



# United States Department of the Interior



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This letter briefly outlines several criticisms and concerns regarding the Veterinary Medicine Advisory Committee (VMAC) Briefing Packet for AquaAdvantage Salmon. While I feel I can provide a general overview and constructive criticism of this briefing document, more time would allow for a detailed review.

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;
- 5) environmental consequences

Much of my major concerns are with the environmental risk analysis provided by VMAC and are addressed below. I do not feel comfortable commenting on the analyses of food feed and safety because they are not my areas of expertise. I would also recommend that the American Fisheries Society and National Academy of Sciences review this and other supporting documents as unbiased third party reviewers.

#### Major criticisms:

The Briefing Packet provides compelling evidence that the risk of escapement by GE AquaAdvantage salmon is minimal; however, it falls short of providing an actual risk assessment of putative environmental damages in the event of escapement. The environmental analysis should provide an overview of the general risks associated with escapement or hybridization of GE and wild type individuals. 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.

I am also concerned with phrases like "are unlikely to survive if exposed to high salinity and low temperature" when no data have been collected on AquaAdvantage salmon to evaluate the likelihood of these scenarios. Survival under geographical and geophysical conditions should be evaluated at all life stages in an effort to quantify the likelihood of such escapement scenarios.

Finally, while Aqua Bounty Technologies currently have in place various standard operating procedures to minimize escapement and test for durability of the gene construct, I fail to see any policy in place for monitoring and enforcement of these SOPs by the Food and Drug Administration. The environmental impact of escaped GE salmon is of great concern; therefore, the FDA should carefully monitor each facility and establish/enforce a zero tolerance policy for failure to meet specified containment guidelines.

Minor criticism:

- 1) Who were the reviewers (including their backgrounds) for this document? I have concerns over whether salmon ecologists and biologist have critiqued the environmental analysis of this document.
- 2) Scientific names of ocean pout, Chinook, and Atlantic salmon should be reported.
- 3) page 13 section B.5. A reference should be provided.
- 4) page 13 section C indicates that supporting data was provided – please reference these data in an appendix.
- 5) page 14 section A. Again, “data submitted support the Molecular Characterization of . . . .” please reference these data.
- 6) page 16. section i. “Repeat regions like this are quite variable and nonessential”. This needs a citation. While they do not code for anything, repeat regions are probably not non-essential; rather, they serve some purpose.
- 7) page 43 “AquAdvantage salmon may have reduced tolerance for low DO” – there is much uncertainty in this statement as there is no data to support or reject this. Either a citation is warranted or consider eliminating this statement.
- 8) page 110 section A the working definition of AquAdvantage salmon. So what are the ones called that are <100 g body weight but are genetically engineered?
- 9) page 111. “The VMAC meeting will be held to solicit comments from the appropriated outside experts (VMAC members)”. Do VMAC members really have the expertise to rule on the environmental assessment? I would argue that outside experts such as salmon biologists be considered as a part of this panel.
- 10) page 123 section a. Again, the conclusion is based on limited data. More studies are necessary to determine containment risks (see major criticisms).
- 11) page 126. I would argue that a more stringent 98-99% probability of being triploid be invoked. The risk of escapement is too great to be relying on a 95% probability.

Please feel free to contact me regarding further questions or concerns.

Sincerely,



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Regional Geneticist

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## EXHIBIT SIX

(U.S. FWS Conservation Genetics  
Community of Practice (CoP) letter to U.S.  
FDA, October 6, 2010)