November 22, 2010

Division of Dockets Management (HFA-305)
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

Submitted electronically to Docket No. FDA-2010-N-0385

Re: Docket No. FDA-2010-N-0385; Labeling of AquAdvantage genetically engineered salmon

I. AquaBounty's Genetically Engineered Salmon Should Not Be Approved for Human Consumption

Friends of the Earth is strongly opposed to the Food & Drug Administration's approval of AquaBounty's genetically engineered AquAdvantage salmon. We provided public comments[i] at the FDA's Veterinary Medicine Advisory Committee (VMAC) meeting on the approval of this GE salmon and submitted full written comments[ii] to the VMAC that were signed by twenty other environmental and public interest organizations in the U.S. and Canada. We were also a signatory to a letter[iii] sent to the FDA by twelve of the nation's largest environmental groups on November 8, 2010 asking for a comprehensive and independent Environmental Impact Statement to be completed before any discussions on approval move forward.

These documents, submitted along with our comments, describe our concerns in full on the harms that approval of GE salmon for human consumption will have on the environment and wild salmon populations. At the commercial scale, it will be impossible for AquaBounty to guarantee sterility in their GE fish populations or to guarantee containment. If these transgenic fish escape into our oceans, the effect on endangered salmon populations and local ecosystems could be devastating. The AquaAdvantage salmon may require more food than regular farmed salmon –further depleting wild fish populations that are used for feed and disrupting ecosystems. Additionally, the GE salmon may require more antibiotics than traditionally farmed fish, exacerbating the current problem of over-medicated fish that leads to stronger diseases and parasites that can escape and infect wild salmon populations.

Equally problematic is the fact that the FDA is only looking at the environmental impacts of a single proposed two-facility plan – fertilizing GE fish eggs on Prince Edward Island in Canada, shipping the eggs to Panama to be raised, and then sending the processed fish back to the United States. Despite comments from AquaBounty at the VMAC hearings that they plan to expand operations to the U.S. and around the world the FDA is still limiting its review with the assumption that only these two facilities will grow GE salmon. As members of the VMAC mentioned there is serious concern that the environmental impacts would being segmented by this approach. In other words, the impacts from this operation will be looked at in an Environmental Assessment and all subsequent operations may get their own EA but the cumulative environmental impacts of commercialization of the GE salmon will be ignored.

As the long-shelved AquaBounty transgenic salmon is the first genetically engineered (GE) animal intended for human consumption, the importance of thorough human health studies and consumer opinion cannot be understated. The potential environmental and public health impacts have not been fully studied yet and an Environmental Assessment for this unprecedented proposal is not thorough

enough to identify the many harms GE salmon pose to the environment and biodiversity. Unless further study outlining the impacts to consumers, wild salmon populations and the environment, including an Environmental Impact Statement under the National Environmental Policy Act, is completed, this animal should not be considered for approval.

II. Labeling Must be Mandatory if the GE Salmon is Approved

If the FDA decides to approve AquaBounty's GE salmon for human consumption despite its risks to the environment and public health and despite widespread public opposition, we urge that labeling of the GE salmon be mandatory. Labeling should be required because there are key material differences between wild Atlantic salmon and AquaBounty's AquaAdvantage salmon. Citizens have a right to know what food they consume and labels are the most direct way of educating the public about how their food was produced. Regardless of any FDA determination of material difference between GE salmon and other salmon, the public has cited clear concerns about GE salmon production methods and environmental impacts, necessitating a mandatory label.

Labeling must also be required for those raising and selling AquaBounty's GE salmon to allow the FDA to trace these fish back to their original source in case of food or environmental safety concerns. Labeling the GE fish eggs as genetically engineered would allow those who do not wish to raise genetically engineered fish to avoid this product and would ensure the FDA knows where these fertilized eggs and fish are at all times in case of accidental escape or if the eggs are sold to unauthorized fish farms, such as open-ocean operations.

It was recently made public through a Freedom of Information Act request that a Federal Biological Opinion by the U.S. Fish and Wildlife Service and the National Oceanic and Atmospheric Administration prohibited the use of transgenic salmon in open-water net pens pursuant to the U.S. Endangered Species Act.[iv] Mandatory labeling would be the only way to track GE salmon eggs to ensure AquaBounty's fish are not grown in prohibited areas.

A. Material Differences Exist Between the AquaAdvantage Salmon and Other Salmon Species

The limited data provided by the FDA regarding the composition and nature of the AquAdvantage Salmon supports the call for mandatory labeling of this new salmon since they show material differences between AquaBounty's genetically engineered salmon and other salmon. Additionally, as AquaBounty admits, it culled salmon from their tanks before taking fish randomly for testing. The company has not guaranteed that the culling did not target sick or deformed fish from the populations before health and safety data were tested. This fact alone makes every one of AquaBounty's conclusions suspect and should require independent testing by the FDA.

1. Changes in the Composition of Salmon from the Insert of the AquaAdvantage Genetic Construct

The insertion of AquaBounty's genetic construct, according to the company's own data, changes the composition of the salmon. The company and the FDA identified several possible problems in the morphology of the AquAdvantage salmon. At least two significant findings from this inadequate study demand additional study before the AquAdvantage salmon is considered for approval and if the fish is approved would require labeling to track problems that may relate to ongoing health of the fish:

a) Jaw erosion is linked to the AquaBounty Technologies genetic construct. The effect of small sample size has been suggested by AquaBounty as a limitation on the interpretation of jaw erosions.[v]
b) An increased prevalence of focal inflammation in various tissue types in AquAdvantage Salmon has the strongest correlation with the presence of the AquAdvantage construct among the findings in this study. That these fish may have been immunocompromised as a result of seasonality or other factors confounds the interpretation of these findings.[vi]

The FDA admits that AquaBounty's sample sizes are too small to measure the rate of abnormalities that might be expected in commercial grow out facilities. Even so, they excuse AquaBounty from any requirement to produce the data before the approval of the fish by stating:

> *There is no practical way ABT could have generated the appropriate data without producing – and destroying – commercial lots of fish. Nonetheless, we believe that incorporating an appropriate surveillance/durability plan will provide sufficient data and information to the Agency to minimize this uncertainty*.[vii]

Surveillance and durability plans must be a necessary condition for approval if the FDA does in fact move to approve AquaBounty's transgenic salmon. At the very least, if environmental and public health safety standards are not met through these surveillance and durability plans the FDA should revoke approval.

Additionally, the scant data presented to the public suggest that with larger, better-controlled studies of the fish as they are raised commercially, additional concerns may appear. If the agency is to have an effective monitoring plan after approval, this plan must include labeling. If the GE salmon is not labeled, it would be nearly impossible for the FDA to accurately and appropriately keep track of the salmon products to ensure their safety post-approval.

2. Vitamin and Mineral Content of GE Salmon Worse than in Other Farmed Salmon

The CVM identified six chemicals (folic acid, niacin, Vitamin B6, magnesium, phosphorus and zinc) for which the values from the triploid AquAdvantage salmon differed from the non-GE comparator by more than 10%. The maximum level for Vitamin B6 was more than 20% greater in the GE salmon than the upper range found in other wild and farmed Atlantic salmon.[viii] While it is unclear whether these levels would pose health risks, the small sample size and the fact that the sampling was done under the control of the AquaBounty company argues for a completely independent review using larger samples. These differences should be considered "material" differences of the sort that would require labeling of these fish.

3. Inadequate Testing for Growth Hormone and IGF-1 Levels in the GE Salmon Intended for Human Consumption

For both growth hormone and another insulin-like hormone, IGF-1, there are no data on levels in the flesh of triploid GE salmon, because only inappropriate and insensitive tests were used to detect them. Given this lack of data on two of the identified potential hazards of this GE fish, rather than state that there are no problems, FDA should find that this study is of insufficient quality and must be redone by an independent party using more sensitive test methods. In addition, prior to this GE salmon being approved, the company should provide data on the levels of growth hormone and IGF-1 in the muscle of

triploid GE salmon that have been raised in Panama, not at the PEI facility. This is particularly important for IGF-1, a hormone linked to a number of cancers.

4. The GE Salmon May be More Allergenic than Other Salmon

In addition to the nutritional and morphological differences in the AquAdvantage fish, the study identified differences between AquAdvantage and non-GE comparators in IGF1 levels[ix] and the possibility of the AquAdvantage genetic construct being a new allergen.[x]. The FDA warns ominously:

> *One potential indirect hazard that may result from the insertion of the AquAdvantage construct at the α- locus is a possible increase in the endogenous levels of allergens in ABT salmon due to insertional mutagenesis in a region of the genome that may act as a regulator of the expression of one or more of these proteins. Although the previous study attempted to address this point, its various technical deficiencies make it difficult to determine whether the allergenicity of salmon, or the prevalence of any known endogenous protein that has been implicated in allergic responses (i.e., parvalbumin) have changed, thereby somehow increasing the allergenicity of the fish*[xi].

Without additional certainty about the causes and effects of these differences, labeling is warranted.

5. The AquaAdvantage Salmon Contains Less Healthy Fatty Acids than do Other Farmed Salmon

The FDA claims that the omega 3/omega 6 ratios in the GE salmon are "similar"[xii] to the ratios found in scientific literature for farmed Atlantic salmon. In fact, the ratio for farmed Atlantic salmon is 4.1, nearly 15% higher than the 3.6 recorded for the ABT salmon. For consumers interested in consuming more not less of the healthy fats found in salmon, this should be considered significant and is a material difference in the composition of the salmon that likely leads to a difference in flavor, too.

B. Public Concern Should be Considered When Determining if Products will be Labeled

The American public has voiced strong opposition to the approval of AquaBounty's genetically engineered salmon for human consumption. After providing only a few weeks for the public to respond to the announcement that the FDA is nearing approval of the GE salmon, *171,645 public comments were submitting asking the FDA to deny approval to AquaBounty's transgenic fish*.

According to a recent poll[xiii] conducted by Lake Research Partners for Food & Water Watch, 91% of Americans felt the FDA should not introduce GE fish and meat into the marketplace. Additionally, a Consumer Reports poll[xiv] shows that 95% of respondents said they thought food from genetically engineered animals should be labeled.

The FDA claims it can only label a product if it is materially different from another product, but it has in fact labeled food products in the past based on public concern. In the case of irradiated food, the FDA decided that labels can be required for products, even if they are determined to be safe. In its final rule on food irradiation, the FDA stated information deemed important to consumers can be used to determine if products are labeled. The ruling stated,

> "*Whether information is material under section 201(n) of the act depends not on the abstract worth of the information but on whether consumers view such information as important and whether the omission of label information may mislead a consumer. The large number of consumer comments requesting retail labeling attest to the significance placed on such labeling by consumers.*"[xv]

The rule continued by stating that materiality does not always include "some change in nutritional value, organoleptic properties, or functional characteristics."[xvi] The FDA has and can require food products to be labeled in response to public concern over the safety of certain foods.

Citizens are increasingly concerned about where their food comes from, how it is produced, and the effect food production has on the environment. This concern also includes whether their food is genetically engineered, regardless of material differences. Genetically Modified Organisms (GMO)-free labels are the fastest growing labels on the market,[xvii] with sales up by 67% in 2009 from the previous year and a sales growth of $60.2 million in that sector. The American public cares about what food products reach their plate and increasingly they want to avoid genetically engineered foods. By requiring AquaBounty's genetically engineered salmon to be labeled, the FDA would be providing the U.S. public the choice it clearly desires and deserves.

III. Conclusion

We urge the FDA to deny approval to AquaBounty's AquaAdvantage genetically engineered salmon. If the FDA does decide to approve this GE salmon - against the will of the American public and with questionable scientific studies - it is crucial that these products be labeled. As the FDA and its Veterinary Medicine Advisory Committee admits, the studies conducted by AquaBounty on the environmental and public health risks on this GE salmon are inadequate. If the FDA is indeed committed to tracking products from this GE salmon to ensure no problems arise post-approval, labeling must be mandatory. Labeling and tracking would allow the public and the FDA to know what products are being consumed and by whom in case there are indeed health and environmental harms down the road.

AquaBounty's GE salmon is the first genetically engineered animal to be considered for human consumption and will undoubtedly set precedent for future GE animal applications. Additionally, significant uncertainties still exist around the public health and environmental risks from approving this genetically engineered animal. These two points necessitate the use of precaution moving forward. **We believe the most fundamental precaution is to not provide approval until the FDA has been assured of the safety of this proposed activity, including achieving certainty on the above health concerns and conducting a full Environmental Impact Statement. The data to date fails to provide such certainty.**Further studies on health data, an Environmental Impact Statement, and mandatory labeling if the product is approved – would provide necessary time for the FDA to fully look the risks associated with AquaBounty's GE salmon instead of rushing through the process as they have done so far. It would also allow the FDA to track these products to continue testing for public health and environmental safety while providing consumers with the choice they clearly desire at the market.

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[i] "Public Testimony on Genetically Engineered Salmon Delivered to the Veterinary Medicine Advisory Committee of the Food and Drug Administration." Veterinary Medicine Advisory Committee Public Hearing. Rockville, Maryland. 20 Sept. 2010. Web. <http://www.foe.org/sites/default/files/FriendsoftheEarth-comments-GESalmon-VMAC.pdf>.

[ii] *Written Comments Submitted to the FDA by Friends of the Earth and 20 Other Environmental and Public Interest Groups*. Rep. 16 Sept. 2010. Web. <http://www.foe.org/sites/default/files/FriendsoftheEarth-WrittenComments-VMAC-GE%20Salmon.pdf>.

[iii] "Environmental Group Letter to the FDA Requesting a Full Environmental Impact Statement on the Approval of Genetically Engineered Salmon." Letter to Commissioner Margaret Hamburg. 8 Nov. 2010. <http://www.foe.org/sites/default/files/EnvironmentalGroupLettertoFDA-GESalmonEnvironmentalReview.pdf>.

[iv] Center for Food Safety. *Newly Disclosed Government Documents Conclude GE Salmon Pose A Critical Threat To Marine Environments*. 27 Oct. 2010. <http://ge-fish.org/2010/10/27/newly-disclosed-government-documents-conclude-ge-salmon-pose-a-critical-threat-to-marine-environments/>.

[v] VMAC Briefing Packet, 37.

[vi] ibid, 38.

[vii] ibid, 45.

[viii] ibid, 89-92.

[ix] ibid, 68-72.

[x] ibid, 75-76.

[xi] ibid, 106.

[xii] ibid, 95.

[xiii] Lake Research Partners. *Americans In Near Unanimity in Their Disapproval of Genetically Engineered Fish and Meat in the Marketplace*. Food & Water Watch, 20 Sept. 2010. Web. <http://documents.foodandwaterwatch.org/release-FWW-Omnibus.pdf>.

[xiv] *Food-Labeling Poll 2008*. Rep. Consumer Reports National Research Center, 11 Nov. 2008. Web. <http://www.greenerchoices.org/pdf/foodpoll2008.pdf>.

[xv] 51 Federal Register 13376, 13380 (April 18, 1986).

[xvi] Ibid.

[xvii] Pirovano, Tom. "U.S. Healthy Eating Trends Part 4: Store Brands Expand Healthy Offerings | Nielsen Wire." *Nielson Wire*. Web. <http://blog.nielsen.com/nielsenwire/consumer/u-s-healthy-eating-trends-part-4-store-brands-expand-healthy-offerings/>.