Document discovered through a Freedom of Information Act request by Center for Food Safety | www.centerforfoodsafety.org

Region 5 Fisheries Program Comments on FDA approval process for Aqua Bounty Technologies, Inc. (ABT)/AquAdvantage GMO salmon

Issue: FDA has released an EA and briefing packet which state the application for commercial approval is limited to raising the AquaAdvantage salmon outside the USA and then importing the processed fish for sale as food in the USA.

The transgenic broodstock would be mated and eggs incubated to eyed stage in a multiple-confinement hatchery on Prince Edward Island, Canada. Eyed stage eggs would be shipped to Panama for growout in a multiple-confinement high-elevation, undisclosed location next to a river. At 18 months of age, fish would be harvested and processed in Panama for shipment to USA for sale.

The 'multiple-confinement' includes biological confinement (eyed eggs that are all-female triploids), 3-5 forms of mechanical and physico-chemical confinement, and geographical confinement (if any eyed eggs or fry escaped from PEI hatchery, presume fry would end up in surrounding seawater and die there; if any grow-out fish escaped the Panama grow-out facility fish would enter the river that has lethal water temperatures downstream plus many dams.

Preferred FWS position: Given all the unknowns and uncertainties regarding the possible ecologic and environmental effects of these fish, combined with the awkward situation where an agency (FDA) whose jurisdiction is not focused on natural resources is entrusted with the authority to approve an act which poses such threat to the country's natural resources, we believe it is premature to approve this request for commercial rearing of transgenic salmon.

Comments related to Regulatory Authority/Oversight.

- If the two locations in Canada and Panama are truly the only places these transgenic fish will ever be raised, then perhaps the EA Section 7 endangered species consultations by NOAA and USFWS are unnecessary or of little importance. However, recent statements by AquaAdvantage indicate if their application is approved they intend to sell eyed-eggs to additional confined grow-out operations in other locations. It is my understanding that current regulations would not require the FDA to publicly release these future EAs before approval. It is also unclear what the USFWS or NOAA roles would be if these facilities are in foreign locations. The current EA under review was released publicly because it sets a crucial precedent regarding human consumption of a transgenic vertebrate (fish). This is why the scientific quality of this first EA sets such a crucial precedent. However, our review and those of other scientists found numerous issues with the scientific quality and completeness of the EA. If the FDA approves the sale of processed AquaAdvantage salmon in the USA and the company plans to submit additional EAs to grow fish at other facilities then the current EA is too narrow. The FDA should consider a full EIS that takes into account the full scale at which the company intends to sell eyed-eggs over say the next 10 years.

- How will the FDA assure, monitor, and verify that multiple confinement is continually achieved at the two facilities and in future facilities as farming of these fish proliferates?
    - Failure analysis of triploid induction should quantify the frequency of triploid failure.
    - Do exceptional diploids occur among treated transgenic fish, and if so, are they fertile?

Document discovered through a Freedom of Information Act request by Center for Food Safety | www.centerforfoodsafety.org