) as well as the Gulf Oyster Industry Jobs Protection Act (S. 2752). All three bills would prohibit the use of federal funds to implement the FDA policy to require PHP. S. 2752 would also require the Secretary of Health and Human Services to conduct an education campaign to increase awareness of the risks associated with consuming raw oysters and to develop analyses for the appropriate committees of Congress when regulation or guidance is proposed that affects the harvesting, processing, or transportation of seafood harvested in the United States. Although no action has been taken on any of these bills, S. 510, a comprehensive food safety bill, has passed the Senate with a section that would require the Secretary of HHS to submit a report to Congress before issuing guidance, regulation, or suggested amendments requiring PHP.

Gulf Oil Spill

On April 20, 2010, the Deepwater Horizon oil drilling platform under contract to BP was destroyed by an explosion and fire and the well began releasing oil into the Gulf of Mexico. On May 2, 2010, NOAA closed oil-affected federal waters of the Gulf of Mexico to commercial and recreational fishing. The closure was implemented to ensure that potentially contaminated seafood would not enter markets and pose a risk to human health. The closure grew to include portions of Louisiana, Mississippi, Alabama, and Florida state waters and, at its maximum, 88,522 square miles, or nearly 37%, of federal waters in the Gulf of Mexico. Since the flow of oil was slowed and eventually stopped in July, significant portions of Louisiana state waters and all of Mississippi, Alabama, and Florida state waters have been re-opened to fishing. As of

²⁴ The fourth edition is currently under development at FDA. The third edition is available at <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/SeafoodHACCP/default.htm>.

²⁵ Chris Kirkham, "Louisiana blasts new FDA rule requiring oysters to be sterilized to prevent rare bacterial illness," *The Times-Picayune*, October 28, 2009, http://www.nola.com/dining/index.ssf/2009/10/louisiana_blasts_fda_plan_to_1.html, hereinafter cited as Kirkham 2009.

²⁶ Kirkham 2009.

²⁷ FDA Questions and Answers 2009.

²⁸ FDA Questions and Answers 2009.

November 19, 2010, 87,481 square miles of federal waters had been re-opened and 1,041 square miles remained closed.²⁹ However, public and fishing industry concerns with the safety of seafood have continued, in part because of the volume of oil that escaped the damaged well and the volume of dispersants used during the oil spill response.

Crude oil and other petroleum products contain a mixture of chemicals, including polycyclic aromatic hydrocarbons (PAHs), that may bio-accumulate³⁰ in the tissues of marine organisms. The level of bio-accumulation depends on a number of factors, including the type of organism, length of exposure, concentration of oil, and the type of oil. The presence of PAHs can make seafood unfit for human consumption because some PAHs are carcinogens. Petroleum products may also cause taint, an oily smell and taste. Tainted seafood is classified as adulterated by the FDA and is not permitted to be sold as food.

Dispersants have a lower potential to bio-accumulate in fish because they can be quickly diluted in water and will likely biodegrade in weeks to months. An FDA memorandum concluded that “the available information indicates that dispersants have little or no effect on the bio-accumulation potential of oil contaminants, nor do they themselves accumulate in seafood.”³¹ Of more than 2,500 water samples analyzed for dispersants, two samples indicated dispersant contamination, and they were not from areas under consideration for re-opening.³² However, some scientists oppose the use of dispersants and have voiced concerns related to the potential effect of dispersants on marine organisms. According to their consensus statement, the use of Corexit dispersants (one of the dispersants used in the Gulf of Mexico) increases the concentration of hydrocarbons in the water column.³³ The statement added that the combination of Corexit and crude oil can increase the toxicity of oil because dispersants may allow dispersed oil to be taken up by organisms more readily. According to a recent National Research Council report, “[i]n many instances where a dispersed plume may come into contact with sensitive water column or benthic organisms or populations, the current understanding of key processes and mechanisms is inadequate to confidently support a decision to apply dispersants.”³⁴ The report’s recommendations included setting priorities for research, such as the need to fund a series of toxicity studies to determine the mechanisms of both acute and sublethal toxicity to organisms from exposure to dispersed oil.

FDA, NOAA, and coastal states have established a protocol to determine when areas may be re-opened to fishing.³⁵ Once areas have been determined to be free of oil from the spill, re-opening may be considered on a species-by-species basis. Seafood samples of the species in question must

²⁹ See <http://sero.nmfs.noaa.gov/ClosureSizeandPercentCoverage.htm>.

³⁰ Bio-accumulation occurs when an animal takes in a substance at a rate that is greater than that at which the substance is lost, resulting in higher concentrations of the substance in the animal’s body than in the surrounding environment.

³¹ Kiros Hailemariam, *Oil Spill Chemical Dispersants*, Department of Health and Human Services, Food and Drug Administration, May 14, 2010.

³² See, <http://www.fda.gov/food/ucm210970.htm#safety>.

³³ Susan D. Shaw, *Consensus Statement*, Maine Environmental Research Institute, Scientists oppose the use of dispersant chemicals in the Gulf of Mexico, July 16, 2010, <http://meriresearch.org/Portals/0/Documents/CONSENSUS%20STATEMENT%20ON%20DISPERSANTS%20IN%20THE%20GULF%20updated%20July%2017.pdf>.

³⁴ National Research Council, *Oil Spill Dispersants*, Efficacy and Effects, Washington, DC, 2005, p. 11.

³⁵ Food and Drug Administration, Overview of Testing Protocol to Re-open Harvest Waters that Were Closed in Response to the Deepwater Horizon Oil Spill, September 2010, at <http://www.fda.gov/Food/ucm217598.htm>.

pass both sensory and chemical analyses to ensure there are no harmful oil residues.³⁶ For sensory testing, edible portions of the species are reviewed by a panel of experts who check for oil and dispersant odor and taste. If all tested samples for a given site pass the sensory test, additional samples undergo chemical analysis to test for PAHs. All seafood samples from the area must pass both tests before an area may be reopened to fishing. FDA and NOAA also have added chemical testing to detect dispersants in seafood.

NOAA has collected samples from federal waters while state personnel have collected samples from state waters. On August 19, 2010, FDA stated the following in congressional testimony: “To date all samples have passed sensory testing for oil or dispersants and, as with the surveillance sampling, the results of all chemical analyses have shown PAH levels well below the levels of concern, usually by a factor of 100 to 1,000 below those levels, essentially at the same level as were seen before the spill.”³⁷ For federal waters re-opened through October 22, 2010, sensory analyses have found no detectable oil or dispersant odors or flavors and results of chemical analyses have been well below levels of concern. Further, NOAA and FDA sampling from commercial landing sites and markets have not found seafood contaminated by oil or dispersants. According to the FDA, “fish and shellfish harvested from areas re-opened or unaffected by the oil spill are considered to be safe to eat.”³⁸

The Supplemental Appropriations Act of 2010 (P.L. 111-212) provides funds for a \$15 million strategic marketing plan and health and safety assurance program for Gulf Coast seafood. This funding responds to the fishery disaster that was declared by the Secretary of Commerce on May 24, 2010, for conditions resulting from the Deepwater Horizon oil spill. BP also has agreed to provide Louisiana with \$18 million over a three-year period for seafood testing.

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.³⁹ 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 asserted jurisdiction over the safety of seafood (and other foods). Others such as the Senate Committee on Commerce, Science, and Transportation, also have had roles.

³⁶ Food and Drug Administration, *Gulf of Mexico Oil Spill: Questions and Answers*, at <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/ucm221563.htm>.

³⁷ U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Energy and Environment, *The BP Oil Spill: Accounting for the Spilled Oil and Ensuring the Safety of Seafood from the Gulf*, 111th Cong., 2nd sess., August 19, 2010.

³⁸ FDA, *Gulf of Mexico Oil Spill Update*, Information current as of September 8, 2010, at <http://www.fda.gov/food/ucm210970.htm>.

³⁹ See CRS Report RL32922, *Meat and Poultry Inspection: Background and Selected Issues*.

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 Secretary of the Department of Health and Human Services to submit a report to Congress that

(1) describes the specifics of the aquaculture and seafood inspection program; (2) describes the feasibility of developing a traceability system for all catfish and seafood products, both domestic and imported, for the purpose of identifying the processing plant of origin of such products; and (3) provides for an assessment of the risks associated with particular contaminants and banned substances.⁴⁰

The report was completed on November 20, 2008. 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.

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 provision applies 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. To date, the Secretary has not used this authority.

FSIS did not meet a December 2009 legislative deadline for implementing final regulations; and as of October 2010 proposed regulations have not yet been published. In 2008, the agency reportedly estimated that it would have needed \$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

⁴⁰ Food and Drug Administration, Department of Health and Human Services, *Enhanced Aquaculture and Seafood Inspection - Report to Congress*, November 20, 2008, <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/SeafoodRegulatoryProgram/ucm150954.htm#intro>.

least 15 foreign countries would have to apply for an FSIS determination that their inspection systems were equivalent to the U.S. safety systems before any of their establishments could ship catfish to the United States.⁴¹

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.

Legislation in the 111th Congress

In the 111th Congress, several food safety bills have been introduced, and comprehensive legislation (H.R. 2749) has passed the House. H.R. 2749 is a revised version of H.R. 759, both introduced by Representative Dingell. The Senate comprehensive bill (S. 510) was introduced by Senator Richard Durbin and reported by the Senate Health, Education, Labor, and Pensions Committee on December 18, 2009. In November the Senate resumed consideration of its bill and on November 30, 2010, S. 510 passed in the Senate.

H.R. 2749 and S. 510 would focus primarily on FDA-regulated foods, including seafood, and would achieve their proposed reforms through the agency's existing structure and authorities. Both bills seek to increase the frequency of inspections, tighten record-keeping requirements, and mandate product recalls. Although H.R. 2749 and S. 510 would impose similar requirements, they would achieve them in different ways. Selected changes proposed by both bills include registration of all facilities; new requirements for record-keeping and for tracing products; mandatory FDA recall authority; authority for the agency to require imports to be certified as to their safety; and a requirement that all facilities have food safety plans that include hazard analyses and risk-based preventive controls.⁴² The Senate HELP Committee also adopted an amendment that would require FDA to update guidelines in *Fish and Fisheries Products Hazards and Controls Guidance* within 180 days.

Three seafood-related provisions have been added to the Senate bill that focus on (1) establishing interagency agreements to improve seafood safety (§ 201); (2) assessing changes to regulations for post-harvest processing of raw oysters (§ 114); and (3) sending inspectors to assess production of seafood imported into the United States (§ 306). The scope of interagency agreements identified in § 201 includes examining and testing seafood; coordinating inspections; standardizing data; modifying existing processes; sharing enforcement and compliance information; and conducting joint training and outreach. Section 114 would require the Secretary of HHS to submit a report to Congress before issuing guidance, regulation, or suggested amendments related to post-harvest processing of oysters. It would also require GAO to review the Secretary's report and report its findings to Congress. These reports would be waived if a consensus agreement is reached among federal and state regulators and the oyster industry, acting through the Interstate Shellfish Sanitation Conference. Section 306 would permit the Secretary of

⁴¹ "Details of USDA catfish inspection plan revealed in 5-page memo," *Food Chemical News*, December 1, 2008.

⁴² The bill states that the new provisions for hazard analysis and risk-based controls, for example, are not to limit the HHS Secretary's authority to revise, issue, or enforce product-specific regulations already in force such as those for seafood HACCP. For more details on H.R. 2749 and S. 510, see CRS Report R40443, *Food Safety in the 111th Congress: H.R. 2749 and S. 510*.

Commerce, in coordination with the Secretary of HHS, to send inspector(s) to a country or facility of an exporter of seafood imported into the United States to assess practices and processes used in farming, cultivation, harvesting, preparation for market, and transportation of seafood. Inspectors also may provide technical assistance related to these activities. Reports would be required for each inspection to provide findings to the country or exporter and for use by the Secretary of HHS.

Another bill that would impact seafood producers and processors, particularly those participating in the NOAA-NMFS program, is H.R. 875, introduced by Representative DeLauro. This 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. At this time, however, it appears that since H.R. 2749 has passed the House, H.R. 875 may not see further House action.

As of November 2010, three bills focusing specifically on seafood safety had been introduced. A measure (S. 92) introduced 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 FFDCFA 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. S. 2934, also introduced by Senator Vitter, would amend the FFDCFA to prohibit seafood imports unless the importing country complies with U.S. standards for seafood manufacturing, processing, and holding. The bill would require annual inspections of foreign facilities and requirements for inspection of seafood entering the United States. It would also establish a program for states to conduct inspection, tests, and certification of U.S. seafood imports. In the House, H.R. 1370, introduced 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, require an increase in the number of 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.

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