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April 23, 2009

Joshua M. Sharfstein, M.D.  
Acting 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 Deputy Commissioner Sharfstein:

I am writing on behalf of the Pew Environment Group to call your attention to the use of drugs unapproved by the U.S. Food and Drug Administration (FDA) in farmed salmon imported from three countries into the U.S. market. Specifically, we have evidence of the following: Canada, Scotland and Norway all use the pesticide emamectin benzoate to treat sea lice. In addition to emamectin benzoate, Scotland and Norway use other unapproved drugs to treat sea lice. Further, Norway uses several unapproved antibiotics—including oxolinic acid and flumequine. We also understand that the FDA has allowed the domestic farmed salmon industry in Maine to use emamectin benzoate on an experimental basis since 2006. None of these drugs are approved for use in aquaculture and all are of concern due to various environmental and human health risks associated with them. We urge the FDA to take appropriate action to explore the validity of the evidence provided within this letter and to seek immediate remedies.

Earlier this year, the Pew Environment Group obtained documents from the FDA via Freedom of Information Act (FOIA) requests that showed at least three Chilean companies exporting farmed salmon to the U.S. processed farmed salmon that had been treated with drugs not approved by the FDA for use in aquaculture.<sup>1</sup> These unapproved drugs include the antibiotics flumequine, oxolinic acid and emamectin benzoate.<sup>2</sup> Within the documents obtained via FOIA requests, the FDA explained to these Chilean companies that "if the drug is not listed in the approved drugs list...they [Chilean companies] are not allowed to use the drug to treat salmon destined to be distributed in the U.S., not even if they meet withdrawal periods and no tissue residue can be detected."

We have both privately and publicly recognized that, through its efforts to inspect facilities exporting farmed salmon to the U.S. and to require that Chilean companies follow FDA aquaculture drug regulations, the FDA has made laudable progress to reduce environmental harms and ensure the safety of imported farmed seafood.<sup>3 4</sup> In

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<sup>1</sup>[http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/News/Press\\_Releases/Protecting\\_ocean\\_life/salmon\\_reports.pdf](http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/News/Press_Releases/Protecting_ocean_life/salmon_reports.pdf)

<sup>2</sup> U.S. Food and Drug Administration, FDA/CVM Approved Drugs for Use in Aquaculture, <http://www.fda.gov/cvm/drugsuseaqua.htm>

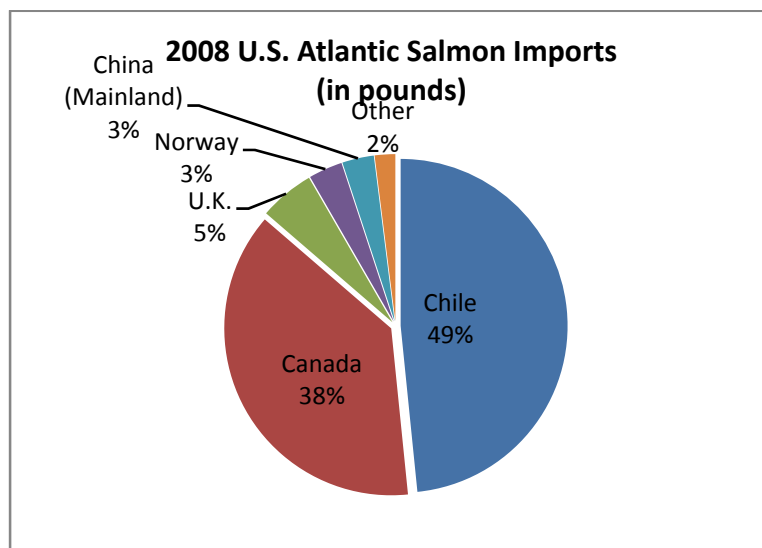
<sup>3</sup> February 5, 2009, U.S. FDA REPORTS SHOW UNAPPROVED CHEMICAL USE BY LARGEST CHILEAN SALMON FARMS, [http://www.puresalmon.org/pr\\_5\\_feb\\_2009.html](http://www.puresalmon.org/pr_5_feb_2009.html)

<sup>4</sup> January 13, 2009, Letter from Andrea Kavanagh, Pew Environment Group, to Commission von Eschenbach, U.S. Food and Drug Administration, [http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/News/Press\\_Releases/Protecting\\_ocean\\_life/FDA\\_FOIA\\_ltr\\_01-13-08.pdf](http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/News/Press_Releases/Protecting_ocean_life/FDA_FOIA_ltr_01-13-08.pdf)

our January 2009 letter, we also applauded the FDA’s increased focus on aquacultured seafood as a “high priority for sampling and surveillance activities”<sup>5</sup> (attached).

To date, the FDA seems to have focused its attention on Chilean farmed salmon imports while paying little attention to farmed salmon imports from other regions. This focus has been warranted since Chile has consistently comprised a large portion of Atlantic (farmed) salmon imports in the U.S. The latest figures show that in 2008 alone, the United States imported more than 212 million pounds of Chilean Atlantic salmon.<sup>6</sup> As our January 2009 letter laid out in detail, there continues to be a growing body of evidence that Chilean salmon farming companies use drugs not approved by the FDA/Center for Veterinary Medicine (CVM) and that residues of these drugs had been detected in Chilean farmed salmon exported to foreign markets.<sup>7</sup>

Currently, however, a sizeable percentage of farmed salmon imported to the United States is coming from other countries, notably Canada. Recent figures from the U.S. Department of Agriculture show that, out of a total of approximately 439 million pounds imported to the U.S., more than 166 million pounds of Atlantic salmon came from Canada.<sup>8</sup>



**Data Source:** U.S. Department of Agriculture (USDA), Aquaculture Date: U.S. Atlantic salmon imports, volume by selected sources, <http://www.ers.usda.gov/Data/Aquaculture/SalmonImportsVolume.htm>

Moreover, due to persistent and significant disease problems plaguing the Chilean salmon farming industry, analysts project that Chilean salmon production will drop by 50 percent this year and by 70 percent in 2010 and 2011.<sup>9</sup> As such, industry publications suggest that “Chilean smolt releases this year will amount to one-quarter of

<sup>5</sup> 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.cfscan.fda.gov/~lrd/seartc08.html>

<sup>6</sup> U.S. Department of Agriculture (USDA), Aquaculture Date: U.S. Atlantic salmon imports, volume by selected sources (1,000 pounds), <http://www.ers.usda.gov/Data/Aquaculture/SalmonImportsVolume.htm>

<sup>7</sup> January 13, 2009, Letter from Andrea Kavanagh, Pew Environment Group, to Commission von Eschenbach, U.S. Food and Drug Administration, [http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/News/Press\\_Releases/Protecting\\_ocean\\_life/FDA\\_FOIA\\_ltr\\_01-13-08.pdf](http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/News/Press_Releases/Protecting_ocean_life/FDA_FOIA_ltr_01-13-08.pdf)

<sup>8</sup> U.S. Department of Agriculture (USDA), Aquaculture Date: U.S. Atlantic salmon imports, volume by selected sources (1,000 pounds), <http://www.ers.usda.gov/Data/Aquaculture/SalmonImportsVolume.htm>

<sup>9</sup> March 4, 2009. Fisheries Information Service. Salmon output to tumble 70 pct in 2010.

<http://www.fis.com/fis/worldnews/worldnews.asp?l=e&country=&monthyear=&day=&id=31584&ndb=1&df=0>

those set out by Norway."<sup>10</sup> Executives from the world's two largest salmon producers have recently stated that the European producers must pick up the slack in supply in order not to lose the U.S. salmon market.<sup>11</sup> In other words, future U.S. imports of farmed salmon will increasingly come from other major producing regions such as Norway, Scotland, Ireland and Canada. This also presents an opportunity for domestic salmon production in the state of Maine to gain U.S. market share.

Given the shift toward even greater farmed salmon imports from outside Chile, we believe it is imperative that the FDA focus its attention on farmed salmon imports from other regions in addition to Chile, especially Canada, Scotland, Ireland, Norway and potentially China. Furthermore, similar to Chile, there is solid evidence that other farmed salmon producing regions, including our own industry, report using drugs that are not approved for use in aquaculture by the FDA. This evidence includes:

#### **British Columbia (Canada):**

- Marine Harvest, the world's largest farmed salmon producer, states that, "Information from the British Columbia Ministry of Agriculture and Lands indicates that the amount of emamectin benzoate administered to farmed fish in British Columbia in 2005 and 2006 was, respectively, 0.27g and 0.19g / tonne of fish produced."<sup>12</sup>
- Marine Harvest admits using emamectin benzoate (Slice) in Canadian operations. "Marine Harvest Canada's sea lice and salmon monitoring and management actions are designed to limit the potential for our salmon to infect wild fish by timing of entries into saltwater, scheduling of harvest of adult fish and application of SLICE, a medication that disrupts the growth and breeding of lice on our fish."<sup>13</sup>

#### **Scotland (U.K.):**

- According to information obtained by the Pew Environment Group from the Scottish Environment Protection Agency (SEPA), Scottish salmon farms report using three parasiticides to control sea lice in 2007, including cypermethrin (Excis), emamectin benzoate (Slice), and teflubenzuron (Calcide). Total reported use of all three parasiticides by Scottish salmon farmers increased dramatically from 2006 to 2007, with SLICE use increasing from approximately 11,600 kgs to more than 30,000 kgs between 2006 and 2007. All three drugs are not listed on the *FDA/CVM Approved Drugs in Aquaculture* list.
- The Pew Environment Group recently received SEPA's site-specific drug use data from 2008, but we are currently in the process of summarizing this data. We are happy to make this new data and all past data (2004 - 2007) available to FDA upon request.

#### **Norway:**

- The latest drug use data the Pew Environment Group has obtained from Norwegian authorities<sup>14</sup> shows that Norwegian salmon farms used oxolinic acid (Oksolinsyre) – an antibiotic not on the *FDA/CVM Approved Drugs in Aquaculture* list - every year between 1984 and 2004. The Norwegian Institute of Public Health also provides data on its website showing consistent use of oxolinic acid by Norwegian fish farms between 2001 and 2008, with 2008 oxolinic acid use at 681 kg active ingredient.<sup>15</sup>

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<sup>10</sup> March 3, 2009. IntraFish. Dramatic downturn in release of Chilean smolt.

<sup>11</sup> March 5, 2009. IntraFish. Marine Harvest, Cermaq demand industry action to save U.S. market.

<sup>12</sup> [http://www.marineharvestcanada.com/documents/AAVBC\\_Slice\\_\(2004\)updated\\_Jan2008.pdf](http://www.marineharvestcanada.com/documents/AAVBC_Slice_(2004)updated_Jan2008.pdf)

<sup>13</sup> [http://www.marineharvestcanada.com/farming\\_fish\\_health\\_sea\\_lice.php](http://www.marineharvestcanada.com/farming_fish_health_sea_lice.php)

<sup>14</sup> <http://farmedsalmonexposed.org/pdfs/Norway/Norway%20Information/Chemical%20Use.pdf>

<sup>15</sup> [http://www.fhi.no/eway/default.aspx?pid=238&trg=MainLeft\\_5812&MainLeft\\_5812=5825:68486::0:5970:46::0:0&5111=5970:2](http://www.fhi.no/eway/default.aspx?pid=238&trg=MainLeft_5812&MainLeft_5812=5825:68486::0:5970:46::0:0&5111=5970:2)

- The Norwegian Institute of Public Health data also shows that Norwegian fish farming companies used the antibiotic flumequine between 2001 and 2008 and lincomycin/spectromycin (1:2) from 2006 through 2008. Neither of these drugs appears on the *FDA/CVM Approved Drugs in Aquaculture* list. The Norwegian Institute of Public Health lists 2008 flumequine use at 1 kg active ingredient and lincomycin use at 70 kg active ingredient.<sup>16</sup>
- These data sets also state that Norwegian fish farms consistently used the sea lice drugs cypermethrin (Excis, Beta Max) between 1996 and 2008, deltamethrin (Alpha Max) between 1998 and 2008 and emamectin benzoate (Slice) from 1999 onwards. 2008 drug use is recorded at 32 kg active ingredient, 39 kg active ingredient and 81 kg active ingredient, respectively.<sup>17</sup> Further, the Norwegian Institute of Public Health data shows emamectin benzoate use increasing every year since 2001. Again, all of these sea lice drugs are not listed within the *FDA/CVM Approved Drugs in Aquaculture* list.

### Maine (U.S):

- Based on our discussions with the FDA and the Maine Department of Environmental Protection (DEP), it appears that Maine salmon farming companies are using the sea lice drug, emamectin benzoate (Slice), via an Investigational New Animal Drug (INAD) permit from the FDA. The *FDA/CVM Approved Drugs in Aquaculture* list does not include emamectin benzoate as an “approved” drug.
- Through several Freedom of Access requests, the Maine DEP has provided the Pew Environment Group with information on the use of emamectin benzoate in Maine. According to the data provided, approximately 20 Maine salmon farm sites used emamectin benzoate in 2006, 2007 and 2008. Within this time period, it appears that both the average drug dosage and average days of treatment increased.
- A publication by a technical working group (comprised of academic scientists and a Canadian government scientist) brought together through the World Wildlife Fund helps to put drug use in salmon aquaculture into perspective regionally.<sup>18</sup> This working group estimated the following drug use per unit production among farmed Atlantic salmon producing countries in 2003:

Country	Kg antibiotic/Metric Tons salmon produced	Kg anti-louse therapeutant/Metric Tons salmon produced
Chile	0.477	0.0005
Norway	0.0016	0.0002
UK	0.0045	0.0007
Canada (includes data from Maine, USA)	0.273	0.00011

Given this evidence of the use of drugs not approved by FDA/CVM in regions exporting salmon to the U.S. market, we urge that any communications or actions the FDA has taken in response to use of unapproved drugs

<sup>16</sup>Ibid.

<sup>17</sup> Ibid.

<sup>18</sup> March 20, 2009, Burrige, L. et al. Chemical Use in Salmon Aquaculture: A Review of Current Practices and Possible Environmental Effects, <http://www.worldwildlife.org/what/globalmarkets/aquaculture/WWFBinaryitem8842.pdf>

by Chilean salmon companies be equally applied to all other exporting regions. Additionally, there appears to be some contradiction that the FDA would require an exporting country such as Chile to use only those drugs “approved” by the FDA/CVM, but would exempt some in its domestic farmed salmon industry from the same requirement.

Please consider this letter a formal request for additional information on FDA’s position on the use of “unapproved” drugs in aquaculture. Specifically:

- Does the FDA intend to require all companies exporting salmon to the U.S. to adhere to the *FDA/CVM Approved Drugs in Aquaculture* list? In other words, will the FDA issue warnings or take action against companies using unapproved drugs in the production of farmed salmon exported to the U.S. market?
- How does the FDA reconcile its requirement that Chilean salmon companies use only “approved” drugs in aquaculture with the fact that the U.S. salmon farming industry is permitted to use one of these unapproved drugs – emamectin benzoate – through an INAD permit?
- Has the FDA visited or does it plan to visit salmon production or processing facilities in Canada, Scotland, Ireland, Norway, China or other salmon exporting regions? If so, please provide information on those planned visits including dates, companies, etc.

I thank you in advance for your prompt response to this request. Additionally, I would be happy to provide all evidence of drug use referenced within this letter.

Sincerely,

Andrea Kavanagh  
Manager, Marine Aquaculture Campaign  
Pew Environment Group

Attachment