CENTER FOR FOOD SAFETY● FRIENDS OF THE EARTH
FOOD AND WATER WATCH ●CENTER FOR ENVIRONMENTAL HEALTH
ALLIANCE FOR NATURAL HEALTH● ORGANIC CONSUMERS ASSOCIATION
BRISTOL BAY REGIONAL SEAFOOD DEVELOPMENT ASSOCIATION
GLOUSTER FISHERMEN'S WIVES ASSOCIATION ● PCC NATURAL MARKETS
NORTHWEST ATLANTIC MARINE ALLIANCE ●MANGROVE ACTION PROJECT

December 19, 2011

Dr. Margaret Hamburg, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Via Fax: 301-847-3531

Dear Dr. Hamburg:

Last week, Canadian fisheries authorities revealed that the AquaBounty facility that is rearing the AquAdvantage salmon, which FDA is considering approving, had problems with Infectious Salmon Anaemia (ISA) in 2009 before the FDA hearing on the approval of the fish in September 2010. None of the material presented in the VMAC hearing mentioned that the Prince Edward Island facility had tested positive for ISA the year before the hearing. In fact, the VMAC Briefing document on page 23 says:

b. Specific Facility Conditions
The PEI facility is an aquaculture facility almost entirely dedicated to hatchery operations. The facility is licensed by the Canadian Department of Fisheries and Oceans (DFO) and is certified as disease-free under Schedule II of the Canadian Fish Health Protection Regulations (FHPR), C.R.C., c. 812. Schedule II pathogens include, among others, those that cause: viral hemorrhagic septicemia (Egtved virus, VHSV), infectious hematopoietic necrosis (IHNV), infectious pancreatic necrosis (IPNV), whirling disease (Myxobolus cerebralis), ceratomyxosis (Ceratomyxa shasta), furunculosis (Aeromonas salmonicida), and enteric redmouth disease (Yersinia ruckeri).

We know now that this statement misrepresented the actual disease situation at the facility.

A 2009 memo from Fisheries and Oceans Canada (DFO) entered into evidence at Canada's federal Cohen Inquiry into the collapse of Fraser River sockeye on Thursday, Dec. 15, 2011 reveals that salmon at the AquaBounty facility in Prince Edward Island tested positive for the Infectious Salmon Anaemia (ISA) virus in November 2009. An email from a senior DFO fish health official notified the Canadian Food Inspection Agency of the positive test results (attached).

AquaBounty has promoted that its system is a safer facility and less prone to disease than typical salmon culture facilities. The presence of ISA in its facility undermines this claim. Unless the ISA came through water pumped to the facility from the nearby sound, the virus could only have entered its closed facility through eggs or smolts. The presence of ISA in AquaBounty' s eggs means that they should not be shipped across the US without evidence of rigorous testing and certification by the Canadian authorities that they are free of the disease, even if the ultimate destination is Panama. A real possibility exists that ISA from the AquaBounty facility could infect Atlantic salmon in Canada and an accident in shipping the eggs to Panama could infect wild or cultured US salmonid fishes.

In the notification to the Canadian food health authority, DFO notes that based on molecular strain testing at two separate laboratories, the virus appears to be a new strain of ISA. The email also states: "With respect to international exports of live fish or eggs from this facility, DFO would identify that the facility has tested positive for ISA should we be asked to sign a fish health certificate for export."

It is disturbing that this email is from 2009, prior to the VMAC hearing. If the FDA had this in its files, it should have revealed this at the VMAC hearing. If the company did not reveal to the FDA that their eggs had tested positive for ISA, we would hope that the FDA would demand from the company all testing data from its facilities in both Canada and Panama. We note also that the Panamanian Aquatic Resources Agency ordered AquaBounty to destroy the fish that it had raised in Panama. This makes us wonder if the Panamanian authorities had received reports of ISA in the eggs being produced in Canada and shipped to Panama.

We urge you to release promptly all data that have been received by the FDA on the health of the AquAdvantage fish so that the public can have a chance to review and assess these data. We ask that you suspend any and all steps towards approval until both this information is disclosed and FDA's prior knowledge of this information is fully investigated.

Finally, we urge your agency to conduct an Environmental Impact Statement that looks at the full range of environmental risks posed by approval – including risks of spreading diseases, like ISA, antibiotic use, and the full environmental impacts of full-scale commercialization of genetically engineered fish – before making a final decision on the approval of the AquAdvantage salmon.

Sincerely,

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President, Friends of the Earth

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