THE CENTER FOR
FOOD SAFETY

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Testimony to Alaska House of Representatives on House Joint Resolution 8 (HJR8)

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Good afternoon. My name is Jaydee Hanson and I am the Senior Policy Analyst for the Center for Food Safety, an organization based in Washington, D.C. that works to protect human health and the environment by curbing the proliferation of harmful food production technologies. Thank you for allowing me the opportunity to provide testimony today on this important and precedent setting decision.

Overview of Flawed Process

As you are aware, on August 25, 2010, U.S. Food and Drug Administration (FDA) officials announced their process for making a decision on an application relating to the first genetically engineered (GE) animal intended for human consumption, the AquAdvantage Salmon (AA Salmon) produced by Aqua Bounty Technologies. FDA held two back to back public meetings in September less than three weeks after announcing they would probably approve the application to discuss the AA Salmon. The first FDA meeting was a convening of the Veterinary Medicine Advisory Committee (VMAC) on September 19-20 to consider issues regarding the safety and effectiveness of the transfer of genes from two fish species into an Atlantic salmon as a "new animal drug" (NAD) that is the subject of the GE fish new animal drug application (NADA).[i] Unlike other animal drugs, these new "drugs" reside in every cell of the animal while it is eaten. The second meeting was a public hearing on September 21 to present the public with FDA's existing legal framework for food labeling, and to receive public input on whether food from GE Salmon should be labeled.[ii]

The decision-making process proposed by FDA failed to provide the public with sufficient time or available data that would have allowed for full and meaningful participation prior to the VMAC and labeling meetings. The exceedingly short timelines for public comment were exacerbated by the lack of transparency. AquaBounty filed a New Animal Drug (NAD) application for AquAdvantage salmon with FDA in 2001, yet the agency chose not to disclose any data relating to its decision until just 10 working days before the public meeting. Despite the short time line, some 79, 000 people wrote the FDA asking them not to approve the salmon.

FDA's announcement regarding its process is the first of its kind, for any GE food animal. Similarly the decision whether to label any such GE animal if approved will be a first. FDA and the VMAC recognize that whether or not to approve the first GE animal for use as food is a critical and precedent-setting decision. As such, the public must demand that FDA must require additional environmental and food safety data as well as gather as much information as possible about its next steps from all interested parties, especially the public.

The data the FDA provided to the public on food safety was altogether deficient given that the FDA had 10 years to review the product. The study on changes in the morphology of the new GE salmon involved only 12 fish. The limited study on possible allergic reactions involved only 6 fertile GE fish and 6 infertile GE fish. These small sample sizes are completely inadequate for a full review of the health and safety of these fish when they are raised in a commercial operation. The absence of data on disease resistance and inadequate nutritional composition data leave the safety of these animals largely unknown. Additionally, the Environmental Assessment (EA), a less comprehensive review, 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 will have on the environment, such as what would happen if these fish escaped.

The VMAC raised many concerns during the public meeting regarding small sample sizes, incomplete data, questionable culling practices, the numerous physical abnormalities that may occur after fish reach market size and poor scientific assessments. Regarding the potential allergenicity, one Committee member noted "I don't have adequate evidence to determine if it's safe." This was followed by his colleague who said "the short answer as a professor is I don't know." In light of the numerous unknowns raised throughout the VMAC meeting, FDA officials announced that any approval will require post-market review and data requirements. Yet the VMAC expressed its concerns with FDA's plan to require post-market reviews as sufficient for gaps in current safety data. Post-market review and labeling are not an adequate substitution for proper regulation and safety assessments. Additionally, Dr. Gary Thorgaard, the only fisheries biologist on the committee, called on FDA to conduct a full Environmental Impact Statement, a sentiment reiterated by other members of the Committee.

Human Health Risks of Genetically Engineered Salmon

We are very concerned about the potential toxicity, allergenicity, and diseases posed by the commercialization of transgenic fish. While data on human health impacts of GE fish are sparse, especially since FDA has yet to share all the data it has reviewed, there is cause for concern. With regard to food allergies, FDA stated: "the technical flaws in this [AquaBounty's allergy] study so limit its interpretation that we cannot rely on its results."[iii] Additionally, AquaBounty salmon went largely untested for increased disease susceptibility, despite focal inflammations and elevated white blood cell counts suggestive of infection.[iv]

Disease is a massive problem in crowded farmed salmon operations, and increased susceptibility would mean unhealthy fish treated liberally with antibiotics, resistant bacteria, and antibiotic residues in fish [6].Some research suggests that transgenic fish may be susceptible to more diseases than fish currently grown in aquaculture facilities.[v] Consequently, the amount of antibiotics given to transgenic fish may be higher than the amount currently given to farmed fish; already farmed salmon are given more antibiotics than any other livestock by weight. Aqua Bounty Technologies provided no data on their antibiotic use with these fish. The absence of data on disease resistance and inadequate nutritional composition data leaves the safety of these animals largely unknown. By eating geneticially engineered farmed fish treated with more antibiotics humans will be ingesting antibiotics that may be harmful.[vi] Indeed, some antibiotics are toxic and can even cause fatal allergic reactions.[vii] Finally, if these genetically engineered fish increase the use of antibiotics in aquaculture, they would also exacerbate the significant problem of antibiotic resistant bacteria.

The potential human health concerns connected with the use of antibiotics in aquaculture, including the unique role transgenic fish may play in exacerbating such use, must be fully assessed by FDA.

A 2009 study commissioned by the European Union revealed that fish engineered to grow faster have a resultant high tolerance to environmental toxins.[viii] The study's authors expressed grave concerns that both toxins and growth hormones engineered into the fish had a high potential to end up in consumers' bodies, calling for further tests to determine safety.

Ecological Risks of Genetically Engineered Salmon

Genetically engineered fish pose serious risks to wild populations of fish and our marine environment. Each year millions of farmed salmon escape from open-water net pens, outcompeting wild populations for resources and straining ecosystems. We believe any approval of GE salmon would represent a serious threat to the survival of native salmon populations, many of which have already suffered severe declines.

Escaped GE salmon can pose an additional threat – genetic pollution resulting from what scientists call the "Trojan gene" effect. 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. It could be inferred that the fish could also breed with Atlantic salmon being farmed in the Pacific Basin.

In addition to the threat of these GE salmon displacing native salmon populations, such farming of these GE salmon could encourage the propagation of deadly fish diseases, the concentration of harmful wastes and industrial drugs and chemicals escaping into open waters, and the over-fishing of vast quantities of non-commercial fish to feed carnivorous farmed fish, such as salmon; it generally takes three pounds of wild fish to grow one pound of farmed salmon[ix]. Since these salmon have been engineered for fast growth, it stands to reason that their feed requirements will be even higher.

Economic Risks to Fishermen

A potential escape of GE salmon will both directly and indirectly affect the livelihoods of the tens of thousands of salmon fishers and fishing communities in the U.S. and will have ripple effects throughout markets. In the Northeastern United States, wild Atlantic salmon is on the endangered species list and commercial fishing is prohibited. Therefore, the escape of GE salmon would pose serious risks to the restoration of wild populations of fish and any approval of GE fish will have direct and indirect effects on wild stocks as well as the fisheries themselves.

As you are well aware, in the Northwest the salmon industry is a paramount sector of the economy. The seafood industry in Alaska is the largest private sector employer creating 56,600 direct and 22,000 indirect jobs annually, more jobs than oil, gas and mining combined.[x] In 2007, the overall value of the Alaska seafood industry alone was over $1.5 billion paid to fishermen and $3.6 billion at the wholesale level. Total 2007 value at the dock for the non-Indian commercial salmon fisheries within Washington, Oregon and California was $11.6 million.[xi] Research published by Andrew Dyke and U. Rashid Sumaila notes that wild fisheries can also have significant economic impacts in other sectors, such as agriculture, forestry, manufacturing and financial services, observing that "changes in the fishing industry could affect livelihoods in and the viability of many economic sectors." The researchers found that regionally, every $1 of fisheries-sector output supports more than $3 of output throughout the North American economy.[xii] Many of Alaska's salmon processors are based in Seattle and elsewhere in Washington, Oregon or California, meaning that revenue and value is generated and spread across many states. At the same time, the increased demands by salmon farms for forage fish and fishmeal additionally affect the health of wild stocks and place an added stress on wild fisheries.

Additionally, the risk of market confusion or rejection resulting from GE salmon approval would have additional effects on the U.S. salmon and seafood industry. Consumer confusion about what types of salmon or seafood are genetically engineered may deter shoppers from purchasing such products. This confusion would be made worse by the absence of mandatory GE labeling requirements. Approving GE salmon is a sharp contradiction to the agreements the United States has signed at the North Atlantic Salmon Conservation Organization, where transgenic salmonids are considered a serious threat to wild salmon. Furthermore, GE salmon could result in trade disparities and the potential loss of foreign markets that may have differing opinions on labeling or safety assessments - for example in the EU, all GE animals must be labeled. Virtually, every European and Canadian fish farming association has announced that their members will not grow these GE salmon. If the US approves these GE salmon for growth in the US without labeling. Consumers will fear that every US salmon is genetically engineered. Concerns over potential food contamination or environmental impacts may also affect consumer choice in the U.S. which could lead to consumers' forgoing buying wild and farmed salmon altogether. A recent poll from Lake Research Partners found that 91 percent of Americans felt FDA should not introduce GE fish and meat into the marketplace.[xiii] A 2008 Consumer Reports poll found that 95 percent of respondents said they thought food from genetically engineered animals should be labeled.[xiv]

Labeling

To ensure meaningful public comment and confidence in the Agency's processes, the agency should have separately convened the labeling hearing, only if and after any initial decision on approval. To have a discussion about labeling presupposes that FDA has already made up its mind on the approval without proper input, yet even labeling is not an adequate substitution for proper regulation and safety assessments prior to approval. The deadline for comments on the labeling of the fish was Nov. 22, 2010 and this time some 400,000 people asked the FDA to require labeling. The public clearly wants these fish labeled.

Should FDA decide to approve the transgenic salmon despite overwhelming consumer opposition and potential threats to the environment, human health, and native salmon populations, mandatory labeling must be unconditional.

Conclusion

I would like to finish by expressing the Center for Food Safety's support for House Joint Resolution 8 (HJR8), which we feel takes the necessary strides toward protecting human health, the environment and Alaska's thriving fishing economy from the risks association with genetically engineered salmon.

Respectfully Submitted,

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[i] Federal Register / Vol. 75, No. 165 / Thursday, August 26, 2010 / Notices/ pp. 52605. (Public VMAC Meeting)
[ii] Federal Register / Vol. 75, No. 165 / Thursday, August 26, 2010 / Notices/ pp. 52602. (Public Meeting on Labeling)
[iii] *AquAdvantage Salmon Briefing Packet for Veterinary Medicine Advisory Committee*, Center for Veterinary Medicine, Food and Drug Administration, Sept. 20, 2010, page 104

[iv] Briefing Packet, p. 41: "Comprehensive disease challenge tests have not been conducted on these fish." "An increased presence of focal inflammation in various tissue types in AquAdvantage salmon has the ***strongest correlation*** with the presence of the AquAdvantage construct [inserted gene] 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." In other words, FDA waves off the strongest finding of difference between GE and control salmon with airy speculation, and fails to demand further study to clarify these "confounded" findings. In particular, FDA does not demand "comprehensive disease challenge" tests to determine, based on SCIENCE and DATA, whether these GE salmon are more susceptible to disease. This is inexcusable, particularly given peer-reviewed literature showing that salmon engineered with a growth hormone gene are more susceptible to a significant salmon pathogen (*Vibrio anguillarum*) that causes the devastating salmon disease vibriosis than non-GE salmon. See Jhingan et al (2003). "Disease resistance, stress response and effects of triploidy in growth hormone transgenic coho salmon," Journal of Fish Biology 63: 806-823. For elevated white blood cell (lymphocyte) counts, see p. 35, and Figure 5, p. 147).

[v] William Muir et al., Possible ecological risks of transgenic organism release when transgenes affect mating success: Sexual selection and the Trojan gene hypothesis, 96 PNAS 13853-13856, at 13853 (Nov. 23, 1999).

[vi] Rebecca Goldberg and Tracy Triplett. Murky Waters: The Environmental Effects of Aquaculture in the U.S. (p 44). Environmental Defense Fund (1997).

[vii] Id.

[viii] Centre for Aquaculture and Environmental Research. (2009) "Ecological Risk Assessment of Transgenic Salmon." Study commissioned by the European Union, the Swedish Research Council Formas and the University of Gothenburg. Vancouver, Canada.

[ix] Naylor et al, Effect of Aquaculture on World Fish Supplies. Nature, Vol.405, June 29, 2000, pg.1017-1024 and Dr. Rebecca Goldberg, Murky Waters: Environmental Effects of Aquaculture in the United States. Environmental Defense Fund, October 1997.

[x] Northern Economics of Anchorage (January 2009) *The Seafood Industry in Alaska's Economy*. Commissioned by the Marine Conservation Alliance, At-sea Processors Association and the Pacific Seafood Processors Association.

[xi] Pacific Fishery Management Council. 2008. *Review of 2007 Ocean Salmon Fisheries*. (Document prepared for the Council and its advisory entities.) Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 200, Portland, Oregon 97220-1384

[xii] Dyck, A.J. and U.R. Sumaila. 2010. Economic impact of ocean fish populations in the global fishery. *Journal of Bioeconomics*. DOI: 10.1007/s10818-010-9088-3 [See attached summary by PEW Environment Group]

[xiii] Lake Research Partners, Commissioned by Food and Water Watch. 9/20/10 http://documents.foodandwaterwatch.org/release-FWW-Omnibus.pdf

[xiv] Consumer Reports. 11/11/08 http://www.greenerchoices.org/pdf/foodpoll2008.pdf