STATE CAPITOL P.O. BOX 942849 SACRAMENTO, CA 94249-0115



September 16, 2010

Dr. Margaret Hamburg, Commissioner United States Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE: Docket No. FDA-2010-N-0001 and Docket No. FDA-2010-N-0385 VMAC Meeting on approval of AquAdvantage genetically engineered salmon

Dear Commissioner Hamburg:

We, the undersigned members of the California State Legislature, are writing to express our deep concern with the agency's current review of the AquAdvantage genetically engineered salmon. A decision to approve this hybrid farmed Atlantic salmon as the first genetically engineered animal for human consumption is a risky precedent and a threat to the future of California wild salmon. We respectfully request that the Food and Drug Administration deny AquaBounty Technologies' application until these critical issues are satisfactorily addressed.

While the proposed decision to approve this application applies only to Atlantic salmon eggs reared in Canada and grown to market size in a land-based facility in Panama, we are deeply concerned that approval will lead to numerous other applications to grow this and other genetically modified fish in other production systems such as open net-pen culture in marine and freshwater habitats. Until there is ample, publicly available research and a comprehensive national framework to address the full suite of environmental and food safety concerns of genetically modified organisms, we believe this decision is premature and thus should be postponed.

Without an environmentally-protective national policy in place to fully protect natural ecosystems from the risk of escaped animals, the risks involved in this approval are simply too great. California's wild salmon runs are at historical lows and are not capable of withstanding an additional assault that could come from escaped genetically-modified farmed salmon in the future. Each year, millions of farmed salmon escape from open water net-pens around the world, competing with wild fish for resources and straining ecosystems. Although Atlantic salmon don't successfully breed with our native pacific salmon, they can reduce their survival through competition for space and food and by spreading disease. Once GMO salmon is in commercial production and in the U.S. marketplace, the FDA's existing authority can not properly take into consideration these potential impacts to our native fish stocks and our environment.



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This proposed decision is also of great concern to California because of the potential to undermine laws we have already enacted to address the risks of genetically modified organisms. California law currently prohibits the rearing of salmon or any transgenic finfish in the open ocean waters of the state (F&GC Section 15007). Furthermore, a permit is required from our state Department of Fish and Game for all other types of aquaculture to address environmental risk. Should FDA approve this petition it could preempt our state from enforcing stronger laws or imposing additional conditions.

Finally, we conclude that the FDA's decision-making process fails to provide the public with sufficient time or access to the necessary data to allow for meaningful participation and a transparent and robust decision. The result is that stakeholders and the public at large are being denied access to the relevant scientific studies made available to FDA; the rushed timeline for approval is also limiting the ability of stakeholders to provide additional input to the Veterinary Medicine Advisory Committee as well.

We respectfully request that the Food and Drug Administration deny AquaBounty Technologies' application until such time as these critical issues are satisfactorily addressed.

Thank you for your consideration.

Sincerely,

Jared Huffman, 6th Assembly District

Speaker John Pérez, 46th Assembly District

Mike Gatto, 43rd Assembly District

Bill Monning, 27th Assembly District

Wes Chesbro, 1st Assembly District

Marty Block, 78th Assembly District

Ira Ruskin, 21st Assembly District

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Paul Fong, 22nd Assembly District

Ellen Corbett, 10th Senate District

Loni Hanock, 9th Senate District

DeSaulnier, 7th Senate District

CC:

Dr. Joshua M. Sharfstein, Principal Deputy Commissioner, Food and Drug Administration

Mr. Tom Vilsack, Secretary, U.S. Department of Agriculture

Dr. Jane Lubchenco, Administrator, National Oceanic and Atmospheric Administration

Dr. Rowan W. Gould, Acting Deputy Director, Fish and Wildlife Service

Mr. Ken Salazar, Secretary, Department of Interior

Ms. Kathleen Sebelius, Secretary, Department of Health and Human Services

President Barack Obama