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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: Docket No. FDA–2009–N–0166: Request for Comments, Economically Motivated Adulteration

The Southern Shrimp Alliance ("SSA") submits the following comments in response to the Food and Drug Administration's ("FDA") notice of public meeting and request for comments regarding Economically Motivated Adulteration ("EMA"), as published in 74 Fed. Reg. 15,497 (April 6, 2009). It is our firm belief that practices that constitute EMA distort the domestic marketplace for seafood products, create serious health risks for consumers, and create a substantial disadvantage for those who do not take part in these practices. Thus, we commend the FDA for focusing on this issue, especially as it pertains to related public health risks.

The SSA, founded in 2002, is a non-profit alliance of the thousands of small businesses that comprise the U.S. warmwater shrimp industry. The SSA is the national voice for warmwater shrimp fishermen and processors in eight states: Alabama, Florida, Georgia, Louisiana, Mississippi, North Carolina, South Carolina, and Texas. The SSA is committed to defending and advancing the interests of the domestic industry, which means ensuring that all shrimp, both domestic and foreign, being sold to U.S. consumers meets the highest level of integrity, quality, and safety.

In recent years, the domestic seafood industry, and the shrimp industry in particular, has had to overcome a number of obstacles, including illegal trade practices by foreign producers, in order to remain competitive. The widespread use of EMAs with respect to shrimp trade has caused serious harm to all participants in the marketplace that do not engage in such fraudulent practices. The FDA has proposed a working definition of EMA as "the fraudulent, intentional substitution or addition of a substance in a product for the purpose of increasing the apparent value of the product or reducing the cost of its production, i.e., for economic gain."[1] In the case

[1] 74 Fed. Reg. 15,497, 15,498 (April 6, 2009).

of the domestic seafood market, the method of EMA that poses the most significant health risk to consumers is the use of antibiotics, pesticides, and other chemicals in farm-raised seafood.

Moreover, it is essential that this issue be considered in conjunction with the related issue of fraudulent mislabeling of country of origin of seafood imported into the United States. While the use of antibiotics, pesticides, and other chemicals in the production of farm-raised seafood is a fairly evident example of EMA, insofar as contaminants are intentionally added to the food in order to reduce the cost of production of the shrimp while capturing the prices paid for non-contaminated shrimp, the mislabeling of country of origin of seafood products presents a similar problem. Where shrimp is mislabeled as to the country of origin, the party committing the fraudulent practice substitutes shrimp from a country that obtains a lower price in the marketplace for shrimp from a country that commands higher places. This is especially problematic for the domestic shrimp industry that principally produces wild-caught shrimp that is sold at the premium in the U.S. marketplace. Where farmed, imported shrimp is falsely labeled as a product of the United States, the consumer's confidence in receiving safe, wholesome, natural shrimp is significantly undermined and the price premium attached to domestic product deteriorates.

The FDA's statute clearly draws a distinction between "adulteration" and "misbranding," however, both acts violate the statute and, especially with respect to seafood production, are closely related.[2] The FDA has stated that food labeling statements regarding geographical origin must not be false or misleading in any particular.[3] Thus, while country of origin labeling is not a requirement under the FDC Act, the FDA advises it is possible that a violation of Customs' requirements concerning country of origin labeling, whether by omission or deviation, may also result in false or misleading labeling that violates the FDC Act and FDA regulations.[4]

As discussed herein, because the use of antibiotics and other banned substances in aquaculture is more prevalent in foreign production of seafood, the mislabeling of country of origin of such products (a documented problem) is intimately tied to the issue of EMA. Thus, any serious evaluation of EMA in the seafood industry, especially where health risks are a primary concern, must include a discussion about the mislabeling of country of origin.

Antibiotics, Pesticides, and Other Chemicals

Aquaculture ponds have become the primary breeding ground for shrimp and other seafood that is imported into the United States because the conditions can be manipulated and the seafood being raised is contained and, therefore, more easily harvested. Unfortunately, many of these ponds also provide ideal breeding conditions for harmful bacteria, and other organisms.

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[2] See generally, 21 U.S.C. §§ 342-343.

[3] FDA Compliance Policy Guides § 560.200

[4] See generally, 21 C.F.R. § 101.18; FDA Compliance Policy Guides § 560.200.

Imported farm-raised seafood is often produced with minimal quality control, in over-crowded and dirty ponds alongside dead and decaying fish and fish waste.[5] As such, bacteria, fungus, parasites and other unwanted pests that interfere with the production of shrimp and other fish, and can even wipe out entire harvests, regularly thrive in these ponds. Thus, controlling these impediments is essential to the profitability of aquacultured seafood.

In order to protect their crops, seafood farmers in many regions of the world rely on antibiotics, fungicides, and other chemicals, and in many countries where seafood farms are prevalent, there are few or no restrictions on the use of such products.[6] Thus, seafood imported into the United States and sold to U.S. consumers often contains a host of harmful contaminants that are absorbed during production. Among the most harmful of these contaminants is chloramphenicol, which the FDA has concluded "is not and cannot currently be generally recognized as safe for use in a manner that can reasonably be expected to result in its becoming a component of food" because of the severe health consequences of exposure to even low levels of the drug.[7] The FDA has found that 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.[8]

Regarding aplastic anemia, the FDA has found that "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

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[5] See, e.g., "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).

[6] "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.").

[7] Letter from the U.S. Food and Drug Administration to Olsson, Frank, and Weeda, P.C., Re: 02P-0321, p.13 (Jul. 29, 2003) ("FDA Chloramphenicol Decision"). The letter states that chloramphenicol has been reviewed three times by the WHO/FAO Joint Expert Committee on Food Additives ("JECFA"), which has consistently concluded that there is no acceptable daily intake for chloramphenicol in the human diet (citing 12th JECFA, 1968; 32nd JECFA, 1987; 42nd JECFA, 1994).

[8] FDA Chloramphenicol Decision, p.17.

shown that fatal aplastic anemia is 13 times more likely to occur after use of chloramphenicol."[9] With respect to carcinogenicity, the FDA has 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 data reported in studies by the World Health Organization and the U.S. National Toxicology Program.[10] 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."[11] Thus, exposure to even low levels of chloramphenicol puts consumers at immediate risk, and also presents serious long-term health risks.

In addition to these direct health risks posed by exposure to chloramphenicol, the use of these and other antimicrobial agents in aquaculture has been instrumental in the development of 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.[12]

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 also shrimp produced from aquaculture exported to other markets may be a vector by which antibiotic resistant strains of bacteria are spread throughout the world.[13]

The FDA not only has established that exposure to chloramphenicol has serious adverse health effects for consumers, but it also has concluded that "there is abundant evidence that chloramphenicol is still in widespread use abroad, particularly in Southeast Asia."[14] The FDA based its conclusion on the following finding:

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[9] Id. at 19-20 (footnotes omitted).

[10] Id. at 21 (footnotes omitted).

[11] Id.

[12] 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.

[13] 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).

[14] FDA Chloramphenicol Decision, p.22.

> [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 [seafood] in these ways.[15]

The use of chloramphenicol in aquaculture is a major health concern, but it is not the only harmful chemical agent widely used in aquaculture to protect seafood crops. In fact, as negative publicity surrounding its use has increased, a number of aquaculture producers have converted to using nitrofurans, an antibiotic that has long been recognized by the FDA as a dangerous carcinogen and which is prohibited in the United States for use in food-producing animals.[16] Other harmful chemical agents, such as malachite green, gentian violet, and fluoroquinolones, also are widely used. The widespread use of these other banned substances in Chinese aquaculture ponds led to the 2007 implementation by the FDA of an Import Alert on imports of shrimp and other seafood from China.[17] The enormity of the threat to U.S. consumers of banned substances in imported seafood was highlighted in that alert, as the FDA pointed to the extensive commercialization and increased consumption of aquacultured seafood products in the United States and worldwide, particularly from China. Specifically, the agency noted that:

- Aquacultured seafood has become the fastest growing sector of the world food economy, accounting for approximately half of all seafood production worldwide.

- Approximately 80% of the seafood consumed in the United States is imported from approximately 62 countries, and over 40% of that seafood comes from aquaculture operations.

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[15] Id. at 16 (footnotes omitted).

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

[17] Food and Drug Administration Import Alert 16-131 (Detention Without Physical Examination Of Aquacultured Catfish, Basa (Pangasius Sp), Shrimp, Dace, And Eel Products From The People's Republic Of China Due To The Presence Of New Animal Drugs And/Or Unsafe Food Additives) ("FDA Import Alert on Certain Seafood from China"). As a result of this alert, no aquacultured shrimp, catfish/Basa, dace, or eel from China can be imported into the United States without first being shown to be safe.

- As the aquaculture industry continues to grow and compete with wild-caught seafood products, concerns regarding the use of unapproved animal drugs and unsafe chemicals and the misuse of animal drugs in aquaculture operations have increased substantially.

- China is the largest producer of aquacultured seafood in the world, accounting for 70% of the total production and 55% of the total value of aquacultured seafood exported around the world. China is currently the third largest exporter of seafood to the United States.

- Shrimp and catfish products represent two of the top ten most consumed seafood products in the U.S.[18]

The import alert was the product of the FDA's increased monitoring of imported aquacultured seafood from October 1, 2006 through May 31, 2007. During that period, the FDA continued to find residues of unapproved new animal drugs and/or unsafe food additives in seafood imported from China. 25% of shipments of shrimp and other seafood tested were found to contain drug residues, including nitrofurans, malachite green, gentian violet, and fluoroquinolones.[19] The alert further noted that Chinese authorities acknowledged permitting the use of fluoroquinolones in aquaculture.

The FDA also stated that there is clear scientific evidence that the use of antibiotics and other chemicals during the various stages of aquaculture can result in the presence of trace residues of the substances in the seafood when it is eventually consumed. The presence of these antibiotic residues may contribute to an increase of antimicrobial resistance in human pathogens and, as with chloramphenicol, prolonged exposure to nitrofurans, malachite green, and gentian violet has been shown to have a carcinogenic affect. [20]

The health risks discussed above represent just some of the risks posed by aquacultured seafood products imported into the United States. The FDA has never contested, and in fact has confirmed, the severity of the risks presented, yet the agency's efforts at regulating seafood imports does not reflect the significance of those risks and, as a result, the United States lags woefully behind other developed nations when it comes to protecting consumers from the dangers presented by contaminated products.

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[18] Id. In addition, the FDA has cited National Oceanic and Atmospheric Administration's Fisheries Service statistics showing that 100% of shrimp imported into the United States is aquacultured. "CFSAN – Questions and Answers on FDA's Import Alert on Farm-Raised Seafood From China," http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/ucm119105.htm (accessed July 28, 2009).

[19] FDA Import Alert on Certain Seafood from China.

[20] Id.

As the FDA investigates means for countering the incentives that lead to the intentional addition of substances in products for the purpose of reducing the cost of their production, the intentional use of antibiotics and other harmful substances in aquaculture needs to be a primary focus of the discussion. These substances are used for the sole purpose of artificially lowering the costs of raising fish in environments that are often not conducive to producing healthy fish. The use of illegal and dangerous antibiotics, pesticides, and other substances in the aquaculture of shrimp and other seafood is, per the definition proposed by the FDA, a quintessential example of a widespread EMA practice that endangers the health of seafood consumers in the United States: such substances are intentionally added to a product for the purposes of reducing the cost of the production, i.e., for economic gain.

Mislabeling With Respect to Country of Origin

Because the health risks associated with the use of banned substances in foreign aquaculture are so severe, the practice of mislabeling seafood products with respect to country of origin is an essential issue that must be simultaneously addressed in order for any regulatory control to be effective. While not all of the motivation for such fraudulent mislabeling is related to the use of antibiotics and other banned substances in foreign fish farms, the two issues are intimately interrelated and must be considered in conjunction with one another. The United States has become the market of both first and last resort for shrimp and other seafood exporters as a result of foreign shrimp producers' unfair trade practices and lax U.S. regulation of food safety standards. While not the subject of these comments, it is important to understand the interconnected issue of unfair trade practices as it relates to mislabeling.

A number of circumstances regarding the production of farm-raised shrimp result in various distortions and problems in the international shrimp market. Overproduction of foreign farm-raised shrimp is the result of several factors, including national and international subsidies, and the use of antibiotics and other banned substances in their production. In particular, foreign producers of farm-raised shrimp have powerful economic incentives to use banned substances to increase production yields in crowded shrimp ponds and to reduce the risk of total crop failure. Use of these banned substances, along with the availability of various subsidies, encourages overproduction and uneconomic pricing.

As discussed previously, the artificial reduction of production costs comes by the creation of significant health risks to unwitting seafood consumers in the United States. Thus, the use of banned substances raises serious concerns about the safety of imported shrimp, concerns that the United States' system of regulation has failed to resolve. In contrast, strict food safety regimes in major importing markets such as the EU, Canada, and Japan mean that foreign shrimp that is or may be contaminated is diverted to the U.S. market because of the relatively ineffective U.S. testing of imports. For example, the massive surge of U.S. shrimp imports from China in 2002 and 2003 was due in substantial part to the closure of the EU market to Chinese imports after the detection of banned antibiotics.

The SSA's concerns regarding mislabeling of country of origin are a result of the domestic shrimp industry's direct experience with the administration of both trade relief and food safety laws by the Federal Government. In February 2005, the U.S. Department of Commerce ("Commerce") imposed antidumping duties on certain frozen warmwater shrimp from Brazil, China, Ecuador, India, Thailand, and Vietnam after SSA demonstrated that the domestic industry had been injured by unfairly priced imports.[21] Unscrupulous foreign exporters and U.S. importers of shrimp from these countries reacted to this by engaging in unlawful transshipment (i.e., shipment through another country) to mask the true origin of shrimp imported into the United States in order to avoid antidumping duties.

In the first year that antidumping duties were in place, U.S. Customs and Border Protection ("CBP") and Immigration and Customs Enforcement ("ICE") officials successfully discovered and took action against the unlawful transshipment of Chinese shrimp through Indonesia to avoid these duties. This scheme was detected through one of CBP's five National Targeting and Analysis Groups (NTAG) that was established to research and monitor trade trends to identify changes or patterns in trade that may signal potential fraudulent activity. The group found a sharp decrease in shrimp imports from China after the antidumping duty order was issued in early 2005 and a concurrent increase in shrimp products from Indonesia, among other countries. With the help of ICE, CBP found that in 2005, approximately $6 million worth of Chinese shrimp had been illegally transshipped through Indonesia.[22]

While the 2005 transshipment of Chinese shrimp presented severe economic consequences for the domestic shrimp industry, it was subsequent transshipments that clearly demonstrated that such schemes also present serious health risks to U.S. consumers. As discussed previously, in 2007 the FDA implemented an import alert on imports of shrimp from China that has spurred even more brazen transshipment schemes in an effort to mask the true origin of Chinese shrimp. In particular, CBP determined that Chinese shrimp was being transshipped through Malaysia in an effort to circumvent not only the antidumping order, but also the FDA import alert. In September 2007, CBP tested shipments of suspected Chinese

[21] Certain Frozen Warmwater Shrimp from Brazil, 70 Fed. Reg. 5143 (Feb. 1, 2005)(Amended Final Determination of Sales at Less than Fair Value and Antidumping Duty Order); Certain Frozen Warmwater Shrimp from Thailand, 70 Fed. Reg. 5145 (Feb. 1, 2005)(Amended Final Determination of Sales at Less than Fair Value and Antidumping Duty Order); Certain Frozen Warmwater Shrimp from India, 70 Fed. Reg. 5147 (Feb. 1, 2005)(Amended Final Determination of Sales at Less than Fair Value and Antidumping Duty Order); Certain Frozen Warmwater Shrimp from China, 70 Fed. Reg. 5149 (Feb. 1, 2005)(Amended Final Determination of Sales at Less than Fair Value and Antidumping Duty Order); Certain Frozen Warmwater Shrimp from Vietnam, 70 Fed. Reg. 5152 (Feb. 1, 2005)(Amended Final Determination of Sales at Less than Fair Value and Antidumping Duty Order); Certain Frozen Warmwater Shrimp from Ecuador, 70 Fed. Reg. 5156 (Feb. 1, 2005) (Amended Final Determination of Sales at Less than Fair Value and Antidumping Duty Order).

[22] See "Seafood Fraud: FDA Program Changes and Better Collaboration among Key Federal Agencies Could Improve Detection and Prevention," U.S. General Accounting Office, Report to Congressional Requesters, GAO-09-258, pp.14-15 (February 2009) ("GAO Report on Seafood Fraud").

shrimp that had been transshipped through Malaysia and detected the presence of unapproved drugs.[23]

While the transshipment of Chinese shrimp through Malaysia appears to be open and obvious, the volume of purportedly "Malaysian" shrimp entering the United States continues to grow unchecked – import information for the first eight months of 2008 indicates that imports of shrimp from Malaysia had increased by over 40% in terms of volume versus the same period in 2007. At the same time, *reported* imports of Chinese shrimp entering the United States have decreased markedly. Thus, the logical explanation is that vast quantities of Chinese shrimp containing unapproved substances are bypassing necessary FDA inspections and ending up on the plates of U.S. consumers who do not know that they have purchased Chinese shrimp intended to avoid the FDA's Import Alert.

Avoidance of antidumping duties and heightened inspections related to import alerts through transshipment are not the only economic motivations for mislabeling the country of origin of seafood products. Because of the health benefits and superior taste qualities of domestic wild-caught shrimp, consumers will pay a premium for such seafood. Moreover, concerns regarding poor internal regulation of the means of production of aquacultured shrimp in some countries means that consumers are willing to pay a premium for seafood that is sourced from countries, like the United States, that impose strict safety standards on their seafood producers.

Domestic wild-caught shrimp is healthier not only because of what is *not* in it (banned antibiotics and other contaminants), but also because of what *is* in it. In a study conducted by ABC Research of Gainesville, Florida in 2007, researchers evaluated domestic wild-caught shrimp in comparison to pond-raised shrimp from Indonesia, Thailand, and Vietnam. The study showed that domestic wild-caught shrimp had higher levels of iron, protein, calcium, vitamin B-12, and omega-3 fatty acids,[24] all nutrients that make wild-caught shrimp one of the healthiest seafood choices. Thus, the health benefits associated with wild-caught shrimp are significantly greater than those associated with farm-raised shrimp.

These factors, along with many consumers' desire for seafood with superior taste qualities, result in a price premium for domestic shrimp. An article in Seafood Business magazine acknowledged that there are "upper-end buyers who understand they are going to pay 25 to 30 percent more for [wild-caught American shrimp]," and that this is borne out by an example of previously frozen wild shrimp selling for $14.99 a pound while at the same time, previously frozen imported farmed shrimp of the same size/count was selling for $10.49 a pound in the same geographic market.[25] Thus, there is substantial economic motivation for parties

[23] Id. at 15.

[24] See "Study: Wild shrimp more nutritious," *Seafood Business Magazine* (Oct. 3, 2007).

[25] See "Wild shrimp: Sellers of this crustacean seek upscale markets," *Seafood Business Magazine* (Oct. 3, 2007).

selling shrimp in the U.S. market to mislabel foreign shrimp as domestic shrimp to fraudulently seek to benefit from the benefits inherent in domestic, wild-caught shrimp.

While the consequences of mislabeling country of origin may be solely economic for the domestic shrimp industry (i.e., foreign producers can undercut the premium price for domestic shrimp by fraudulently labeling foreign farm-raised shrimp as such while simultaneously destroying the reasons why consumers are willing to pay such a premium), there is no denying that the consequences are both economic *and* health-related for consumers. Thus, U.S. consumers who make an educated decision to purchase domestic wild-caught shrimp – and pay a premium for it – because of the increased health benefits and lack of contaminants are being defrauded *and* putting their health at risk, despite their efforts to make an intelligent consumer choice.

What Is Being Done to Protect Consumers and Safeguard the Domestic Industry?

It is clear that the United States has an enormous problem with respect to the safety of its seafood due to the use of banned substances in production and the willful circumvention by foreign producers and importers of U.S. laws that are intended to protect U.S. consumers and producers. Government agencies with the responsibility for providing such protection have acknowledged the problem. Nonetheless, the question remains – what is being done to safeguard the domestic seafood industry and protect consumers? The simplest and most accurate answer to that question is "not enough."

As highlighted in the recent GAO Report on Seafood Fraud, three federal agencies play key roles in detecting and preventing seafood fraud: CBP, the Department of Commerce's National Marine Fisheries Service ("NMFS"), and the FDA. CBP is responsible for collecting customs duties on imports, including seafood, and preventing the evasion of customs duties. NMFS provides fee-for service inspection services on request to the seafood industry, including processors, distributors, and other firms, that address economic integrity issues, such as the accuracy of a seafood product's label, as well as seafood safety issues. The FDA is responsible for ensuring that the nation's food supply, including seafood, is safe, wholesome, and properly labeled. In that regard, the FDA issues regulations that prohibit the misbranding or adulteration of food products, which includes the mislabeling of seafood products that constitutes seafood fraud. The FDA inspects both U.S. importers and domestic and foreign processors to ensure their compliance with applicable requirements, and provides guidance to the seafood industry on food safety hazards.[26]

While three agencies have varying degrees of responsibility in this area, the GAO report concludes that more can be done. In particular, the report concludes that while CBP and NMFS take a variety of actions to detect and prevent seafood fraud, including the falsification of import

[26] GAO Report on Seafood Fraud at 2.

information, the FDA considers economic issues a low priority compared with health and safety issues.[27] The reality is that the issue of fraudulent mislabeling of the country of origin is not only an economic one, but also is a serious health and safety issue. As noted above, the reaction of Chinese exporters to the FDA's import alert – widespread circumvention by transshipment through other countries – exemplifies the substantial significance of this type of economic fraud on the agency's efforts to improve the safety of seafood sold in our market. Thus, detecting and preventing such fraud should be a top priority of the FDA.

Due to concerns that federal efforts to ensure seafood safety are inadequate, many states have begun their own testing programs for harmful contaminants in imported seafood. Louisiana, Georgia, Alabama, Mississippi, Arkansas, Tennessee, Oklahoma, and Florida all have administered their own testing programs of imported seafood, and have repeatedly detected the presence of banned antibiotics and other contaminants. As just one example, Arkansas's Public Health Laboratory has equipped itself so that it can independently test imported seafood for harmful contaminants and began its testing program in 2007. Testing of seafood by the state of Arkansas has resulted in the discovery of seafood contaminated by harmful analytes that were not detected upon importation. In response to these efforts, the FDA should assume an active role assisting state testing programs.

Many of the FDA's counterparts in other major importing nations have adopted more effective programs for detecting contaminants in imported seafood. This is true despite the views expressed by opponents of meaningful reform to the FDA's imported food safety controls who misleadingly and inaccurately imply that our regulatory system is stringent in comparison to other major seafood importing countries.[28] In reality, the FDA could and should significantly enhance its food safety program. Other major food importing markets have already done so and, as a result of the significant differential in regulatory requirements and enforcement, the United States affirmatively attracts contaminated, adulterated, filthy, and unfit seafood products.

The FDA should develop a full understanding of the stringent import safety regimes of other major seafood importing countries, notably the EU, Japan, and Canada, as well as the standards put in place by the U.S. Department of Agriculture ("USDA"). For example, 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),

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[27] Id. At 13-18.

[28] 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").

the EU, Japan, Canada, and even the USDA all have made a commitment to ensure the safety of imported food products throughout their life-cycles:

- 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.[29]

- Japan has a strict risk-based system that is reinforced by high inspection rates –25 percent for shrimp imports – as well as certification requirements and significant penalties for noncompliance.[30]

- Canada imposes a minimum standard inspection rate of 15 percent for all imported seafood products and strict licensing requirements for importers.[31] In addition, Canada conducts "specialized testing" at a rate of "5 to 15 percent, depending on the product history and nature of the product."[32]

- 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. [33]

- In contrast to these regulatory regimes, the FDA's regulatory enforcement efforts rely on point-of-entry inspection. Such inspections cover approximately 1 percent of all FDA-regulated imports.[34] The FDA does not certify an exporting country's

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

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

[31] 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").

[32] 2005 FAO Fisheries Paper at p. 22.

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

[34] 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

equivalence to U.S. food safety standards and conducts only limited on-site examinations of foreign production facilities.

The Federal Government and, In Particular the FDA, Must Do More

The burden of ensuring that imported seafood is safe to consume should be a federal priority, not something addressed only when the country faces a crisis or the government is overwhelmed with public outrage. For this reason, the SSA believes that the FDA must take more responsibility for the safety of seafood imports coming into this nation, and SSA has developed a number of proposals 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 should not be able to 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 should be required to certify equivalence with the United States' standards on critical control points in the manufacturing process, monitoring and sampling requirements, and record-keeping obligations.

   • The FDA should conduct periodic on-site inspections of *all* 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 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 should lead to the imposition of producer and country bans.

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).

3. Fund FDA Oversight of Private and Public Laboratory Facilities

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

- 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 should be renewed annually.

- All FDA and private laboratories must test each class of imports based on a standardized list of controlled substances.

4. Limit Imports to Designated Ports of Entry

- Imported seafood should be 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. 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 should also describe the FDA's plans for addressing these issues in the coming year.

6. 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 should seize and destroy the import unless the importer can meet the requirements for re-export.

- The FDA should 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 should only be released to importers under controlled circumstances within 45 days of notification. Otherwise, the shipment should be destroyed.

- If the rejected shipment is bound for a third country, the importer should first have to 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 should, as previously proposed by the agency but never enacted, 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," should result in significant civil and possible criminal penalties.

- Knowingly falsifying these certifications should result in significant monetary penalties and denial of trading privileges.

9. Authorize Country Bans Until Demonstrated Improvement

- Detection of systemic use of prohibited substances should 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

- Detection of systemic use of prohibited substances should result in a complete ban of a particular product from the exporter.

- The particular product should be denied entry to the U.S. market altogether rather than being issued an import alert that subjects the exporter to 100 percent consignment testing.

11. International Coordination for Cooperative Agreement and Information Exchange

- The FDA should monitor and recognize foreign findings and bans issued by certain countries and regional organizations, including the EU, 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 appears to be only limited 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 seafood importing countries.

The potential threat to the safety of America's consumers caused by economically motivated adulteration practices like the intentional addition of harmful substances in aquaculture and false country of origin labeling is severe. The United States cannot fall further behind all other major seafood importing markets and further solidify a position as the dumping

ground for the rest of the world. Recent history, fully documented by the U.S. government, has shown that unscrupulous participants in the seafood market will do whatever it takes to maximize profitability, whether by exporting seafood contaminated with banned substances or by fraudulently mislabeling product to avoid trade duties and the closer scrutiny required by an FDA import alert. These two issues, ostensibly discrete, are so intimately related that they must be meaningfully addressed simultaneously.

The Southern Shrimp Alliance appreciates the FDA's request for comments on the use of EMAs that present a significant health risk to consumers. Such action is a necessary step toward bringing an end to these practices. But talking about the problems is insufficient to significantly curtail these fraudulent practices, and this will have been a futile step if the FDA does not act quickly to improve the safety of our nation's seafood.

Thank you in advance for considering the foregoing comments on an issue of great importance to our members. Please contact me should you have any questions or require clarification of any aspect of this submission.

Respectfully submitted,

John Williams
Executive Director
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