AquaBounty TECHNOLOGIES

January 14, 2013

Dear Colleague:

As you may be aware, the Food and Drug Administration has posted its draft Environmental Assessment ("EA") for the New Animal Drug Application (NADA) for AquAdvantage Salmon. This application was filed by AquaBounty Technologies, and has been the subject of intensive review and public debate. In 2010 the FDA held public meetings, and disclosed the results of their scientific review of the application and concluded that AquAdvantage Salmon was identical to the traditional food and was as safe to eat as the traditional food. Similarly FDA concluded that if approved under the conditions of use proposed in the NADA, AquAdvantage represented no threat to the environment. FDA's Veterinary Medical Advisory Committee (VMAC), a committee composed of outside academic experts concurred with the FDA review. The materials released to the public for these meetings can be found on the FDA's web site (http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/ucm201810.htm).

Along with the EA, FDA has published its preliminary Finding of No Significant Impact (FONSI). The FONSI is a very important document, because it represents the agency's preliminary conclusions based upon the information in the EA that no further environmental assessment is required (for example, the conduct of an Environmental Impact Study, or EIS) as a prerequisite for possible FDA approval of the AquAdvantage NADA. This process presents the opportunity for the public, opponents and supporters alike, to submit comments to the FDA with respect to its preliminary conclusions.

It is my request that you will consider commenting on these two documents. I have supplied a one page summary of the FDA's findings for your information. As FDA will consider all comments received, it is customary for you to file comments on both the EA docket (FDA-2011-N0899-0002) as well as the FONSI docket (FDA-2011-N-0899-0003). Because the FDA will count form letters as a single comment, comments should clearly represent an individual's or entity's unique perspective and reaction.

This letter and the appended summary are intended only to provide backround and information you might wish to utilize in formulating comments. Our website (AquaBounty.com) has additional information if you choose to visit. Please, as you see fit, share this letter with other interested individuals and organizations.

Sincerely,

Ronald L. Stotish, Ph.D.

CEO & President, AquaBounty Technologies

AquAdvantage Salmon

Draft Environmental Assessment and Preliminary Finding of No Significant Impact

1. AquAdvantage Salmon will be produced and grown-out in secure facilities inspected and approved in advance by FDA, with multiple and redundant forms of physical containment. As a result the possibility GE fish could escape from containment, enter the local environments of PEI or Panama, and survive to reproduce is extremely remote.

2. Because the production process for AquAdvantage Salmon will ensure populations produced will be triploid (effectively sterile), all-female animals, the possibility of their reproducing in the wild is extremely remote.

3. Finally, the environmental conditions found around the proposed egg production and grow-out facilities represent types of geographical/geophysical containment that further reduce the possibility of survival, establishment and spread.

4. FDA, having reviewed the materials submitted in support of an NADA for AquAdvantage Salmon, has made a "no effect" determination under the Endangered Species Act (ESA), 16 USC § 1531 et seq., that approval of the AquAdvantage Salmon NADA will not jeopardize the continued existence of United States populations of threatened or endangered Atlantic salmon, or result in the destruction or adverse modification of their critical habitat when produced and reared under the conditions described within the draft EA.

5. The two federal agencies responsible for administering the ESA-- the National Marine Fisheries Service (NMFS) of the National Oceanic and Atmospheric Administration(NOAA, U.S. Department of Commerce) and the U.S. Fish and Wildlife Service (FWS) of the U.S. Department of Interior -- have reviewed with this "no effect" determination and all underlying information supporting FDA's determination, provided within the draft EA. Both of these agencies have either concurred with or indicated no disagreement with, FDA's "no effect" determination. Further, these two agencies have been regular, integral participants in the overall FDA review of the AquaAdvantage Salmon NADA as part of mandated interagency review and sign-off.

Conclusion :

FDA carefully considered the potential environmental impacts of the proposed action and has made a preliminary determination this action would not have a significant effect on the quality of the human environment in the United States (Finding of No Significant Impact) . Therefore, FDA has made a preliminary determination that an environmental impact statement need not be prepared.

PROCEDURE FOR SUBMITTING COMMENTS TO FDA IN SUPPORT OF THE AQUADVANTAGE SALMON APPLICATION

On Dec. 26, 2012 the U.S. FDA published in the Federal Register (http://www.gpo.gov/fdsys/pkg/FR-2012-12-26/pdf/2012-31118.pdf) an announcement soliciting public comments on two documents. The documents are the FDA's Center for Veterinary Medicine's (CVM) Environmental Assessment, and their Preliminary Finding of No Significant Impact for AquAdvantage Salmon. The FDA has established a 60-day comment period during which the public is encouraged to submit comments.

The FDA will tally and evaluate the number and quality of comments it receives from the public, and consider those comments before finalizing their action. If you support the scientific review process and the FDA's New Animal Drug Application (NADA) process, we encourage you to submit your comments to both dockets.

IMPORTANT: the FDA is requesting comments ONLY in regards to the two aforementioned documents, which address specifically the potential environmental impact of our salmon and the FDA's preliminary findings of no significant impact on the environment. Your comments should focus on these two issues.. For example, you could focus on the fact the AquAdvantage salmon will be sterile, and all-female (they cannot establish reproductively active, self sustaining populations, nor can they breed with other fish). The fact that the fish will be reared in land-based contained systems with multiple, redundant containment barriers, such that the potential risk to the environment is further reduced is also a point to consider in your remarks.

At the end of this document, you will find some talking points on the environmental aspects of our salmon, which you may find helpful in composing your comments. Please do not cut and paste "verbatim" the talking points; rather, please use the points as you see fit to support your opinion.

Also, accompanying this document will be a one-page summary of the FDA's evaluation of the environmental assessment of the AquAdvantage Salmon, as well as the FDA's Finding of No Significant Impact (FONSI). This is not an AquaBounty talking point document, but rather a synopsis of the FDA's published documents.

You do not have to be an expert in this topic to comment. If you understand the documents, and the attached materials, your opinions are important and should be

expressed. We would also strongly recommend that you pass along these instructions to any person whom you feel might be interested in commenting and encourage them to follow your lead. Your comments must be posted by February 25, 2013.

FDA Docket Number

The FDA assigns "docket numbers" to the regulatory folders that contain the documents, instructions, and comments pertinent to a specific application. The docket number ID assigned to our regulatory folder is: **FDA-2011-N-0899**

Deadline for submission

- Feb. 25, 2013
- Important: it is suggested that you wait until after Jan. 25, 2013 to submit your comments)

Instructions for submitting comments electronically (preferred method)

1. Go to the FDA designated web site: http://www.regulations.gov/ - !docketDetail;D=FDA-2011-N-0899

2. Under the heading "Primary Documents", you will note three primary documents:

[O] Finding of No Significant Impact for Genetically Engineered Atlantic Salmon (AquAdvantage Salmon) ID:FDA-2011-N-0899-0003

[N] Environmental Assessments; Availability, etc.: Genetically Engineered Atlantic Salmon ID: FDA-2011-N-0899-0001

[O] Draft Environmental Assessment for Genetically Engineered Atlantic Salmon (AquAdvantage Salmon) ID: FDA-2011-N-0899-0002

The first "O" document is the FDA's FONSI document, which has been assigned a docket number of **FDA-2011-N-0899-0003**; you **should** provide comments to that docket. The "N" document is the FDA's formal announcement in the Federal Register, which has been assigned a docket number of **FDA-2011-N-0899-0001; you do NOT need to submit comments to that docket. The third**

document (the second [O] document) is the CVM's draft environmental assessment, which has been assigned the docket number FDA-2011-N-0899-0002; you should provide comments to that docket .

3. Click on the blue "Comment Now!" box for each of the two documents cited above (0003 and 0002).

4. Fill in the appropriate sections. If you do not wish your name to be associated with your comment (we recommend that you provide your name), type in "Anonymous" in the appropriate "Enter Information" window. For those of you not working in the industry or any of the other professions listed in the "category" window, the last category option is "Individual Consumer".

5. Write your comment. IMPORTANT: do not repeat exactly the same comment for both documents, as the FDA may consider that as "one" comment. Your response should be tailored to either the Preliminary Finding of No Significant Impact docket (0003) or the Draft Environmental Assessment document (0002).

6. Preview your comment (clicking on the "Preview Comment" box)

7. Submit your comment (clicking on the "Submit" box)

Instructions for submitting comments by conventional mail

If you wish to submit your comments in writing, send them to:

Division of Dockets Management (HFA–305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Important: when submitting comments in writing, be sure to reference our Docket No. (FDA-2011-N-0899) at the top of your letter.

Follow the same instructions described above for submitting electronically, especially No. 5. Submit one letter for each of the two comments, and vary the contents of the two letters so that they do not appear to be the same comments.

TALKING POINTS

- AquAdvantage Salmon (AAS) will be sterile, and all female, and therefore cannot establish reproductively active, self-sustaining populations in their rearing systems, or in the wild.

- AquAdvantage Salmon cannot successfully breed with themselves, or with wild fish populations.

- AquAdvantage Salmon do not represent a threat to wild salmon populations in the Northwest, including Alaska, because it is a different species than (and cannot breed with) the five species of salmon found in the Northwest.

- Under the FDA's proposed conditions of use, AquAdvantage Salmon must be reared on land (not in floating sea cages, which is the traditional method for farming salmon). In addition, AAS must be confined to inland contained culture systems possessing multiple, redundant physical barriers designed to prevent the escape of the AAS from their rearing system.

- The application currently under review by the FDA is for only one production site located in the mountains of Central America, which possesses a natural (ecological) thermal barrier which will prevent live AAS from reaching the ocean.

- The combination of biological (sterile, all female), physical (barriers), and ecological (thermal) containment measures in place in the single site under consideration for growout, results in essentially zero, or near zero, environmental risk.

- Due to the unique characteristics of AquAdvantage Salmon, it is at a competitive disadvantage to wild salmonids should it enter the environment.

- The combination of multiple biological, physical and environmental containment measures combined with the fact that Atlantic salmon are reproductively incompatible with Pacific salmon, and that the single growout site under consideration is thousands of miles from the Pacific northwest signifies that AAS reared in Central America pose zero threat to wild salmon fisheries in Alaska or the Pacific northwest.