Testimony of

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before the

Subcommittee on Oversight and Investigations Committee on Energy and Commerce U.S. House of Representatives

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My name is John Williams and I am here today both as the Executive Director of the Southern Shrimp Alliance ("SSA")¹ and as someone with 30 years of experience in the shrimp industry. After starting as a deck hand working aboard shrimp boats in North Carolina, I now operate a small business in Tarpon Springs, Florida and I am proud to have the privilege of representing thousands of other small businessmen and women in the shrimp industry throughout the Gulf of Mexico and South Atlantic.

We are proud that 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 any economic incentive to use antibiotics or pesticides on wild-caught American shrimp. People who eat wild-caught American shrimp can be assured that their shrimp meets the standards for U.S. quality and safety. The same cannot be said for imported shrimp.

I appreciate the opportunity to testify on the U.S. Food and Drug Administration's ("FDA") failure to protect Americans from harmful seafood imports. There can be no denying that the FDA is broken. The essence of the FDA's approach to imported food safety is to accept unverified representations of importers who have repeatedly disregarded the safety of American consumers. The FDA does not require foreign government or foreign producer equivalence as a condition of entry into the United States. In the absence of equivalence agreements or certifications, the FDA relies solely on its very limited testing of imported seafood to identify food safety violations. But because the frequency of FDA testing is not mandated by law, FDA inspection rates have hovered at 1 percent since 2002. In consequence, the FDA is effectively allowing exporters to self-certify their compliance with U.S. food safety standards.

We know, and the FDA knows, that aquaculture in much of the developing world has led to the introduction of harmful contaminants into our imported seafood. Imported farm-raised shrimp are often produced with minimal quality control, in crowded ponds

For additional information about the SSA's food safety efforts and other issues, please visit http://www.shrimpalliance.com/.

filled with feces, banned antibiotics, and toxic chemicals.² And yet, the FDA's only check on self-serving representations from those who profit on imported seafood is to inspect a tiny amount of these imports. Furthermore, the FDA typically tests for a small number of the long list of illegal additives and contaminants well known to have been found in any given shipment of imported shrimp.

The FDA's failure to prevent the importation of massive amounts of contaminated shrimp has a number of negative effects on the U.S. market, the U.S. shrimp industry and U.S. consumers. First and foremost, farmed-shrimp imports contaminated with banned antibiotics, pesticides and other dangerous contaminants put the health of U.S. consumers at serious risk. Bans on these contaminants are not frivolous -- they are based on sound medical science recognized and applied worldwide.³ Second, U.S. consumers are quite often unable to distinguish between safe and unsafe shrimp in retail markets and restaurants. Their fear of buying or being served contaminated imported shrimp is real, and it depresses the overall consumption and demand for all shrimp including healthy wild-caught shrimp produced in the United States. Still further, wholesale shrimp buyers know that the large volume of shrimp sourced from farms in countries with lax controls are likely to be contaminated and so they are able to offer lower prices for this shrimp. This practice tends to depress the overall price of shrimp in the U.S. market including that paid to U.S. shrimpers at the dock. Finally, any of the large volume of contaminated shrimp that the FDA's lax inspection system allows into the U.S. market represents shrimp that should never have been part of the U.S. market supply in the first place. This additional supply further distorts (lowers) the price structure for all shrimp in the U.S. market.

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Additional information on health risks caused by banned contaminants in shrimp imports can be found in the SSA's comments to the President's Interagency Working Group on Import Safety at http://www.shrimpalliance.com/Press%20Releases/Comments%20to%20Interagency%20Working%20Group.pdf.

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).

For example, the FDA issued the following findings on the banned antibiotic chloramphenicol, a common contaminant in shrimp imports: "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." Letter from the U.S. Food and Drug Administration to Olsson, Frank, and Weeda, P.C., Re: 02P-0321, p. 17 (Jul. 29, 2003) (emphasis added).

The combination of stringent imported food safety regimes in other major importing markets and lax enforcement of U.S. law encourages the diversion of contaminated seafood to the United States. Canada, Japan, and the European Union ("EU") all do significantly more to protect consumers than the FDA does to safeguard the American public. As a result of more strict enforcement of food safety laws in other seafood importing countries, our nation has become a dumping ground for rejected and inferior seafood products that could not be exported to other countries.

A careful comparison of the food safety regimes of our trading partners with that operated by the FDA makes clear the deficiencies of our system. Unlike the FDA's model, which relies solely on point-of-entry inspection of 1 percent of imported seafood products, the EU, Japan, and Canada all have rigorous systems to ensure the safety of seafood imports throughout the product's life-cycle.⁴

European Union: A central tenet of the EU's imported food safety regime is that a system like that employed by the FDA is inherently flawed and cannot effectively protect the consumer. In describing its import conditions for seafood products, the EU declares that "Spot checks on the end product alone would not provide the same level of safety, quality and transparency to the consumer." The EU guarantees equivalence in food safety controls by conducting foreign on-site inspections and certifying exporting countries and individual exporters prior to importation of a product. In addition, the EU currently inspects 20 percent of seafood imports at its borders.

Japan: Japan has a strict risk-based system that is reinforced by high inspection rates, certification requirements and significant penalties for noncompliance. Annually, Japan assesses the risks posed by different types of imported food products, and issues inspection guidelines for the upcoming year based on risk potential. Thus, while the general inspection rate of imported foods is 10.2 percent, the food safety risks posed by imported shrimp have resulted in annual inspection rates of around 25 percent. In addition, Japan's food safety agency has the authority to issue mandatory 100 percent testing and absolute import bans of a particular product and/or a particular country if it finds that more than 5 percent of consecutive shipments of the inspected import is adulterated. For example, Japan instituted compulsory testing of 100 percent of Vietnamese shrimp imports in December 2006 after repeated detection of chloramphenicol, a banned antibiotic, in shipments of Vietnamese shrimp.

Canada: Canada imposes a minimum standard inspection rate of 15 percent for all imported seafood products and has strict importer licensing requirements. Exporting countries with bilateral equivalence agreements with Canada are

For a comprehensive description of the imported food safety regimes of the EU, Japan, Canada, and the FDA, please refer to the SSA's comments to the President's Interagency Working Group

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on Import Safety at http://www.shrimpalliance.com/Press%20Releases/Comments%20to%20Interagency%20Working

subject to reduced inspection requirements. In return, the exporting country agrees to inspect and certify products bound for Canada. In Canada, if an import fails inspection, subsequent shipments are inspected until four consecutive shipments pass inspection. Repeated failure of inspections may lead to the imposition of an import alert and 100 percent testing of shipments from the exporter or exporting country.

In stark contrast, the FDA does not require certification of equivalence, choosing instead to rely solely on 1 percent inspection of imports. While FDA inspects only about 1 percent of imported food products, an even smaller percentage, 0.2 percent, is tested in a laboratory. Private testing laboratories need not be licensed or accredited by the FDA in order to certify the food safety of seafood imports. Further, the FDA does not quarantine imports at U.S. borders, meaning that importers may take delivery of even the most suspicious seafood imports. On the off chance that an import shipment is rejected, the FDA does not impose any marking requirements nor does it otherwise have any procedures to prevent importers from sending rejected shipments to other U.S. ports (i.e., "port-shopping").

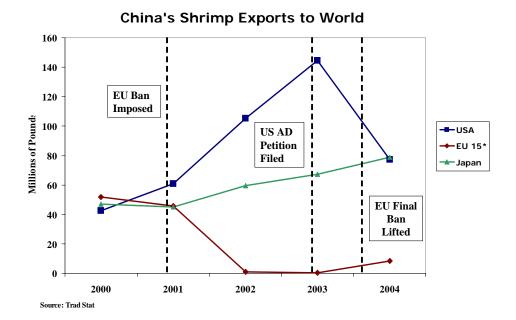
In the absence of effective FDA enforcement, there is nothing to stop shippers, like the company advertising in SeaFood Business below, from importing rejected products through other ports -- either in this country or elsewhere -- with no disclosure of the harmful nature of the product.



Source: SeaFood Business Magazine, p. 52 (Sept. 2007)

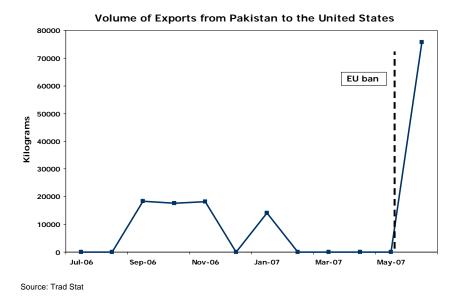
When faced with lax enforcement in the United States and rigorous policing in other markets, it is easy to see why contaminated imports are diverted to our market. Our poor food safety regime has effectively made the United States a magnet for potentially dangerous seafood exports.

The shrimp industry is painfully familiar with the perverse incentives that the FDA's food safety regime has created in this market. For example, when the EU imposed a complete ban on shrimp from China in 2002 because of illegal antibiotic use, Chinese shrimp imports to the United States shot up 30 percent in one year; adding millions of additional pounds of shrimp to this market. 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.



The same thing happened when the EU decertified Pakistani seafood producers. In early 2007, the EU completed an on-site review of seafood safety systems in Pakistan that revealed numerous and egregious violations of EU food safety standards. Based on these findings, the EU <u>decertified all seafood producers</u> from Pakistan in April 2007. As a result, shrimp exports from Pakistan to the EU plummeted, resulting in no reported exports of shrimp to the EU in June 2007.

At the same time, Pakistan's shrimp exports to the United States skyrocketed in June 2007. In just two months, Pakistani shrimp to the U.S. jumped from zero to 75,000 kilograms, or 165,000 pounds. To put it in perspective, the volume of shrimp exports to the United States from Pakistan in June 2007 was larger -- approximately four times greater -- than the monthly volume of Pakistani shrimp exports to the United States in any previous month since 2005. 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.



Now we are facing the same problem with Vietnam. Markets in Canada, Japan, the EU, and the United States account for roughly 90% of Vietnam's average annual 268 million pounds of shrimp exports. With the exception of the United States, every major seafood importing market has acted to address the food safety problems posed by Vietnamese seafood products.

<u>Canada</u>: From 2003 to 2005, Canada imposed a country-wide alert and instituted 100 percent testing of all seafood exports from Vietnam after finding repeated seafood products tainted with chloramphenicol. In July 2006, Vietnam committed to inspect and certify that all seafood exports to Canada were free of antibiotics in a bilateral agreement reached to address the problems with Vietnamese seafood exports.

<u>Japan</u>: Beginning in December 2006, Japan began testing 100 percent of all Vietnamese shrimp exports because of repeated chloramphenicol findings. Vietnam agreed to certify 100 percent of their shrimp exports to Japan. Even with the certification system, Japan continues to find antibiotics in Vietnamese shrimp exports. Japan has threatened a complete ban on Vietnamese shrimp products.

<u>EU</u>: In 2007, the EU conducted an on-site inspection of Vietnamese seafood processors and found that while shrimp tainted by antibiotics were not exported to the EU, the contaminated shrimp were not destroyed, leaving open the possibility

that it was exported to other markets with less stringent regulations (like the United States).⁵

While other major importing countries are in near consensus about tainted Vietnamese seafood, the United States, which receives approximately one-third of Vietnam's shrimp exports, has not subjected Vietnamese seafood imports to increased testing. A review of the FDA's import refusals list indicates that the FDA has not refused a single shipment of Vietnamese shrimp based on antibiotics since March 2006.

The FDA has sufficient evidence of the hazards of farm-raised seafood from Vietnam through its own investigations and, as we have been told by reliable U.S. government sources, through direct admissions by Vietnamese authorities of the widespread use of banned substances in the production of farm-raised seafood. And for some of those substances, the FDA apparently has no testing protocols to detect them.

Concerns about the FDA's inability to assure the safety of imported seafood have risen to the point that states have been doing their own testing of seafood imports. And these states have repeatedly found harmful, banned substances in the imported seafood they test -- seafood allowed by the FDA to enter this country. Some notable examples of states taking action against contaminated seafood imports include:

<u>Louisiana</u>: Louisiana has had an Emergency Rule in place since 2002 to test imported shrimp and crawfish for the contaminant chloramphenicol. In 2007, Louisiana required testing for fluoroquinolones in seafood from China and Vietnam.

<u>Mississippi</u>: Mississippi currently tests imported seafood for the presence of fluroquinolones and chloramphenicol, both banned contaminants in food products. Mississippi's laboratories have repeatedly found Ciprofloxacin, Enrofloxacin, and chloramphenicol -- all banned antibiotics -- in imported seafood.

<u>Florida</u>: Florida began testing imported seafood in 2002, focusing its testing efforts on fluroquinolones and chloramphenicol. In 2005, 15 of 19 seafood samples tested for fluoroquinolones came back positive. In 2007, 3 of 16 samples tested positive for fluoroquinolones.

<u>Georgia</u>: Since 2003, the results of Georgia's laboratory tests on imported seafood have repeatedly shown the presence of Ciprofloxacin and Enrofloxacin in imported seafood.

<u>Arkansas</u>: When Arkansas began its imported seafood testing program with the FDA in 2007, the FDA found that one out of the six shipments of imported

In addition, Russia imposed strict certification requirements on Vietnamese shrimp imports in 2007 after finding repeated food safety violations. Singapore has banned several Vietnamese shrimp producers for similar food safety violations.

seafood from China it sampled contained harmful contaminants. Arkansas sought to undertake additional tests, but the FDA expressed an unwillingness to assist with future imported seafood testing efforts. As a result of the FDA's unresponsiveness, Arkansas's Public Health Laboratory devoted significant resources to testing equipment so that it could independently test imported seafood for harmful contaminants.

While we are pleased that state governments have attempted to step into the breach, the burden of ensuring that imported seafood is safe to consume should not be forced upon them. There is no substitute for a strong federal food safety system. Unfortunately, the FDA appears to take action only when facing a crisis or public outrage. We respectfully suggest that this Committee should be outraged.

We believe that the FDA must be made to take responsibility for the safety of seafood imports coming into this nation. As such, we have created an 11-point proposal for legislative reform that would bring the FDA in line with our international counterparts and significantly improve the safety of imported seafood in the United States.

1. Require Equivalence Agreements

- An exporting country may not export to the United States unless it establishes and certifies that its food safety laws and procedures are equivalent to U.S. standards.
- Individual exporters within approved countries must certify equivalence with the United States' standards on critical control points in the manufacturing process, monitoring and sampling requirements, and recordkeeping obligations.
- The FDA would conduct periodic on-site inspections -- at least annually -of foreign production facilities.

2. Mandate Inspection and Testing Rates

- At a minimum, the United States should mandate a 20 percent inspection and testing rate for all seafood imports.
- New exporters to the United States should be subject to 100 percent testing for the first fifteen (15) shipments into the United States.
- If an importer fails an inspection or test, all subsequent imports are subject to 100 percent testing until fifteen (15) consecutive shipments pass inspection.
- Repeated failure may lead to the imposition of producer and country bans.

3. Fund FDA Oversight of Private and Public Laboratory Facilities

• FDA should bolster its own inspection and testing capabilities with sufficient funding for qualified staff and testing equipment.

- Importers would be required to pay an import inspection fee to help offset the cost of inspection and testing.
- Testing should be conducted primarily by the FDA. If test results are issued by private laboratories, then these laboratories must be fully accredited, certified and licensed by the FDA. Such accreditations and licenses must be renewed annually.
- All FDA and private laboratories must test each class of imports based on a standardized list of controlled substances.

4. <u>Limit Imports to Designated Ports of Entry</u>

 Imported seafood are allowed entry only through designated ports of entry staffed with trained inspectors and equipped with proper technical resources for testing and evaluating imported merchandise.

5. Require an Annual Report and Prospective Enforcement Plan

- The FDA should publish an annual report describing significant incidents of import noncompliance and other areas of concern, as well as summary statistics. The report would describe the FDA's plans for addressing these issues in the coming year.
- The FDA would be mandated to implement its enforcement plan within 3 months of publication of the annual report.

6. Authorize Seizure and Destruction of Contaminated Imports

- If an import is found to violate U.S. food safety standards (i.e., contains banned substances), the FDA must seize and destroy the import unless the importer can meet the requirements for re-export.
- The FDA must establish an expedited system of notification between the FDA and port-of-entry officials that a shipment has been rejected and must be destroyed.

7. Limit Re-export of Rejected Shipments

- Rejected shipments will only be released to importers under controlled circumstances within 45 days of notification. Otherwise, the shipment will be destroyed.
- If the rejected shipment is bound for a third country, the importer must first notify that country's food safety agency. The third-country destination must notify the FDA of its acceptance before the rejected shipment is released.
- Rejected shipments must be conspicuously marked "United States Refused Entry."

8. Increase Penalties for Purposeful Deception

- Knowingly mislabeling, and other knowing violations of U.S. food safety laws, such as "port shopping," will 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 would result in mandatory monetary penalties and denial of trading privileges.

9. <u>Authorize Country Bans Until Demonstrated Improvement</u>

- Systemic detection of prohibited substances would result in a complete ban of a particular product, or all products, from the exporting country.
- The country ban would only be lifted when the foreign government proves to the satisfaction of the U.S. government that they have met U.S. food safety standards.

10. Authorize Producer Ban Until Demonstrated Improvement

- Systemic detection of prohibited substances may result in a complete ban of a particular product from the exporter.
- The particular product is denied entry to the U.S. market altogether rather than issued an import alert that subjects the exporter to 100 percent consignment testing.

11. <u>Mandate International Coordination for Cooperative Agreement and Information Exchange</u>

- The FDA would monitor and recognize foreign findings and bans issued by certain countries and regional organizations, including the European Union, Japan and Canada. Review of other countries' findings and alerts would help prevent the United States from becoming a dumping ground for inferior products.
- Currently, there is insufficient exchange of information and cooperation between countries on food safety issues. This makes it easy for importers who are unable to meet the stricter standards of the Japanese and European markets to channel low quality and likely unsafe food products to the United States. 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 should be for the FDA to achieve parity, or "no less stringent" requirements than other large importing countries.

For the health of our consumers, for the integrity of our nation's food supply, and on behalf of U.S. producers of healthy wild American shrimp, I urge the Committee to seriously consider our 11-point proposal and enact meaningful FDA reform. The FDA

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has promised before that it can change on its own, but the evidence demonstrates just how dangerous the FDA's broken promises have become.

Thank you.