

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. 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. 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 AquaAdvantage salmon pose a threat to wild salmon populations and the health of marine and freshwater ecosystems around the world.

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 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.

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. 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. 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. 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. 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,

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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).