

United States Senate

WASHINGTON, DC 20510

April 24, 2013

Dr. Margaret Hamburg, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Docket No. FDA-2011-N-0899

Dear Dr. Hamburg:

We the undersigned members of the United States Senate have serious concerns with how the Food and Drug Administration (FDA) has reviewed the application of AquaBounty Technologies for genetically engineered (GE) Atlantic salmon intended for human consumption as a New Animal Drug Application (NADA). We believe this process has not been adequate to ensure this genetically engineered salmon is safe for our environment and our consumers. The FDA must develop and implement a robust review process for GE salmon, and set an appropriate path forward for future food animal applications. Finally, we urge the FDA to also develop clear and transparent labeling requirements should this GE Atlantic salmon or other GE food animal product be approved.

Our first concern involves the U.S. Food and Drug Administration's (FDA) draft Environmental Assessment (EA) and preliminary Finding of No Significant Impact (FONSI) concerning GE Atlantic salmon. This finding is the next step toward approval of the first GE animal for human consumption, yet the FDA did not consider broad environmental and public health risks of commercial GE fish production in their assessment. Therefore, a more robust Environmental Impact Statement (EIS) should be completed in consultation with the Environmental Protection Agency and the National Oceanic & Atmospheric Administration.

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. AquaBounty claims its eggs will produce reproductively sterile fish to 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. AquaBounty plans to produce and transport *millions* of eggs, creating significant risk. If released accidentally, 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.

Dr. Margaret Hamburg M.D.

April 24, 2013

Page 2

There are also serious risks of environmental damage posed by the widespread production of GE salmon which would follow FDA approval. While FDA's review envisions these fish would only be manufactured and reared in a single set of land-based facilities, such a narrow review fails to consider the implications of the broader application of this technology which surely would occur should the FDA's final approval be granted. Whether released by accident or negligence, escaped GE salmon, waste, pollutants, or infectious diseases could be spread to the natural environment and cause extensive damage. The history of invasive species is replete with examples of far-reaching unintended consequences that have caused significant environmental and economic impacts.

Our second concern is about the food safety of the GE salmon product. GE salmon grow faster than normal salmon, may have abnormal behaviors, and contain higher concentrations of two growth hormones compared to natural salmon. Increased concentrations of these growth hormones could have food safety implications. Increased salmon growth rates could have negative implications for animal health, such as increasing the incidence of diseases or the need for the use of critically important antimicrobial drugs. This could negatively impact food safety by increasing the exposure of consumers to pathogens or antimicrobial drug resistance. These risks have not been fully assessed by the current NADA review process. Thus, FDA's Center for Food Safety & Nutrition should undertake a comprehensive food safety assessment of these issues before approving GE salmon.

Finally, we are concerned with the precedent that this ruling could set, as companies will likely seek FDA approval for other genetically engineered fish such as tilapia and trout, as well as its application for other animals. It would mark a shift in national policy of managing seafood for sustainability in favor of engineered species that, by its proponent's claim, is patently unsustainable. Therefore, we believe that FDA should develop an appropriate and comprehensive review process in order to set a precedent that is sufficient to protect environmental and public health.

If after performing a comprehensive EIS and food safety risk assessment, the agency still proceeds with approval of the product, labeling requirements should be developed to distinguish the product as "genetically engineered." This is important so consumers are empowered to make informed choices regarding the food they will feed their families. FDA should also coordinate or require post-marketing studies to assess if there is any difference in food safety outcomes in consumers of the GE salmon as compared to natural salmon.

Given the concerns we have regarding the FDA's current approval process and the myriad of potential human health and ecological risks associated with production and consumption of GE animals, we ask that the FDA develop a more rigorous environmental and food safety review process and GE labeling requirements before further action is taken to consider the approval of GE animal products. We look forward to working with you collaboratively to ensure we maintain a sustainable and safe salmon supply.

Sincerely,



Mark Begich
United States Senator



Lisa Murkowski
United States Senator



Kirsten Gillibrand
United States Senator



Sheldon Whitehouse
United States Senator



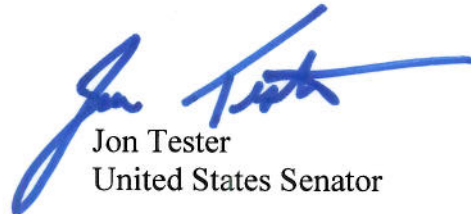
Barbara Mikulski
United States Senator



Maria Cantwell
United States Senator



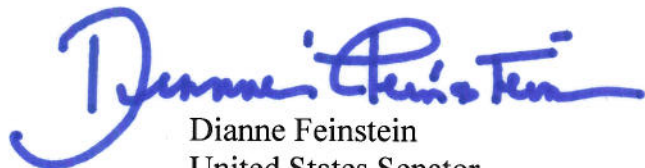
Patty Murray
United States Senator



Jon Tester
United States Senator



Barbara Boxer
United States Senator



Dianne Feinstein
United States Senator



Bernard Sanders
United States Senator



Jeff Merkley
United States Senator