United States Senate
WASHINGTON, DC 20510

September 28, 2010

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Commissioner Hamburg:

We the undersigned members of the United States Senate request you halt all proceedings related to the U.S. Food and Drug Administration (FDA) approval of the first genetically engineered (GE) animal for human consumption – a hybrid salmon produced by AquaBounty Technologies. There are a number of serious concerns with the current approval process and many potential human health and environmental risks that are associated with producing GE fish have not been fully or openly reviewed. Critical information has been kept from the public and consequently, only FDA and AquaBounty know important details about the approval process for this GE salmon, or the product itself. Accordingly, we urge you to discontinue the FDA's approval process of the GE salmon at this time to protect consumers, fishing and coastal communities, and the environment.

AquaBounty's GE product is a transgenic Atlantic salmon egg, in which genes from an ocean pout have been inserted into the genes of Chinook salmon, and then inserted into an Atlantic salmon. The egg is meant to produce a fish that grows to full size twice as fast as a normal Atlantic salmon. The eggs are intended for sale to aquaculture companies which will grow them to market-sized fish to be sold for human consumption.

One of the most serious concerns regarding AquaBounty's application is the FDA has no adequate process to review a GE animal intended as a human food product. FDA is considering this GE fish through its process for reviewing a new drug to be used by animals, not for creation of a new animal, especially one intended for human consumption. Clearly, this is inappropriate. Creation of a new genetically engineered species should not be treated as an animal drug issue but undergo formal evaluation by FDA's Center for Food Safety and Applied Nutrition to review the product's potential health effects on humans.

Such a limited review of the first GE animal for human consumption is wholly inadequate to review potential public safety concerns associated and recklessly and needlessly endangers consumer health. A recent *New York Times* article reported, "the engineered salmon have slightly higher levels of insulinlike growth factor," and "some

studies suggest that high levels of [this] insulinlike hormone in the bloodstream are associated with greater cancer risk."

The FDA's review process lacks transparency. It has been nearly impossible for the public to obtain clear information about the FDA's process or particulars about the fish itself. According to existing regulations, FDA is not required to release important details regarding AquaBounty's GE salmon as this is considered a "trade secret." Even though the proposal has been pending for nearly a decade, the FDA only recently released some information on the matter barely two weeks before public hearings began on Sunday, September 19. FDA should have made public all information regarding the salmon well in advance of any hearings to encourage full and knowledgeable public participation. To have facilitated broader public participation, hearings on such a contentious issue should not have been held in Rockville, Maryland, but rather in a more central location and with outreach to regions dependent on wild salmon production.

There are serious concerns about damage to the environment if FDA approves AquaBounty's GE salmon. While the current application only covers the grow-out of GE salmon at a land-based facility, we believe that any approval must also include a thorough review of the possible devastating effects were fish farmers to grow GE fish in open water net pens and cages. Such a review is essential given the threats posed by escaped fish, fish waste, other pollutants, and infectious diseases that could spread to the natural environment.

AquaBounty claims its eggs will produce reproductively sterile fish to help prevent any escaped fish from interbreeding with wild fish. However, the company's own data suggests 5 percent of its eggs may not be sterile and it plans to produce millions of eggs. Studies suggest that an invasion of transgenic fish that escape into a natural fish population could lead to the extinction of both wild and transgenic fish in that region even if they are sterilized. Concerns include competition for habitat and food, abnormal behaviors of farmed fish and their interactions with wildlife and uncertainty regarding all potential impacts. Finally, we are concerned about the dangerous precedent that this ruling could set, as companies will likely seek FDA approval for other genetically engineered products such as GE tilapia and GE trout.

Given the inappropriate approval process, the lack of transparency for over ten years regarding this particular application, and the myriad of potential human health and ecological risks associated with production and consumption of GE animals, we believe the AquaBounty salmon should not be approved for human consumption. We strongly urge you to stop the approval process immediately to allow for review and examination

of the various concerns associated with genetically engineered animals, openly and with meaningful public input.

Sincerely,

Mark Begich

Lisa A. Murkowski

Patty Murray

Bernard Sanders

Maria Cantwell

Ron Wyden

Patrick J. Leahy

Kirsten E. Gillibrand

Barbara A. Mikulski

Jeff Merkley

Jon Tester

Cc: Kathleen Sebelius, Secretary of Health and Human Services
Michael, M. Landa, J.D., Acting Director, Center for Food Safety and Applied Nutrition
Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research