



1200 18th Street NW, 5th Floor
Washington, DC 20036
www.pewtrusts.org

202.887.8800 Phone
202.887.8877 Fax

January 13, 2009

The Honorable Andrew C. von Eschenbach, M.D.
Commissioner
U.S. Food and Drug Administration
U.S. Department of Health and Human Services
5600 Fishers Lane, Room 15-47
Rockville, Md. 20857

Dear Commissioner von Eschenbach:

Documents recently obtained from your agency show that at least three Chilean companies exporting farmed salmon to the U.S. processed farmed salmon that had been treated with drugs that U.S. Food and Drug Administration (FDA) has not approved for use in aquaculture and, in some cases, contained residues of unapproved drugs. These documents highlight the question as to whether this evidence constitutes isolated cases, or whether there may be a systematic disregard for FDA regulations necessitating sanctions.

The Pew Environment Group works to promote improved environmental practices in salmon aquaculture. Certain drugs identified in the FDA reports are associated with environmental harms. Respecting the FDA's primary obligation to human health issues, we address our observations and questions initially in line with these more conspicuous findings of your documents. The documents, obtained by the Pew Environment Group by way of a request under the Freedom of Information Act (FOIA), relate to a visit undertaken by FDA officials to Chile in April 2008 and contain a number of critical observations.¹

Of most immediate importance, in the inspection reports for each of the three companies, FDA detected the use of "unregulated/unapproved drugs administered to aquaculture fish [that] pose a potential human health hazard. These substances may be carcinogenic, allergenic, and/or may cause antibiotic resistance in man." These drugs include the antibiotics flumequine and oxolinic acid and the sea lice treatment emamectin benzoate. Further, documents obtained by your agency as part of your inspections stated that residues of these drugs had been found in the flesh of the companies' farmed salmon products on numerous occasions. This suggests that these Chilean processors intending to export to the U.S. not only used salmon that had been treated with drugs unapproved by FDA, but also used salmon that came from facilities that did not follow proper withdrawal periods for these drugs, which resulted in residues of these chemicals in farmed salmon intended for market.

While it is worrying that Chile, the largest exporter of farmed salmon to the U.S., uses drugs not legal in the U.S., FDA's findings are not surprising. While FDA has approved only a few drugs for use in aquaculture, the Chilean government has approved a number of antibiotics and antiparasitics for use in Chilean salmon aquaculture including the three drugs identified in the April

¹ Note: The Pew Environment Group received three documents, each identified as Establishment Inspection Reports, which we conclude to be the entirety of publicly available documents generated during this visit. These documents concern specific processing plants: one owned by Marine Harvest, a Norwegian based firm, and the largest producer in the world; a second by AquaChile, a Chile-based firm and one of the largest producers in Chile; and a third by Inverciones Estefal Limitada, a German-based firm affiliated with Virginia-based Cuisine Solutions.

2008 FDA inspection reports – emamectin benzoate, oxolinic acid and flumequine.² Official estimates of chemical use provided by Chilean salmon farming companies to Chilean authorities document that at least several large salmon farming companies expected to use the antibiotics oxytetracycline, oxolinic acid, flumequine, florphenicol and the sea lice drug emamectin benzoate in 2005, 2006 and 2007. For instance, in a February 2007 “Environmental Impact Declaration” (DIA) for a farm site in the 11th region, Marine Harvest estimated it would use a daily dosage of 100 mg/kg salmon of oxytetracycline, 30 mg/kg salmon of oxolinic acid, 30 mg/kg salmon of flumequine and 15-30 mg/kg salmon of florphenicol.³

Within its April 2008 inspection reports, FDA makes it clear that even though certain drugs may be permitted by Chilean authorities for use in aquaculture production, those drugs may not be used for production of farmed fish exported to the U.S. unless explicitly approved for use in aquaculture by FDA. As two of the reports state: “We explained to them [producer] that if the drug is not listed in the approved drugs list ...they are not allowed to use the drug to treat salmon destined to be distributed in the US, not even if they meet withdrawal periods and no tissue residue can be detected.” In FDA’s November 20, 2008 “Enhanced Aquaculture and Seafood Inspection” document, you elaborate on this point:

All substances used as new animal (aquaculture) drugs during the farming of seafood imported into the U.S. are required to be approved under Section 512 of the FFDCA. Unapproved new animal drugs administered in any dosage form (including via feed) to an animal are considered to be unsafe new animal drugs and are not allowed to be used...Tissue residue tolerances may be established for FDA approved drugs. If there is no tolerance established, any amount of drug residue found is considered a violation and renders the product adulterated. The use of unapproved drugs or misuse of approved drugs in farm-raised seafood raises significant public health concerns. The application of these drugs during the various stages of aquaculture can result in the presence of the drugs or their metabolites in the edible portion of the aquaculture products. This may have an effect on the safety of these products for consumers because, for example, some of these drugs are associated with increased risk for cancer with prolonged exposure or antibiotic resistance in human pathogens.⁴

It could be argued that the Chilean salmon companies that were the subject of the April 2008 inspections were aware that certain drugs approved for use in Chile are not considered legal according to FDA. For instance, the April 2008 inspection report for Marine Harvest references a warning letter issued in August 2003 regarding the use of oxolinic acid and flumequine, noting that “the firm continued to use these drugs but has a program to keep them under control and has worked on reducing the amounts used each year.”⁵ Additionally, the Pure Salmon Campaign, a global

² December 7, 2007, Servicio Agrícola y Ganadero, “Medicamentos de uso veterinario autorizados.”

³ February 2007, SEIA-CONAMA, Government of Chile, National Environmental Commission, Official Declarations of Environmental Impact Submitted to the Chilean Government, Marine Harvest Chile S.A. Environmental Impact Declaration, Center 110604 Level Island, Canal King/11th Region, www.conama.cl.

⁴ November 20, 2008, U.S. Food and Drug Administration, Andrew C. von Eschenbach, M.D. Commissioner of Food and Drugs, Report to Congress Food and Drug Administration Amendments Act of 2007 Public Law 110-85 Section 1006 – Enhanced Aquaculture and Seafood Inspection, <http://www.cfsan.fda.gov/~lrd/seartc08.html>

⁵ U.S. Food and Drug Administration, EI Start April 23, 2008, Establishment Inspection Report, Cultivadora De Salmones Linao Ltda, Puerto Montt, Chile, pgs 9, 10.

coalition of which Pew is a partner, has sent multiple letters to Sernapesca (the Chilean aquaculture industry regulatory body) addressing its use of drugs that are unapproved by FDA. In an April 11, 2008 formal request for information addressed to Sernapesca, the Pure Salmon Campaign noted: “specific antibiotics [drugs] approved for use in Chilean salmonid aquaculture and reported in Environmental Impact Declarations by Chilean salmon farming companies, namely – flumequine, oxolinic acid, florphenicol and emamectin – are not approved for use in salmonids by the US FDA.”

We understand that FDA’s common procedure for policing unapproved drugs relies largely on drug residue tests of imported products once they have landed in U.S. territory. Thus, we applaud the FDA’s initiative with its April 2008 trip to Chile and on previous trips to inspect conditions within an exporting country. We further applaud FDA’s recent decision to open field offices outside the United States, including South America.

According to your November 20th “Enhanced Aquaculture and Seafood Inspection” document, aquacultured seafood is now one of “the products that FDA currently considers high priority for sampling and surveillance activities, as determined by relative likelihood and severity of potential food safety concerns.”⁶ Additionally, this document states that: “Testing of imported aquacultured species over the past 4 years revealed that products imported from Asia (mainly the PRC, Vietnam, and Indonesia) and South American countries have been the primary sources of origin of violative product.” Below, we offer additional justification for FDA to consider Chilean farmed salmon imports of utmost priority:

- 1) **Significant Imports of Chilean Salmon** - Roughly 84 percent of seafood consumed in the U.S. in 2007 was imported, up from 61 percent ten years earlier.^{7 8} Salmon has become the third best selling seafood in the U.S., rising from per capita consumption of 0.44 pounds in 1987 (when it was the eighth most popular seafood among American consumers by weight) to two pounds in 2006.⁹ The majority of salmon consumed in the United States is farmed. And the largest single source of farmed salmon sold in the United States is Chile.^{10 11 12}
- 2) **Evidence of Use of Unapproved Drugs** – Beyond the April 2008 FDA inspection report findings, official estimates of chemical use provided by Chilean salmon farming companies to Chilean authorities document that at least several large salmon farming companies expected to use the antibiotics oxytetracycline, oxolinic acid, flumequine, florphenicol and the sea lice drug emamectin in 2005, 2006 and 2007.¹³

⁶ Ibid.

⁷ NOAA Fisheries, “Fisheries of the United States-1997”, Review: Per Capita Consumption, <http://www.st.nmfs.noaa.gov/st1/fus/fus97/percapita/pc-text.pdf>

⁸ NOAA Fisheries, “Fisheries of the United States-1997”, Per Capita Consumption, http://www.st.nmfs.noaa.gov/st1/fus/fus07/08_perita2007.pdf

⁹ <http://aquaculture.noaa.gov/pdf/econ/9.pdf>

¹⁰ Data from 2005 shows relative figures for domestic salmon, which is wild caught from Alaska, and imported salmon, which is farmed. P. 137,

http://www.iser.uaa.alaska.edu/Publications/greatsalmonrun/SalmonReport_Ch_9.pdf,

¹¹ http://www.st.nmfs.noaa.gov/st1/fus/fus07/06_trade2007.pdf,

¹²

http://www.st.nmfs.noaa.gov/pls/webpls/trade_prdct.data_in?qttype=IMP&qmnth=01&qyear=2008&qprod_name=SALMON+ATLANTIC&qoutput=TABLE.

¹³ February 2007, SEIA-CONAMA, Government of Chile, National Environmental Commission, Official Declarations of Environmental Impact Submitted to the Chilean Government, Marine Harvest Chile S.A. Environmental Impact Declaration, Center 110604 Level Island, Canal King/11th Region, www.conama.cl.

Additionally, documents from a wrongful dismissal suit illuminate ongoing controversy within the industry over antibiotic use in Chile. In *Trent v. Salmon of the Americas*, Alex Trent (ex-executive director of the farmed salmon trade association, Salmon of the Americas) alleges he was terminated as executive director after “having internally criticized high-volume Chilean production methods as illegal, unsafe for consumers and environmentally unsound...”¹⁴ The amended complaint also states that Rafael Puga, the President of SOTA and Manager of Marine Harvest USA, told Trent that “his concerns about Chilean producers’ use of FDA-prohibited antibiotics...including the use of quinolones...and the presence of substantial levels of emamectin benzoate... were ‘none of your business.’”¹⁵

- 3) **Evidence of “Excessive” Use of Antibiotics** – The Salmon Aquaculture Dialogue commissioned a March 2008 report by leading scientists to document the chemical inputs in salmon production around the world. The Salmon Aquaculture Dialogue (which counts Marine Harvest and SalmonChile on its nine-person steering committee) is a multi-year dialogue initiated by the World Wildlife Fund aimed at developing and supporting implementation of standards that reduce or eliminate key impacts of salmon farming globally. The report suggested that antibiotic use in Chile is several hundred times the volume employed in Norway, and described Chilean antibiotic use as “excessive.”¹⁶ It is important to note that Norway and Chile are relatively comparable in production volume, with Norway the larger.

In September 2008, the Chilean government released a report declaring that its farmed salmon industry “intensively” uses antibiotics. The government report stated (translated from Spanish): “One of the real problems in salmon farming is the intensive use of antibiotics. Although permitted, we concluded that their use should be rationalized...”¹⁷

- 4) **Numerous Import Alerts for Drug Residues** - Several import alerts have been issued in relation to malachite green, Emamectin/ivermectin, crystal violet, oxolinic acid and amphenicol contamination of Chilean farmed salmon by food safety authorities in Canada, the U.K., Taiwan, Germany and the U.S. in 2006, 2007 and 2008:
 - a. **U.S.** – In 2006 and 2007, FDA tested 47 samples and 40 samples of Chilean farmed salmon respectively for four chemical residues – ivermectin, oxolinic acid, flumequine and malachite green. In February 2006, the FDA issued an Import Alert in relation to oxolinic acid in Chilean farmed salmon at a level of 15.6 ppb. None of the 40 samples tested positive in 2007, samples were not test for residues of certain chemicals such as emamectin, florphenicol and other antibiotics. An FDA official has informed the Pure Salmon Campaign that 2008 testing would include crystal violet but not emamectin benzoate, but was unaware of the results of 2008 testing to date.¹⁸

¹⁴ *Alex Trent v. Salmon of the Americas, et al.*, No. 1:08-cv-21267 (S.D.F.L.) First Amended Complaint. p.1-2

¹⁵ *Alex Trent v. Salmon of the Americas, et al.*, No. 1:08-cv-21267 (S.D.F.L.) First Amended Complaint. p.9

¹⁶ Burridge et al, March 20, 2008, “Chemical Use in Salmon Aquaculture: A Review of Current Practices and Possible Environmental Effects,” p 8,13,

<http://www.worldwildlife.org/what/globalmarkets/aquaculture/WWFBinaryitem8842.pdf>

¹⁷ Original in Spanish: “Uno de los problemas actuales en la salmonicultura es el uso intensivo de antibióticos, a pesar de que están permitidos, pensamos que se debieraracionalizar el uso de estos. Con este propósito, se propone el cronograma para la elaboración del plan de manejo y uso de antibióticos que se adjunta al documento, que finalizará con un conjunto de medidas a diciembre de 2008”, www.subpesca.cl/mostrarchivo.asp?id=5941.

¹⁸ 2007 and 2008 emails from Barbara Montwill, U.S. FDA to Don Staniford, Pure Salmon Campaign.

- b. **Canada** - During the last 18 months, the Canadian Food Inspection Agency (CFIA) has issued at least seven Import Alerts for Emamectin/Ivermectin in Chilean farmed salmon. In February 2008, CFIA issued an Import Alert for "Amphenicol" in a Chilean farmed salmon sample from AquaClaras.¹⁹
 - c. **U.K.** - An Alert Notification was published by the U.K. on 12th December 2006 for the "unauthorised substance crystal violet in frozen salmon skewers". The country of origin was listed as Thailand,²⁰ though the producing country was ultimately identified as Chile.²¹
 - d. **Taiwan** - In September 2007, Taiwanese health authorities detected 1.7ppb of Leucomalachite Green in a 523-kilogram shipment of Chilean salmon. Malachite green is prohibited for use in aquaculture in numerous countries, including Chile and Taiwan.²²
 - e. **Germany** - A report released in October 2008 by the German Federal Office of Consumer Protection and Food Safety listed banned chemicals found in samples of Chilean salmon shipped to Germany. The presence of crystal violet, an anti-fungal chemical, and abamectin, a pesticide most often used in agricultural practices, were detected in two samples analyzed by the German food inspection authorities. Neither chemical is authorized by Germany or the U.S. for use in aquaculture production.
- 5) **Environmental Concerns Related to Drug Use** - We appreciate that FDA's primary obligation is to human health however, if human health regulations are disregarded by the exporting country, we are concerned about even less regard for environmental health. In particular, we are concerned about the potential environmental harm caused by excessive use of certain antibiotics and antiparasitics. For example:
- a. Product information for emamectin benzoate states that it is "very toxic to aquatic organisms" and "may cause long-term adverse effects in the environment."²³ It is important to note that emamectin benzoate is traditionally administered to farmed fish via fish feed. Given the fact that most Chilean farmed salmon are produced in open net pens, any drugs administered via feed have a strong chance of entering into the marine environment through uneaten feed and fish feces. In fact, emamectin benzoate has been found in sediments under salmon farms.²⁴ A number of studies demonstrate

¹⁹

<http://fis.com/fis/worldnews/worldnews.asp?monthyear=42008&day=11&id=28033&l=e&country=&special=&nd=1&df=0>

²⁰ European Commission, Rapid Alert System for Food and Feed, http://ec.europa.eu/food/food/rapidalert/reports/week50-2006_en.pdf

²¹ Ibid., Pure Salmon Campaign website: <http://www.puresalmon.org/chile.html>

²² September 23, 2007, The China Post, "Salmon imports from Chile test positive for banned drug," <http://www.chinapost.com.tw/taiwan/2007/09/23/123666/Salmon-imports.htm>.

²³ Syngenta, Material Safety Data Sheet, emamectin benzoate, http://www.chiletaskforce.org/res/242/proclaim_msds.pdf

²⁴ Scottish Environment Protection Agency (SEPA), February 2005, "The Occurrence of Chemicals used in Sea Louse Treatments In Sediments Adjacent to Marine Fish Farms: Results of Screening Surveys During 2004", <http://www.sepa.org.uk/pdf/aquaculture/projects/TR-050202JBT.pdf>

concerns regarding impacts of emamectin benzoate use in aquaculture on the marine environment.^{25 26 27 28 29 30}

- b. While the impacts of flumequine and oxolinic acid on the marine environment do not appear to be well-documented, the Salmon Aquaculture Dialogue report on chemical use in salmon aquaculture stated: "Antibiotics treatment in aquaculture is achieved by medicated baths and medicated food. In both cases, the likelihood exists for antibiotics to pass into the environment, affecting wildlife in the environment for extended periods of time and exerting their antibiotic effects."³¹ Additionally, it states: "Because of their [antibiotics] toxicity, they also affect the composition of the phytoplankton, the zooplankton, and even the diversity of population of larger animals."

In light of FDA's Enhanced Aquaculture and Seafood Inspection and knowledge of Chilean salmon farming production practices and potential disregard for importing country regulations, we urge FDA to exercise special vigilance with farmed salmon imports from Chile. Among the specific items that we believe deserve attention are the following:

- Given the findings of use and residues of unapproved drugs during the April 2008 inspection of Chilean salmon companies, will FDA increase its testing for drug residues in farmed salmon imports from Chile?
- Given admission by Chilean salmon companies of use of emamectin benzoate (and documentation of residues of emamectin in farmed salmon flesh), will FDA now begin testing for emamectin benzoate in 2009?
- Has FDA put all Chilean salmon producers exporting to the U.S. on notice that drugs not approved by FDA for use in aquaculture cannot be used in the production or processing of Chilean salmon intended to be exported to the U.S. market?

²⁵ Mayor DJ, Solan M, McMillan H, Killham K & Paton GI (In press). Effects of copper and the sea lice treatment Slice[®] on nutrient release from marine sediments. *Marine Pollution Bulletin*, doi:10.1016/j.marpolbul.2008.11.015

²⁶ Mayor DJ, Solan M, Martinez I, Murray L, McMillan H, Killham K & Paton GI (2008). Acute toxicity of UK-registered sea lice treatments to *Corophium volutator* and *Hediste diversicolor*: whole sediment bioassay tests. *Aquaculture* 285: 102-108, doi:10.1016/j.aquaculture.2008.08.008

²⁷ Burridge, L E et al (2004), Acute toxicity of emamectin benzoate (SLICE) in fish feed to American lobster, *Homarus americanus*. *Aquaculture Research* 35 (8), 713-722: www.blackwell-synergy.com/links/doi/10.1111/j.1365-2109.2004.01093.x/abs/

²⁸ Waddy, S L et al (2002) Emamectin induces moulting in American lobster, *Homarus americanus*. *Canadian Journal of Fisheries and Aquatic Sciences*, 1096-1099: <http://pubs.nrc-cnrc.gc.ca/rp/rppdf/f02-106.pdf>

²⁹ Willis, K J and Ling, N (2003) The toxicity of emamectin benzoate, an aquaculture pesticide, to planktonic marine copepods. *Aquaculture* 221, 289-297.

³⁰ Bright, D and Dionne, S (2004) Use of Emamectin Benzoate in the Canadian Finfish Aquaculture Industry: A Review of Environmental Fate and Effects. Environment Canada, Vancouver: http://www.agf.gov.bc.ca/ahc/fish_health/sealice.htm

³¹ Burridge et al, March 20, 2008, "Chemical Use in Salmon Aquaculture: A Review of Current Practices and Possible Environmental Effects," p 8,13, <http://www.worldwildlife.org/what/globalmarkets/aquaculture/WWFBinaryitem8842.pdf>

- Has FDA requested and/or obtained information from Chilean authorities regarding the type and quantity of drugs and chemicals used in Chilean salmon production? Additionally, has FDA requested and/or obtained official information regarding the type and results of residue testing performed by Chilean authorities?
- Has FDA completed and/or scheduled and/or plan to schedule any additional inspections of Chilean salmon facilities since its April 2008 visit? If so, will FDA increase the number of site visits/inspections beyond the three companies inspected in April 2008?
- Has FDA communicated its findings to relevant Chilean authorities and/or any other national food safety or environmental authorities outside Chile?
- As FDA notes in its April 2008 inspection reports, according to the FD&C Act Sec. 706 [21 U.S.C. 376], Sec. 803a-803b [21 U.S.C. 383], and as stated in FDA Guide to International Inspections and Travel, "[the] FDA has authority to request inspections in foreign countries." In light of the information provided above and heightened suspicions on the use of prohibited chemicals in Chilean farmed salmon production, will FDA consider undertaking its own inspections of salmon production sites? Additionally, does FDA plan to or would it consider performing its own tests of farmed salmon samples within the exporting country. (In the April 2008 inspection, it appears FDA relied solely on test results from an external source)?
- In the summer of 2007, the U.S. took extraordinary measures to limit the import of Chinese seafood.³² This action followed continued detection of unapproved animal drugs, including fluoroquinolones. What measures does the FDA intend to undertake to decide whether the use of unapproved drugs in Chile, while permitted in that country, rises to the level that prevailed in China that led to the import restrictions?

Again, we commend FDA for taking important steps to safeguard human health and the environment with respect to the U.S.'s most important source for farmed salmon. We look forward to your response to these questions and learning more about FDA's vigilance related to this important seafood import.

Sincerely,



Andrea Kavanagh
Manager, Salmon Aquaculture Reform Campaign
Pew Environment Group

³² U.S. Food and Drug Administration, Office of Regulatory Affairs, IA #16-131, 8/3/07, 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", ATTACHMENT 11/21/08,
http://www.fda.gov/ora/fiars/ora_import_ia16131.html