



Southern Shrimp Alliance

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October 5, 2011

Dr. Margaret Hamburg, MD
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Safety of Imported Seafood from Vietnam

Dear Commissioner Hamburg,

Acting Deputy Director William Jones' letter, dated June 15, 2011, to the Southern Shrimp Alliance stated that "FDA relies on and appreciates input from its stakeholders as it continues to improve its programs to assure the safety of all imported seafood products" Consistent with this sentiment, we are writing to draw your attention to continued incidents of intentional adulteration of shrimp products produced for export in Vietnam.

Problems with the safety and wholesomeness of Vietnamese seafood exported to the United States are not novel to FDA. In letters to the House Committee on Energy and Commerce (April 17, 2008) and then U.S. Representative Charlie Melancon (July 7, 2008), the agency gave detailed descriptions of actions taken to address unsafe seafood imported from Vietnam. The correspondence asserted that FDA "has worked closely with the seafood regulator in Vietnam, National Fisheries Quality Assurance and Veterinary Directorate (NAFIQAVED), to deal with the issue of unapproved animal drug residues in its seafood products. FDA has addressed this issue proactively with Vietnam over the last few years and has seen a steady decrease in violative seafood products." Specifically, in October 2005, "FDA met with a Vietnamese government delegation" to discuss the agency's findings regarding violative residues in seafood imports. In response, NAFIQAVED "committed to developing and implementing a program of short-term and long-term actions to address the aquaculture drug problem."

As part of this program, NAFIQAVED temporarily tested "all shipments of seafood products for chloramphenicol, nitrofurans, malachite green, and fluoroquinolones intended for export to the U.S.," but reduced the examination to random testing in March 2007. In the interim, FDA joined the Canadian Food Inspection Agency (CFIA) in April 2006 on an inspection mission to Vietnam "that focused exclusively on aquacultured products." The result of the mission was a

conclusion that “since November 2005, Vietnam has been generally ensuring that products shipped to the U.S. and Canada are free of violative residues.”¹ However, the mission also concluded that there were 38 veterinary drugs approved for use in Vietnam, “most of which are not approved for aquaculture use in the U.S.”

FDA subsequently conducted training for Vietnamese officials on Good Aquaculture Practices (GAqP) in November 2006, met with NAFIQAVED in December 2007 “to enhance the exchange of information and to enhance our understanding of their structure and organization,” participated in meetings with Vietnamese government officials in April 2008 “to continue our dialogue,” and, at the time of the letters, was tentatively scheduled to visit Vietnam in September 2008 “to further evaluate Vietnam’s control measures for animal drug residues in aquaculture products, to assess implementation of GAqP principles on farms, and to inspect firms that ship these products to the U.S.” The July 7th letter additionally noted that “FDA is currently negotiating a bilateral arrangement with Vietnam regarding the inspection of aquacultured fish and fishery products by Vietnamese competent authorities.”²

Nevertheless, despite these efforts, reports of intentional adulteration of shrimp and other seafood products produced for export continue to be widespread. Most recently, on September 30,

¹ CFIA appeared to have drawn a different conclusion. On July 17, 2006 – over one year after the joint inspection mission – NAFIQAVED and CFIA entered into a bilateral agreement requiring NAFIQAVED to “analyze consignments of all aquaculture fish and fish products destined for export to Canada for Chloramphenicol, Nitrofurans, Malachite Green and Leucomalachite Green” “Arrangement Concerning the Inspection and Certification of Aquaculture Fish and Fish Products Exported from Vietnam to Canada for Drug Residues,” at http://www.spsvietnam.gov.vn/Agreement%20on%20Fisheries/Thoa%20thoan%20giua%20viet%20nam%20va%20Canada_Eng.pdf.

² Although FDA reached a Memorandum of Understanding with the Ministry of Health of the Socialist Republic of Vietnam concerning food, animal, feed, and medical products (<http://www.fda.gov/InternationalPrograms/Agreements/MemorandaofUnderstanding/ucm107648.htm>) in June of 2008, FDA does not appear to have completed a bilateral agreement with Vietnamese authorities regarding the inspection of aquacultured fish and fishery products. Vietnam currently has bilateral agreements on fish and fishery products in place with Cambodia, Canada, China, the Republic of Korea, and Thailand (http://www.spsvietnam.gov.vn/EnglishSPS/pages/Bilateral_AquaticProduct.aspx), while FDA has memorandum of understandings or other cooperative agreements in place with respect to seafood products from Australia (shellfish safety), Canada (shellfish safety), Iceland (shellfish safety), Japan (shellfish safety & Puffer fish), Mexico (fresh and frozen aquacultured molluscan shellfish), New Zealand (shellfish safety & fish and fishery products), Norway (smoked salmon), and the United Kingdom (shellfish safety) (<http://www.fda.gov/InternationalPrograms/Agreements/MemorandaofUnderstanding/default.htm>).

2011, the subscription industry news aggregating service SEAFOOD.COM News published a story attributed to Vietnam News Brief titled “Unscrupulous Chinese Traders Accused of Disrupting Shrimp Purchases in Mekong Delta.” The article quoted government media sources alleging that Chinese seafood traders were “hoarding” seafood produced in the Mekong Delta region and were “even encourag[ing] local sellers to treat shrimps with substances to increase the volume.” The article continued, “[s]ome Vietnamese said they were trained by Chinese traders how to inject substances in shrimp.”

This recent publication builds upon multiple reports similarly bemoaning the intentional adulteration of shrimp exports. These reports are available for public review on the Web sites of several Vietnamese seafood processors and exporters. For example, the Web site for Vietnamese shrimp processor and exporter Phu Gia Co. Ltd.³ carries a story dated July 4, 2011 (and attributed to Thanh Nien News⁴) that describes businesses as “injecting impurities” in shrimp products purportedly destined for export to the Chinese market.⁵ Vietnam’s Deputy Minister of Agriculture and Rural Development characterizes the practice as a setback for national efforts to build a “clean and safe brand” of shrimp for Vietnam. Similarly, the seafood processor Song Bien Co., Ltd.’s (SOBICO) Web site⁶ features an article on the subject (sourced to “Land Vietnam”) dated March 25, 2011. That article describes the economic incentives that have led to the injection of contaminants into shrimp products and warns that these impurities will eventually be discovered in Vietnam’s export markets.⁷ The story quotes the deputy general director of JSC Minh Phu Seafood, Mr. Chu Van An, as calling for criminal penalties for parties involved in injecting shrimp with “impurities” because “this is not just a matter of commercial fraud or violations of safety and hygiene” but further potentially undermines the Vietnamese economy.

The problem appears to be long-standing, as the Web site for Vina Seafood,⁸ a Vietnamese seafood trading company, carries an article dated June 22, 2009 (attributed to “CafeF”)⁹ that alleges that shrimp in Vietnam is injected with “foreign substances . . . to gain more 20%-30% of weight [sic].” Reportedly, concerns in 2009 led the Vietnam Association of Seafood Exporters and Producers (VASEP) to develop a list of businesses that did not employ illegal weight-gaining

³ <http://www.phugiaseafood.com/en/>

⁴ <http://www.thanhniennews.com/Pages/default.aspx>

⁵ <http://www.phugiaseafood.com/en/index.php?menu=view&id=30651>

⁶ <http://sobico.com.vn/>

⁷ <http://sobico.com.vn/newsdetail/81>. Note that the March 25th date is not listed on this page of the website, but can be found at the listing of national news stories here: <http://sobico.com.vn/news/1>.

⁸ <http://www.vinaseafood.com.vn/>

⁹ http://www.vinaseafood.com.vn/news_details.php?cid=1&nid=646

practices – such as soaking shrimp in sugar water or injecting shrimp with agar (a gelling agent sometimes used as a laxative) – to combat such fraud.¹⁰

This latest string of press reports appears to be yet another example of widespread, endemic problems with aquacultural production in Vietnam. In November of last year, a Vietnamese press report described a meeting between Japanese importers and Vietnamese shrimp exporters to try and stop the injection of Trifluralin – a dangerous herbicide – into shrimp exported from Vietnam to Japan.¹¹ The article reported that a Japanese importer warned VASEP that “Vietnam should deal with the Trifluralin issue as soon as possible, otherwise Japanese authorities will likely ban imports of Vietnamese shrimp” and that “[o]ther importing countries such as the U.S. and EU will also tighten inspection on Vietnamese shrimp”

The Japanese government’s findings of Trifluralin in Vietnamese shrimp was cited as one of the reasons behind VASEP reaching a cooperation agreement with My Thanh Shrimp Association (MTSA) as “the closer linkage between farmers and processors *is urgently needed to proactively prevent the chronic* [sic] *issues of shrimp such as chemical and anti-biotic residues and foreign matter injection* as well as developing a strategy for sustainable and stable development of Viet Nam’s shrimp industry. Acknowledging such need, VASEP and MTSA both signed the agreement for the sake of the ‘safe’ shrimp [sic].”¹²

Notably, the Vietnamese government responded to the government of Japan’s findings by committing to inspect all shrimp and pangasius exports *to Japan* for trifluralin residue until “the residue is no longer detected or when Japanese authority decides to cancel the enhanced inspection over such products from Viet Nam.”¹³

Although the Southern Shrimp Alliance appreciates VASEP’s public commitment to exporting safe shrimp and other seafood products, Vietnam’s serious problems with aquacultural production do not appear to have been meaningfully addressed.

¹⁰ Vietnews, “Shrimp Exports Show Signs of Recovery” (July 28, 2009) <http://www.vietnewsonline.vn/news/business/6932/shrimp-exports-show-signs-of-recovery.htm>.

¹¹ Viet Press, “Vietnam, Japan Firms Seek to Deal with Trifluralin Substance in Shrimp” (November 4, 2010) http://www.vietpress.info/node/1155?page=13&quicktabs_1=0.

¹² Vietfish International, “VASEP and MTSA Join Forces” (Jan-Feb 2011) (emphasis added) <http://www.vietfish.org/2011022310132219p49c64/vasep-and-mtsa-join-forces.htm>.

¹³ Vietfish International, “Vietnam Tightens Control Over Use of Trifluralin in Aquaculture” (Nov-Dec 2010) <http://vietfish.org/20101221105154300p49c82t69/vietnam-tightens-control-over-use-of-trifluralin-in-aquaculture.htm>.

In an annual report recently published by NOAA Fisheries,¹⁴ the government agency observed that Vietnam accounted for 5.58% of the volume of edible seafood imported into the United States in 2010 (304.2 million pounds of 5.5 billion pounds of edible seafood imports) and 5.9% of the value of edible seafood imported into the United States in 2010 (\$867 million of \$14.8 billion). However, a review of FDA's Import Refusal Reports through September of this year¹⁵ indicates that Vietnamese seafood imports accounted for 234 of the 1,973 seafood entry lines refused entry. In other words, despite accounting for less than six percent of the volume and value of seafood imports into the United States, Vietnamese seafood accounted for nearly twice that amount (11.9%) of seafood imports refused entry into this country.

Thirty-six (36) of the 234 refusals were for shrimp products, including three in January of this year for imports contaminated by veterinary drug residues from a Vietnamese exporter, Investment Commerce Fisheries Corporation (INCOMFISH), that has been listed on Import Alert 16-124 ("Detention Without Physical Examination of Aquaculture Seafood Products Due to Unapproved Drugs")¹⁶ since September of 2009 for the presence of enrofloxacin in its shrimp exports to the United States. Remarkably, a review of ship manifest data indicates that INCOMFISH has exported nearly 316,000 pounds of shrimp to U.S. ports since June of this year, despite being listed on Import Alert 16-124 since September of 2009 and despite the three additional refusals for veterinary drug residues in January.¹⁷

These findings are consistent with continued widespread discovery of serious food safety violations for seafood products by Vietnam's other trading partners. In addition to Japan's recent actions in response to the introduction of Trifluralin in shrimp exports to that market, the most recent European Union "Stop & Test" list¹⁸ includes multiple Vietnamese seafood exporters, including one for the presence of Trifluralin in seafood exports, three for nitrofurans, two for chloramphenicol, one for quinolones, three for malachite green, and one for the presence of pesticides. Further, a review of the CFIA's Mandatory Inspection List (MIL) indicates that it has fourteen (14) Vietnamese exporters listed for fluoroquinolones as the reason for the agency's refusal of entry of products in 2011.¹⁹ Another Vietnamese exporter was listed by CFIA on the

¹⁴ Fisheries of the United States – 2010 at p. 49,
<http://www.st.nmfs.noaa.gov/st1/fus/fus10/index.html>

¹⁵ http://www.accessdata.fda.gov/scripts/importrefusals/ir_months.cfm?LType=P

¹⁶ http://www.accessdata.fda.gov/cms_ia/importalert_27.html

¹⁷ Entry line numbers: AZZ-1960975-0/1/1, AZZ-1960975-0/1/2, and AZZ-1960975-0/1/3.

¹⁸ Available at: www.bvet.admin.ch (Sept. 22, 2011).

¹⁹ <http://active.inspection.gc.ca/scripts/fispoi/ial/IALFront.asp?lang=e>. The 14 are: Bentre Aquaproduct Import and Export Joint Stock Company (July 8, 2011); Cuu Long Fish Joint Stock Company (June 24, 2011 and July 25, 2011); Dong Thap Trading Corporation's Branch (DOCIFISH) (July 8, 2011 and September 20, 2011); Hung Vuong – Vinh Long Co., Ltd. (September 1, 2011); Mekong Delta Food Factory (CASEAMEX) (June 9, 2011); Nam Hai Company Limited (February 25, 2011); Phuong Dong Seafood Ltd. (June 21,

MIL for the presence of quinolones.²⁰ Another ten (10) Vietnamese exporters are listed for net weight determinations.²¹

The recent regulatory actions of FDA and other food safety agencies with respect to Vietnamese seafood exports come on the heels of disappointing contamination inspection results from the FDA's limited sampling and testing of shrimp imports. FDA's July 7th Letter to Rep. Melancon stated that "positive findings of violative residues in Vietnamese fish products have been on the decline" The letter supported this optimistic view by explaining that in fiscal year 2005, 20 out of 84 samples (23.8%) had positive drug residue results, falling to 9 out of 52 (17.3%) in FY 2006, 5 out of 46 (10.9%) in FY 2007, and, as of March 31, 2008, 4 out of 57 (7.0%) in FY 2008. However, according to the last figures released to the Southern Shrimp Alliance, in 2009, the FDA found five (5) of the 48 samples of shrimp tested from Vietnam (10.4%) to be contaminated with banned antibiotics – a reversal of the trend previously emphasized by FDA.

If the contamination rate found by FDA's limited sampling program was projected out to all imports of shrimp from Vietnam in 2009, 9.2 million pounds (out of 88.5 million pounds) may have entered the United States contaminated with harmful substances. In the meantime, the volume of shrimp imported into the United States from Vietnam has increased significantly. The total volume imported in 2010 reflected nearly 14% growth over the volume imported in 2009 and, through July of this year, the total volume imported in 2011 reflects nearly 20% growth over the first seven months of 2010.

As you know, seafood from the Gulf of Mexico, including shrimp, has been subjected to rigorous testing to ensure the safety and wholesomeness of our product before it reaches American consumers. The domestic shrimp industry has welcomed this scrutiny. Yet, we continue to compete in the U.S. market with products that do not comply with our food safety laws and regulations and, in direct result, are available for sale at substantially lower prices.

2011); Phuong Nam Co. Ltd. (January 27, 2011 and May 26, 2011); Quang Minh Seafood Co. Ltd. (June 7, 2011 and June 28, 2011); Tan Thanh Loi Frozen Food Co. Ltd. (April 19, 2011); TG Fishery Holdings Corporation (August 3, 2011); Thuan Thien Producing Trading Limited Company (September 29, 2011); Tra Vinh Food-Stuffs and Agricultural Products Company (TAVIFACO) (August 23, 2011 and September 23, 2011); and Workshop II – Hung Vuong Corporation (August 31, 2011).

²⁰ Ngoc Tri Seafood Joint Stock Company (September 26, 2011).

²¹ The 10 are: An Phu Seafood Corporation (Feb. 4, 2011); K&K Aquafish ImEx Company Ltd. (March 9, 2011); Khanh Hoa Sea Product Exploitation and Service (KHASPEXCO) (March 31, 2011 and June 7, 2011); Minh Hai Jostoco (July 12, 2011); Nam Hai Company Ltd. (February 16, 2011); Ngoc Tri Seafood Joint Stock Company (September 26, 2011 and September 29, 2011); Nhat Duc Co., Ltd. (April 18, 2011); Quang Minh Seafood Co., Ltd. (July 18, 2011); Quoc Viet Seaproducts Processing Trading and Import-Export Co., Ltd. (July 7, 2011 and August 5, 2011); and Seaprimexco Vietnam (January 27, 2011).

This is not a level playing field. Worse, the pervasiveness of the intentional adulteration of shrimp produced for export in Vietnam for economic reasons poses serious risks to American consumers.

FDA's approach, to date, does not appear to have been successful in eliminating these practices. While FDA has worked with NAFIQAVED authorities to address the intentional adulteration of seafood exports, there is little public evidence indicating that additional measures were undertaken when these efforts fell short.

FDA has not, for example, conducted significant inspections of Vietnamese seafood processing facilities. According to a recent report by the U.S. Government Accountability Office (GAO) ("Seafood Safety: FDA Needs to Improve Oversight of Imported Seafood and Better Leverage Limited Resources," GAO-11-286 (Apr. 2011)),²² between fiscal years 2005 and 2010, the FDA inspected 17 of the 801 processing facilities in Vietnam (2.1%), with nearly half (8) of those inspections taking place in fiscal year 2005.

Further, additional measures undertaken by FDA, if any, to prevent shrimp "injected" with "impurities" or contaminated with Trifluralin from reaching American consumers does not appear to have been publicized. Nor does it seem that FDA's Import Alert system has prevented a Vietnamese exporter from shipping large quantities of the same type of merchandise that is the subject of an Import Alert to the U.S. market. Further, to the extent that VASEP developed a list in 2009 of businesses not engaged in fraudulently increasing the weight of shrimp and other seafood exports, such a list does not appear to have been publicly disclosed or led to any regulatory action with respect to exporters who, by virtue of their exclusion, were likely to have trafficked in inappropriately altered shrimp.

The Southern Shrimp Alliance is grateful for the effort and care taken by FDA to provide additional background and explanation in response to our previous correspondence on similar issues. We are grateful, in advance, for any further information on what changes in approach FDA has adopted to deal with the continued significant problem of intentional adulteration of shrimp and other seafood products exported from Vietnam. Should you believe that our review of the available data has led to erroneous conclusions, we would again be grateful for any clarification to assist in our understanding of FDA's oversight of imported seafood.

Sincerely,



John Williams
Executive Director

Dr. Margaret Hamburg, MD

October 5, 2011

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cc: Senator Tom Harkin, Chairman, Committee on Health, Education, Labor and Pensions
Senator Michael B. Enzi, Ranking Minority Member, Committee on Health, Education,
Labor and Pensions
Senator Kay R. Hagan, Member, Committee on Health, Education, Labor and Pensions
Senator Richard Burr, Member, Committee on Health, Education, Labor and Pensions
Senator Johnny Isakson, Member, Committee on Health, Education, Labor and Pensions
Congressman Fred Upton, Chairman, Committee on Energy and Commerce
Congressman Henry A. Waxman, Ranking Minority Member, Committee on Energy and
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