United States Department of the Interior

FISH AND WILDLIFE SERVICE

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This letter briefly outlines several concerns that the Conservation Genetics Community of Practice (COP) has raised regarding the Veterinary Medicine Advisory Committee (VMAC) Briefing Packet for AquAdvantage Salmon.

The AquAdvantage Atlantic salmon (*Salmo salar*) is a genetically engineered (GE) salmon that grows at a rapid rate due to the alteration of their growth hormone gene. Specifically, a gene construct is synthesized using a growth hormone gene (GH; derived from the Chinook salmon, *Oncorhynchus tshawytscha*, pituitary gland) that is linked to an anti-freeze protein regulator sequence (opAFP) found in Ocean pout (*Zoarces americanus*). The anti-freeze regulator acts like a switch keeping the GH protein from turning off and allowing for continued growth of the fish. This gene construct (opAFP-GH) is then injected into Atlantic salmon eggs to form an all female broodstock that will produce future product.

The Briefing Packet provided by VMAC is a detailed synopsis regarding the safety and effectiveness of genetically engineered (GE) Atlantic salmon produced by Aqua Bounty Technologies. The packet provides relevant data to assess the following five critical issues or risks associated with genetically engineered organisms:

1) molecular consequences of the insertion of a gene construct into a lineage of Atlantic salmon,
2) phenotypic effects of the insertion of a gene construct in a lineage of triploid mono-sex Atlantic salmon,
3) genotypic and phenotypic durability of such gene construct,
4) analysis of food feed and safety, and
5) environmental consequences.

COP comments are based on concerns that deal with the environmental risk analysis provided by VMAC and the regulatory oversight of such a program. While this document has been reviewed by the COP, we strongly recommend that other genetic communities such as the American Fisheries Society and National Academy of Sciences review this and other supporting documents as unbiased third party reviewers.

Environmental/Ecological Impacts

The Briefing Packet provides compelling evidence that the risk of escapement by GE AquAdvantage salmon is minimal; however, *it falls short of providing an actual risk assessment of putative environmental damages in the event of escapement.*

First, the environmental analysis should provide an historical overview of the general risks associated with escapement or hybridization of GE and wild type individuals. Has escapement of a GE organism ever occurred? What were the environmental consequences of such an escapement? An overview would provide readers with an understanding of the potential harm (and the degree of harm) posed by GE organisms even when the risks of escapement is low. Both of these risks (risk of escapement and degree of harm if escaped) should be more accurately quantified prior to any Environmental Assessment ruling.

Second, the biological containment at either the PEI or Panama facilities along with the possible interaction of AquAdvantage salmon with endangered wild salmon stocks is of great concern to the COP. To this regard, Aqua Bounty Technologies has established several physical and biological containment mechanisms to prevent the escape of AquAdvantage salmon and the Environmental Assessment indicated escapement risk and establishment risks were low. However, history dictates that fish held in aquaculture facilities, either land- or water-based, escape. In addition, the information provided by Aqua Bounty Technologies for the likelihood of establishment relies on the assumption that farmed Atlantic salmon have not established themselves in North America. This assumption is clearly violated because Atlantic salmon juveniles have been found in several streams in the state of Washington as well as British Columbia. While interactions of these fish with native salmon are unknown, any interaction between wild and transgenic salmon must be considered a serious threat. Numerous scientific publications have documented that interactions of wild and introduced fish have led to decreased numbers of wild fish (for ESA listed Atlantic stocks this is of great concern).

As highlighted in the previous paragraph, the Environmental Assessment does not give the full information needed to predict the environmental effects of AquAdvantage salmon. The interpretation of findings could be very misleading because conclusions are based on data for only a few traits that do not span the life-cycle of the organism and are measured under a limited range of environmental conditions and time frames. The COP recommends incorporating the following scientific data in future environmental risk assessments:

- differences in overall fitness between transgenic and non-transgenic fish (e.g., Sundstrom et al 2007);
- shifts in primary prey and utilization of habitat for AquAdvantage salmon (Sundstrom et al 2003).
- assessing how fitness of transgenic fish, when they first escape, translates into environmental risk (Kapuscinski 2007 and Ahrens and Devlin in press)

It is the view of the COP that the Environmental Analysis is overly simplistic and does not adequately capture the actual risk of environmental damages to wild Atlantic salmon or the ecosystem. Additional studies will be necessary to assess this risk and include (but not limited to)

- interbreeding with wild salmon, gene introgression into wild salmon stocks, hybridization with brown trout,
- disturbance of habitat or displacement of wild stocks as a result of competition for resources, predation, or even cross-mating resulting in population impact,

- spread of bacteria, viruses, parasites to wild salmon and other aquatic/estuarine species,
- ecological impacts associated with their degree of fitness, interaction with other organisms, role in ecological processes, and potential for dispersal and persistence.

Regulatory Authority/Oversight comments

Aqua Bounty Technologies currently has various standard operating procedures to minimize escapement and test for durability of the gene construct; however, the COP fails to see any oversight policy in place for assessment, monitoring, and enforcement of these procedures. The current regulatory process is ineffective in handling such a situation. Economics and development take priority over the potential impact to the species or ecosystem. Instead, agencies (FDA, NOAA, USFWS) might benefit from a tiered approach to regulatory authority where such activities are reviewed, evaluated, and if approved, move to the next level for review. The ultimate or final review should lie with the authorities who manage the potentially impacted species (in the case of Atlantic salmon, those public resources are also far beyond just U.S. jurisdiction and include Panama, Canada, the European Union, and Russia). This approach would promote a "first do no harm" strategy designed to protect public resources (i.e., the target species or ecosystem of concern).

Concluding remarks

There are several unknowns and uncertainties regarding possible genetic, ecological, and environmental effects of AquAdvantage salmon that must be elucidated before an environmental risk assessment can be thoroughly evaluated and approved. This, along with a situation where regulatory oversight is adequate at best, suggests that approval of Aqua Bounty Technologies' request for commercial rearing of AquAdvantage salmon is premature.

Sincerely,

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