

December 21, 2010

Dr. Joshua M. Sharfstein, Principal Deputy Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Deputy Commissioner Sharfstein:

Ocean Conservancy and Center for Food Safety write on behalf of our many members and volunteers concerned with the potential approval of genetically engineered salmon ahead of a full and complete environmental impact review. We urge the Food and Drug Administration to uphold its commitment to review all public comments received to date and to establish an additional 30-day public comment period to seek further public input. We recommend that the agency postpone a decision on the AquaBounty Technology Inc. application until that public input is received on the agency's revised environmental assessment.¹ Doing so will demonstrate a recognition that decisions of such magnitude are being made with full transparency to ensure "a culture of scientific integrity."² We urge FDA to refrain from approving the AquaAdvantage salmon application ahead of this important internal and public review process.

A full environmental impact statement (EIS) is warranted and must evaluate a range of potential production scenarios for GE salmon, given the company's intention to expand production beyond a small facility in the mountains of Panama,³ and beyond the current application for AquaAdvantage salmon.⁴ A comprehensive review is critical to provide FDA with the information it needs to determine whether to approve or deny AquaBounty's application.

We believe that a final decision on the AquaBounty application along with a simultaneous release of a revised Environmental Assessment would be inconsistent with your stated intentions, as well as those expressed by Dr. Rudenko, Dr. Dunham, and Dr. Silberhorn at the Veterinary Medicine Advisory Committee Hearings earlier this year to conduct a comprehensive review and consider public input.⁵ We urge you to withhold a final decision until all public comments and relevant information has been fully considered.

Sincerely,



Andrew Kimbrell
Executive Director
Center for Food Safety



Vikki Spruill
President
Ocean Conservancy

¹ VMAC Hearing transcript, 9/20/10 at p. 251. Online:

<http://www.fda.gov/newsevents/publichealthfocus/ucm224089.htm>

² Holdren, John P. 2010. Memorandum for the heads of executive departments and agencies (Dec. 17).

Online: <http://www.whitehouse.gov/sites/default/files/microsites/ostp/scientific-integrity-memo-12172010.pdf>.

³ www.aquabounty.com.

⁴ www.aquabounty.com.

⁵ VMAC Hearing transcripts (9/19/10 at p. 62 and 9/20/2010 at pp. 10, 251, 392).