

American Anti-Vivisection Society • Farm Sanctuary • Born Free USA • Animal Place • Physicians Committee for Responsible Medicine • Kindred Spirits • National Anti-Vivisection Society • In Defense of Animals • Woodstock Farm Animal Sanctuary • New England Anti-Vivisection Society • World Society for the Protection of Animals

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Ms. Aleta Sindelar
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Food and Drug Administration
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RE: **Docket No. FDA-2010-N-0001**, VMAC Meeting on approval of AquaAdvantage genetically engineered salmon

We, the undersigned animal protection organizations, representing nearly one million members and supporters across the United States, are writing to express our opposition to the approval of Aqua Bounty's AquaAdvantage salmon genetically engineered for faster growth.

We are particularly concerned about the impacts that production of AquaAdvantage salmon have on animal health and welfare. As part of the New Animal Drug Application (NADA) for the AquaAdvantage salmon, Aqua Bounty is required to demonstrate the safety of its genetic modification to the animals involved. However, it is not possible to assess animal health impacts when fish who are severely deformed or unhealthy are precluded from the study, samples involve just 6-12 fish, and very limited data are collected.

The little data that are provided, however, clearly indicate that fish reared in aquaculture facilities, which are intensive confinement systems used to factory farm fish, are prone to abnormalities, more susceptible to disease, and have low rates of survival. The AquaAdvantage salmon fare no better, and possibly worse, in these conditions.

The adverse outcomes experienced by AquaAdvantage salmon are particularly concerning given research that demonstrates that fish experience pain, fear, and distress. The importance of assuring the well-being of these animals should not be dismissed.

We are further concerned about the FDA's regulatory process for genetically engineered animals. The FDA cannot adequately address the risks associated with genetically engineering animals, particularly the animal health and welfare concerns, using the New Animal Drug (NAD) rubric. The FDA's attempt to apply the NAD rubric to AquaAdvantage salmon is especially flawed, employing faulty logic, overlooking several factors that impact animal health, and failing to specify requirements to minimize risks. The AquaAdvantage salmon application

does not meet the standards of a traditional NADA and furthermore sets a dangerous precedent for future applications involving genetically engineered animals.

We are enclosing with this letter a document, “Humane and Animal Health Concerns Related to AquAdvantage Salmon,” that details our concerns as outlined above. On the basis of these concerns, and those shared by numerous other stakeholders, we request that the application for approval of AquAdvantage salmon be denied. We further request that the FDA discontinue review of any other applications for genetically engineered animals under the New Animal Drug rubric.

Sincerely,

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Humane and Animal Health Concerns Related to AquAdvantage Salmon (Genetically Engineered Atlantic Salmon produced by Aqua Bounty)

Background

Aqua Bounty Technologies, Inc. has genetically engineered Atlantic salmon to grow faster than normal. The GE salmon (AquAdvantage salmon) are intended to be raised in aquaculture facilities, which are essentially highly intensive factory farms for fish.

The AquAdvantage salmon contain a growth hormone gene from Chinook salmon under the control of regulatory sequences derived from ocean pout. In addition, they have undergone procedures to induce triploidy (containing three sets of chromosomes rather than the normal two sets) to reduce fertility.

Aqua Bounty has applied to the FDA for approval to grow the AquAdvantage salmon commercially. If approved, the AquAdvantage salmon would be the first genetically engineered animals to be sold as food for human consumption.

The AquAdvantage salmon is only one of several GE animals nearing approval. Aqua Bounty has several other GE fish in the pipeline, and other companies have also filed applications with the FDA for approval of other GE animals. Many of these GE animals have been designed to facilitate factory farming.

The EnviroPig, a pig genetically engineered to produce less phosphorous in its waste, and cows genetically engineered to be resistant to mad cow disease are among the GE animals in development. Goats genetically engineered to produce a blood clotting pharmaceutical, ATryn, in their milk have already received approval from the FDA.

The FDA currently regulates genetically engineered animals as “drugs” using the New Animal Drug rubric. Specifically, the FDA considers the rDNA construct in the genetically engineered animal to meet the definition of a “drug,” as it is an article that is intended to alter the structure or function of an animal.

There are numerous shortcomings with the FDA’s use of the New Animal Drug rubric to regulate genetically engineered animals. Animal health and welfare, in particular, are not adequately considered.

The New Animal Drug Application for the AquAdvantage salmon, and the FDA’s assessment of the NADA, raise numerous concerns regarding animal health safety and the FDA regulatory process.

Aqua Bounty’s studies are highly limited, poorly designed, and inadequate to demonstrate safety, while also providing indications that AquAdvantage salmon are indeed frequently malformed and have low survival rates.

Nevertheless, the FDA appears to accept Aqua Bounty’s data uncritically, warping the data to fit with what appears to be a foregone conclusion to support approval of AquAdvantage salmon.

GE Salmon – Animal Health

Contrary to their claims, Aqua Bounty and the FDA have failed to demonstrate that Aqua Bounty's proposed genetic modification to Atlantic salmon is safe for the animals.

To understand how the health of fish is affected by the proposed genetic modification, it is important to know if the GE fish are more likely to experience health problems, require medical intervention, or die prematurely than conventionally farmed fish.

The impacts associated with the genetic modification itself (both intended and unintended), as well as the impacts associated with the attempts to establish the GE line, need to be considered.

Aqua Bounty's studies are poorly designed and incapable of detecting differences in adverse outcomes between the genetically engineered AquAdvantage salmon and non-GE salmon. Limited data were collected, sample sizes were very small (only 6-12 animals in the main study), and the most severely deformed and unhealthy animals were excluded from the studies.

Nevertheless, the data indicate that AquAdvantage salmon are unhealthy animals, experiencing high rates of abnormalities and mortality, which are made worse by the induction of triploidy and aquaculture practices used for commercial production.

The production of AquAdvantage salmon is also associated with a large loss of animal life due to excessive, on-going culling to remove unhealthy individuals, "non-performing" individuals, and "excess inventory."

The FDA has failed to consider the implications of these findings for animal health and welfare, concentrating instead on only the implications for commercial viability. According to the FDA's reasoning, deformed, unhealthy, or culled fish are inconsequential since they would likely be excluded from the food supply.

The data indicate that certain aquaculture conditions, procedures, or genetic crosses may increase the occurrence of adverse outcomes, but the FDA has failed to specify standards to promote animal health and minimize adverse outcomes.

The FDA has also failed to consider the large numbers of animals who are used in the process of producing the AquAdvantage line of genetically engineered fish.

The FDA makes conclusions asserting the health of AquAdvantage salmon that are unsupported by the data and without any statistical analysis.

GE Salmon – Regulatory Process

Application of the New Animal Drug rubric to the regulation of genetically engineered animals does not adequately address all the concerns associated with this technology.

Use of the NAD rubric is akin to trying to fit a square peg into a round hole. A genetic modification is conceptually different from a drug.

The NAD rubric is particularly ill-suited for handling impacts to animal health and welfare associated with genetic engineering.

The FDA does not even meet the standards and requirements of a normal drug approval for demonstrating animal safety when applying the NAD rubric to genetically engineered animals.

The FDA does not consider the animal health impacts associated with “administration of the drug,” i.e., the production of the genetically engineered line of animals, even though this uses a substantial number of animals and abnormalities are common.

The FDA only evaluates those animals who would enter commerce, even though a greater number of animals contain the “drug,” and those animals excluded from commerce are most likely to be unhealthy in some way.

The FDA has not demonstrated concern for individual animals or their welfare when evaluating NADAs for genetically engineered animals. Animal health has been a concern only to the degree that it affects the marketability of the animals or human food safety.

Typically, a drug is designed to provide some benefit to animal health, against which the FDA would weigh potential risks. Genetic modifications, at least the kind under evaluation with the AquAdvantage salmon, do not benefit the animal in any way. The FDA has not indicated how it can make approval decisions for a drug that has no benefit but does carry risk of harm.

The New Animal Drug regulatory process is confidential, providing little to no opportunity for broad, informed public participation in the decision-making process.

Data on the AquAdvantage salmon were provided at the discretion of the FDA and only made available to the public two weeks prior to the advisory committee meeting. After 10 years of review, the FDA has provided only 1.25 hours for public comment on the approval of the AquAdvantage salmon.

There are no requirements that data be provided and public input be solicited prior to approvals of future applications of genetically engineered animals.

The FDA has reserved the right to waive the NADA requirements entirely for certain genetically engineered animals.

GE Salmon – Aquaculture

Developed for rapid growth rate, AquAdvantage salmon support the industrial farming model and promote intensive confinement in U.S. aquaculture.

Aquaculture is the fastest growing agriculture industry worldwide, with nearly half of fish consumed globally raised on factory farms.¹

High stocking density and other adverse conditions in aquaculture are known to cause significant welfare implications for fish, including increased aggression, injury, disease and distress.²

Modern aquaculture also creates negative environmental conditions for fish, including poor water quality, inadequate nutrition, improper lighting and unsuitable water temperatures.³

The FDA's limited evaluation concludes that husbandry conditions for AquAdvantage salmon are consistent with those in commercial freshwater aquaculture facilities, despite the significant welfare concerns associated with existing facilities.

Scientists studying the welfare of fish in modern aquaculture facilities conclude that a review of conditions and husbandry practices must be species specific.⁴ However, the FDA's study merely compares GE salmon to normal Atlantic salmon under industrial fish farming conditions without taking into consideration differences between the fish.

Because AquAdvantage salmon grow larger twice as fast, mere comparison with normal Atlantic salmon in aquaculture facilities is insufficient and unlikely to produce an accurate reflection on the fish's health and welfare.

The FDA should not merely accept the similarities between GE salmon and normal salmon under factory farming conditions. Review procedures should also evaluate those conditions specific to AquAdvantage salmon and set appropriate standards specific to the fish.

Scientists warn that GE salmon farming would require extensive administration of antibiotics, because transgenic fish may be more susceptible to disease, and would add to the already existing risks of drug-resistant bacteria and viruses associated with animal agriculture.⁵

Approval of Aqua Bounty's application will likely increase the number of fish maintained in intensive confinement in the U.S. and abroad. The effects of GE salmon approval on aquaculture systems must be considered.

¹ Rosamond L. Naylor et al, *Feeding Aquaculture in an Era of Infinite Resources*, 9 PROC. NAT'L ACAD. SCI. 15103 (Sept. 8, 2009); U.S Dep't Agric. Econ Res. Serv., *U.S. Seafood Market Shifts to Aquaculture*, AMBERWAVES (Apr. 2004).

² T. Håstein, *Animal Welfare Issues Relating to Aquaculture*, in Global Conference on Animal Welfare 219 (Feb. 2004).

³ *See id.*

⁴ Scientific Opinion of Panel on Animal Health and Welfare, *General Approach to Fish Welfare and the Concept of Sentience in Fish*, 954 EUR. FOOD SAFETY AUTHORITY J. 1, 6 (Jan. 29, 2009).

⁵ William Muir et al., *Possible ecological risks of transgenic organism release when transgenes affect mating success*, 96 PROC. NAT'L ACAD. SCI. 13853 (Nov. 23, 1999); Rebecca Goldberg, *Murky Waters: The Environmental Effects of Aquaculture in the U.S.* 44, Env'tl. Defense Fund (1997).

GE Salmon – Fish Sentience

The high incidence of health problems and mortality experienced by AquAdvantage salmon is concerning given current research on fish sentience, which has demonstrated that not only do fish experience pain, fear, and stress, they are also capable of learning and retaining information.⁶

A report by the Animal Health and Welfare Panel in Europe concludes that there is sufficient evidence demonstrating that fish experience pain, fear and distress and that the brain structures of fish indicate they are likely sentient.⁷

Scientists conclude that the concept of welfare for fish is the same as for mammals and birds and that welfare protections for fish should be adequately considered.⁸

Studies comparing fish in natural settings to those on fish farms indicate sentience and suggest adverse emotional, behavioral and physical response to stressors inherent on fish farms.⁹

Natural swimming, feeding, anti-predatory and reproductive behaviors are often lacking in fish raised in aquaculture facilities.¹⁰ Factory farmed fish exhibit chronic stress responses including reduced immune function, growth and reproduction and increased death, similar to responses observed in mammals and birds in agriculture.¹¹

The Animal Health and Welfare Panel report recommends that despite limited research on fish sentience currently available, enough information exists to require that welfare indicators for fish should be “species-specific, validated, reliable, feasible and auditable.”¹²

Based on the existing evidence demonstrating fish sentience, the FDA’s regulatory process of evaluating AquAdvantage salmon as NADs is inappropriate. Evaluation of Aqua Bounty’s application should encompass the health and welfare of fish beyond the extent of commercial fitness and human food safety.

⁶ Lucy Odling-Smee, *The Role of Learning in Fish Orientation*, 4 FISH & FISHERIES 235 (2003).

⁷ Panel on Animal Health and Welfare, *supra* note 4.

⁸ *Id.*

⁹ T. Håstein, *supra* note 2, at 219-23.

¹⁰ Panel on Animal Health and Welfare, *supra* note 4, at 8.

¹¹ *Id.*

¹² *Id.* at 9.