United States Senate

WASHINGTON, DC 20510

January 11, 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 United States Senators, request a 60-day extension to the public comment period for the U.S. Food and Drug Administration's (FDA) draft Environmental Assessment (EA) and preliminary Finding of No Significant Impact (FONSI) concerning genetically engineered Atlantic salmon.

While the AquaBounty Technologies proposal has been under consideration for some 15 years, the surprise publication of the draft EA and FONSI on Dec. 26, 2012, came in the midst of the holiday season when the public was more concerned with family matters than reviewing a 144-page, highly-technical scientific document.

Publication of the FDA's findings also came just days before the new Congress was sworn in. Many incoming members from affected states will be preoccupied with organizational issues during the next few months that will preclude them from giving adequate attention to a precedent-setting decision that could lead to approval of the first genetically engineered animal for human consumption.

We continue to have serious concerns about the AquaBounty proposal and the FDA review process that would regulate a proposed food product as if it were a new animal drug. The FDA review narrowly applies only to a limited set of production and rearing facilities, and fails to consider the implications of the broader application of this technology which assuredly would occur should the FDA's final approval be granted.

Congress has and will continue to raise these and other concerns about this controversial and unsustainable seafood product, including the potential escape of these engineered fish into U.S. waters. Legislation will be introduced in the 113th Congress to seek a more comprehensive environmental review of this and other genetically engineered fish, and require labeling of any such products sold in the U.S. so consumers are aware of what is on their dinner plates.

An extension of the public comment period regarding approval of the first genetically engineered animal for human consumption is necessary and appropriate. A 60-day extension to afford better public review of this draft action is minimal when compared to lengthy review process already afforded this proposal.

Thank you for consideration of this request.

Sincerely,

Mark Begich
United States Senator

Patty Murray
United States Senator

Ron Wyden
United States Senator

Barbara Mikulski
United States Senator

Lisa Murkowski
United States Senator

Maria Cantwell
United States Senator

Jeff Merkley
United States Senator