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**CITIZEN PETITION**

**I. Introduction**

On behalf of the Center for Science in the Public Interest (CSPI), we submit this petition requesting that the Food and Drug Administration (FDA) establish a microbial testing program for hazards in seafood products. CSPI is a non-profit consumer advocacy and education organization that focuses primarily on food safety and nutrition issues and is supported principally by 800,000 subscribers to its *Nutrition Action Healthletter*.

Many health-conscious Americans consume seafood as part of a balanced diet. Despite its nutritional benefits, seafood also can be a source of foodborne illness. Indeed, between 1990 and 2002 seafood was the leading cause of reported foodborne-illness outbreaks where the hazard and vehicle were known, according to CSPI's outbreak tracking.<sup>1</sup> Seafood poses a unique set of food-safety risks to consumers for a number of reasons: First, it remains largely a wild-

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<sup>1</sup> Caroline Smith DeWaal *et al.*, *Outbreak Alert! Closing the Gaps in Our Federal Food-Safety Net* (Washington, D.C.: Center for Science in the Public Interest) 7 ( rev. 2002) [hereinafter *Outbreak Alert!*].

caught food.<sup>2</sup> Second, there are hundreds of seafood species, some with species-related hazards. Third, imports account for more than half of the seafood consumed in the U.S., but very few inspections of food imports are performed.<sup>3</sup>

In light of the known food-safety risks of seafood products and on the recommendation of the National Academy of Sciences (NAS), the FDA in 1995 promulgated regulations to establish a seafood Hazard Analysis and Critical Control Point (HACCP) program. The regulations were designed to hold seafood firms accountable for identifying the microbial, chemical, and physical hazards that are reasonably likely to occur in their products and for establishing critical control points to reduce or eliminate such contamination.<sup>4</sup>

More than four years have passed since the seafood HACCP regulations went into effect. Although the industry has made progress in implementing HACCP systems, FDA data from 2001 document that a significant number of seafood firms still are not fully implementing adequate HACCP plans.<sup>5</sup> FDA's seafood HACCP program has failed to produce any tangible public-health improvements largely because it lacks effective government oversight and

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<sup>2</sup> However, aquaculture is on the rise in the U.S. and other nations.

<sup>3</sup> General Accounting Office, *Food Safety: Federal Oversight of Seafood Does Not Sufficiently Protect Consumers* (GAO-01-204) 4, 6 (Jan. 2001) [hereinafter *GAO Seafood Report*]. Even with the new resources from the FY2002 bioterrorism supplemental appropriations, the FDA still lacks sufficient resources for inspections of imported foods. See *Hearing on FY 2003 Food and Drug Administration Appropriations Before the Subcommittee on Agriculture, Rural Development, FDA and Related Agencies of the House Committee on Appropriations* (written responses of Lester M. Crawford, Deputy Commissioner).

<sup>4</sup> Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products, 60 Fed. Reg. 65096, 65104, 65117, 65198 (1995) [hereinafter *Seafood HACCP Final Rule*].

<sup>5</sup> Although a recent FDA report indicates that 88 percent of seafood firms were in compliance with the HACCP plan requirement in 2001, this figure includes 31 percent of firms that were not required to have a HACCP plan. Food and Drug Administration, *FDA's Evaluation of the Seafood HACCP Program For Fiscal Years 2000/2001* 7 (2002) [hereinafter *FDA Seafood HACCP Data*]. Moreover, processors of scombroid species and of cold-smoked seafood lag behind other industry segments in HACCP implementation. *FDA Seafood HACCP Data*.

verification, which led the General Accounting Office (GAO) in January 2001 to conclude that the FDA is not sufficiently protecting consumers from unsafe seafood.<sup>6</sup> In response to the GAO report, the agency promised a “mid-course correction” of its seafood HACCP program.<sup>7</sup> To date that promise remains unfulfilled.<sup>8</sup>

## II. Action Requested

We request that the FDA develop and implement a program to test raw and ready-to-eat seafood for hazards related to harvest and those related to post-harvest handling and processing. Tests would be performed in processing plants, at retail, and at ports-of-entry. Such testing would verify the ability of each seafood firm to control hazards in its products and would help to assess the effectiveness of the seafood HACCP program as a whole.

Specifically, we ask the agency to design a mandatory government testing program for the following hazard/product combinations:

1. The presence of *Listeria monocytogenes* in ready-to-eat finfish and shellfish;
2. The levels of ciguatera in tropical and sub-tropical reef fish;<sup>9</sup>
3. The levels of methylmercury in large predatory finfish;

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<sup>6</sup> *GAO Seafood Safety Report*.

<sup>7</sup> Food and Drug Administration, *FDA’s Seafood HACCP Program: Mid-Course Correction* (Feb. 13, 2001), available at <<http://www.cfsan.fda.gov/~comm/shaccp1.html>>.

<sup>8</sup> While the government does conduct some sampling of seafood products, there is no comprehensive testing program of the size and scope necessary to verify that HACCP plans are adequately controlling the hazards reasonably likely to occur. The FDA’s guidance for seafood inspectors states: “A limited number of HACCP verification samples will be collected. They will be used as a means of judging the overall effectiveness of the HACCP system.” Food and Drug Administration, *Food Compliance Program Guidance Manual, Domestic Fish and Fishery Products*, available at <<http://www.cfsan.fda.gov/~comm/cp03842.html>> [hereinafter *FDA Guidance*].

<sup>9</sup> Although the Food and Drug Administration’s Bacteriological Analysis Manual does not include methods for detecting ciguatera, ciguatoxin detection tests are being marketed. See, e.g., information on the Cigua-Check® test kits at <<http://www.cigua.com>>.

4. The presence of *Vibrio* species in raw shellfish;
5. The levels of histamines in raw and ready-to-eat scombroid finfish; and
6. The levels of coliforms in all other raw (non-scombroid, non-tropical or sub-tropical reef) finfish.

As discussed in Section B, below, the FDA has the legal authority to test for each of these hazards in seafood products pursuant to the Federal Food, Drug, and Cosmetic Act's (FDCA)<sup>10</sup> adulteration standards.

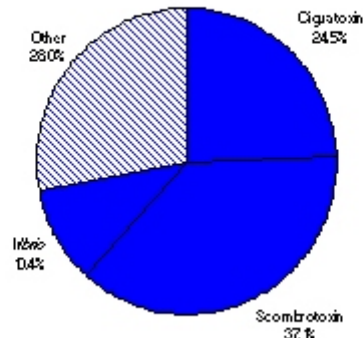
### III. Statement of Grounds For Petition

#### A. Factual Grounds

##### 1. Contaminated Seafood Is A Critical Public-Health Problem.

Tainted seafood is a significant cause of foodborne illness in the United States. CSPI has documented 539 seafood outbreaks with a known etiology that occurred between 1990 and 2002.<sup>11</sup> Sixty-five percent (351) of the seafood outbreaks and 30

**Seafood Hazards Linked To Outbreaks, 1990-2002**



Source: CSPI's *Outbreak Alert!* 2002

percent (2,035) of the outbreak-related illnesses in CSPI's database were linked to finfish. Shellfish were responsible for just 15 percent (82) of the seafood outbreaks, but 40 percent

<sup>10</sup> 21 U.S.C. §§ 301 *et seq.*

<sup>11</sup> *Outbreak Alert!*, at 8, 18-24.

(2,681) of the illnesses.<sup>12</sup> Taken together, ciguatoxin, scombrototoxin, and *Vibrio* bacteria were responsible for nearly three-quarters of the seafood outbreaks in CSPI's database.

By the FDA's own estimates, seafood causes nearly 114,000 illnesses annually, not counting the illnesses and deaths caused by *Listeria monocytogenes* in ready-to-eat seafood products.<sup>13</sup> The rate of illnesses and outbreaks from seafood products is particularly striking because seafood is consumed far less frequently than other animal proteins.<sup>14</sup> Per capita, American consumers ate 15.2 pounds of fish and shellfish in 2000, while beef consumption, for example, was 64.5 pounds per person, more than four times the amount of seafood consumed.<sup>15</sup>

Significant seafood contamination occurs because of pathogens from three sources: those present in the harvest waters, those related to handling after the seafood is harvested, and those associated with processing.

#### **a. Contamination Related To Harvest Area**

Seafood is subject to a wide range of hazards arising from the harvest area. Two types of harvest-area hazards are of particular public-health concern: ciguatera and methylmercury.

Ciguatera poisoning is caused by consumption of tropical and sub-tropical reef fish that have been contaminated by toxic algae.<sup>16</sup> The FDA has classified ciguatera poisoning as

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<sup>12</sup> *Outbreak Alert!*, at 8, 18-24.

<sup>13</sup> *Seafood HACCP Final Rule*, 60 Fed. Reg. at 65185-65186.

<sup>14</sup> *GAO Seafood Report*, at 7.

<sup>15</sup> Economic Research Service, *Food Consumption (Per Capita) Data System*, available at <http://www.ers.usda.gov/data/foodconsumption> (accessed on July 8, 2002).

<sup>16</sup> Ciguatoxins are produced by dinoflagellates, which are consumed by reef-feeding herbivorous fish. The toxins bioaccumulate as the tainted herbivorous fish are eaten by large predatory reef fish such as barracuda and amberjack. Consumers are sickened by eating either herbivorous or predator fish that contain ciguatoxin.

“perhaps the most significant problem associated with a natural toxin,” in part because this hazard cannot be cooked out of tainted product.<sup>17</sup> Nor is the toxin destroyed by freezing.<sup>18</sup>

Experts believe that all consumers are susceptible to ciguatera poisoning.<sup>19</sup> Victims typically experience acute gastrointestinal symptoms, as well as numbness, hot-cold temperature reversal, and other neurologic symptoms. Cardiovascular effects such as an irregular heartbeat and reduced blood pressure may be experienced. While these symptoms usually resolve within days, the symptoms can last for months or even years. In extremely severe cases, ciguatera victims may die from respiratory and cardiovascular failure.<sup>20</sup> The FDA estimates that ciguatera causes approximately 1,600 illnesses each year, and CSPI has documented 132 ciguatoxin outbreaks reported between 1990 and 2002.<sup>21</sup> The agency estimates that ciguatera cases impose an annual economic burden of \$24.4 million.<sup>22</sup>

Another harvest-area contaminant, methylmercury, is a highly toxic substance that may be found in seafood. Because the toxin bioaccumulates, it is most likely to reach hazardous

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*Epidemiologic Notes and Reports Ciguatera Fish Poisoning—Vermont*, 35 Morbidity and Mortality Weekly Report 263-64 (1986).

<sup>17</sup> Proposal to Establish Procedures for the Safe Processing and Importing of Fish and Fishery Products, 59 Fed. Reg. 4142, 4143-44 (1994) [hereinafter *Seafood HACCP Proposed Rule*].

<sup>18</sup> *Ciguatera Fish Poisoning—Texas, 1997*, 47 Morbidity and Mortality Weekly Report 692-94 (1998).

<sup>19</sup> Food and Drug Administration, *Foodborne Pathogenic Microorganisms and Natural Toxins Handbook*, Chapter 36, available at <<http://www.cfsan.fda.gov/~mow/chap36.htm>> (accessed on May 10, 2002) [hereinafter *Bad Bug Book*].

<sup>20</sup> *Bad Bug Book*, Chapter 36, available at <<http://www.cfsan.fda.gov/~mow/chap36.htm>> (accessed on May 10, 2002).

<sup>21</sup> *Seafood HACCP Final Rule*, 60 Fed. Reg. at 65185; *Outbreak Alert!*, at 18-24.

<sup>22</sup> *Seafood HACCP Final Rule*, 60 Fed. Reg. at 65185-86.

levels in large predatory fish. Developing fetuses of pregnant women who eat these fish are the most vulnerable to neurological deficits from methylmercury exposure.<sup>23</sup> A July 2000 National Academy of Sciences (NAS) report estimated that more than 60,000 children are born each year in the U.S. at risk of neurological impairment due to mercury-contaminated seafood their mothers ate while pregnant.<sup>24</sup> More recently, data from the National Health and Nutrition Examination Survey (NHANES 1999-2000) showed that approximately eight percent of women of childbearing age in the U.S. had mercury levels high enough to raise concern.<sup>25</sup> Extrapolating from the NHANES data indicates that hundreds of thousands of children may be born each year at risk of neurological deficits due to mercury-contaminated seafood.<sup>26</sup>

The FDA in March 2001 advised pregnant women and women of childbearing age not to eat four types of fish—shark, swordfish, king mackerel, and tile fish—due to concerns about mercury contamination and to limit consumption of other types of fish to 12 ounces per week.<sup>27</sup>

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<sup>23</sup> Centers for Disease Control and Prevention., *Blood and Hair Mercury Levels in Young Children and Women of Childbearing Age—United States, 1999*, 50 Morbidity and Mortality Weekly Report 140, 141 (2001). See also, National Academy of Sciences, *Toxicological Effects of Methylmercury* 53-54 (2000) [hereinafter *NAS Mercury Report*].

<sup>24</sup> *NAS Mercury Report*, at 327.

<sup>25</sup> Dr. Susan Schober, Presentation of National Health and Nutrition Examination Survey (NHANES) 1999-2000 Data Before the FDA Food Advisory Committee Meeting on Methylmercury, July 23, 2002.

<sup>26</sup> As many as 300,000 children may be born each year in the U.S. suffering from developmental problems from mercury exposure, based on an analysis of the NHANES data together with U.S. population and live-birth-rate data. (The Census Bureau estimates that 61.8 million women in the U.S. are aged between 15 and 44. U.S. Census Bureau, P. 8, Sex by Age, available at [http://factfinder.census.gov/OTTable?t\\_ts=51213200973](http://factfinder.census.gov/OTTable?t_ts=51213200973)) (accessed on Sept. 10, 2002). The U.S. live-birth rate is approximately 65 per 1,000 women aged 15-44. Joyce A. Martin *et al.*, Centers for Disease Control and Prevention, *Births: Final Data for 2000*, 4 (2002).) Unfortunately, the government lacks accurate consumption data to further refine this analysis.

<sup>27</sup> Food and Drug Administration, *Consumer Advisory* (March 2001), available at <http://www.cfsan.fda.gov/~dms/admehg.html>.

Recently, the FDA Food Advisory Committee recommended a stronger warning, urging pregnant women and young children to limit tuna consumption as well. However, consumer advisories can be confusing, and they do not address product sampling or prevent heavily contaminated seafood from being marketed.<sup>28</sup>

### **b. Contamination Related to Post-Harvest Handling**

Improper handling after harvest also affects contamination levels, especially the levels of *Vibrio* spp. in raw molluscan shellfish and histamines in scombroid-forming finfish.<sup>29</sup> The failure to promptly refrigerate seafood is an important factor in this regard. For example, *V. vulnificus* can reach dangerous levels in Gulf Coast shellfish-harvesting beds in warmer months. If shellfish are not refrigerated after harvest, these levels can increase by one log in 3.5 hours and two logs in 14 hours.<sup>30</sup> *V. vulnificus* can cause one of the most severe foodborne infections—septicemia—for consumers with certain underlying medical conditions. This blood infection is especially dangerous and leads to death in half of all cases.<sup>31</sup>

Two other *Vibrio* species, *V. parahaemolyticus* and *V. cholerae* non-O1, also multiply when shellfish are not rapidly refrigerated after harvest. Although these species typically cause

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<sup>28</sup> In April 2000 the Mercury Policy Project and California Communities Against Toxics reported that the FDA had stopped sampling domestic tuna, shark, and swordfish for mercury. Mercury Policy Project and California Communities Against Toxics, *The One That Got Away* 8 (April 2000).

<sup>29</sup> The class of scombroid toxin-forming species is defined at 21 C.F.R. § 123.3(m).

<sup>30</sup> Center for Science in the Public Interest, Petition for Regulatory Action to Establish a Standard for *Vibrio vulnificus* in Raw Molluscan Shellfish of Undetectable Levels 10 (1998), citing Letter from Patricia S. Schwartz, Food and Drug Administration, to Ken B. Moore, Interstate Shellfish Sanitation Conference, Aug. 17, 1995.

<sup>31</sup> Charlotte Christin *et al.*, *Death On The Half-Shell: The Failure of Regulators and the Shellfish Industry To Prevent Deaths and Illnesses From Gulf Coast Shellfish* (Washington, DC: Center for Science in the Public Interest) 7 (2001) [hereinafter *Death On The Half-Shell*].

milder illnesses than *V. vulnificus*, both species have caused fatalities.<sup>32</sup> *V. parahaemolyticus* also has been linked to large-scale U.S. outbreaks in recent years. More than 700 people were sickened by *V. parahaemolyticus*-tainted shellfish outbreaks occurring in 1997 and 1998.<sup>33</sup>

While the Centers for Disease Control and Prevention (CDC) has reported that the incidence of a number of foodborne illnesses have declined in recent years, the incidence of reported *Vibrio* infections was 83 percent higher in 2001 than it was in 1996.<sup>34</sup> The FDA has estimated that *V. vulnificus* and *V. parahaemolyticus* cause an average of 4,800 illnesses annually and cost the economy nearly \$142 million annually.<sup>35</sup>

Scombroid poisoning results from eating fish with histamines formed because of temperature abuse.<sup>36</sup> Once decomposition of scombroid species has begun, subsequent refrigeration will slow, but not stop, histamine formation.<sup>37</sup> Victims of scombroid poisoning

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<sup>32</sup> *Bad Bug Book*, Chapter 9, available at <<http://www.cfsan.fda.gov/~mow/chap9.html>> (accessed on May 8, 2002); M. Fyfe *et al.*, *Outbreak of Vibrio parahaemolyticus Infections Associated with Eating Raw Oysters—Pacific Northwest, 1997*, 47 *Morbidity and Mortality Weekly Report* 457-62 (1998); *Bad Bug Book*, Chapter 8, available at <<http://www.cfsan.fda.gov/~mow/chap8.html>> (accessed on May 9, 2002); Food and Drug Administration, *Bacteriological Analytical Manual Online*, available at <<http://www.cfsan.fda.gov/~ebam/bam-9.html>> (accessed on May 9, 2002).

<sup>33</sup> *Outbreak Alert!*, at 22.

<sup>34</sup> FoodNet Working Group, *Preliminary FoodNet Data on the Incidence of Foodborne Illnesses—Selected Sites, United States, 2001*, 51 *Morbidity and Mortality Weekly Report* 325-29 (2002) [hereinafter *FoodNet Data, 2001*].

<sup>35</sup> Specifically, the FDA estimates that the average nationwide yearly incidence of *V. parahaemolyticus* illnesses caused by raw molluscan shellfish is 4,750 cases per year at an economic cost of \$21,082,000. Food and Drug Administration, *Draft Risk Assessment on the Public Health Impact of Vibrio parahaemolyticus in Raw Molluscan Shellfish*, 60-65, 84 (2000); Discussion Paper on Risk Management Strategies for *Vibrio* spp. in Seafood, Joint FAO/WHO Food Standards Programme, Codex Committee on Food Hygiene (CX/FH 03/5 - Add. 3), Aug. 2002. The FDA estimates that 60 shellfish-related *V. vulnificus* cases occur annually, at an economic cost of \$120,535,039. *Seafood HACCP Final Rule*, 60 Fed. Reg. at 65185-86.

<sup>36</sup> National Academy of Sciences, *Seafood Safety* 95 (1991) [hereinafter *NAS Seafood Safety Report*].

<sup>37</sup> *Seafood HACCP Proposed Rule*, 59 Fed. Reg. at 4174.

usually first experience a tingling or burning sensation in the mouth. The illness may progress to nausea, vomiting, and diarrhea and may require hospitalization.<sup>38</sup> Scombrototoxin is estimated to cause 8,000 illnesses annually, according to the FDA, and caused half of the finfish outbreaks between 1990 and 2002 in CSPI's database.<sup>39</sup> The agency has calculated that scombroid poisoning costs the economy \$2.7 million annually.<sup>40</sup>

### **c. Contamination Related To Seafood Processing**

Insanitary conditions in seafood-processing firms contribute to foodborne illnesses. Such contamination can be monitored by testing for coliforms in raw finfish and *Listeria monocytogenes* in ready-to-eat seafood products.

*L. monocytogenes* contaminates ready-to-eat seafood processed or packaged in unsanitary conditions.<sup>41</sup> A recent draft risk assessment on *L. monocytogenes* concluded that smoked seafood was the second most likely ready-to-eat food to cause listeriosis, following meat pâtés.<sup>42</sup> *L. monocytogenes* is of particular concern with cold-smoked seafood, which is not heated sufficiently to eliminate those dangerous bacteria.<sup>43</sup> A 1997 FDA study found *L. monocytogenes*

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<sup>38</sup> *Bad Bug Book*, Chapter 38, available at <<http://www.cfsan.fda.gov/~mow/chap38.htm>> (accessed on May 10, 2002).

<sup>39</sup> *Seafood HACCP Final Rule*, 60 Fed. Reg. at 65185-86; *Outbreak Alert!*, at 18-24.

<sup>40</sup> *Seafood HACCP Final Rule*, 60 Fed. Reg. at 65185-86.

<sup>41</sup> Caroline Smith DeWaal *et al.*, *Unexpected Consequences: Miscarriage and Birth Defects From Tainted Food* (Washington, D.C.: Center for Science in the Public Interest) 3 (2000).

<sup>42</sup> Specifically, smoked seafood was the second most likely ready-to-eat food category in the predicted relative risk of illness to consumers per 100 million servings. Food and Drug Administration and U.S. Department of Agriculture, Interpretive Summary; Draft Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods 16 (Jan. 2001) [hereinafter *Interpretive Summary*].

<sup>43</sup> *U.S. v. Blue Ribbon Smoked Fish, Inc. et al.*, 179 F.Supp. 30, 37 (E.D.N.Y. 2001).

in ten out of 16 New York smoked-fish processing plants it tested and 17.5 percent of the cold-smoked fish products sampled nationwide between 1991 and 1995.<sup>44</sup>

*L. monocytogenes* is an especially virulent pathogen, causing 20 deaths per 100 cases of illness.<sup>45</sup> The CDC estimates that approximately 2,300 people are hospitalized and 500 die from foodborne listeriosis each year in the U.S.<sup>46</sup> *L. monocytogenes* is particularly threatening to infants, pregnant women, the elderly, and those with compromised immune systems. A pregnant woman with listeriosis can suffer a miscarriage, premature delivery, infection of the newborn with serious, long-term consequences, or even stillbirth. In other vulnerable consumers, *L. monocytogenes* can cause septicemia, in which bacteria poison the bloodstream.<sup>47</sup> This frequently leads to death. Due to the deadly nature of listeriosis, the FDA established a zero tolerance for *L. monocytogenes* in ready-to-eat seafood.<sup>48</sup>

In addition, coliform bacteria, though largely non-pathogenic, can be used as indicator organisms to determine the sanitary quality of foods, because they are from the intestinal tracts of humans and animals. The presence of coliforms may be an indication of contamination with the fecal discharges of humans or animals due to insanitary handling by workers or the lack of cleanliness in the food production area. Subsequent improper handling and storage can allow

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<sup>44</sup> *Blue Ribbon Smoked Fish*, 179 F.Supp. at 38.

<sup>45</sup> *Interpretive Summary*, at 12 (Jan. 2001).

<sup>46</sup> P. Mead *et al.*, *Food-Related Illness and Death in the United States*, 5 *Emerging Infectious Diseases* 607, 611 (1999).

<sup>47</sup> *Bad Bug Book*, Chapter 6, available at <<http://www.cfsan.fda.gov/~mow/chap6.html>> (accessed on May 10, 2002).

<sup>48</sup> The FDA's zero-tolerance policy for *L. monocytogenes* in ready-to-eat seafood was recently upheld. *Blue Ribbon Smoked Fish*, 179 F.Supp.2d at 48-49.

coliform levels to increase.

Coliforms are a good general food-safety indicator because they originate from the same source as many other pathogens. Moreover, laboratory tests for coliforms also are widely available and inexpensive compared to other types of tests.<sup>49</sup>

## **2. The FDA's Seafood HACCP Program Must Be Strengthened To Better Protect Consumers From Tainted Seafood.**

Despite implementation of the FDA's seafood HACCP program, consumers remain highly vulnerable to becoming ill from unsafe seafood. In 2001, four years after the new HACCP regulations went into effect, only 57 percent of the seafood establishments inspected had written HACCP plans.<sup>50</sup> Moreover, half of all seafood firms inspected in 2001 lacked adequate sanitation controls, a significant finding given that the FDA has, in effect, exempted 31 percent of establishments from the requirement to have a HACCP plan.<sup>51</sup> Gaps in implementation prevent the benefits of the seafood HACCP program from being fully realized. Consumers are at risk from seafood firms that fail to operate under HACCP systems that adequately identify and control food-safety hazards.<sup>52</sup>

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<sup>49</sup> R. Worobo, *Food Safety and You: Coliform Bacteria as Indicators of Food Sanitary Quality*, 2 Venture (Spring 1999), available at <[http://www.nysaes.cornell.edu/fst/fvc/Venture/venture5\\_safety.html](http://www.nysaes.cornell.edu/fst/fvc/Venture/venture5_safety.html)>; Canadian Food Inspection Agency, Standard Procedures for Bacteriological Analysis Manual, Chapter 3: Procedures for the Enumeration of Coliforms, Faecal Coliforms and *Escherichia coli*, available at <<http://www.inspection.gc.ca/english/anima/fispo/manman/bacter/Chap3e.html>>.

<sup>50</sup> Although a recent FDA report indicates that 88 percent of seafood firms were in compliance with the HACCP plan requirement in 2001, this figure includes 31 percent of firms that were not required to have a HACCP plan. Food and Drug Administration, FDA's Evaluation of the Seafood HACCP Program For Fiscal Years 2000/2001 7 (2002) [hereinafter *FDA Seafood HACCP Data*].

<sup>51</sup> *FDA Seafood HACCP Data*, at 4, 7. The FDA should consider eliminating its de facto exemptions from the seafood HACCP requirements.

<sup>52</sup> *GAO Seafood Safety Report*, at 14.

But inadequate seafood HACCP implementation is not the only reason that seafood-related illnesses continue unabated. The seafood HACCP program is fundamentally flawed because it lacks objective measures of accountability for controlling and reducing hazards in seafood products, such as a mandatory government program of testing for HACCP verification.

**a. Mandatory Government Testing Is Needed To Fulfill FDA’s HACCP-Verification Responsibilities.**

Verification is one of the seven key HACCP principles. The National Advisory Committee on Microbiological Criteria in Foods (NACMCF) defines “verification” as “the use of methods, procedures, or tests in addition to those used for monitoring, to determine if the HACCP system is in compliance with the HACCP plan and/or whether the HACCP plan needs modification and revalidation.”<sup>53</sup> While food firms are responsible for initial validation, ongoing reviews, and periodic reassessments of the HACCP plan, the government’s duty is to ensure that safe product is being produced under conditions that minimize preventable food-safety risks.<sup>54</sup>

The FDA has acknowledged its responsibility for HACCP verification. In its seafood HACCP proposal, the agency stated: “The regulator’s primary role should be to verify that the industry is meeting this responsibility [to produce safe food] and to take remedial action when it is not.”<sup>55</sup> The agency also conceded that “[f]ew hazards associated with seafood are detectable

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<sup>53</sup> Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems; Proposed Rule, 60 Fed. Reg. 6774, 6811 (1995) [hereinafter *FSIS HACCP Proposed Rule*].

<sup>54</sup> See, e.g., Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems; Final Rule, 61 Fed. Reg. 38806, 38817 [hereinafter *FSIS HACCP Final Rule*]; *FSIS HACCP Proposed Rule*, 60 Fed. Reg. at 6811.

<sup>55</sup> *Seafood HACCP Proposed Rule*, 59 Fed. Reg. at 4143-4144. Similarly, in the final rule, the agency stated: “FDA has a responsibility to verify that the industry is meeting its obligation [to produce safe food] and to take remedial action if industry fails to do so.” *Seafood HACCP Final Rule*, 60 Fed. Reg. at 65154.

through visual inspection.”<sup>56</sup> Nevertheless, the seafood HACCP rule didn’t establish a system of mandatory end-product or in-process testing for verification purposes.<sup>57</sup>

By contrast, government verification testing is a cornerstone of the HACCP system in meat and poultry plants. The Food Safety and Inspection Service (FSIS) has explained:

Without some objective measure of what constitutes an acceptable level of food safety performance with respect to pathogenic microorganisms, it would be impossible to determine whether an establishment’s HACCP plan is acceptable and functioning effectively.<sup>58</sup>

The FDA should follow the lead of its sister agency and establish a mandatory government testing program to meet its duty of HACCP verification.

**b. Government Testing Is Important To Ensure That Firms’ Processes Are Under Control.**

The success of a HACCP system depends on the efforts of individual plants to identify and control hazards in their products. Even before the FDA issued its final seafood HACCP rule, the agency conceded that many in the seafood industry lacked knowledge about seafood hazards.<sup>59</sup> Although the FDA developed a program to train industry personnel in HACCP principles, the agency allowed its training requirement to be met through prior job experience. Moreover, the agency did not approve HACCP plans before they were implemented in plants. It is not surprising, therefore, that FDA inspectors in 1999 found that more than half of the seafood HACCP plans contained serious deficiencies, such as the failure to identify serious hazards,

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<sup>56</sup> *Seafood HACCP Proposed Rule*, 59 Fed. Reg. at 4146.

<sup>57</sup> 21 C.F.R. § 123.8.

<sup>58</sup> *FSIS HACCP Proposed Rule*, 60 Fed. Reg. at 6811.

<sup>59</sup> *Seafood HACCP Proposed Rule*, 59 Fed. Reg. at 4143-4144.

critical control points, critical limits, monitoring, or corrective action procedures.<sup>60</sup>

Inspection data from 2001 show modest improvement, but also demonstrate that some segments of the seafood industry still lag, such as firms that process scombroid species and those that produce cold-smoked seafood. Indeed, the agency concedes:

[P]erformance of the scombroid species processing sector remains among the lowest in the seafood industry . . . in large part due to a delay by the industry in either adopting appropriate harvest vessel controls to prevent histamine formation before the fish reach the first processor, or in engaging in histamine testing (as an alternative to harvest vessel controls).<sup>61</sup>

Given that only 71 percent of scombroid-species processing firms were implementing adequate monitoring procedures in 2001, government testing would be critical to verify process control.<sup>62</sup>

Similarly, smoked-seafood processors have done poorly in HACCP implementation—just 69 percent have properly implemented monitoring procedures and only 71 percent have properly identified critical limits.<sup>63</sup> Although the FDA attributes the problem to control of *Clostridium botulinum*, the agency’s own risk assessment on *L. monocytogenes* showed that smoked seafood was the second most likely ready-to-eat food to cause listeriosis, following meat pâtés.<sup>64</sup> Thus, it is imperative for the FDA to begin testing cold-smoked seafood and other ready-to-eat seafood products to verify that firms are controlling *L. monocytogenes* in their products.

In establishing a testing program, the FDA should not overlook other well-established

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<sup>60</sup> GAO Seafood Report, at 18.

<sup>61</sup> FDA Seafood HACCP Data, at 5.

<sup>62</sup> FDA Seafood HACCP Data, at 9.

<sup>63</sup> FDA Seafood HACCP Data, at 8.

<sup>64</sup> See, supra, note 42.

seafood hazards: ciguatera in tropical and sub-tropical reef fish, methylmercury in large predatory finfish, and *Vibrio* spp. in raw shellfish. The numbers of recent illnesses and outbreaks linked to these pathogen-product combinations demonstrate that seafood firms continue to have problems in identifying and preventing these hazards.

The FDA has acknowledged that improvements in seafood HACCP compliance leveled off in 2001.<sup>65</sup> The agency speculated that this finding may indicate that “processors that are most willing and able to achieve compliance have done so . . . [and] regulatory action may be necessary to correct much of the remaining non-compliance.”<sup>66</sup> An objective means of verification would be an appropriate tool to help the FDA and the industry to identify problems in plant HACCP plans. The FDA also should consider requiring all seafood firms to test their own products for coliforms, as a general measure of plant sanitation. At a minimum, the FDA should establish a mandatory government testing program to ensure that seafood firms are achieving acceptable levels of performance on food-safety measures and maintaining that performance over time.

**c. Government Testing Would Help To Evaluate The Effectiveness Of The Seafood HACCP Program.**

The Government Performance and Results Act (GPRA) calls for federal agencies to develop and use objective and measurable performance standards to demonstrate progress toward achieving their goals. The GAO has criticized the FDA for failing to gather “objective measurable data to determine whether its HACCP program for seafood is effectively reducing

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<sup>65</sup> *FDA Seafood HACCP Data*, at 4.

<sup>66</sup> *FDA Seafood HACCP Data*, at 4.

hazards.”<sup>67</sup> The GAO auditors concluded:

[W]e continue to believe that FDA should identify the hazards of most concern (e.g., scombrototoxin), develop baseline information on such hazard(s), and use that information to assess the effectiveness of its programs in reducing the prevalence of such hazards.<sup>68</sup>

The FDA’s efforts to address this criticism have fallen short. In April 2001, seafood inspectors were asked to collect samples “as a means of judging the overall effectiveness of the HACCP system.”<sup>69</sup> The FDA made clear, however, that only a “limited number of [such] samples” would be collected from seafood firms.<sup>70</sup>

By contrast, the FSIS’s HACCP program for meat and poultry establishments has documented reductions in *Salmonella* prevalence through FSIS verification testing in meat and poultry slaughterhouses and plants that produce raw ground products. The CDC has credited the FSIS’s Pathogen Reduction/HACCP program with being one of the factors leading to a 15 percent decline in salmonellosis at FoodNet sites since 1996.<sup>71</sup> The CDC has stated: “The decline in the rate of *Salmonella* infections in humans coincided with a decline in the prevalence of *Salmonella* isolated from FSIS-regulated products to levels well below baseline levels before

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<sup>67</sup> *GAO Seafood Safety Report*, at 22. The FDA has argued that its compliance data can be used in lieu of a performance-based method of measuring reductions in seafood hazards. Both the GAO and the National Academy of Sciences have rejected such an approach. *GAO Seafood Safety Report*, at 23; *NAS Seafood Safety Report*, at 269.

<sup>68</sup> *GAO Seafood Safety Report*, at 58.

<sup>69</sup> *FDA Guidance*, *supra* note 8. The FDA Compliance Program Guidance Manual is non-binding.

<sup>70</sup> *FDA Guidance*, *supra* note 8.

<sup>71</sup> *FoodNet Data, 2001*.

HACCP was implemented.”<sup>72</sup>

The FSIS data also demonstrate the value of a HACCP program that includes government verification testing at the smallest food-producing establishments, such as are common in the seafood industry. Small and very-small meat and poultry firms have cut *Salmonella* in all seven product categories with performance standards. Very-small establishments have reduced the pathogen prevalence in five of the seven product types.<sup>73</sup> Some of the results are quite dramatic. For example, *Salmonella* prevalence in ground chicken was reduced from a baseline of 44.6 percent to 16 percent in small establishments and 11.3 percent in very-small establishments for all relevant years between 1998-2001.<sup>74</sup> *Salmonella* prevalence in ground turkey was cut from a baseline of 49.9 percent to 25.6 percent in small establishments and 28.1 percent in very-small establishments.<sup>75</sup> The performance of small and very-small meat and poultry plants under the FSIS’s Pathogen Reduction/HACCP rule makes clear that small food-processing firms can comply with a mandatory government HACCP-verification program. Indeed, the FSIS data show small food firms achieving significant reductions in product contamination.

A performance-based system of measuring contamination rates in seafood plants would, among other things, encourage greater compliance with the seafood regulations among the

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<sup>72</sup> *FoodNet Data, 2001.*

<sup>73</sup> Very-small plants that slaughter broilers and cows/bulls seem to be having difficulty meeting the applicable performance standard. Food Safety and Inspection Service, *Progress Report on Salmonella Testing of Raw Meat and Poultry Products, 1998-2001*, available at <<http://www.fsis.usda.gov/OPHS/haccp/salm4year.htm>> [hereinafter *FSIS Salmonella Progress Report*].

<sup>74</sup> HACCP implementation in small establishments began on January 25, 1999, and in very-small establishments on January 25, 2000. *FSIS HACCP Final Rule*, 61 Fed. Reg. at 38806-989.

<sup>75</sup> *FSIS Salmonella Progress Report.*

industry and inspire consumer confidence in seafood safety. It also would help to fulfill the agency's GPRRA requirements and its duty to protect public health.

**d. Government Testing Would Supplement, Not Supplant, Industry Testing.**

Industry testing is an important complement to a program of mandatory government HACCP-verification testing. A plant that routinely tests its products can track levels of bacterial contamination and thus will be alerted when some component of its operations is performing poorly. In such firms, government testing becomes a fail-safe mechanism to identify problems. Indeed, the NACMCF principles endorse both government and industry HACCP verification.<sup>76</sup> Product testing also bolsters public confidence in seafood safety. For example, leading seafood purveyor Legal Sea Foods, Inc. uses its product sampling as a selling point for consumers.

Although CSPI is not asking for mandatory industry testing as part of this petition, we recognize that significant benefits that would accrue from across-the-board testing by industry. The FDA should consider requiring all seafood plants to test for coliforms, because half of the firms inspected in 2001 lacked adequate sanitation controls.<sup>77</sup> At a minimum, the FDA should continue to encourage seafood firms to perform end-product testing as a means to verify that their HACCP plans are controlling hazards.

**B. Legal Grounds**

**1. The FFDCFA Authorizes The FDA To Establish A Mandatory Government Testing Program For Verification of Seafood HACCP.**

The Federal Food, Drug, and Cosmetic Act (FDCA) was enacted to safeguard public

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<sup>76</sup> *FSIS HACCP Final Rule*, 61 Fed. Reg. at 38819.

<sup>77</sup> *FDA Seafood HACCP Data*, at 7.

health and prevent deceit of the purchasing public.<sup>78</sup> Indeed, the Supreme Court has established that “the public interest in the purity of its food is so great as to warrant the imposition of the highest standard of care on distributors.”<sup>79</sup> FDCA section 402(a)(1) establishes certain classes of food adulterants, depending on whether or not the substances are “added.”<sup>80</sup> A food containing an “added” substance is adulterated if the substance “may render it injurious to health.”<sup>81</sup> A food containing a naturally occurring (hence, not “added”) substance is adulterated only if the quantity of the substance in the food would “ordinarily render it injurious to health.”<sup>82</sup> A food is also deemed adulterated if it has been “prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.”<sup>83</sup> Through these provisions, Congress empowered the FDA to set requirements to assure that firms are producing foods that are safe, unadulterated, and wholesome, including the authority to control conditions in food-processing facilities.

Both FDA regulations and legal precedent have defined “added” substance broadly for the purposes of the adulteration standard under section 402(a)(1). Under FDA’s regulations, the “added”-substances adulteration standard applies where a naturally occurring substance “is

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<sup>78</sup> Dunn, Federal Food, Drug, and Cosmetic Act 997 (1987) (Conference Report) [hereinafter *FDCA Legislative History*].

<sup>79</sup> *U.S. v. Park*, 421 U.S. 658, 671 (1975).

<sup>80</sup> 21 U.S.C. § 342(a)(1).

<sup>81</sup> 21 U.S.C. § 342(a)(1).

<sup>82</sup> 21 U.S.C. § 342(a)(1).

<sup>83</sup> 21 U.S.C. § 342(a)(4).

increased to abnormal levels through mishandling or other intervening acts.”<sup>84</sup> A substance is “added” to a food even if it derives in part from man and in part from nature.<sup>85</sup> The FDA is only required to show some portion of the substance is attributable to the acts of man and that the total amount may be injurious to health.<sup>86</sup> In *United States v. Anderson Seafoods, Inc.*, the Fifth Circuit held that mercury in swordfish is an “added” substance because at least some of the mercury present in the swordfish was present in the ocean because of “the acts of man.”<sup>87</sup>

Just as mercury in seafood is an added substance, so too *Vibrio* species in raw shellfish meet the “added”-substance provision. Shellfish harvesters perform “intervening acts” by removing shellfish from harvest beds where *Vibrio* species are present. Once the shellfish are out of the water, harvesters leave their catch on the deck without refrigeration. Under such conditions, the levels of any *Vibrio* bacteria in the shellfish will grow to significantly higher levels than when the shellfish were in the water. For example, *V. vulnificus* in unrefrigerated shellfish can increase by one log within 3.5 hours and two logs within 14 hours.<sup>88</sup> The “acts of man” in failing to immediately cool the shellfish allow *Vibrio* species to reach “abnormal levels” in raw shellfish, rendering all of the substance present in shellfish as an “added” poisonous or deleterious substance, according to the reasoning in *Anderson Seafoods*.

The same analysis applies to the presence of scombroid toxin in scombroid-forming

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<sup>84</sup> 21 C.F.R. § 109.3(d).

<sup>85</sup> *United States v. Anderson Seafoods, Inc.*, 622 F.2d 157, 160-62 (5<sup>th</sup> Cir. 1980).

<sup>86</sup> *Anderson Seafoods*, 622 F.2d at 162.

<sup>87</sup> *Anderson Seafoods*, 622 F.2d at 161-62.

<sup>88</sup> *Death On The Half-Shell*, at 15-16.

finfish species--all of the toxin that forms is due to the “acts of man” because scombroid toxin is a substance that develops once decomposition has begun. If the cold chain is maintained, scombroid will not form.

Under FDCA section 402(a)(1), a naturally occurring substance also may be considered an adulterant where it is in a quantity sufficient to cause the food to be “injurious to health.”<sup>89</sup> Ciguatera is considered the most common non-bacterial, fish-borne poisoning in the United States.<sup>90</sup> Tropical and sub-tropical reef fish larger than two kilograms may contain significant amounts of toxin and readily produce toxic effects when ingested.<sup>91</sup> Accordingly, the presence of the toxin in such fish causes it to be “injurious to health.”

Under FDCA section 402(a)(4), food that is prepared, packed or held under insanitary conditions whereby it may become injurious to health also is considered adulterated. This section gives broad authority to control conditions in food processing facilities because it does not require proof of actual contamination.<sup>92</sup> When this section was being deliberated in Congress, then-FDA chief Walter Campbell testified:

We are aware of a great many instances where we think public health is placed in jeopardy. At least, people are permitted to consume products that are possibly filthy, potentially dangerous, and which unquestionably they would not consume if they were conscious of the conditions of production . . . Now, a provision of the kind in this bill will make it necessary for those who enjoy the profits that come from the production of that food to observe, it seems to me, a reasonable concern

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<sup>89</sup> 21 U.S.C. § 342(a)(1).

<sup>90</sup> Thomas Arnold, *Toxicity, Ciguatera*, eMedicine Clinical Knowledge Base (updated Apr. 12, 2002), available at <http://www.emedicine.com/emerg/topic100.htm> [hereinafter *Ciguatera*].

<sup>91</sup> *Ciguatera*.

<sup>92</sup> See, e.g., *United States v. Nova Scotia Food Products Corp.*, 568 F.2d 240, 247 (2d Cir. 1977).

about the freedom of the product from contamination.<sup>93</sup>

Verification testing would help the FDA to ensure that effective methods are used to control hazards in the harvest, preparation, packing, and holding of seafood products. If such hazard controls are lacking or are ineffective, the potential exists that the food may be rendered injurious to health and thus would be deemed “adulterated” under section 402(a)(4).

FDCA case law is in accord with this interpretation. In *United States v. Nova Scotia Food Products Corp.*, a smoked-fish processor challenged the FDA’s good manufacturing practices regulations, which provided that the failure to eliminate *Clostridium botulinum* through adequate processing created insanitary conditions that rendered the fish adulterated under section 402(a)(4). The *Nova Scotia* court specifically rejected arguments by the seafood processor that “insanitary conditions” were limited to conditions in the plant itself and not conditions that inhibit the growth and spread of organisms already in food when it enters the plant.<sup>94</sup>

*Listeria spp.* and coliforms also are subject to the FDA’s regulatory authority, including verification testing, under FDCA section 402(a)(4). *Listeria spp.* and coliforms are considered indicator organisms—that is, their presence in the plant environment or on the product itself signals a breakdown in the plant’s sanitation measures. The presence of *Listeria spp.*, in particular, means that conditions are present that could also support the growth of *L. monocytogenes*, a dangerous pathogen in smoked fish and cooked ready-to-eat seafood products, thus indicating a potential for product adulteration.

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<sup>93</sup> *FDCA Legislative History*, at 1144 (S. Hearing on S. 2800).

<sup>94</sup> *Nova Scotia*, 568 F.2d at 245-46.

Moreover, *L. monocytogenes* has been found to be an “added” substance that is injurious to the health of significant populations of consumers.<sup>95</sup> In *United States v. Blue Ribbon Smoked Fish, Inc.*, the court found that one of the important goals of the FDCA is to keep contaminated fish processed under conditions of filth off consumer’s tables.<sup>96</sup> Microbiological testing is within FDA’s authority as a mechanism to verify the adequacy of an establishment’s sanitation procedures and assures that fish are being processed under conditions that prevent product adulteration and ensure a high level of cleanliness and safety.

Under the broad authority of the FDCA, the agency can issue regulations that are reasonably related to the purposes of the Act.<sup>97</sup> Section 701(a) authorizes the FDA to adopt regulations for the efficient enforcement of the FDCA.<sup>98</sup> Establishing a mandatory government verification testing program would be a reasonable exercise of the FDA’s authority to ensure that seafood products are not “prepared, packed or held under insanitary conditions.”<sup>99</sup> Moreover, it would advance the purposes of the FDCA – to ensure that consumers are protected from unsafe food.

## **2. The PHS Act Authorizes The FDA To Establish A Mandatory Government Testing Program For Verification of Seafood HACCP.**

Section 361 of the Public Health Service Act (PHSA) authorizes the FDA, by delegation,

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<sup>95</sup> *Blue Ribbon Smoked Fish*, 179 F. Supp.2d at 46-47.

<sup>96</sup> *Blue Ribbon Smoked Fish*, 179 F. Supp.2d at 44-46, 51.

<sup>97</sup> *Nova Scotia*, 568 F.2d at 246.

<sup>98</sup> *FDA Seafood HACCP Proposed Rule*, at 42.

<sup>99</sup> 21 U.S.C. § 342(a)(4).

to adopt and enforce regulations to prevent the introduction, transmission, or spread of communicable diseases into or within the U.S.<sup>100</sup> “Communicable diseases” have been defined by the agency as follows:

Illnesses due to infectious agents or their toxic products, which may be transmitted from a reservoir to a susceptible host either directly as from an infected person or animal or indirectly through the agency of an intermediate plant or animal host, vector, or the inanimate environment.<sup>101</sup>

Illnesses caused by tainted seafood clearly fall within this ambit.

In implementing its PHSa mandate, the FDA is authorized to provide for the inspection, disinfection, and sanitation of animals and articles that are so infected or contaminated as to be sources of infection to humans and other necessary measures.<sup>102</sup> Thus, the agency has wide latitude to issue regulations ensuring that foods are manufactured, processed, packed or held under sanitary conditions so as to be safe, wholesome, and otherwise fit for food. So, for example, in 1987 the FDA issued a rule requiring pasteurization of milk products and in 2001 issued the juice HACCP final rule. In this instance, establishing a mandatory government testing program would be a reasonable exercise of the agency’s PHSa authority to prevent the spread of communicable disease. Verification of firms’ hazard controls will help to minimize the likelihood that seafood products will become agents in disease transmission.

#### **IV. Environmental Impact**

The action requested in this petition does not fall within the categories of actions

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<sup>100</sup> 42 U.S.C. § 264.

<sup>101</sup> 21 C.F.R. § 1240.3(b).

<sup>102</sup> 42 U.S.C. § 264.

requiring an environmental impact statement under 21 C.F.R. § 25.21 or an environmental assessment under 21 C.F.R. § 25.22. The action requested is of a type that does not individually or cumulatively have a significant effect on the human environment, as required under 21 C.F.R. § 25.23. The action also is subject to categorical exclusion under 21 C.F.R. § 25.24 because it will not result in the introduction of any substance into the environment.

#### **V. Economic Impact**

An economic impact statement under 21 C.F.R § 10.30(b) is not necessary at this time.

#### **VI. Certification**

The undersigned parties certify that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioners which are unfavorable to the petition.

Respectfully submitted,

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