The Honorable Harry Reid
Senate Majority Leader

The Honorable John Boehner
Speaker of the House

The Honorable Dick Durbin
Senate Assistant Majority Leader

The Honorable Eric Cantor
House Majority Leader

April 26, 2013

Animal Protection Community Opposes GE Salmon, Finds FDA Ignoring Harms

On behalf of 22 animal protection organizations representing millions of constituents, we are writing to express our opposition to FDA's proposed approval of genetically engineered (GE) AquAdvantage salmon for commercial food production. FDA's assertions that the genetic modification is safe[1] and that there would be no significant environmental impacts[2,3] do not stand up to rigorous scientific scrutiny. Moreover, FDA's assessment fails to address numerous concerns about the welfare of GE salmon, as well as related concerns about the ethical implications, the economic and social impacts, and the human health consequences of genetic engineering.

As advocates for animals, we are concerned that the genetic modification and conditions of approval specified by FDA are not safe for the fish, resulting in significant welfare concerns. Though few data have been provided, preliminary findings indicate that AquAdvantage salmon experience high rates of abnormalities and mortality, and that they are prone to jaw deformities, lesions, and skeletal malformations.[4] We are further concerned that approval of GE salmon for commercial-scale production on fish farms essentially "releases" this still-experimental technology into the environment, presenting unique and unknown risks for wildlife and ecosystems.

As the first GE animal intended to be sold for food, the AquAdvantage salmon sets a precedent for how risks associated with future GE animals will be evaluated. It paves the way for approvals of other GE animals already in development, and raises questions about the ethical implications of genetically engineering animals for food. It is therefore essential that FDA apply stringent criteria in reviewing any application for genetically engineered animals to ensure that animal health, human health, and the environment are protected.

FDA has been regulating GE animals as New Animal Drugs. However, the New Animal Drug Application (NADA) process was not designed to handle the unique animal health, welfare, ethical, societal, and environmental implications of genetically engineering living beings who can think, feel, suffer, and interact with the environment. FDA's evaluation of AquAdvantage salmon in particular is scientifically unsound and fails to consider several important questions.

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[1] FDA (2010). Briefing Packet for Veterinary Medicine Advisory Committee: AquAdvantage Salmon. http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM224762.pdf

[2] FDA (2012). AquAdvantage Salmon Draft Environmental Assessment. http://www.fda.gov/downloads/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/UCM333102.pdf

[3] FDA (2012). AquAdvantage Salmon Preliminary Finding of No Significant Impact. http://www.fda.gov/downloads/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/UCM333105.pdf

[4] FDA (2010). Briefing Packet for AquAdvantage Salmon Veterinary Medicine Advisory Committee, P. 43 for example.

The animal health studies on AquAdvantage salmon, for example, are characterized by extremely small sample sizes (just 12 fish in the main study) and limited data collection. There are no data on how the genetic modification affects the fish at different life stages or past market size, no data on how environmental conditions or genetic background affect the expression of the genetic modification (despite knowledge that such factors create a high degree of variability), and no data on fish not intended for the food supply. In addition, although there was "extensive culling" of deformed, diseased, and dying fish, these fish were specifically excluded from the study.

Nevertheless, this is the science FDA uses to claim in the NADA that the genetic modification is safe. This is also the same science FDA uses in the environmental assessment (EA) to evaluate consequences of approval despite receiving during the public comment period numerous complaints about its assessment from the health, environmental, consumer protection, and animal welfare communities, and from its own Veterinary Medicine Advisory Committee.[5]

The EA also falls short in other ways, specifically by failing to consider the full range of direct, indirect, and cumulative impacts associated with approval of AquAdvantage salmon. Given the significance of the potential impacts, an EA should not be allowed as a substitute for the more comprehensive Environmental Impact Statement (EIS).[6]

We are concerned about the impact that approval of AquAdvantage salmon would have on the promotion of aquaculture practices, which extend the concept of factory farming -- and all its associated environmental, welfare, safety, and ethical problems -- to fish. The need for AquAdvantage salmon also remains unclear. FDA has provided neither data on AquAdvantage salmon growth to market size nor other pertinent information regarding issues such as feed efficiency, waste, or antibiotic use and related environmental impacts.

AquaBounty has repeatedly indicated it intends to sell GE fish to aquaculture farms around the world once it receives approval, but FDA has not examined the environmental implications of these entirely foreseeable future actions. It is imperative to consider these impacts now, both because other GE fish farms may not be subject to future FDA oversight (e.g., if the fish will not be sold in the U.S.) and because future review processes are likely to be even less thorough and transparent than this one.

Despite working on AquAdvantage salmon for nearly a decade, FDA's assessment has many gaps and is inadequate to ensure the safety of the public health, the welfare of this fish produced, and the environment should production be approved for commercial purposes. We urge that AquAdvantage salmon be kept off the market.

cc: U.S. Senate
U.S. House of Representatives
FDA, Docket No. FDA-2011-N-0899

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[5] See, for example, Transcript for the September 20, 2010 Veterinary Medicine Advisory Committee Meeting on AquAdvantage Salmon, P. 340-344; 349-351, 353, 355.
http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM230471.pdf

[6] See also, Citizen Petition Regarding AquaBounty Technologies' Application for Approval of Genetically Engineered Salmon, filed May 25, 2011. http://earthjustice.org/sites/default/files/FinalGESalmonCitizenPetition.pdf

Sincerely,

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