

On November 8, 2010, several environmental organizations sent the following letter to Commissioner Margaret Hamburg at the U.S. Food and Drug Administration, calling for a full environmental impact statement before granting approval of AquaBounty Technologies' AquAdvantage Salmon. In their letter, they make several outrageous and inaccurate allegations for the purpose of inciting fear and spreading misunderstanding. AquaBounty responds to these statements.

November 8, 2010

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

Cc: Secretary Kathleen Sebelius, U.S. Department of Health and Human Services
Dr. Jane Lubchenco, Administrator, National Oceanic and Atmospheric Administration
Rowan W. Gould, Acting Director, U.S. Fish and Wildlife Service

Dear Commissioner Hamburg:

On behalf of our millions of members and activists, we are writing to urge the U.S. Food and Drug Administration (FDA) to fully assess the impacts of genetically engineered (GE) Atlantic salmon before acting on AquaBounty Technologies' application for the first ever approval of a GE animal for human consumption. Currently, the only environmental analysis before FDA consists of an environmental assessment prepared by AquaBounty that sidesteps the weighty issues FDA must address.

[ABT: There is no basis for this statement. The entire public summary of the Environmental Assessment (EA) for the AquAdvantage Salmon NADA is available. The summary addresses every aspect of the cultivation of AquAdvantage Salmon.]

We ask that FDA conduct a full environmental impact statement (EIS) and consult with NOAA Fisheries on the impacts on wild Atlantic salmon which have been listed as an Endangered Species since 2000. This EIS must evaluate a realistic range of potential production scenarios for this fish given the company's clear intention to expand production well beyond the scenarios proposed in the current application.

[ABT: There is no basis or precedent for this position. The pending application is for the cultivation of AquAdvantage Salmon as all female, infertile fish raised in FDA-approved, physically contained facilities. Only one such facility is currently before FDA for approval. Future facilities will require separate review and authorization.]

Only then will FDA have the information it needs to decide whether to approve or deny AquaBounty's application. We anticipate that a comprehensive EIS will show that AquAdvantage salmon pose a threat to wild salmon populations and the health of marine and freshwater ecosystems around the world.

[ABT: There is no factual basis for this statement. In fact, all existing data and information are directly at odds with this assertion, identifying the assertion as unfounded and irresponsible speculation.]

GE salmon could pose serious threats to biodiversity and, in particular, to the viability of wild Atlantic salmon should they escape from production facilities. We already have extensive experience with salmon escaping from aquaculture facilities, interbreeding with wild salmon, and diminishing the fitness of the wild populations. In fact, Atlantic salmon were placed on the endangered species list, in part, due to genetic and fitness impairments caused by inbreeding with farmed salmon escaping from net pens.ⁱ If salmon genetically engineered to grow faster than wild fish escape confinement, they will threaten the health and survival of wild salmon populations. According to research from Purdue University, if just 60 GE fish were released into a wild population of 60,000, the wild population could be extinct within forty generations. This result is driven by the "Trojan gene effect" in which specific fitness advantages in an otherwise less fit organism result in gene spread and an ultimate weakening and eventual collapse of the species.ⁱⁱ

[ABT: The author of this work has publicly stated on several occasions his theory does not apply to the AquaAdvantage Salmon. Further, the author of the "Trojan gene effect," Dr. William Muir, Purdue University, attended the recent Veterinary Medical Advisory Committee (VMAC) meeting where he carefully and convincingly addressed the relevant facts. Dr. Muir also detailed why his theory does not apply to the AquaAdvantage Salmon. Many of the signatories of this letter attended Dr. Muir's VMAC presentation, yet they persist in making this accusation here and in other statements.]

Similarly, another study published by the Canadian government in 2004 has shown that natural and GE salmon located together in the laboratory under conditions of low food availability lead to population collapse and eventual extinction of the entire study population because GE salmon are more aggressive and sometimes resort to cannibalism.ⁱⁱⁱ The effect that hungry and aggressive GE salmon could have on natural ecosystems and local food chains in the wild has not been studied; these types of deleterious effects must be fully considered before GE salmon are approved for sale in the United States.

[ABT: This is a stark misrepresentation. The study cited was conducted by Dr. Robert Devlin, a researcher at the Department of Fisheries and Oceans in Canada. The study was not published by the "Canadian government." Further, Dr. Devlin has said publicly his findings apply only to his specific transgenic Coho Salmon. The transgenic Coho Salmon has been modified by a different construct in a different species with a different genotype and phenotype from the AquaAdvantage Salmon. Simply stated, there is no scientific basis on which to attribute Dr. Devlin's findings to the AquaAdvantage Salmon.]

While steps can be taken to reduce the risks that fertile salmon will escape, these risks cannot be eliminated. For example, AquaBounty proposes to sterilize the salmon eggs before shipment to Panama to be reared in the grow-out tanks, but its own data show their sterilization techniques to induce triploidy are not effective in up to 5% of all eggs treated.

[ABT: AquaBounty's research - the results of which are publicly available - reveal the triploidy process has been validated to be greater than 98 % effective. The numbers in the validation experiments all exceed this value. Moreover, in addition to being triploid (infertile), the fish are all female and will be raised in physically contained facilities which will be inspected and approved in advance by FDA. This redundant biological containment and the rigorous physical containment the facilities provide assures a much higher degree of certainty of no interaction with any wild population than does any other current production method, and in fact, renders comparisons with other current production methods wholly inappropriate.]

Additionally, the company must rely on fertile male and female GE fish to produce eggs in their production facility in Canada. While the application before the FDA only considers growth in these land-based facilities, the global aquaculture industry is dominated by cage culture in open ocean environments. Hundreds of thousands of salmon escape from these aquaculture facilities every year.^{iv} No land-based infrastructure currently exists to accommodate the 15 million eggs for which AquaBounty claims to have orders;^v meaning upwards of 750,000 fertile, genetically engineered salmon could escape from cage culture systems as the farming of GE salmon proliferates.

[ABT: AquaBounty had to search for the origin of this statement of “pending orders.” It appears it is a comment attributed to Elliot Entis, CEO of A/F Protein, in 2000. AquaBounty is mystified by the use of such an old and irrelevant charge, and is unaware of any factual basis for this statement. Additionally, the conditions of use in our application clearly indicate these fish cannot be grown in net pens or sea cages.]

Escaped fish will compete for food and mates with wild populations. Because GE fish may also be more susceptible to diseases and parasites,^{vi} this will increase the likelihood that sick fish, parasites, and pathogens will enter local waterways and infect native fish populations.

Since this is the first application for GE salmon, the FDA should conduct a comprehensive environmental impact statement that goes far beyond what AquaBounty has prepared in support of its application. AquaBounty limits its assessment to its proposed operations in Canada and Panama. At the same time, the company has revealed plans to expand operations to the U.S.

[ABT: AquaBounty has been entirely truthful in its application and in its public statements. Yet the firm is being attacked with 10-year-old misleading quotes, inaccurate references, misrepresented scientific citations and hyperbole. During the VMAC discussions, AquaBounty and FDA described the process by which additional facilities will be approved.]

FDA should assess the extent to which a successful GE salmon operation might lead to the proliferation of such facilities and the overall risks of escaping GE salmon if the U.S. pursues this path. This type of comprehensive analysis ahead of development is imperative since the FDA can extend an original drug approval to cover new manufacturing facilities with little or truncated public process and environmental review.^{vii}

Given this range of concerns, the FDA must not rush the approval process for AquAdvantage salmon.

[ABT: FDA has been reviewing AquAdvantage data for more than 10 years. To represent this as a “rush to judgment” is a disservice to FDA, to the firm and to the general public. The assertions in this letter do not reflect the facts, the history of the application or the “science behind the product”. The allegations of this letter are without basis in fact, and the representation is wholly unfair to and disrespectful of FDA.]

How FDA approaches this first request for approval of a GE animal for mass production and human consumption will set a precedent for future GE animal applications, including both fish and land animals. The risks to the viability of wild Atlantic salmon and biodiversity are too great to proceed without full identification and mitigation of genetic and environmental risks.

Sincerely,

Rebecca Wodder
President
American Rivers

Margie Alt
Executive Director
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Vikki Spruill
President & CEO
Ocean Conservancy

Carroll Muffett
President & CEO
**Center for Int'l Environmental
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- i McGinnity, P., P. Prodöhl, A. Ferguson, R. Hynes, N. O Maoiléidigh, N. Baker, D. Cotter, B. O'Hea, D. Cooke, G. Rogan, J. Taggart & T. Cross. 2003. Fitness reduction and potential extinction of wild populations of Atlantic salmon, *Salmo salar*, as a result of interactions with escaped farm salmon. *Proceedings of the Royal Society B: Biological Sciences* 270(1532): 2443–2450.
- ii Howard, R.D., J.A. DeWoody & W.M. Muir. 2004. Transgenic Male Mating Advantage Provides Opportunity for Trojan Gene Effect in a Fish. *Proceedings of the National Academy of Sciences* 101.9.
- iii Devlin, R.H., M. D'Andrade, M. Uh & C.A. Biagi. 2004. Population effects of growth hormone transgenic coho salmon depend on food availability and genotype by environment interactions. *Proceedings of the National Academy of Sciences* 101:9303–9308.
- iv Committee on the Biological Confinement of Genetically Engineered Organisms, National Research Council. Biological Confinement of Genetically Engineered Organisms. Rep. National Academies, 2004. Page 35.
- v Kaufman, M. "Frankenfish' or Tomorrow's Dinner?; Biotech Salmon Face a Current of Environmental Worry." *Washington Post* 17 Oct. 2000.
- vi McKie, R. 2010. "Why the Case for GM Salmon Is Still Hard to Stomach." Latest News, Comment and Reviews from the Guardian. *The Guardian* (27 Aug.). Online: <http://www.guardian.co.uk/environment/cif-green/2010/aug/27/gm-fish-meat-environment>.
- vii 21 U.S.C. § 356a(c); 21 C.F.R. § 514.8(b)(3).