October 1, 2007

VIA E-MAIL
Division of Dockets Management (HFA-305)
Department of Health and Human Services
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Request for Comments to the Presidential Interagency Working Group on Import Safety [Docket No. 2007N-0330]

Dear Members of the Working Group:

The Southern Shrimp Alliance ("SSA"), founded in 2002, is a non-profit alliance of the hard-working men and women of the U.S. shrimp industry. The SSA is the national voice for shrimp fishermen and processors in eight states: Alabama, Florida, Georgia, Louisiana, Mississippi, North Carolina, South Carolina, and Texas. In addition to defending and advancing the interests of the domestic industry, the SSA is committed to preserving the safety and integrity of the nation's shrimp supply.

The SSA submits the following comments in response to the U.S. Food and Drug Administration's ("FDA") Request for Comments to the Presidential Interagency Working Group on Import Safety ("Working Group"), as published in 72 Fed. Reg. 50,374 (August 31, 2007) ("Request for Comments").

I. Introduction

The American public is gravely and justifiably concerned that the imported food products, particularly imported seafood products, they consume may not be safe and that the

federal government is not taking the necessary steps to safeguard the health and safety of its people. For American seafood producers, a lack of meaningful regulations of seafood imports presents two problems. First, American seafood producers are subject to strenuous food safety controls that are not applied equally to foreign seafood producers. Second, to the extent that consumers are concerned about the safety of their food, their caution impacts the whole market, not just the market for imported seafood. Unfortunately, systemic deficiencies in our imported food safety regime heighten consumers' fears insofar as these deficiencies not only allow but affirmatively attract contaminated and dangerous imports into the U.S. market.

In issuing its Report to the President on "Protecting American Consumers Every Step of Way" ("Import Safety Report"), the Working Group has taken a first step towards changing the culture of our government's deficient approach to food safety by calling for a "paradigm shift from an intervention, border-focused strategy to a life-cycle approach that stresses a risk-based approach to prevention with verification . . . ."[1] While this paradigm shift will necessarily require all actors in an imported product's life-cycle to undertake significant reforms, such a shift will not effectuate meaningful food safety regulations without the active oversight of the federal government.

Stringent government oversight and enforcement of U.S. import safety standards are essential to guaranteeing the safety of imported products entering the U.S. market. However, for the vast majority of U.S. food imports, the federal agency charged with imported food safety supervision, the FDA, has largely abdicated its responsibility to ensure the safety of such imports.

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[1] Protecting American Consumers Every Step of Way: A strategic framework for continued improvement in import safety, A Report to the President, Interagency Working Group on Import Safety, p. 11 (Sept. 10, 2007) ("Import Safety Report").

Particularly with imported seafood products, the FDA's lax enforcement efforts has had several troubling consequences. Given the FDA's appallingly low import inspection rate of approximately 1 percent, seafood imports contaminated with harmful drug residues, pesticides, salmonella, and common filth enter the United States virtually undetected. Compounding this problem is the laxity of the FDA's food safety controls relative to the stringent imported food safety regimes of other major importing markets, which creates irresistible incentives for exporters to ship unsafe seafood products to the United States. As shown from the trade patterns of imported shrimp, the FDA's lax enforcement of U.S. food safety standards is affirmatively attracting contaminated food imports to the United States that would be rejected by other major seafood importing nations.[2]

No other federal agency discussed in the Import Safety Report is in more dire need of a "paradigm shift" than the FDA. If meaningful reform is to be implemented, a shift in paradigm must include the following four fundamental principles:

- **Demonstrated Equivalence**: Exporting countries and foreign producers must be subject to certification of equivalence with U.S. food safety standards, foreign on-site inspections and revocation of exporting privileges for repeated food safety violations, consistent with the practice of other major seafood importing markets;
- **Inspection and Testing**: Mandatory minimum inspection testing rates must be imposed at U.S. borders, with testing increased as problems are detected, consistent with the practice of other major seafood importing markets;
- **Enforcement**: The FDA must impose significant penalties for noncompliance with U.S. food safety standards, consistent with the practice of other major seafood importing markets; and
- **Multilateral Cooperation**: Increased multilateral cooperation with other major seafood importing countries.

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[2] Because of the systemic deficiencies in the FDA's import enforcement regime and its devastating consequences for U.S. consumers and the integrity of our nation's food supply, SSA's comments focus exclusively on recommendations to improve the FDA's enforcement efforts of U.S. food safety standards for imported seafood products. See infra at Section V.

In the wake of revelations regarding numerous imported food safety problems, U.S. consumers have made it clear that they are willing to pay a bit more if it means they can be assured of uncontaminated and safe food.[3] But the cost of a lax import enforcement regime is more than dollar and cents. The FDA must safeguard the quality and integrity of our nation's food supply. Consumers rely on the FDA to ensure that imported food products are meeting U.S. food safety standards.[4] But with imported shrimp, Americans cannot be sure what it is they are eating. Farm-raised in crowded and dirty ponds, with almost no quality control, imported shrimp develop in poor sanitary conditions, in ponds with high feces concentrations, banned antibiotics, and toxic chemicals.[5] As a result, imported shrimp often contain harmful antibiotics, pesticides, salmonella, and filth.

In contrast, wild-caught American shrimp is premium-quality seafood caught by American shrimpers and delivered fresh to local docks. Wild-caught American shrimp mature at a natural pace, flourishing in nutrient-rich marshes and estuaries before naturally migrating to the Atlantic Ocean or Gulf of Mexico. Because they are grown naturally in oceans, there is no need nor is there economic incentive to use antibiotics or pesticides on wild-caught American shrimp.

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3 "You Are What They Eat," CONSUMER REPORTS (July 2007) ("American consumers are willing to pay more for greater safety guarantees . . . .").

4 "Fish Farming: Is it Safe for Humans and the Environment," 17 CQ RESEARCHER 27, p. 630 (July 27, 2007).

5 See "Shrimp's Success Hurts Asian Environment, Group Says," NATIONAL GEOGRAPHIC NEWS (Dec. 20, 2004) (discussing the Environmental Justice Foundation's "concerns over the levels of antibiotics, disinfectants, fertilizers, pesticides, and other chemicals used by shrimp farmers to maximize profits and combat disease."); Global and Local: Food Safety Around the World, Center for Science in the Public Interest, pp. 14-16 (June 2005); "Chicken from China?," BOSTON.COM (May 9, 2007) ("In China, some farmers try to maximize the output from their small plots by flooding produce with unapproved pesticides, pumping livestock with antibiotics banned in the United States, and using human feces as fertilizer to boost soil productivity. But the questionable practices don't end there: Chicken pens are frequently suspended over ponds where seafood is raised, recycling chicken waste as a food source for seafood, according to a leading food safety expert who served as a federal adviser to the Food and Drug Administration.") (emphasis added).

People who eat wild-caught American shrimp can be assured that their shrimp meets the standards for U.S. quality and safety. Moreover, unlike many of their foreign seafood producer competitors, U.S. producers are subject to strict Hazard Analysis Critical Control Point ("HACCP") systems monitoring and inspections.

II. Structure of Import Enforcement Regimes

The Request for Comments noted that the Working Group's mission includes a mandate to identify the best practices of "federal, state, and local governments regarding the safety of imports . . . ." [6] As is made clear in the Working Group's Import Safety Report, there is a wide gulf between the stringency of the U.S. Department of Agriculture's ("USDA") import safety regime for meat and poultry products on the one hand, and the FDA's lax imported food safety controls for the remaining 80 percent of our nation's food supply on the other. The substantial differences in the food safety controls of the USDA and FDA, as described below, are essential to understanding the ways in which American consumers are at risk from imported foods ostensibly monitored by the FDA.

However, an understanding of the differences between the United States' imported food safety regulatory system and the food safety regulatory regimes of other major food importing markets is perhaps even more important. Opponents of meaningful reform to the FDA's imported food safety controls misleadingly and inaccurately imply that our regulatory system is stringent in comparison to other major seafood importing countries.[7] As explained below, there is no basis for this claim. Moreover, substantial differences in the regulatory systems regarding

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[6] Import Safety Report at 2.

[7] See, e.g., Letter from National Fisheries Institute to the U.S. Food and Drug Administration, FDA Docket No. 2000N-1633 (May 14, 2001), p. 4 (claiming that "U.S. food safety standards are, in many cases, more restrictive than those of other countries.") ("2001 National Fisheries Institute Letter").

imported foods means that because the FDA operates the most lax system relative to other major food importing markets, we affirmatively attract contaminated, adulterated, filthy, and unfit seafood products to this country. As such, just as the Import Safety Report recognizes the need for "greater international consistency in safety standards that facilitates compliance and permits mutually reinforcing enforcement activities,"[8] the Working Group must also recognize the importance of developing a full understanding of the stringent import safety regimes of other major seafood importing countries, including the European Union ("EU"), Japan, and Canada, and the impact that those regimes have on the U.S. market.

Unlike the model employed by the FDA (which relies on importers to ensure our nation's food safety with only insignificant border inspections to verify that importers live up to their obligations), the EU, Japan, Canada, and the USDA all have made a commitment to ensure the safety of imported food products throughout its life-cycle. The EU guarantees equivalence by conducting on-site inspections and certifying exporting countries and individual exporters prior to importation of a product. Stringent follow-up inspections are conducted both at the EU's border, currently 20 percent of seafood products are inspected, and regularly at the exporters' facilities.[9] Japan has a strict risk-based system that is reinforced by high inspection rates -- currently 25 percent for shrimp imports -- as well as certification requirements and significant

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8 Import Safety Report at p. 18.

9 See EU Import Conditions for Seafood and Other Fishery Products, Directorate-General of Health and Consumer Protection, European Commission ("EU Import Conditions").

penalties for noncompliance.[10] Canada imposes a minimum standard inspection rate of 15 percent for all imported seafood products and strict licensing requirements for importers.[11]

For USDA-regulated food imports, equivalence is a prerequisite for import into the United States. Equivalence is verified through foreign on-site inspections and every import is inspected at the U.S. port of entry. In contrast, the FDA "relies solely on point-of-entry inspection."[12] Such inspections cover approximately 1 percent of all FDA-regulated imports.[13] Further, the FDA does not certify an exporting country's equivalence to U.S. food safety standards and, as such, the safety of seafood imports into the United States is entirely dependent on the importer. As it stands now, however, it would appear that importers have insufficient economic and legal incentives to effectively protect the safety of imported food.

The following overview of the import enforcement regimes of the EU, Japan, Canada, and the USDA are in stark contrast to the lax import enforcement regime of the FDA.

A. European Union

The EU's imported food safety regulatory controls take a full "life-cycle" approach and are applied throughout the supply chain, meaning that for imported shrimp, European consumers

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10 See Handbook for Agricultural and Fishery Products Import Regulations, Japan External Trade Organization (Dec. 2005) ("JETRO Handbook for Import of Fishery Products").

11 See Guide to Canadian Regulatory Requirements and Examination Procedures for Imported Fish, Canadian Food Inspection Agency; L. Ababouch, G. Gandini & J. Ryder, Causes of Detentions and Rejections in International Fish Trade, Food and Agriculture Organization of the United Nations, FAO Fisheries Technical Paper 473, pp. 21-22 (2005) ("2005 FAO Fisheries Paper").

In addition, Canada conducts "specialized testing" at a rate of "5 to 15 percent, depending on the product history and nature of the product." 2005 FAO Fisheries Paper at p. 22.

12 Importing Meat, Poultry & Egg Products into the United States, USDA Food Safety and Inspection Service, (Dec. 2003) ("USDA Import Guidelines").

13 FDA's Imported Seafood Safety Program Shows Some Progress, But Further Improvements are Needed, U.S. General Accounting Office, Report to Congressional Requesters, GAO-04-246, p. 3 (2004) ("2004 GAO FDA Report"); Diminished Capacity: Can the FDA Assure the Safety and Security of the Nation's Food Supply - Part 2, Hearing before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, 110th Cong., p. 2 (July 17, 2007) (Statement of David Nelson, Senior Investigator) ("David Nelson Testimony").

are afforded the protection of their food supply from foreign shrimp aquaculture farms all the way to the EU consumer market.[14] A central tenet of the EU's system of imported food regulation is that a system like that employed by the FDA is inherently flawed and cannot possibly effectively protect the consumer:

> Spot checks on the end product alone would not provide the same level of safety, quality and transparency to the consumer.[15]

Country Certification: The EU's two-step equivalence certification process is imposed on every country and every producer wishing to export shrimp to the EU. An exporting country may not export shrimp to the EU unless it first has established that its food safety program and procedures are at least equivalent to the EU's standards.[16] Only after affirmatively establishing equivalence may the exporting country be eligible to export shrimp to the EU. Nevertheless, even with approval, the EU may impose special import conditions on a specific exporting country if concerns remain or develop regarding the food safety protections in the exporting country, including additional health certification requirements.[17]

Individual Producer Certifications: In addition, individual foreign shrimp producers within an approved country must also obtain approval to export to the EU by demonstrating equivalence with EU safety standards and certifying that their food safety controls are in compliance with the EU's standards. EU authorities conduct mandatory on-site inspections of

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14 EU Import Conditions.

15 Id. at p. 1 (emphasis added).

16 Id., Council Directive on Animal Health Requirements for Aquaculture Animals and Products thereof, and on the Prevention and Control of Certain Diseases in Aquatic Animals, Council Directive 2006/88/EC, art. 23, 2006 O.J. (L 328/14) (while EU Member States have until August 1, 2008 to implement Directive 2006/88/EC, the existing Directive, 91/67/EEC, O.J. (L 46), has essentially identical import requirements) ("2006 Council Directive").

17 2006 Council Directive, art. 25.

aquaculture production, processing and distribution facilities as part of the approval process.[18] At a minimum, foreign shrimp producers must demonstrate equivalence with the EU's standards on critical control points in the manufacturing process, monitoring and sampling requirements, and recordkeeping obligations.[19]

Mandatory On-Site Inspections: The EU's Food and Veterinary Office (the "FVO") conducts mandatory on-site inspections of the exporting country's aquaculture farms and production facilities as part of the approval process for export.[20] The on-site inspection and assessment of foreign facilities ensure that the company and the exporting country's food safety conditions are on par with the EU's standards, especially in the areas of production, manufacture, handling, storage, and dispatch of seafood exports.[21] The FVO conducts rigorous examination of foreign production facilities, no matter the size of the country. These examinations are conducted regularly as a part of a series of FVO missions on residue controls in third countries.[22]

The on-site inspections result in the issuance of a public report that summarizes the investigators' findings and discusses the recommendations made to the government of the country visited.[23] Frequently, these public reports reveal troubling deficiencies in the internal

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18 Laying Down the Health Conditions for the Production and the Placing on the Market of Fishery Products, Council Directive 91/493/EEC, art. 11(4), 1991 O.J. (L 268/15) ("Health Conditions for Fishery Products"); see General Guidance on EU Import and Transit Rules for Live Animals and Animal Products from Third Countries, Directorate-General, Health and Consumer Protection, European Commission, SANCO/10357/2005Rev 6 (2006), p. 12 (Apr. 30, 2006) ("General Guidance on EU Import Rules").

19 Health Conditions for Fishery Products, art. 6.

20 2006 Council Directive at Article 23(3)(f); General Guidance on EU Import Rules.

21 General Guidance on EU Import Rules.

22 Id.

23 See, e.g., Inspection Reports, European Commission, Health & Consumer Protection Directorate - General, Directorate Food and Veterinary Office available at http://ec.europa.eu/food/fvo/ir_search_en.cfm.

seafood production safety controls of countries that export significant quantities of seafood to the United States. For example:

Ecuador

- In a report following on-site inspections in Ecuador, FVO officials noted that inspection reports prepared by Ecuadorian government officials "do not identify a large number of deficiencies observed by the mission team, *e.g.* presence of chilled aquaculture shrimps in one establishment reception area which were soiled with earth/slime/faeces and kept at high temperatures (8-13 ^{o}C) for long periods of time (up to 12 hours) . . . ."[24]

India

- In a report following on-site inspections in India, FVO officials explained their misgivings regarding the program implemented by Indian officials to regulate the use of banned antibiotics in aquaculture. The report noted: "The situation with regard to . . . veterinary medicines has not changed since 2003. It is concerning that chloramphenicol, nitrofurans and nitroimidazoles are available on the market, and whilst prohibited from use . . . are obviously being used in these sectors as evidenced by both the results of the various residues monitoring programmes in operation and the [Rapid Alert System for Food and Feed] RASFF."[25]

- The report concluded that problems related to the use of antibiotics in Indian aquaculture were systemic: "The ongoing problem with residue detections of several EU-banned substances, particularly in the aquaculture sector, demonstrates that controls on the distribution and use of medicines are not currently sufficient and across the sectors, there is no consistent approach in respect of legal prohibitions on the use of such substances."[26]

Bangladesh

- In a report following on-site inspections in Bangladesh, FVO officials revealed that the visits uncovered falsified reports provided to the FVO prior to the mission: "The mission team was informed . . . that no positive results had been

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[24] Final Report of a Mission Carried Out in Ecuador from 19 to 26 October 2005: Assessing the Conditions of Production of Fishery Products Intended for Export to the European Union, European Commission, Health & Consumer Protection Directorate - General, Directorate Food and Veterinary Office, DG(SANCO)/7751/2005 - MR Final, p. 5 (Nov. 2005).

[25] Final Report of a Mission Carried Out to India from 13-22 September 2006 Concerning the Evaluation of the Controls on Veterinary Medical Products, European Commission, Health & Consumer Protection Directorate - General, Directorate Food and Veterinary Office, DG(SANCO)/8015/2006 - MR Final, pp. 22-23 (Dec. 2006).

[26] Id. at p. 23.

detected for either chloramphenicol or nitrofurans in shrimps. However, during an inspection . . . positive results were obtained for both substances in shrimp in 2004. In the version of this document supplied with the pre-mission questionnaire, these results had been altered and all reported as 'not detected.'"[27]

- The report also noted that there was reason to question claims regarding the lack of use of harmful substances in Bangladeshi aquaculture: "The mission team noted . . . the existence of a recently emptied box of ciprofloxacin and was informed that malachite green is used for the treatment in the case of fungal inspections, even though the DF official was convinced that no drugs were used."[28]

Suriname

In February 2007, the EU banned farm-raised shrimp imports from Suriname after a September 2006 inspection of Surinamese production facilities showed intolerable levels of antibiotic residues and other contaminants. The EU inspection found:

- "For aquaculture farms, no monitoring plan for residues is in place."[29]

- Of the ten facilities inspected by the EU mission team, "one establishment was considered compliant . . . the remaining nine were found be non-complaint to varying degrees. The following shortcomings were noted in one or more establishments: storage and processing of rotten fish . . . lack of reliability in the traceability system . . . rotten fish processed after being kept in the establishment for 24 days at a temperature not below -5 °C . . . ."[30]

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27 Final Report of a Mission Carried Out in Bangladesh from 8 to 16 November 2005: Assessing the Public Health Conditions of Production of Fishery and Aquaculture Products Intended for Export to the European Union, European Commission, Health & Consumer Protection Directorate - General, Directorate Food and Veterinary Office, DG(SANCO)/7555/2005 - MR Final, p. 5 (Nov. 2005).

28 Id.

29 Final Report of a Mission Carried Out in Suriname from 18-26 September 2006 in Order to Access the Public Health Controls and Conditions of Production of Fishery Products Intended for Export to the EU, European Commission, Health & Consumer Protection Directorate - General, Directorate Food and Veterinary Office, DG(SANCO)/8251/2006 - MR Final, p. 5 (Jan. 2007).

30 Id. at pp. 10-11.

Import Entry Only Through Veterinary Inspection Posts: Products approved for import may enter the EU only through official border inspection posts ("BIPs") under the authority of an official veterinarian.[31]

All seafood imports at BIPs must be accompanied by a health certification form signed by the regulatory authority of the exporting country.[32] The health certification form represents the exporting country's guarantee that it is in compliance with the EU's food safety standards.[33] EU BIP officials may subject imports to additional veterinary checks.[34]

User Fees: For fish imports, the EU charges a minimum standard level of €5 per tonne of fish, with a minimum of €30 per consignment, although fees may be reduced for additional amounts above 100 tonnes.[35]

Effective Prevention of "Port Shopping": If an imported product is found to be noncompliant with EU import food safety standards, the consignment "shall either be destroyed or, under certain conditions, re-dispatched within 60 days."[36] Specifically, the EU only will allow a re-dispatch of the noncompliant shipment to a third country designation if (1) the destination is predetermined; (2) the importer has first informed the third country destination of

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31 Laying Down the Principles Governing the Organisation of Veterinary Checks on Products Entering the Community from Third Countries, Council Directive 97/78/EC, art. 4, 1997 O.J. (L 24/9) ("EU Council Directive 97/78/EC").

Approved food imports may enter the EU only through one of 274 of approximately 1200 EU BIPs. See European Sea Ports Organization available at http://www.espo.be/Home.aspx.

32 EU Council Directive 97/78/EC; see General Guidance on EU Import Rules.

33 Id.

34 Id.

35 Council Directive 96/43/EC, O.J. (L 162), Ch. 2 (Jan. 7, 1996).

A typical import container contains 20 tonnes of shrimp. As such, the EU inspection user fee would amount to €100, or approximately US$140.88 (20 tonnes x €5 = €100).

36 EU Import Conditions at p. 3.

the reasons for rejection; and (3) the third country destination has notified the EU that it is prepared to accept the consignment.[37]

Significant Penalties for Noncompliance: If there are systemic problems with an exporter or exporting country, the EU has imposed absolute importation bans, meaning that no shipment from the violative exporter or exporting country may enter the EU until the ban has been lifted. EU inspections have resulted in import bans, including a ban on all fishery products from Pakistan beginning in April 2007 and a thirty month ban on shrimp imports from China.[38] The EU agreed to recertify Chinese shrimp imports only after the Chinese government guaranteed that it would test and certify 100 percent of Chinese exports to the EU.[39]

The EU has been able to maintain such high standards for food safety primarily because foreign exporters and exporting governments have the burden of demonstrating that their standards for ensuring the safety of shrimp products are equivalent to the EU. This is in stark contrast to the FDA, where the burden is on the FDA to discover, through a minimal testing regime at U.S. ports of entry, whether imported seafood is unsafe for human consumption.

B. Japan

Like the EU, Japan has also taken a full "life-cycle" approach to the regulation of imported food and believes in a comprehensive food safety regime at "each step of the food

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37 Regulation on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules, Commission Regulation No. 882/2004, art. 21.1, 2004 O.J. (L 191) (2004).

38 "EU bans fish imports from Pakistan citing poor quality," SEAFOOD.COM NEWS (Mar. 19, 2007); "EU eases food imports from China after significant improvements in veterinary standards," Press Release, European Commission, IP/04/943 (July 16, 2004); see infra at Section IV.

39 Id.

supply process both in Japan and overseas."[40] Instead of a strict equivalence-based import regime, however, Japan's Ministry of Health, Labour and Welfare, Office of Import Food Safety ("MHLW") employs a risk analysis approach to ensure the food safety of its seafood imports.[41] Despite the different approach, the MHLW recognizes the vital importance of what is taking place in the exporting countries:

> [A]ppropriate measures must be taken from the stages of production, manufacturing and processing . . . in exporting countries, to the stages of import and distribution in the domestic market for the purpose of maintaining the safety of the imported foods.[42]

Inspection Rates Based on Annual Risk-Based Assessment: Annually, the MHLW assesses the risks posed by seafood imports, and issues implementation and inspection guidelines for the upcoming year.[43] Thus, while the general inspection rate of imported foods is 10.2 percent, the food safety risk posed by imported shrimp, prawn and lobster has resulted in inspection rates of around 25 percent.[44] Import notifications are required for all shipments of shrimp imports.[45] The decision as to whether to inspect a particular imported product is based on the import documentation, the MHLW's annual inspection guidelines, and the circumstances of the particular exporting country.[46]

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40 Development of Imported Foods Monitoring and Guidance Plan for FY 2006, Notice No. 0324002, Department of Food Safety, Pharmaceutical and Food Safety Bureau, Japan Ministry of Health, Labour and Welfare (Mar. 24, 2006).

41 See JETRO Handbook for Import of Fishery Products.

42 Id. (emphasis added).

43 See, e.g., Development of Imported Foods Monitoring and Guidance Plan for FY 2007, Director of the Department of Food Safety, Pharmaceutical and Food Safety Bureau, Japan Ministry of Health, Labour and Welfare (Mar. 23, 2007) ("Japan FY 2007 Imported Foods Monitoring Plan")

44 Statistics of Imported Foods Monitoring for 2005, Department of Food Safety, Pharmaceutical and Food Safety Bureau, Japan Ministry of Health, Labour and Welfare, p. 9 (June 2006) ("Japan 2005 Imported Food Statistics").

45 JETRO Handbook for Import of Fishery Products.

46 See Japan 2005 Imported Food Statistics.

Entrance Only After Clearing Quarantine Stations: Imports of food products may not enter Japan unless first cleared by the quarantine station.[47]

Foreign On-Site Inspections: In addition to the MHLW's strict border inspection regime, MHLW conducts on-site inspection of production facilities in exporting countries.[48]

Introduction of a Positive List System for Chemical Residues: On May 29, 2006, the MHLW implemented a standardized positive list system for chemical residues in food products. The positive list system prohibits the distribution of foods that contain agricultural chemicals above a uniform level of 0.01 parts per million ("ppm") if maximum residue limits ("MRLs") have not already been established.[49] The MHLW's quarantine stations conduct monitoring tests of imports to ensure compliance with Japan's uniform level and MRLs.[50] Any product found in excess of an established MRL or any chemical residues above 0.01 ppm, even if not specifically listed by MHLW, is prohibited from entering Japan.[51]

Significant Penalties for Noncompliance: The MHLW may issue compulsory 100 percent testing and/or an import ban of a particular import if it finds that more than 5 percent of

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47 Procedures of Import Notification of Foods and Related Products, Department of Food Safety, Pharmaceutical and Food Safety Bureau, Japan Ministry of Health, Labour and Welfare available at http://www.mhlw.go.jp/english/topics/importedfoods/1-1.html.

48 See Results of Monitoring and Guidance Based on the Imported Foods Monitoring and Guidance Plan for FY 2005, Department of Food Safety, Pharmaceutical and Food Safety Bureau, Japan Ministry of Health, Labour and Welfare (June 2006) ("Japan FY 2005 Imported Foods Monitoring Plan").

49 Introduction of the Positive List System for Agricultural Chemical Residues in Foods, Department of Food Safety, Pharmaceutical and Food Safety Bureau, Japan Ministry of Health, Labour and Welfare (June 2006).

Maximum residue limits have been established for approximately 758 agricultural chemicals. Summary of Japan's New Positive List System for Regulation of Agricultural Chemical Residues, USDA Foreign Agriculture Services, Global Agriculture Information Network ("GAIN"), GAIN Report No. JA6004 (Feb. 6, 2006) ("2006 GAIN Report on Japan").

50 Id.

51 Id.

consecutive shipments of the inspected import is adulterated.[52] In December 2006, Japan instituted a 100 percent testing policy on and threatened to ban Vietnamese shrimp imports after finding that 6.7 percent of such imports were contaminated with chloramphenicol.[53] Japan has also ordered increased testing rates of shrimp imports from China and Indonesia.[54]

Additional Health Certification for Certain Countries: After repeated detection of chloramphenicol in shipments of Vietnamese shrimp, Japan began testing 100 percent of Vietnamese shrimp imports in December 2006.[55] In response to the comprehensive testing, Vietnam agreed to inspect and pre-certify all shrimp exports bound for Japan for the presence of chloramphenicol and nitrofurans.[56] Under the agreement between Japan and Vietnam, only shipments tested and certified by Vietnamese health officials would be permitted for export to Japan.[57] At the same time, Japanese officials continued to vigorously inspect Vietnamese shrimp imports and for good reason: despite the certifications provided by Vietnamese officials, 54 shipments of Vietnamese shrimp were found to be contaminated with chloramphenicol in the six-month period following the imposition of Japan's compulsory inspection policy in December 2006.[58]

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52 Food Sanitation Law in Japan, art. 8 (April 2006) (translation by Japan External Trade Organization); Japan FY 2007 Imported Foods Monitoring Plan at p. 3; 2006 GAIN Report on Japan at p. 8.

53 "Controlling banned chemicals and antibiotics in fishery," Statement of the Vietnamese Ministry of Fisheries National Fisheries Quality Assurance and Veterinary Directorate of the Vietnam Ministry of Fisheries ("NAFIQAVED"), Ref. 2983/CLTY-CL (Dec. 19, 2006).

54 Japan FY 2005 Imported Foods Monitoring Plan.

55 "NAFIQAVED declares three reasons for unsafe seafood," VIETNAM ECONOMY (Dec. 15, 2006).

56 Id.

57 "Vietnam Checks Shrimps Exported to Japan for Contaminants," THANHNIEN NEWS (Mar. 3, 2007).

58 "VASEP asks Minister to declare emergency as Japan threatens to halt Vietnamese shrimp exports," SEAFOOD NEWS (July 9, 2007).

C. Canada

Canada has also instituted a risk-based approach to regulating the safety of imported food. Inspection of a food import is "based on food safety risk, the history of compliance of a particular product, the history of compliance of the processor, and the country of origin of the product."[59] Foreign producers that have demonstrated a history of poor compliance with Canada's food safety standards are subject to increased inspection testing.[60]

Equivalence Agreements: Exporting countries with bilateral equivalence agreements with Canada are subject to reduced inspection requirements.[61] In return, the exporting country agrees to inspect and certify products bound for Canada.[62] Canada established a bilateral agreement with Vietnam in July 2006 following a two-year country-wide alert and 100 percent inspection policy for all Vietnamese seafood imports because of repeated findings of chloramphenicol in shrimp and other contaminants in other seafood products.[63] The bilateral agreement requires Vietnamese health officials to inspect and certify shrimp exports bound for Canada for banned chemicals and antibiotics.[64] In return, no more than 5 percent of Vietnamese-certified shipments would be tested upon arrival.[65]

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59 The Regulation of Imported Fish and Seafood Products in Canada, Canadian Food Inspection Agency ("The Regulation of Imported Fish and Seafood Products in Canada").

60 Import Inspection Program, Canadian Food Inspection Agency.

61 Id.

62 Id.

63 Arrangement Concerning the Inspection and Certification of Aquaculture Fish and Fish Products Exported from Vietnam to Canada for Drug Residues, Canadian Food Inspection Agency (July 17, 2006) ("Canada-Vietnam Aquaculture Fish MOU").

64 Id.

65 Id.

All New Exporters Inspected: Shipments from new exporters undergo every type of test required for that product.[66] If the shipment fails inspection, subsequent imports are inspected until four consecutive shipments pass inspection.[67] Repeated failure of inspections may lead to the imposition of an import alert and 100 percent testing of shipments from the particular exporter or exporting country.[68]

User Fees: Canada imposes an inspection service fee for each kilogram of imported fish. For fish (including shrimp) that is imported for consumption without further processing, Canada imposes an inspection service fee of C$0.15 per kilogram.[69] In addition to inspection user fees, Canada charges for each type of testing service it provides in connection with the approval of an imported product. If a foreign producer has not exported a type of fish to Canada within the previous two years, that importation shall undergo every type of testing applicable to that type of fish.[70] For example, the full range of testing for ready-to-eat aquaculture shrimp imports includes: (1) escherichia coli; (2) staphylococcus aureus; (3) listeria monocytogenes; (4) salmonella; (5) drug residues; (6) sulphites; and (7) phosphates.[71] At a minimum, these testing fees would add up to be C$722.

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66 Fish Inspection Regulations, C.R.C., c. 802, § 6.5(4) (current to Aug. 28, 2007) ("Fish Inspection Regulations").

67 Id. at § 6.5(2).

68 Id.

69 Canadian Food Inspection Agency Fees Notice, Canadian Food Inspection Agency, Part 16 at Table 2 (current to Nov. 30, 2005) ("CFIA Fees Notice"); see Fish Inspection Regulations, C.R.C., c. 802, §6(4).

A typical import container contains 20,000 kilograms of shrimp, a ready-to-eat product. This would amount to an inspection user fee of C$3,000, or US$3,000 (20,000 kg x C$0.15 = C$3,000).

70 Fish Inspection Regulations, c. 802, §6.5(4).

71 Fish Products Inspection Manual, Canadian Food Inspection Agency, Chapter 3 - Imported Fish and Fish Products Inspection, Appendix B (last modified May 10, 2007).

For routine export shipments, Canadian officials may subject any fish import on a random basis to testing of any type listed in its regulations.[72] Canada charges varying fees for different types of testing services, such as C$139 for salmonella testing and C$235 for drug residue testing.[73]

D. U.S. Department of Agriculture

As stated in the Import Safety Report, the USDA will not allow an exporting country to ship meat, poultry and egg products to the United States unless it has certified equivalence with U.S. food safety standards.[74] Equivalence is verified through a three-part evaluation: (1) document analysis; (2) foreign on-site audit; and (3) port-of-entry reinspection.[75] Currently, only 34 countries are eligible to export meat, eggs, and poultry to the United States.[76]

Document Analysis: As an initial step and much like other major importing countries, the USDA reviews the exporting country's laws, regulations and implementing policies regarding food safety.[77] The USDA issues questionnaires "to every exporting country" seeking "extensive details about how they regulate for hazards . . . ."[78]

Mandatory Foreign On-Site Audit: If the exporting country's laws and regulations are deemed equivalent to U.S. food safety standards, USDA officials conduct an on-site audit of the exporting country's plants, laboratories, distribution facilities, and the relevant government

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72 Fish Inspection Regulations, c. 802, §6.5(1).

73 Request for an Inspection of Fish, Canadian Food Inspection Agency, Form CFIA/ACIA (2003/05).

74 Import Safety Report at p. 20.

75 See Process for Evaluating the Equivalence of Foreign Meat and Poultry Food Regulatory Systems, Food Safety Inspection Service, United States Department of Agriculture, p. 2 (Oct. 2003) ("USDA Equivalence Guide").

76 Eligible Foreign Establishments, USDA Food Safety and Inspection Service ("USDA Eligible Establishments").

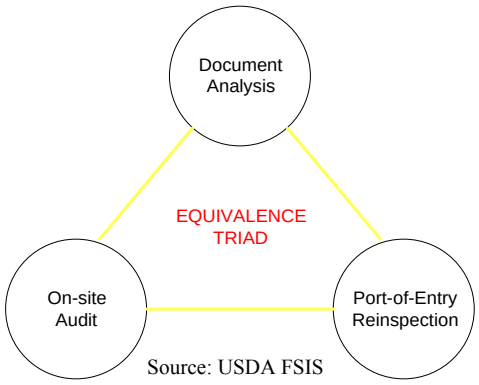
77 USDA Equivalence Guide at p. 14.

78 Id.

entities.[79] Such foreign on-site audits are then "conducted at least annually in every country that exports meat or poultry products to the United States."[80] A country's certification may be revoked if these audits reveal inadequate health and safety controls.

Port-of-Entry Reinspection: As noted in the Import Safety Report, every import of meat, poultry, and egg products is inspected for safety by the USDA.[81] While exporting governments must inspect and certify each shipment of meat and poultry exports to the United States, the USDA's Food Safety and Inspection Service ("FSIS") reinspects every imported shipment at the U.S. port of entry.[82]

USDA 3-Part Approach to Verifying Equivalence



Source: USDA FSIS

Additional Risk-Based Testing: Of all the imports reinspected by the USDA, certain shipments are selected for more extensive testing based on the USDA's risk analysis database, the Automated Import Information System ("AIIS").[83] When an import is presented for port-of-entry reinspection, "the AIIS scans its existing records to determine if the foreign country, the

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79 Id. at p. 15.

80 Id.

81 Import Safety Report at 6.

82 Id.; USDA Equivalence Guide at p. 16.

83 Managing Meat, Poultry and Egg Products Imports, USDA Food Safety Inspection Service (June 2007).

establishment, and the product are eligible for export to the United States. The shipment is refused entry if any component of eligibility is absent."[84]

The USDA also has access to U.S. Customs and Border Protection ("Customs") data via the Automated Commercial Environment, which enables the USDA to (1) determine whether shipments arrive from ineligible sources, (2) monitor ports of entry and importers of rejected shipments, and (3) track rejected or suspect shipments from the time of entry until Customs determines whether to detain or redeliver the shipment.

FDA's import database (the OASIS system), in contrast, while purporting to select shipments for further scrutiny based on risk, actually removes "80 percent of the so-called 'low risk' imports from any field inspection."[85] Thus, only 20 percent of all FDA-regulated imports are even under consideration for "any field inspection."[86]

Marking and Pre-approval Required for Re-export: The USDA requires an adulterated food import to be re-exported or destroyed within 45 days of rejection.[87] Rejections on health and safety grounds are immediately reported to the port of entry.[88] Importers of rejected consignments must supply information about when and how the shipment will be reexported.[89] If the shipment is going to a third country, the country in question must give consent.[90] Those shipments must be labeled "United States Refused Entry."[91]

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84 USDA Equivalence Guide at p. 16.

85 David Nelson Testimony at p. 4.

86 Id.

87 9 C.F.R. § 327.13(a)(2) (2007).

88 Id. at § 327.13(a)(1).

89 Id. at § 327.13(a)(3).

90 Id.; Meat and Poultry Products Refused Entry Into the U.S., USDA Food Safety Inspection Service, FSIS Directive 9020.1, sec. X (Apr. 3, 2001) ("USDA Refused Entry Guidance").

91 9 C.F.R. at § 327.13(a)(2); USDA Refused Entry Guidance at sec. VII.

III. The FDA's Lax Import Enforcement Regime

As the Import Safety Report notes, the USDA's import food safety regime is far more stringent than the import enforcement efforts of the FDA. The USDA "approves foreign countries for the export of meat, poultry, and egg products to the U.S. and inspects every imported shipment of those products for safety."[92] In contrast, the FDA "electronically and/or physically screens every shipment of food . . . ."[93] The FDA, however, only inspects approximately 1 percent of its regulated food imports. The testimony from a senior investigator for the U.S. House of Representatives Committee on Energy and Commerce ("House Energy and Commerce Committee") summarizes the fundamental disparity between the USDA and FDA:

> Compared to USDA, FDA's resources and activities appear to be woefully short of its food import responsibilities. FDA is responsible for assuring the safety of 80 percent of the food supply, but lacking a user fee system, is able to inspect only about 1 percent of all food imports, and does not ensure that foreign food processors and suppliers meet U.S. food safety standards.[94]

Moreover, the USDA itself emphasizes the comparative paucity of the FDA's regulatory scheme in light of the USDA's model:

> FDA relies solely on point-of-entry inspection. FSIS, on the other hand, works collaboratively with the importing establishment's government and uses a three-part process to verify that other countries' regulatory systems for meat, poultry and egg products are equivalent to that of the U.S. and that products entering the U.S. are safe and wholesome.[95]

The absurd consequences of this irrational disparity between the USDA and the FDA was recognized, albeit perhaps unintentionally, by the Import Safety Report:

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92 Import Safety Report at p. 6 (emphasis added).

93 Id. (emphasis added).

94 David Nelson Testimony at p. 4 (emphasis added).

95 USDA Import Guidelines (emphasis added).

> [I]n 2006, [Customs] intercepted 45 containers with chicken, chicken parts, pork and meat products being smuggled into the U.S. as frozen seafood. These meat products were prohibited entry into the U.S. because they were from a country that was not approved by USDA to export them to the U.S.[96]

This example is important for two reasons. First, seafood products routinely enter the United States from countries that USDA does not permit to export meat, poultry, or egg products.[97] Second, even where seafood imports enter the United States from countries that the USDA determines do not administer U.S.-equivalent food safety laws, the chances that the FDA will inspect the shipment are so low that importers believe that they can bring in a container filled with meat products, label it as seafood, and enter the product into the United States. Indeed, the fact that the scheme was discovered does not provide much comfort as the shipment was interdicted by U.S. Customs and Border Protection and not the FDA.

When faced with 100 percent inspection by the USDA and a 1 percent chance of being inspected by the FDA, it is easy to understand why unscrupulous importers would chose to misidentify poultry, pork, and meat products as frozen seafood. By the same token, it is even easier to understand why exporters choose to ship unsafe product to this country and why importers appear not to feel compelled to insure that seafood brought into the United States is free of harmful contaminants.

Certification Not Required for Import: The FDA does not require foreign government or foreign producer certification as a condition of entry into the United States. In the absence of certification or equivalence agreements with other countries or foreign agencies, the FDA is reliant on its own testing to identify safety violations. Because the frequency of FDA testing is

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96 Import Safety Report at p. 9 (emphasis added).

97 Large seafood exporting countries to the United States, such as Thailand,Ecuador, and Vietnam, are not certified to export USDA-regulated products. See USDA Eligible Establishments.

not mandated by statute, FDA inspection rates have hovered at approximately 1 percent since 2002.[98] In essence, exporters are allowed to self-certify their compliance with U.S. food safety standards.

Reliance on Unaccredited, Unlicensed Private Laboratories: While FDA inspects only about 1 percent of imported food at the border, an even smaller percentage, 0.2 percent, is tested in a laboratory.[99] Private testing laboratories need not be licensed or accredited by the FDA in order to certify the food safety of seafood imports.[100] A proposed accreditation system was dropped by the FDA following resistance from private laboratories.[101] The House Energy and Commerce Committee investigation on the FDA's import enforcement procedures found that

> One particularly important problem that staff field investigation uncovered dealt with the unverified reliance by FDA on the use of private laboratory tests to release suspect imports . . . . FDA neither accredits nor debars private laboratories that analyze imported food samples, despite the fact that these laboratories often use incorrect methods or report incorrect results.[102]

For exporters and products subject to an "import alert," the FDA generally requires 100 percent testing.[103] However, an importer need only obtain five consecutive analyses by private laboratories demonstrating negative test results -- from samples chosen by the importer -- to

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98 2004 GAO FDA Report at p. 4; H.R. REP. 109-255, p. 101 (Oct. 26, 2005) (Conf. Rep.) (accompanying H.R. 2744 on Making Appropriations for Agriculture, Rural Development, Food and Drug Administration, and Related Agencies for Fiscal Year 2006).

99 A. Barrionuevo, "Food Imports Often Escape Scrutiny," NEW YORK TIMES (May 1, 2007) ("Food Imports Often Escape Scrutiny").

100 David Nelson Testimony at pp. 2-3.

101 Letter from the American Council of Independent Laboratories, FDA Docket No. 02N-0276 and 02N-0278, p. 8 (May 14, 2004).

102 David Nelson Testimony at pp. 2-3 (emphasis added).

103 "'Import Alert' For Chinese Seafood Ignored," CBS NEWS (Aug. 8, 2007) ("The frozen shrimp, catfish and eel arrived at U.S. ports under an 'import alert," which meant the FDA was supposed to hold every shipment until it had passed a laboratory test. But that was not what happened, according to an AP [Associated Press] check of shipments since last fall. One of every four shipments the AP reviewed got through without being stopped and tested. The seafood, valued at $2.5 million, was equal to the amount 66,000 Americans eat in a year.").

exempt the exporter from all testing requirements.[104] Of course, there is no logic to this policy. A determination by unaccredited laboratories that five self-selected samples test negative for contaminants in no way indicates that subsequent shipments of the product will likewise be free of contaminants. If an exporting country or producer has been determined to have a problem so significant (with chloramphenicol contamination for example) that an import alert is warranted, there is no basis to conclude from five uncontaminated samples that the systemic problem has been resolved permanently or even addressed in the exporting country. As could be expected, importers of seafood products have been particularly prone to exploit this testing loophole.[105]

No Interdiction of Unsafe Product and No Prevention of Port-shopping: The FDA does not require imports to be physically quarantined for inspection or testing prior to entry into the United States, which allows "importers to take possession of even highly suspect goods and arrange for their testing by private laboratories."[106] Even imports subject to an FDA import alert are not physically quarantined and may be delivered straight to importers.[107] Further, "FDA does not require a separate bond be posted by the importer taking delivery."[108] In the interim, there is ample time for product to slip into the U.S. market. Reviewing the FDA's administration of its food safety program, the U.S. Government Accountability Office ("GAO") found that it takes an

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104 David Nelson Testimony at p. 3

105 Id. at p. 6 ("Another safety concern uncovered by the [FDA] staff's fieldwork relates to seafood products and the manipulation of laboratory testing.").

106 David Nelson Testimony at p. 2.

107 Import Program System Information, U.S. Food and Drug Administration, Office of Regulatory Affairs (last updated May 17, 1999) ("When a sample of an article offered for import has been requested by FDA, the owner or consignee shall hold the shipment and not distribute it until further notice is received regarding the results of the examination of the sample.").

108 David Nelson Testimony at p. 3.

average of 348 days for the FDA to notify port-of-entry officials of a rejected import shipment.[109]

While the USDA clearly marks all rejected shipments "United States Refused Entry" and tracks all shipments through its AIIS database system, the FDA does not have any marking requirements nor does it otherwise have any procedures to prevent importers from sending rejected shipments to other U.S. ports, or "port-shopping" rejected imports. Congress explicitly gave the FDA the authority "to require the marking of refused food" in the Bioterrorism Act of 2002, [110] but to date, the FDA has yet to use this authority or issue final regulations.[111] The FDA has proposed "marking" rules that would prevent port-shopping but the FDA's proposals have been bitterly opposed by seafood importers.[112] The reasons given for opposition to the development of rules preventing port-shopping are frequently ludicrous. For example, the National Fisheries Institute has argued that a "refused" mark "may serve to unduly stigmatize" a shipment of unsafe seafood and has proposed that any markings be "applied with invisible ink."[113] A few years later, a group of importer interests (including the National Fisheries Institute) challenged the FDA's authority to implement marking requirements -- the same

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109 2004 GAO FDA Report at p. 5.

110 Implementation of the Food Security Provisions of the Public Health Security and Bioterrorism Preparedness and Response Act, Pub. L. No. 107-188, § 308 (2002).

111 Implementation of the Food Security Provisions of the Public Health Security and Bioterrorism Preparedness and Response Act, Hearing before the H. Comm. on Energy and Commerce, 108th Cong. (2004) (Statement of Lester M. Crawford, Acting Commissioner, Food and Drug Administration).

112 See Marking Requirements for and Prohibitions on the Reimportation of Imported Food Products That Have Been Refused Admission into the United States: Proposed Rule, U.S. Food and Drug, 66 Fed. Reg. 6,502 (Jan. 22, 2001).

The proposed rule was subsequently withdrawn without action in August 2002. Marking Requirements for and Prohibitions on the Reimportation of Imported Food Products That Have Been Refused Admission Into the United States: Withdrawal, U.S. Food and Drug, 67 Fed. Reg. 54,138 (Aug. 21, 2002).

113 Letter from National Fisheries Institute to the U.S. Food and Drug Administration, FDA Docket No. 2000N-0120 (Feb. 29, 2000), p. 4 (unnumbered).

marking requirements that are currently administered by the USDA -- in a Citizen Petition to the FDA alleging that any marking requirement could impinge on importers' first amendment rights:

> The Bioterrorism Act's marking provision, when implemented, is a form of compelled commercial speech that implicates the First Amendment rights of importers. The marking will force an importer to make a derogatory statement about its own product.[114]

The more traditional argument presented by importing interests like the National Fisheries Institute against marking requirements is that there is no "evidence that food importers on a systematic re-occurring basis undertake port shopping, with the intent of re-entering previously rejected goods."[115] The burden that importers seek to place on the government prior to the implementation of measures to prevent port-shopping is remarkably complicated and divorced from the reality of the marketplace -- a reality that seafood importers are acutely aware of. Indeed, one need only flip to the classified section of the September 2007 issue of SeaFood Business magazine to see the following advertisement:[116]

Source: SeaFood Business

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114 Citizen Petition to the U.S. Food and Drug Administration, American Spice Trade Association, the Association of Food Industries, the Cheese Importers Association of America, the Cocoa Merchants' Association of America, the International Dairy Foods Association, the National Fisheries Institute, and the National Food Processors Association, FDA Docket No. 02P-0321, p. 6 (Feb. 26, 2003) (submitted by Olsson Frank and Weeda P.C.).

115 2001 National Fisheries Institute Letter at p. 2.

116 SEAFOOD BUSINESS MAGAZINE, p. 52 (Sept. 2007).

There is no reason why consumers in this country or, for that matter, any other country should be unwittingly subjected to products contaminated by harmful substances such as antibiotics and pesticides. The failure to implement and administer marking rules, however, leaves open the possibility that shippers, like the company advertising in SeaFood Business, can bring product tainted by chloramphenicol into other ports -- either in this country or elsewhere -- with no disclosure of the harmful nature of the product.

Reliance on Importers: The FDA's regulatory model, such as it is, depends almost exclusively on importers taking responsibility for the safety of food products brought into the United States. Under the FDA's model "[i]mporters have a responsibility . . . to verify that the fish and fish products they are importing meet" the agency's HACCP and sanitation prerequisite requirements.[117] Accordingly, importers must take "affirmative steps" to "verify that the products they are importing have been processed in accordance with the regulations (21 CFR part 123.12)."[118] The regulations, however, "do not mandate what affirmative steps importers must take, but gives examples of affirmative steps that importers may select."[119] One such example of an affirmative step that would be deemed sufficient by the FDA's standards is for an importer to purchase from a list of processors that are in "good standing" with an exporting government. The FDA makes clear, however, that "importers should be aware that FDA has not verified the lists or the information on them."[120]

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117 Fish and Fishery Product Imports: Affirmative Steps, U.S. Food and Drug Administration, CFSAN/Office of Seafood (Apr. 1998; Updated Feb. 2007).

118 Id.

119 Id.

120 Id.

Moreover, importers themselves have frequently admitted that they are unable to verify that the products they import meet the FDA's requirements. For example, in presenting the facially spurious argument that strong marking laws could result in an increase in unsafe product entering the United States, the National Fisheries Institute posited that "[c]onceivably, an unscrupulous overseas buyer will be able to purchase refused product for pennies on the dollar, repack the product, re-sell them to unwitting U.S. importers and still make a tidy profit."[121] According to the FDA's rules, however, there should never be an "unwitting U.S. importer" as every importer is required to verify that the product they are bringing in was processed according to the FDA's regulations. The National Fisheries Institute's hypothetical nevertheless presumes that innocent importers would regularly have no knowledge of whether the product they purchase was, in fact, processed according to the FDA's regulations. This reality was echoed in a submission by the AAC Consulting Group, Inc. -- a group that represents domestic and foreign manufacturers and importers -- in comments made to the FDA. Opposing the FDA's proposals regarding marking certain products "refused," AAC Consulting stated that "most small importers who purchase product from a foreign food broker will not know who the manufacturer is until the product arrives."[122]

Under these circumstances, reliance on importers to safeguard the health and safety of the American public is plainly misplaced.

"Seafood Imports Remain Especially Problematic": The House Energy and Commerce Committee investigators were particularly concerned about the food safety concerns posed by seafood imports.

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[121] 2001 National Fisheries Institute Letter at p. 2 (emphasis in original).

[122] Letter from AAC Consulting Group to the U.S. Food and Drug Administration, FDA Docket No. 00N-1633, p. 2 (Feb. 16, 2001).

> From the [FDA] staff field investigation, it was learned that FDA has known for years about the widespread use of antibiotics and fungicides to treat farm-raised fish from China. It appears, however, that only after the Subcommittee [on Oversight and Investigations] and other Congressional committees began to investigate FDA's less-than-aggressive approach to the regulation of fish imports, did FDA issue its [import] alert.[123]

In fact, official documents from the FDA have recognized that the problem of the use of antibiotics and fungicides in aquaculture extend well beyond China. In rejecting the Citizens Petitions that challenged the agency's testing of chloramphenicol in crabmeat, the FDA stated that "there is abundant evidence that chloramphenicol is still in widespread use abroad, particularly in Southeast Asia."[124] The FDA based its conclusion on the following finding:

> [G]iven the evidence of widespread use of chloramphenicol and the absence of any regulatory controls in China, the previous acknowledgements by the governments of China and Vietnam that chloramphenicol has been added to seafood products, and FDA's knowledge of seafood practices in Southeast Asia, FDA concludes that there are several potential routes of contamination by chloramphenicol: (1) through shrimp feed or by direct addition to shrimp ponds, holding tanks, or other containment areas; or (2) in a wash, dip, spray, or other treatment used during processing, such as the hand treatments documented by the Chinese government as late as June of 2002 . . . . Due to its apparent ready availability, low price, and broad anti-spectrum antibiotic activity, it is reasonably likely that chloramphenicol is added to crabmeat in these ways.[125]

Worse, the same document recognizes the extremely severe health hazards presented by chloramphenicol. The FDA concluded that "chloramphenicol is not and cannot currently be generally recognized as safe for use in a manner that can reasonably be expected to result in its being a component of food" because of the severe health consequences of exposure to even low levels of chloramphenicol. The FDA found that:

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123 David Nelson Testimony at p. 6 (emphasis added).

124 Letter from the U.S. Food and Drug Administration to Olsson, Frank, and Weeda, P.C., Re: 02P-0321, p. 22 (Jul. 29, 2003) ("FDA Chloramphenicol Decision").

125 Id. at 16 (footnotes omitted).

> There are at least three known potential human health risks from exposure to chloramphenicol at low dietary levels: (1) aplastic anemia, (2) carcinogenicity, and (3) reproductive toxicity. Concern for these three health risks currently exists at all levels of exposure.[126]

On aplastic anemia, the FDA found:

> Chloramphenicol-associated aplastic anemia remains an extremely serious and potentially fatal disease. … FDA has substantial evidence based on the oral and injected medical use of chloramphenicol that exposure to chloramphenicol is known to cause a fatal aplastic anemia, that the likelihood of a fatal aplastic anemia occurring cannot be predicted from the chloramphenicol dose, and that studies have shown that fatal aplastic anemia is 13 times more likely to occur after use of chloramphenicol.[127]

On carcinogenicity, the FDA found "data that cause significant concern for genetic toxicity, (i.e., chromosome breaks and DNA damage), and carcinogenicity, (i.e. leukemia), associated with chloramphenicol," including studies by the World Health Organization and the U.S. National Toxicology Program.[128] Finally, "in addition to the risks of aplastic anemia and carcinogenicity, chloramphenicol presents a risk of reproductive toxicity. There are data to show that chloramphenicol crosses the placenta and is thus a danger to fetuses during late gestation."[129]

Thus, exposure to even low levels of chloramphenicol puts consumers at immediate risk (in the case of aplastic anemia) and additionally presents long-term health risks (carcinogenicity). As publicity regarding the harmful effects of chloramphenicol has increased, some aquaculture producers have converted to using nitrofurans, an antibiotic that has long been recognized by the FDA as a dangerous carcinogen and is prohibited for use in food-producing animals.[130]

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126 Id. at 17 (emphasis added).

127 Id. at 19-20 (footnotes omitted).

128 Id. at 21 (footnotes omitted) (emphasis added).

129 Id. (emphasis added).

130 Tropical Nitrofurans; Extralabel Animal Drug Use; Order of Prohibition, 67 Fed. Reg. 5470 (Feb. 6, 2002).

Moreover, the use of antimicrobial agents, such as chloramphenicol, in aquaculture has been instrumental in developing antibiotic-resistant bacteria that poses a significant threat to humans. In a paper written by Dr. Frederick Angulo of the Centers for Disease Control and Prevention, Foodborne and Diarrheal Diseases Branch, National Center for Infectious Diseases, Dr. Angulo concluded:

> These data demonstrate that use of antimicrobial agents in aquaculture has selected for resistance among bacteria in the exposed ecosystems. This resistance can disseminate through the environment and can be transmitted to a variety of bacterial species, including bacteria that can infect humans.[131]

Subsequent academic study has found that not only is the use of antimicrobials in aquaculture leading to the development of antibiotic-resistant bacteria that imperils humans, but shrimp produced from aquaculture exported to other markets may be a vector by which antibiotic-resistant strains of bacteria are spread throughout the world.[132]

The health risks discussed above represent a fraction of the risks posed by aquaculture products imported into the United States. The FDA has never contested the severity of the risks presented but, at the same time, the agency's model for regulating seafood imports does not reflect the significance of those risks.

IV. A Magnet for Contaminated Imports: Consequences of the FDA's Lax Enforcement Efforts

The consequence of stringent import regimes of other major shrimp importing countries coupled with the FDA's lax enforcement of U.S. food safety standards has been hard-felt by U.S. consumers: the United States has become a magnet for unsafe and contaminated shrimp imports.

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131 Dr. F. Angulo, "Antimicrobial Agents in Aquaculture: Potential Impact on Public Health," Alliance for the Prudent Use of Antibiotics Newsletter, Vol. 18, No. 1, p. 4 (2000).

Dr. Angulo's findings were formally presented to the FDA in a memorandum dated October 18, 1999.

132 G. M. Durán & D. L. Marshall, "Ready-to-Eat Shrimp as an International Vehicle of Antibiotic-Resistant Bacteria," 68 Journal of Food Protection 11, 2,395-2,401 (Nov. 2005).

The FDA's lax oversight of imported food products is putting U.S. consumers at risk and threatens the integrity of our nation's food supply. When other major importing markets take action against unsafe seafood products, those products are diverted to the United States. As further shown below, the incentives created by the FDA for foreign producers to export unsafe products is not a matter of conjecture, but instead can be conclusively demonstrated with trade data. There is a direct cause and effect between market closures or restrictions on imports in major importing countries and the diversion of contaminated and likely contaminated products to the United States.

Importing interests have, however, offered arguments in opposition to any meaningful regulation of imported food that fly in the face of this reality, alleging that improvement of U.S. food safety laws would be "protectionist" and potentially violative of this country's international trade obligations. A recent example of this brand of sophistry can be gleaned from recent testimony provided to the House Committee on Energy and Commerce, Subcommittee on Health opposing the imposition of any user fees to importers:

> [W]e are concerned that a user fee on imports would violate our trade commitments by creating a preference for domestic sources of food products and ingredients. We're also concerned that such a fee could invite other countries to place similar fees on our food exports.[133]

As the discussion of comparative food safety programs in other major seafood importing nations above shows, the FDA's regulatory oversight of imported food lags substantially behind those employed in other countries (and the oversight of the USDA). Accordingly, any improvement in

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[133] Food and Drug Import Safety Act: Hearing on H.R. 3610, Subcomm. on Health of the H. Comm. on Energy and Commerce, 110th Cong., pp. 6-7 (Sept. 26, 2007) (Written Testimony of the Honorable Cal Dooley, Grocery Manufacturers/Food Products Association, President and Chief Executive Officer); see also Food and Drug Import Safety Act: Hearing on H.R. 3610, Subcomm. on Health of the H. Comm. on Energy and Commerce, 110th Cong., p. 13 (Sept. 26, 2007) (Written Testimony of Hallock Northcott, American Association of Exporters and Importers, President & CEO).

the FDA's regulatory authority would, at most, simply bring the U.S. in line with international best practices. Moreover, as the FDA has previously recognized,[134] Article XX of the General Agreement on Tariffs and Trade (GATT) explains that nothing in the GATT prevents a nation from adopting or enforcing any measure "necessary to protect human, animal, or plant life or health . . . ."[135] Further, Article VIII of the GATT specifically contemplates and allows for fees to be charged for the "analysis and inspection" of imported goods so long as the fees are "limited in amount to the approximate cost of services rendered and shall not represent an indirect protection to domestic products or a taxation of imports or exports for fiscal purposes."[136] Accordingly, the improvement of FDA's regulatory program related to the safety of imported seafood would not be inconsistent with our international trade obligations.

The real trade implications of the FDA's regulatory program can be discerned by reference to trade patterns. The fact that the United States' failure to implement a strong safety program with regard to imported seafood creates incentives for exporters to ship harmful product to this market is widely recognized. In an op-ed piece published this summer in the New York Times, author Taras Grescoe observed that "if you're a shady seafood dealer trying to unload a container of dodgy shrimp or tilapia, chances are 98 in 100 it will make it into the United States."[137] Indeed, even the mouthpiece of U.S. seafood importing interests, the National Fisheries Institute, has asserted that foreign seafood packers will ship to the market of least resistance.[138] As such, the most disastrous consequence of the FDA's inability to administer a

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134 FDA Chloramphenicol Decision at p. 22.

135 General Agreement on Tariffs and Trade, Oct. 30, 1947, 61 STAT. A-11, 55 U.N.T.S. 194.

136 Id. at Art. VIII.

137 T. Grescoe, "Catfish With a Side of Scombroid," NEW YORK TIMES (July 15, 2007).

138 2001 National Fisheries Institute Letter at p. 4.

meaningful seafood import safety program is that the regulatory failure acts as a magnet for attracting unsafe imports to this country.

The following case studies of shrimp exports from China, Pakistan, Cambodia, and Vietnam demonstrate the cause and effect relationship between market restrictions on imports in major importing countries and the diversion of contaminated and likely contaminated products to the United States.

A. China

In November 2001, a routine on-site inspection of Chinese production facilities by EU officials "revealed serious deficiencies of the Chinese residue control system and problems related to the use of banned substances in the veterinary field."[139] In addition, EU border inspection officials found repeated shipments of Chinese shrimp imports contaminated with chloramphenicol.[140] As a result, the EU banned all shrimp, honey, mollusks, rabbit and poultry meat, and pet food imports from China in January 2002.[141]

Following a 30-month ban of Chinese shrimp imports, in July 2004, the EU agreed to recertify Chinese shrimp imports only after the Chinese government guaranteed that it would test 100 percent of Chinese shrimp exports bound for the EU, and that it would ship only certified consignments that met the EU's food safety standards.[142]

As a direct result of the EU's 30-month ban, shrimp exports from China flooded the U.S. market, as demonstrated in the chart below. As Chinese exports of shrimp to the EU fell, shrimp

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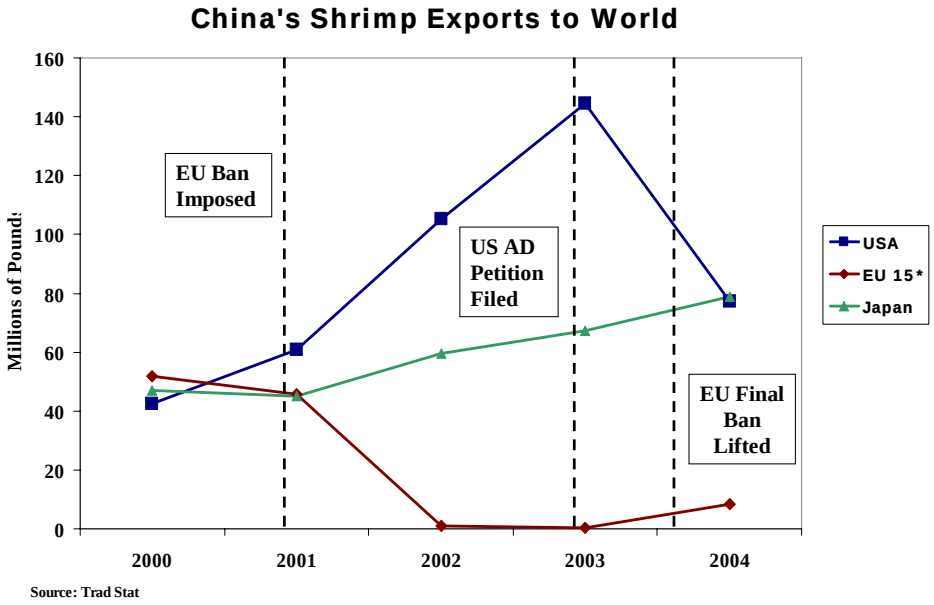
139 "EU Standing Veterinary Committee agrees on suspension of imports of products of animal origin from China," Press Release, European Commission, IP/02/143 (Jan. 28, 2002).

140 Id.

141 Id.

142 "EU eases food imports from China after significant improvements in veterinary standards," Press Release, European Commission, IP/04/943 (July. 16, 2004).

exports to the United States exploded, leading to a 30 percent increase of Chinese shrimp exports to the United States from 2002 to 2003.[143] The influx of Chinese shrimp imports began to abate only when the U.S. domestic shrimp industry filed an antidumping petition to seek relief from unfairly traded imports.



B. Pakistan

In early 2007, the EU completed an on-site review of seafood safety systems in Pakistan. What the EU officials found was staggering:

- An inspected processing facility, which had repeatedly been found in non-compliance with food safety regulations, had failed to rectify the problems but nevertheless continued to export seafood products to the EU; [144]

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143 "Chinese Exports to the United States: January 1999 to January 2005," DIALOG TRADSTAT (2007).

144 Final Report of a Follow-Up Mission Carried Out in Pakistan from 22 to 26 January 2007: In Order to Evaluate the Control Systems in Place Governing the Production of Fishery Products Intended for Export to the European Union, European Commission, Health & Consumer Protection Directorate - General, Directorate Food and Veterinary Office, DG(SANCO)/2007-7298 - MR Final, p. 9. (Jan. 2007) ("EU Report on Pakistan").

- Significant deficiencies observed firsthand by EU officials were not reflected in the inspection reports completed by Pakistani officials;[145]
- Exporters could not trace the source of their seafood products;[146]
- Information regarding HACCP was routinely hidden, adulterated, or destroyed and, in the absence of original information, exporters presented documents to EU officials that had been manipulated by company officials; [147] and
- EU officials "observed the presence and processing of FP [fishery products] unfit for human consumption according to Community [European Community] requirements (croakers, sole and shrimps) in some establishments."[148]

Based on these findings, the EU decertified all seafood producers from Pakistan in April 2007. A review of publicly-available export statistics from Pakistan shows a substantial decline in monthly shrimp exports from Pakistan to the EU, resulting in no reported exports of shrimp to the EU in June 2007.[149] At the same time, Pakistan's shrimp exports to the United States skyrocketed in June 2007. The value of shrimp exports to the United States from Pakistan in June 2007 was larger than the monthly value of Pakistani shrimp exports to the United States in any previous month since 2005 and more than twice the monthly average value for Pakistani shrimp exports to the United States.[150] Again, while the EU has refused to accept shrimp products from Pakistan because of the dangers posed by these products to consumers in the EU, substantial quantities have begun to enter the United States, apparently unhindered, and will likely continue to be shipped to this country.

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145 Id.

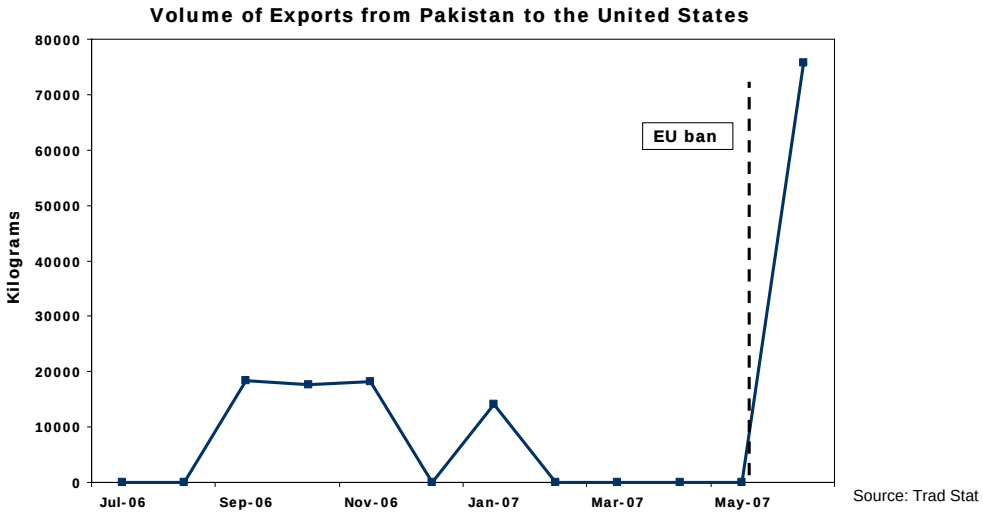
146 Id. at p. 17.

147 Id. at p. 18.

148 Id.

149 "Pakistani Exports to the United States: July 2006 to July 2007," DIALOG TRADSTAT (2007).

150 Id.



C. Cambodia

In 2005, EU authorities conducted an on-site investigation of seafood processing plants in Cambodia. The results of the EU officials' investigation were disturbing:

- Cambodian regulatory officials did not have the legal authority to perform checks of facilities for food safety compliance;[151]
- The Cambodian Department of Fisheries was supposed to license processing establishments, but there was no evidence that the agency had actually done so;[152] and
- Site visits to processing facilities found a "very poor hygiene situation."[153]

Worse, EU officials found that the process of certifying the food safety of export shipments was a sham. Specifically, EU officials reported that Cambodian officials providing these certifications "could not have the knowledge of, and could not have the possibility to ascertain and verify the matters they are certifying, which is against the international standards in the field

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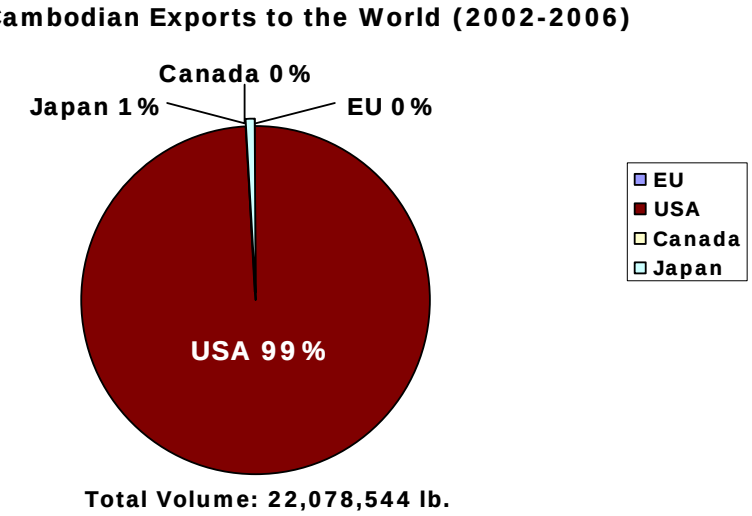
151 Final Report of a Mission Carried Out in Cambodia from 19 to 30 September 2005: For the Assessment of the Conditions of Production of Fishery Products Intended to be Exported to the European Union, European Commission, Health & Consumer Protection Directorate-General, Directorate F - Food and Veterinary Office, DG(SANCO)/7765-2005-MR, at p. 5 (Oct. 2005) ("EU Report on Cambodian Fishery Products").

152 Id.

153 Id.

of certification."[154] Based on these findings, the EU maintained its existing prohibition on Cambodia's ability to export seafood products to the EU.

At the same time, a review of Cambodia's export statistics indicates that between 2002 and 2006, Cambodia exported over 22 million pounds of shrimp to the world.[155] Ninety-nine percent of that shrimp was exported to the United States. U.S. import statistics show that between 2004 and 2006, the United States imported 21.7 million pounds of shrimp from Cambodia.[156] Thus, while the EU refused to accept shrimp products from Cambodia because of the dangers posed by these products to consumers in the EU, substantial quantities freely entered the United States.



Source: Trad Stat

D. Vietnam

With the exception of the United States, every major export market for Vietnamese seafood products has acted to address food safety problems with Vietnamese seafood exports.

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154 Id. at p. 8.

155 "Cambodian Exports to the United States: January 2002 to July 2007," DIALOG TRADSTAT (2007).

156 Id.

As shown in the above examples, if and when Vietnam loses access to these markets because of a failure to address food safety problems, the country's unsafe shrimp will likely be diverted to the United States.

Canada: From 2003 to 2005, Canada imposed a country-wide alert and implemented a 100 percent inspection policy on seafood exports from Vietnam after Vietnamese seafood products repeatedly tested positive for chloramphenicol.[157] In July 2006, the governments of Vietnam and Canada reached a bilateral agreement whereby the government of Vietnam committed to inspecting and certifying that seafood exports to Canada were free of antibiotics.[158] Vietnamese exports not accompanied by a certification are subject to 100% testing by Canadian officials; and, to insure compliance, Canadian officials continue to test even some of those exports that are accompanied by certificates.[159]

Japan: Beginning in December 2006, Japan began testing 100 percent of all Vietnamese shrimp exports because of repeated positive tests for chloramphenicol.[160] Vietnam agreed to certify 100 percent of their shrimp exports to Japan.[161] However, even with the certification system established, Japan continued to find banned antibiotics in Vietnamese shrimp imports and has threatened a complete ban of Vietnamese shrimp products unless the problem is resolved.[162]

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157 "Removal of the Country Import Alert for Chloramphenicol in Aquacultured Fish Products from Vietnam," Press Release, Canadian Food Inspection Agency (Sept. 30, 2005).

158 Canada-Vietnam Aquaculture Fish MOU.

159 Id.

160 "NAFIQAVED declares three reasons for unsafe seafood," VIETNAM ECONOMY (Dec. 15, 2006).

161 Id.

162 "VASEP asks Minister to declare emergency as Japan threatens to halt Vietnamese shrimp exports," SEAFOOD NEWS (July 9, 2007).

Russia: Press reports indicate that Russia banned the import of Vietnamese seafood after conducting an on-site inspection in March 2007, citing problems with food safety standards.[163] Russia requires exporters to meet Russian food safety standards and provide quality assurance from the exporting country's government.[164] Russian officials conducted follow-up inspections of twenty seafood processing facilities in July 2007 and mid-September 2007 and, recently, announced that thirteen of these facilities -- and only these thirteen -- would be approved to export seafood to Russia.[165] These exporters were selected from nearly two hundred companies that applied for inspections from the visiting Russian authorities.[166]

European Union: In 2007, the EU conducted an on-site inspection of Vietnamese seafood processors and the food safety system administered by the Vietnamese government.[167] The findings of the EU officials conducting the inspection help to explain why every major seafood importing market, besides the United States, is taking action to address Vietnamese seafood exports. Specifically, the EU's final report observed:

> The ongoing detections of veterinary drug residues in exported consignments tested at EU border inspection posts raise concerns on the effectiveness of residues controls which are weakened by the general availability of drugs without prescription, the limited scope of official testing, the capacity of the laboratory network, and, in some cases, insufficient follow-up.[168]

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163 "Russia names 11 qualified Vietnamese seafood exporters," THANHNIEN NEWS (Aug. 20, 2007).

164 "Fisheries face tough export rules," VIET NAM NEWS (Jan. 27, 2007) ("Fisheries Face Tough export rules").

165 "More seafood processors win Russian import license," VIETNAM ECONOMY (Sep. 18, 2007).

166 Fisheries face tough export rules.

167 Final Report of a Mission Carried Out to Vietnam from 24 January to 1 February 2007 in order to Evualuate the Control of Residues and Contaminants in Live Animals and Animal Products, Including Controls on Veterinary Medicinal Products, European Commission, Health & Consumer Protection Directorate - General, Directorate Food and Veterinary Office, DG(SANCO)/2007/7322 - MR Final, p. 5 (Feb. 2007).

168 Id. at p. 14.

Thus, the EU's report noted that valid concerns existed regarding the ability of the Vietnamese government and its seafood producers to prevent the export of seafood with harmful contaminants because drugs -- including antibiotics -- are widely available without the need for a prescription and the limited scope of the government's ability to test and follow-up on problems.

EU officials also determined that shrimp found to contain antibiotics was not exported to the EU, but neither was the contaminated shrimp destroyed,[169] leaving open the possibility that it was exported to other markets with less stringent regulations (like the United States). The EU's finding is all the more troubling given the recent comments of Huynh Thi Thanh Giang, the Deputy Director General of An Giang Seafood Import-Export Company, a large Vietnamese exporter of seafood, in the Vietnamese press. Mrs. Giang noted that products rejected from importing countries "cannot be consumed domestically" and that "[t]he only way for enterprises to minimise losses when products are discovered as containing antibiotics, according to Mrs. Giang, is to look for easier-to-please markets."[170] As shown above, as between Canada, the EU, Japan, and the United States, the "easier-to-please market" is the United States.

Markets in the EU, Japan, Canada, and the United States account for roughly 90% of Vietnam's average annual 268 million pounds of shrimp exports. At the same time that every major market for Vietnamese shrimp has expressed concerns about the safety of the country's seafood products and has taken action to rectify these problems, the United States, which receives approximately one-third of Vietnam's shrimp exports, has taken no significant action.

In fact, while every other major market has found repeated shipments of Vietnamese shrimp tainted with banned antibiotics, a review of the FDA's import refusals indicates that the

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169 Id. at p. 9.

170 "Unsafe Seafood Exports: No Solutions?," VIETNAM ECONOMY (source: Sài Gòn Tiếp thị) (July 27, 2007).

agency did not refuse a single shipment of Vietnamese shrimp based on the presence of antibiotics in the past year.[171] Worse, Canadian and Japanese refusals of seafood imports, like the FDA's refusals, are publicly available online.[172] A comparison of the Vietnamese exporters that have had seafood products refused from the Canadian and Japanese markets with the lists of Vietnamese exporters of seafood to the United States (available through a subscription service) demonstrates that many of these exporters continue to ship to the United States unabated.[173]

FDA: At least since 2003, the FDA has had active knowledge of Vietnam's pervasive use of chloramphenicol. As addressed above, the FDA recognized, in a letter sent to Citizens Petitions with regards to chloramphenicol in crabmeat, that "there is abundant evidence that chloramphenicol is still in widespread use abroad, particularly in Southeast Asia."[174] Specifically, the FDA detailed a meeting it had with its Vietnamese counterparts, where:

> [D]uring a March 5, 2003 meeting with Vietnam [and the FDA], Vietnamese government officials reported that they continue to have problems with chloramphenicol being used in the production of shrimp in their country, and they have acknowledged the use of chloramphenicol in shrimp farming . . . . With the significant tidal flux that influences many shrimp ponds, water containing chloramphenicol from these ponds could be expected to flow into near-shore, intercoastal areas where indigenous crabs could also become contaminated prior to harvest.[175]

Despite this explicit knowledge, the FDA has yet to issue a country-wide import alert on Vietnamese shrimp or any other seafood imports. As a result, Vietnam is now the third largest

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171 Import Refusal Reports for OASIS By Industry, U.S. Food and Drug Administration (Jan. 2007 - Aug. 2007).

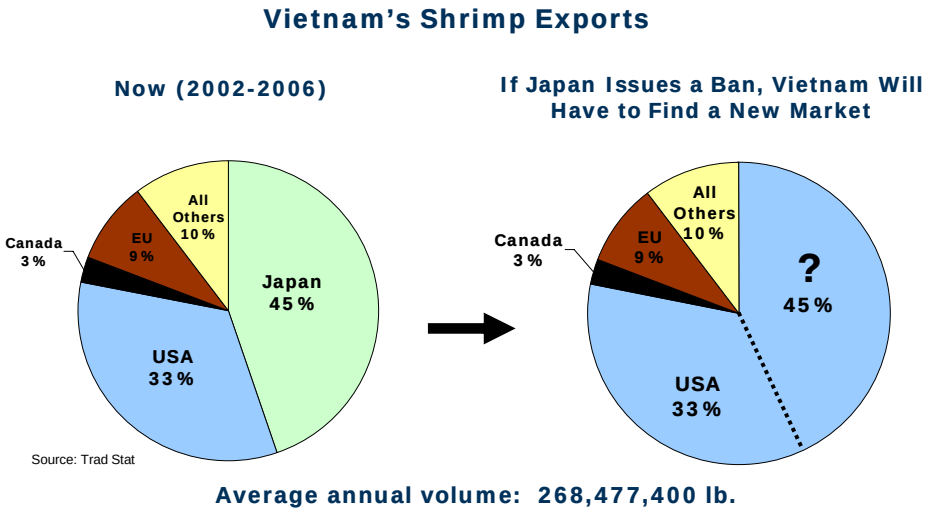
172 The EU's RASFF system refusals are also available online but do not disclose the name of the exporter responsible for the refused product.

173 See Urner Barry's Foreign Trade Data (Seafood Import Data Online) available at http://ftd.urnerbarry.com/.

174 FDA Chloramphenicol Decision at p. 22.

175 Id. at p. 11 (emphasis added).

exporter of shrimp to the United States.[176] The United States comprises thirty-three percent of Vietnam's shrimp exports, and may become an even larger market if Japan decides to issue a comprehensive import ban on contaminated Vietnamese shrimp imports.



V. Best Practice Recommendations

At a minimum, the imported food safety regime administered by FDA must reach parity with the import enforcement regimes of other major seafood importing countries and the USDA. Without consistent and strong enforcement of U.S. food safety standards, there can be no confidence that imported seafood products are safe for consumption. Accordingly, the following recommendations must be implemented to effect a shift in paradigm at the FDA and to ensure that the FDA's import enforcement regime is no less stringent than other major seafood importing markets.

A. Demonstrated Equivalence

Currently, equivalence is not a prerequisite for entry of seafood imports into the U.S. market. Seafood imports are presumed safe unless the FDA can prove otherwise, but as shown

176 U.S. Census Bureau, IM-145, U.S. General Imports (July 2007).

above, the FDA inspects only about 1 percent of all seafood imports and these imports are often contaminated with banned antibiotics, chemicals, salmonella, and common filth. Demonstrated equivalence would eliminate that presumption of entry and require exporters to demonstrate that their seafood products are safe before gaining entry into the United States. In sum, equivalence transfers accountability and places legal responsibility on the exporting country and the individual exporter to certify compliance with U.S. seafood safety standards.

Equivalence through country certification allows the United States to place import requirements on exporting countries in a manner that would address the specific risks posed by the exporting country. For example, countries with consistent and systemic deficiencies in food safety controls, such as Vietnam, Pakistan, and Cambodia, would be subject to higher health certification standards than exporting countries with stringent controls.

Country certification may only be issued by the FDA after a comprehensive analysis of the exporting country's laws, regulations, and implementing policies and an on-site inspection of the foreign facilities. As the FDA itself admitted in its guidance for the domestic fish and fishery products industry:

> The best way for a regulatory authority to determine whether a processor is effectively operating a HACCP system is by inspecting the processor to assess whether the system is operating properly and is appropriate for the circumstances.[177]

At a minimum, the FDA must conduct the same number of on-site inspections for foreign facilities as domestic producers. According to the FDA's budget summary for fiscal year ("FY") 2006, the FDA conducted approximately 2,480 inspections of domestic fish and fishery products

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[177] Refusal of Inspection or Access to HACCP Records Pertaining to the Safe and Sanitary Processing of Fish and Fishery Product, U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Seafood (July 2001) (emphasis added).

facilities for HACCP compliance.[178] In contrast, the FDA made only about 200 inspections for FY 2006 for all foreign food production facilities, from vegetable growers to seafood producers, and estimates that it will make approximately 100 foreign inspections in FY 2007.[179]

The EU's regular on-site inspection of foreign manufacturing facilities demonstrates why site visits made only after a safety issue has arisen cannot effectively ensure consistent adherence to U.S. food safety standards. In the case of Cambodia, the EU's inspection team found that health certificates issued by the Cambodian government claiming to be official confirmation of the food safety of Cambodian fish exports were completely unreliable.[180] The EU inspection team found that:

> [T]he signatories of these certificates could not have the knowledge of, and could not have the possibility to ascertain and verify the matters they are certifying, which is against the international standards in the field of certification. . . .[181]

Certification authority would allow the FDA to decertify certain countries and/or producers if it found repeated violations of U.S. food safety standards. Decertification would put additional pressure on foreign exporters and exporting governments to take immediate corrective action with regards to food safety.

In addition to country certifications, individual foreign exporters within approved countries must certify compliance with the FDA's regulations on HACCP systems, conditions which all U.S. producers must meet.

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178 FDA FY 2007 Budget Summary: Consolidated Narrative, Program Activity Data, Office of Management, Budget Formulation and Presentation (2007).

The FDA has regulatory responsibility over "approximately 210,000 food establishments." Id.

179 Id. The FDA reports that approximately 210,000 foreign establishments -- the same number as domestic food establishments -- are registered to export food to the United States. Domestic and foreign food establishments are required to register their contact information with the FDA.

180 EU Report on Cambodian Fishery Products.

181 Id. at p. 8 (emphasis added).

B. Inspection and Testing

In the United States, currently there is no minimum inspection rate for fishery products mandated by law or regulation, despite the fact that the United States imports more than 80 percent of its seafood. The FDA currently inspects less than 1 percent of all seafood imports, which is far below the standards of other major importing countries and the USDA. Even with more stringent exporter certification requirements, the EU inspects 20 percent of its seafood imports, Japan inspects 25 percent of all shrimp imports, and Canada currently inspects 15 percent of all seafood imports. Even the USDA inspects approximately 16 percent of its regulated imports. At a minimum, the inspection and testing rate for FDA-regulated seafood imports should be 20 percent, a rate that is much more comparable to other major shrimp importing nations. A minimum mandated inspection rate will require FDA to meaningfully screen seafood imports to ensure safety.

Consistent with its counterparts, the FDA should subject new shrimp exporters to the United States to 100 percent testing for the first fifteen shipments. Similarly, if an importer fails an inspection or test, all subsequent imports should be subject to 100 percent testing until fifteen consecutive shipments pass inspection.

Currently, while the FDA only inspects about 1 percent of imported seafood at the border, an even smaller percentage, 0.2 percent, is tested in a laboratory.[182] Earlier this year, the FDA even proposed closing seven of its thirteen testing laboratories, including one of its most effective laboratories in San Francisco, one of the United States' busiest ports of entry.[183]

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182 Food Imports Often Escape Scrutiny.

183 David Nelson Testimony at p. 12.

Importers have gone so far as to ship products by air to Las Vegas "to avoid the scrutiny that the seafood would face in San Francisco . . . ."[184]

Private laboratories must be accredited and licensed by the FDA. In the absence of its own adequate testing facilities, the FDA relies heavily on analysis conducted by private laboratories, but these labs are not subject to accreditation or monitoring by the FDA. Further, the laboratory procedures for testing seafood products are not standardized by the FDA; there is no mandatory list of banned substances that must be inspected by each laboratory.

A proposed accreditation system was dropped by the FDA following resistance from private laboratories. An investigation recently conducted by the House Energy and Commerce Committee reported on the "shoddy" state of private laboratories:

> Officials at all FDA labs visited by Committee staff were critical of private laboratory testing. An FDA Deputy Lab Director, who performs private laboratory reviews, said that some private laboratory work is "decent," while some is "scary." He believes that none of the private laboratory analyses are completely accurate. In general, he described private laboratory work as "not good" and "spooky." An FDA Science Branch Manager concurred with this assessment. He commented that private laboratory work is "shoddy" because results are driven by financial rather than scientific concerns.[185]

In order to facilitate FDA's testing efforts, imports should be limited to designated ports of entry. Currently, exporters may currently ship seafood products to any port in the United States, regardless of whether the port is staffed with FDA inspectors. Designated ports would give the FDA greater ability to detect problems, spot trends, and identify circumvention.

Finally, the FDA must be more transparent in publishing its enforcement activities and plans. The food safety regulatory authorities of the EU, Japan and USDA all issue public reports detailing their enforcement activities. Japan also issues annual prospective monitoring and

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184 Id.

185 Id. at p. 3 (emphasis added).

guidance plans for imported food products. In stark contrast, the FDA fails to consistently disclose its import enforcement efforts. Such information must be gleamed from GAO reports, congressional testimony and news articles. Consistent transparent publication of the FDA's import enforcement efforts will better ensure that the FDA is held accountable for its food safety controls.

C. Enforcement

The FDA should have a presumption of destruction for seafood imports found to be adulterated. An importer may overcome this presumption only if it can meet the following requirements within 45 days of notification of destruction: (1) if the adulterated shipment is bound for a third country, the third-country food safety agency must first notify the FDA of its acceptance before the rejected shipment is released; and (2) rejected shipments must be conspicuously marked "United States Refused Entry." Such a change would make the FDA's regulatory system consistent with that employed by the European Union and the USDA.

Placing conditions on the re-export of adulterated shipments and conspicuous marking of refused shipments will prevent imports from unauthorized re-entry, or "port shopping." Currently, when the FDA discovers an imported product has violated food safety standards, it only issues a letter to importer warning of possible detention. This letter does not result in the product being seized or destroyed. The violative product is delivered to the importer, who may then submit samples to unaccredited and unlicensed private laboratories for testing. If the import is still found unsafe, which is rare, the product is finally rejected by the FDA. As noted above, it takes an average of 348 days for the FDA to notify port-of-entry officials of such a rejection.[186]

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[186] 2004 GAO FDA Report at p. 5.

The FDA proposed a marking requirement for rejected food imports in 2001 and was given specific statutory authority for marking in 2002, but has yet to implement the requirement.

In order for the FDA to have meaningful enforcement power over imported food safety, knowingly mislabeling and other knowing violations of U.S. food safety laws, such as "port shopping," must result in significant civil and possible criminal penalties. An importer must certify the product's country-of-origin and the producer and exporter's identities. Knowingly falsifying these certifications must result in mandatory monetary penalties and denial of trading privileges.

D. Multilateral Cooperation

Exporters that are unable to meet the strict standards of the Canadian, Japanese and European markets often channel low priced, low quality, and likely contaminated products to the United States. A systemic system of review of other countries' findings and alerts would help prevent the United States from becoming a dumping ground for inferior products.

The FDA must monitor and take note of foreign findings and bans issued by certain countries and regional organizations, including the European Union, Japan and Canada. Discussion between exporting and importing countries provides opportunities for importing countries to raise safety concerns and for exporting countries to address their compliance abilities. The objective is for the FDA to achieve parity, or "no less stringent" requirements than other major importing countries.

VI. Conclusion

The FDA's imported food safety regime does not operate in isolation. The consequences of the FDA's lax enforcement of our nation's food safety standards must be analyzed in the context of the imported food safety regimes of other major importing markets, such as the EU, Japan and Canada. While these countries all have taken action to ensure the safety of their food imports, the FDA has shown an astonishing disregard for the safety and integrity of our nation's imported food supply.

The FDA does not require certification of equivalence from an exporting country or individual exporter prior to entry into the United States, choosing instead to rely solely on point-of-entry inspection. The FDA's inspection rates, however, have hovered around 1 percent since 2002 and laboratory testing is an even smaller percentage, 0.2 percent. Such miniscule inspection and testing rates cannot be the sole basis of our nation's imported food safety regime. Even when the FDA does detect adulterated food imports, it does not have systematic procedures to prevent unscrupulous importers from bringing the adulterated shipment into the United States through such methods as "port-shopping" or private laboratory testing manipulation.

In essence, exporters are allowed to self-certify their compliance with U.S. food safety standards.

The only way that our nation can ensure safer food imports is through a paradigm shift in the FDA. To effectuate such a shift, the following four fundamental principles must be included in any recommendations regarding reforms to the FDA's imported food safety regime:

- Demonstrated and verified equivalence of exporting countries and foreign producers;
- Mandatory testing and inspection rates at U.S. borders;
- Significant penalties for noncompliance; and

- Increased multilateral cooperation with other major importing countries.

Without these fundamental reforms, our nation can never be assured of safe and healthy food imports.

Please contact me should you require clarification of any aspect of this submission.

Respectfully submitted,

John Williams
Executive Director
Southern Shrimp Alliance