September XX, 2010

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

Dear Commissioner Hamburg:

We have serious concerns regarding the recent Food and Drug Administration (FDA) process for review and possible approval of the AquaBounty Technologies' genetically engineered (GE) 'AquAdvantage' salmon for sale to consumers. The FDA approval process is inadequate and sets a dangerous precedent: the environmental review is flawed, and the consumer's right to know is ignored.

**The Approval Process is Inadequate**

The FDA's decision on whether to approve the first GE animal for use as food will have far-reaching consequences and will influence other pending GE applications awaiting FDA approval. However, the FDA currently has no adequate means to assess the AquAdvantage salmon as a GE animal intended as a human food product. Rather than developing an appropriate evaluation method, the FDA is currently proceeding to approve the GE fish using its process for reviewing a new drug meant for animals.

While AquaBounty filed a New Animal Drug application for AquAdvantage salmon with FDA in 2001, the Environmental Assessment compiled by AquaBounty for the FDA is inherently flawed and does not take into account the full and broad range of impacts the approval of the GE salmon could have on the environment. The FDA should have initiated a full Environmental Impact Statement (EIS) and consulted with other federal agencies responsible for managing federally listed Endangered Species.

The FDA's decision not to disclose to the public any data relating to environmental, food safety, or efficacy concerns until 10 working days before the public Veterinary Medicine Advisory Committee meeting strongly contradicts the agency's claim of commitment to transparency. The public's skepticism of the FDA's review process for the gene-spliced salmon is magnified by the fact that according to the FDA's 'Advisory Committees' website, it is commonplace to schedule meetings at least two months after their announcement in the Federal Register. However, in this case, the public was given less than a one month notice.

Ultimately, the data the FDA provided to the public on food safety is altogether deficient because it is produced by the very corporation seeking approval for its product; not by the FDA or an independent body. Among the most egregious flaws with the data released is that the sample sizes in the company-provided studies on changes in the morphology of the new GE salmon as well as possible allergic reactions, were only 12. These small sample sizes are completely inadequate to use as a basis for a substantive evaluation of the full range of potential health and safety ramifications of releasing these fish for human consumption, especially since they are likely to be raised in a large-scale commercial setting by the tens of thousands and elevated levels of PCBs and dioxin are already documented in farm raised fish.

**The GE Salmon Raise Significant Environmental Concerns**

Genetically engineered fish could pose serious risks to wild populations of fish such as the Atlantic salmon, as well as the Coho and Chinook salmon (numerous species of which are currently listed under the Endangered Species Act of 1973). Approval of this GE salmon, especially in light of plans to raise them at an egg hatchery facility on Prince Edward Island, Canada, could jeopardize all remaining wild Atlantic salmon populations. Despite AquaBounty's claims that its AquAdvantage salmon poses "less risk" to wild salmon populations due to induced sterility, the company acknowledges that 5% of its fish could remain fertile and would therefore be able to mate with wild populations.

We believe any approval of GE salmon could represent a serious threat to the survival of native salmon populations. Each year, millions of farmed salmon escape from open-water net pens, outcompeting wild populations for resources and straining ecosystems. For example, a GE salmon that grows twice as fast as natural salmon would reach full size more quickly and easily outcompete natural salmon for food, territory, and reproductive access. Even if grown in contained, land-based facilities, the "farming" of fish raises serious environmental and economic risks, and even indoor ponds typically recirculate water into the environment, providing an escape route for fish or eggs. Research published in the *Proceedings of the National Academy of Sciences* notes that a release of just sixty GE fish into a wild population of 60,000 would lead to the extinction of the wild population in less than 40 fish generations.

The FDA must not ignore the lessons from GE crops. Unintended genetic contamination of conventional soybean crops by GE soybeans has been well-documented. The spread and breeding of different varieties of GE canola into areas far from where they were experimentally planted has also been proven. It would now be nearly impossible to eradicate the GE varieties of the crops because of their uncontrollable proliferation. During the approval process, the seed manufacturer offered unenforceable assurances of seed containment that are similar to those being offered by AquaBounty. We must learn from our mistakes instead of repeating them.

We object to a federal agency ignoring major environmental issues by exporting the questionable process overseas. According to the application submitted to the FDA, AquaBounty will raise the engineered eggs in a facility on Prince Edward Island in Canada, and then ship those fish to a land-based facility in Panama where the fish will be grown and processed before being shipped worldwide for commercial sale. We are troubled by reports that that the FDA plans to approve the fish if they are raised outside the U.S., effectively encouraging AquaBounty to dump expected environmental problems onto other countries. Doing so sidesteps the FDA's responsibility to protect public health.

**The FDA's Stance on Labeling Undermines Consumer Choice**

If the FDA chooses to ignore the advice of scientific experts and the will of the public by choosing to approve the genetically altered salmon for public consumption, it must reverse its position that the GE salmon is not "materially" different from natural salmon and require that the product bear a label. A label should not be a substitute for comprehensive risk assessment as Americans have the right to know what they are eating, especially when there are so many unanswered questions about the health effects of consumption and about the impact on the natural salmon species. An informed consumer is the last line of defense against the virtually unchecked ability by the sellers and producers to manipulate the market. The buyer cannot beware if the buyer is not informed.

The FDA's process for review and potential approval of the first genetically engineered animal to be mass-marketed to American consumers has so far raised many more troubling questions than answers. We strongly urge you to immediately suspend your approval process until you thoroughly examine and address the very serious flaws with your process including the need for greater public input and independent scientific data.

Sincerely,

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| _____ | _____ | _____ |
| Peter A. DeFazio<br>Member of Congress | Dennis J. Kucinich<br>Member of Congress | Mike Thompson<br>Member of Congress |
| _____ | _____ | _____ |
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