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September 16, 2010

Center for Veterinary Medicine (HFV3)  
Food and Drug Administration  
7519 Standish Place  
Rockville, MD 20855

Division of Dockets Management (HFA-305)  
5630 Fishers Lane, Rm 1061  
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RE: **Docket No. FDA-2010-N-0001 and Docket No. FDA-2010-N-0385**, VMAC Meeting on approval of AquaAdvantage genetically engineered salmon; Labeling of AquaAdvantage genetically engineered salmon

The undersigned 25 fishing and salmon organizations, representing fishermen and women across North America, are writing to express our opposition to the approval of AquaBounty's genetically engineered, AquaAdvantage salmon.

On August 25, 2010, U.S. Food and Drug Administration (FDA) officials announced their process for making a decision on an application relating to the first genetically engineered (GE) animal intended for human consumption, the AquaAdvantage Salmon produced by AquaBounty Technologies (Docket No. FDA-2010-N-0001). The genetically engineered Atlantic salmon being considered was developed by artificially

combining growth hormone genes from an unrelated Pacific salmon, (*Oncorhynchus tshawytscha*) with DNA from the anti-freeze genes of an eelpout (*Zoarces americanus*). This modification causes production of growth-hormone year-round, creating a fish the company claims grows at twice the rate of conventional farmed salmon, allowing factory fish farms to crowd fish into pens and still get high production rates.

Genetically engineered fish pose serious risks to wild populations of fish. Approving genetically engineered salmon is a sharp contradiction to the agreements the United States has signed at NASCO, where transgenic salmonids are considered a serious threat to wild salmon. Millions of farmed salmon have escaped from open-water net pens<sup>1</sup>, outcompeting wild populations for resources and straining ecosystems<sup>2</sup>. We believe any approval of GE salmon would represent a serious threat to the survival of native salmon populations, many of which have already suffered severe declines related to salmon farms and other man-made impacts.

Escape of GE farmed salmon into the wild carries the risk that genetic material from these fish will invade the wild gene pools of native Pacific salmon populations. Nature is rife with examples of such *genetic introgression*<sup>3</sup> and such gene pool mixing is common among fish,<sup>4</sup> and members of family Salmonidae are no exception.<sup>5</sup> Indeed, Rosenfield et al. 2000 documented that the largest members of the Pacific salmon (Chinook salmon) are capable of successful reproduction in the wild with the smallest members of their genus (pink salmon). The fact that both species were introduced to the environment where the genetic introgression occurred (the Laurentian Great Lakes) and that pink salmon were introduced accidentally when eggs from an "isolated" hatchery were disposed of<sup>6</sup> is particularly chilling in the context of concerns about the *AquaBounty* proposal to contain GE salmon eggs. Research on such genetic pollution resulting from what scientists call the "Trojan gene" effect published in the *Proceedings of the National Academy of Sciences* notes that a release of just sixty GE fish into a wild population of 60,000 would lead to the extinction of the wild population in less than 40 fish generations.

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<sup>1</sup> According to the Ministry of Agriculture and Lands (BCMAL) in Canada, the agency responsible for tracking industry-reported farmed salmon escapes, over 1.5 million farmed salmon escaped into BC waters between 1987 and 2008 ([http://www.al.gov.bc.ca/fisheries/escape/escape\\_reports.htm](http://www.al.gov.bc.ca/fisheries/escape/escape_reports.htm)); This is also referenced in a report by World Wildlife Federation [Eva B. Thorstad, Ian A. Fleming, Philip McGinnity, Doris Soto, Vidar Wennevik & Fred Whoriskey (January 2008). Incidence and Impacts of Escaped Farmed Atlantic Salmon in Nature, Technical Report to the Salmon Aquaculture Dialogue. World Wildlife Federation, p.5. (<http://www.worldwildlife.org/what/globalmarkets/aquaculture/WWFBinaryitem8843.pdf>)

<sup>2</sup> A study published in Conservation Biology reported that non-native Atlantic salmon were found in over 80 wild salmon spawning streams in British Columbia, with feral juvenile Atlantic salmon having been discovered at three locations [Volpe, J.P., Taylor, E.B., Rimmer, D.W. & Glickman, B.W. (2000). Evidence of natural reproduction of aquaculture-escaped Atlantic salmon in a coastal British Columbia river. Conservation Biology 14: 899-903. (<http://www.agobservatory.org/library.cfm?refID=70186>). Additionally, most salmon farmers only report large-scale releases, so these are likely low estimates of escapes <http://www.llbc.leg.bc.ca/public/pubdocs/bcdocs/300626/v1chp5.htm>

<sup>3</sup> Arnold, M. L. 1997. Natural hybridization and evolution. Oxford University Press, Oxford, UK.

<sup>4</sup> Hubbs, C. L. 1955. Hybridization between fish species in nature. *Systematic Zoology* 4:1-20; Rosenfeld, Todd and Greil (2000). Asymmetric Hybridization and Introgression between Pink Salmon and Chinook Salmon in the Laurentian Great Lakes. *Transactions of the American Fisheries Society* 129:670-679, 2000...

<sup>5</sup> Foerster (1935), Dowling and Childs (1992) as reviewed in Rosenfeld, Todd and Greil (2000). Asymmetric Hybridization and Introgression between Pink Salmon and Chinook Salmon in the Laurentian Great Lakes. *Transactions of the American Fisheries Society* 129:670-679, 2000.

<sup>6</sup> Kwain, W. and A. H. Lawrie. 1981. Pink salmon in the Great Lakes. *Fisheries* 6(2):2-6; Wagner, W.C. and T. M. Stauffer. 1982. Distribution and abundance of pink salmon in Michigan tributaries of the Great Lakes, 1967-1980. *Transactions of the American Fisheries Society* 111:523-526.

If the FDA opens this door, GE fish will likely be among the millions of salmon that currently escape from open ocean pens every year. This could be the last blow to wild salmon stocks, and in turn the thousands of men and women who depend on fishing for their livelihoods. Additionally, if the GE fish is approved, Agency officials are undecided as to whether they will require any product labeling. Unlabeled GE salmon may force many people to fear all types of salmon, further hindering an already strained fisheries industry.

According to the application submitted to the FDA, AquaBounty will raise the engineered eggs in a facility on Prince Edward Island in Canada, and then it will ship those fish to a land-based facility in Panama where the fish will be grown out and processed before being shipped worldwide for commercial sale. However, these GE fish are intended for use on a global scale, and a reliable containment regime following commercialization is just not conceivable. For example, according to a 2001 report, the Environmental Risk Management Authority in New Zealand identified flaws in the safety system of the GE salmon tanks of the private company King Salmon where GE salmon eggs could have come into contact with sperm before escaping into the environment. This example highlights the difficulties in designing safety measures which are 100% effective.

Moreover, most salmon farmers in the real world ply their trade in low-lying coastal areas and competing corporations will no doubt race to produce GE fish in crowded open ocean facilities already in use for fish production. While FDA may place initial restrictions on the farming of GE fish, it is merely a matter of time before FDA is bombarded by pressure from corporations wishing to replace conventional fish in open ocean farms with the GE variety.

Even if grown in contained, land-based facilities, the “farming” of fish is already harming salmon fishermen. In addition to the threat of these GE salmon displacing native salmon populations, such fish farming encourages the propagation of deadly fish diseases, the concentration of harmful wastes and industrial drugs and chemicals escaping into open waters, and the over-fishing of vast quantities of non-commercial fish to feed carnivorous farmed fish, such as salmon it generally takes three pounds of wild fish to grow one pound of farmed salmon<sup>7</sup>. Since these salmon have been engineered for fast growth, it stands to reason that their feed requirements will be even higher. Wild Atlantic salmon are already on the Endangered Species List in the U.S.; approving these GE Atlantic salmon will undoubtedly add to the burden on wild stocks.

AquaBounty also says that it will only produce sterile females; however there is no guaranteed method to produce 100% sterility. FDA has difficulty tracking salmonella in hen eggs; to believe that the FDA can track whether salmon eggs are sterile or not is ludicrous. Moreover, the company will need to keep stocks of fertile fish to produce additional offspring. AquaBounty is also reportedly developing GE tilapia and trout, so this decision also sets a precedent for future GE fish approvals.

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<sup>7</sup> Naylor et al, Effect of Aquaculture on World Fish Supplies. *Nature*, Vol.405, June 29, 2000, pg.1017-1024 and Dr. Rebecca Goldberg, Murky Waters: Environmental Effects of Aquaculture in the United States. Environmental Defense Fund, October 1997.

FDA's decision to go ahead with this approval process is misguided and dangerous, and is exacerbated by the lack of any publicly available data. Though this process includes two public meetings as well as a 60-day public comment period on labeling, FDA has failed to provide data on the food safety and environmental risks that this GE fish may pose. The promise that the FDA would provide the data before the hearing is not good enough, in that it affords precious little time to assess the data the FDA is reviewing. FDA has been sitting on this application for 10 years and yet it chose not to disclose any data about its decision until just a few days before the public meeting. While the lack of transparency by FDA prevents the public from submitting informed public comments at the meetings, the absence of a public comment period on the approval of GE salmon following the VMA Committee meetings prevents the public from providing the Committee with relevant scientific studies and data as well as additional stakeholder comment following the meetings and additional release of available data. Holding a comment period solely on labeling presupposes the GE salmon will be approved, without proper public comment solicitation or review.

We all know there is a great appetite for salmon, but the solution is not to "farm" genetically engineered versions to put more on our dinner tables; the solution is to work to bring our wild salmon populations back, and to protect and maintain existing native salmon populations. The approval of these transgenic fish will only exacerbate the problems facing our wild fisheries.

We strongly oppose the approval of these genetically engineered salmon and urge FDA to reject GE salmon. Should FDA decide to approve the AquAdvantage GE salmon despite our opposition, *clear, mandatory labeling is an absolute must* to allow consumers to make informed purchasing decisions.

**Signed:**

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