



United States Department of Interior  
Fish and Wildlife Service  
22 Bridge Street, Unit #1  
Concord, NH 03301



United States Department of Commerce  
National Oceanic and Atmospheric Administration  
National Marine Fisheries Service  
One Blackburn Drive  
Gloucester, MA 01930-2298

OCT 30 2001

Mr. Charles Eirkson  
U.S. Food and Drug Administration  
Center for Veterinary Medicine  
1750 Standish Place  
Rockville, MD 20855

Dear Mr. Eirkson:

We are contacting you regarding the application of Aqua Bounty Farms of Massachusetts for U.S. Food and Drug Administration (FDA) approval for production and marketing of genetically modified Atlantic salmon. The interest of the National Marine Fisheries Service (NMFS) and the U.S. Fish and Wildlife (the Services) in this application is based upon the agencies' responsibilities and authority pursuant to the Endangered Species Act (ESA) of 1973 (as amended).

In November 2001, the Services jointly listed the Gulf of Maine Distinct Population Segment of Atlantic salmon as an endangered species under the ESA. The final rule listing the Gulf of Maine Distinct Population Segment of Atlantic salmon and a recent status review (1999) of the species conclude that the potential for interactions between wild salmon and aquaculture escapees represents a significant threat to the continued existence of endangered salmon in Maine. There is a large body of scientific evidence that clearly indicates genetic and ecological interactions between wild and aquaculture salmon can adversely affect wild populations.

We are confident that the FDA is aware of its responsibility under the ESA to consult with the Services under section 7(a)(2) of the Act. Section 7(a)(2) directs all federal agencies to, in consultation with the NMFS, "insure that any action authorized, funded, or carried out by such agency will not jeopardize the continued existence of an endangered species." The introduction and use of genetically modified salmon by the salmon farming industry has the potential to adversely affect endangered wild salmon and thus, is of concern to the Services.

We urge the FDA to keep the Services fully informed of the status of the Aqua Bounty Farm's application and your agency's review. Moreover, we strongly encourage the FDA to initiate consultation with the Services early in its deliberations on this permit application as it will help ensure that any decision by the FDA addresses any potential adverse impact the decision may have on endangered Atlantic salmon. The Services stand ready to work with the FDA to ensure any outcome of your review of this application is sufficiently protective of endangered wild Atlantic salmon.

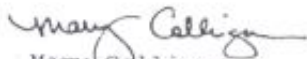
In addition to the ESA, the North Atlantic Salmon Conservation Organization (NASCO), the international organization responsible for



the implementation of the Convention for the Conservation of Salmon in the North Atlantic Ocean, an international treaty to which the United States is a contracting party, has adopted guidelines that obligate the U.S. to keep NASCO informed of any proposal to use genetically modified fish within the U.S.

We appreciate your consideration of these issues and look forward to your response. Please do not hesitate to contact Mary Colligan of NMFS staff at (978) 281-9116 if you wish to discuss this matter further or need any additional information regarding the potential impacts of transgenic fish to endangered Atlantic salmon or how best to initiate consultation on this federal action.

Sincerely,



Mary Colligan  
NER, ARA Protected Resources  
National Marine Fisheries Service



Michael J. Bartlett  
Supervisor, N.E. Field Office  
U.S. Fish and Wildlife Service

Cc: Stephen F. Sundlof, Director, CVM  
Rollie Schmitt, NOAA-Fisheries  
Malcolm Windsor, NASCO  
Gordon Russell, FWS