

Alliance for Natural Health, USA - Californians for GE Free Agriculture - Center for Biological Diversity - Center for Environmental Health – Center for Food Safety - Connecticut Citizen Action Group - Ecumenical EcoJustice Network – Food & Water Watch - FRESH, the Movie - Friends of the Earth – Go Wild Campaign - Institute for Responsible Technology - Institute for Social Ecology – International Center for Technology Assessment - Mangrove Action Project – National Cooperative Grocers Association - Northwest Resistance Against Genetic Engineering - Occidental Arts and Ecology Center – Organic Consumers Association – PCC Natural Markets - Salmon Protection and Watershed Network (SPAWN) – San Francisco Baykeeper - Say No To GMOs - Sierra Club - Sustainable Living Systems - Turtle Island Restoration Network – Waterkeeper Alliance

September 16, 2010

Center for Veterinary Medicine (HFV3)
Food and Drug Administration
7519 Standish Place
Rockville, MD 20855

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

RE: **Docket No. FDA-2010-N-0001 and Docket No. FDA-2010-N-0385**, VMAC Meeting on approval of AquaAdvantage genetically engineered salmon; Labeling of AquaAdvantage genetically engineered salmon

The undersigned environmental, conservation, consumer, and health organizations, representing over one million members and supporters across North America, are writing to express our opposition to the approval of AquaBounty's genetically engineered, AquaAdvantage salmon.

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 AquaAdvantage Salmon produced by AquaBounty Technologies (Docket No. FDA-2010-N-0001). The genetically engineered Atlantic salmon being considered was developed by artificially combining growth hormone genes from an unrelated Pacific salmon, (*Oncorhynchus tshawytscha*) with DNA from the anti-freeze genes of an eelpout (*Zoarces americanus*). This modification causes production of growth-hormone year-round, creating a fish the company claims grows at twice the rate of conventional farmed salmon, allowing factory fish farms to crowd fish into pens and still get high production rates.

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 can not be understated. This animal should not be approved

for human consumption until and unless further study indicates that they are safe for consumers, the environment and native salmon populations.

Genetically engineered fish pose serious risks to wild populations of fish, and to consumers who rely on them for healthy nutrition. We believe any approval of GE salmon would represent a serious threat to the survival of healthy, native salmon populations, many of which have already suffered severe declines related to salmon farms and other man-made impacts.

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.

If the FDA opens this door, GE fish will likely be among the millions of salmon that currently escape into the wild. This could be the last blow to wild salmon stocks.

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 it will ship those fish to a land-based facility in Panama where the fish will be grown out and processed before being shipped worldwide for commercial sale. However, these GE fish are intended for use on a global scale, and a reliable containment regime following commercialization is just not conceivable. For example, the Environmental Risk Management Authority in New Zealand identified flaws in the safety system of the GE salmon tanks of the private company King Salmon where GE salmon eggs could have come into contact with sperm before escaping into the environment. This example highlights the difficulties in designing safety measures which are 100% effective.

Additionally, most salmon farmers in the real world ply their trade in low-lying coastal areas and competing corporations will no doubt race to produce GE fish in crowded open ocean facilities already in use for fish production. While FDA may place initial restrictions on the farming of GE fish, it is merely a matter of time before FDA is bombarded by pressure from corporations wishing to replace conventional fish in open ocean farms with the GE variety.

Even if grown in contained, land-based facilities, the “farming” of fish raises serious environmental risks, and even indoor ponds typically recirculate water into the environment, an escape route for fish or eggs.

We are also 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 is sparse, especially since FDA has yet to share all the data it has reviewed, there is cause for concern. The routine use of antibiotics to control diseases in farm-raised fish may already be impacting human health. Some research suggests that transgenic fish may be susceptible to more diseases than fish currently grown in aquaculture facilities.ⁱ

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. By eating farmed fish treated with antibiotics humans will be ingesting antibiotics that may be harmful.ⁱⁱ Indeed, some antibiotics are toxic and can even cause fatal allergic reactions.ⁱⁱⁱ Finally, the use of antibiotics in aquaculture also exacerbates 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.

In addition to the threat of these GE salmon displacing native salmon populations, such fish farming encourages 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 salmon¹. Since these salmon have been engineered for fast growth, it stands to reason that their feed requirements will be even higher. Wild Atlantic salmon are already on the Endangered Species List in the U.S.; approving these GE Atlantic salmon will undoubtedly be the last blow to these wild stocks.

The AquaBounty company also says that it will only produce sterile females; however there is no guaranteed method to produce 100% sterility. FDA has difficulty tracking salmonella in hen eggs; to believe that the FDA can track whether salmon eggs are sterile or not is ludicrous. Moreover, the company will need to keep stocks of fertile fish to produce additional offspring.

FDA's decision to go ahead with this approval process is misguided and dangerous, and is exacerbated by the lack of all available data. FDA has been sitting on this application for 10 years and yet it chose to disclose only scant data about its decision just 10 days before the public meeting. While the lack of transparency by FDA prevents the public from submitting informed public comments at the meetings, the absence of a public comment period on the approval of GE salmon following the VMA Committee meetings prevents the public from providing the Committee with relevant scientific studies and data as well as additional stakeholder comment following the meetings and additional release of available data. Holding a comment period solely on labeling presupposes the GE salmon will be approved, without proper public comment solicitation or review. A 2008 Consumer Reports poll found that the majority of Americans are concerned about consuming products from GE animals. An additional 95 percent agreed that these products should, at the very least, be labeled.

We all know there is a great appetite for salmon, but the solution is not to "farm" genetically engineered versions to put more on our dinner tables; the solution is to work to bring our wild salmon populations back, and to protect and maintain existing native salmon populations.

¹ 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.

We strongly oppose the approval of these genetically engineered salmon and urge FDA to reject GE salmon. Should FDA decide to approve the AquAdvantage GE salmon despite our opposition, *clear, mandatory labeling is an absolute must* to allow consumers to make informed purchasing decisions.

Signed:

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International Center for Technology Assessment
Mangrove Action Project
National Cooperative Grocers Association
Northwest Resistance Against Genetic Engineering
Occidental Arts and Ecology Center
Organic Consumers Association
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Salmon Protection and Watershed Network (SPAWN)
San Francisco Baykeeper
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ⁱ 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).

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

ⁱⁱⁱ Id.