American Anti-Vivisection Society

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Division of Dockets Management (HFA 305)
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

Re: Docket No. FDA2010N0385 Food Labeling; Labeling of Food Made from AquAdvantage Salmon; Public Hearing; Request for Comments

The American Anti-Vivisection Society is opposed to the approval of the New Animal Drug Application for the AquAdvantage salmon (Docket No. FDA-2010-N-0001), which has been genetically engineered to grow faster than normal and is intended for use in aquaculture facilities. AAVS, founded in 1883, was the first non-profit education and advocacy organization in the U.S. established to monitor and expose problems with animal experimentation.

Please see the attached document for an explanation of why AAVS thinks the AquAdvanatge salmon should not be approved, and why, if it is somehow approved, it must be labeled. Included is an overview of our key points, as well as sections that provide greater detail on the animal health concerns, problems with the regulatory process, poll data in support of labeling, and the impact of aquaculture practices on animal welfare.

We are also including a separate document, "AquAdvantage Genetically Engineered Salmon: Questions on Animal Health and Welfare," that lists our major questions about the AquAdvanatge salmon New Animal Drug Application that the FDA has not yet addressed.

Sincerely,

Nina Mak, M.S.
Research Analyst, AAVS

AquAdvantage GE Salmon: Animal Health

Nina Mak, AAVS
Nov. 2010

Key Points

1. The AquAdvantage GE salmon should not be approved, particularly because of concerns about animal health and safety. From the limited data provided by Aqua Bounty, it is clear that GE fish are not always healthy and normal. There is evidence that AquAdvantage GE salmon are frequently deformed and have jaw erosions, have visible inflammation and lesions, and are more susceptible to disease, leading to high rates of mortality. This raises concerns about animal health and welfare, food safety, and environmental risks if the fish escape. (See Animal Health section for more info.)

2. AquAdvantage salmon are intended to be raised in aquaculture factory farms, which is expected to worsen their health and would lead aquaculture farmers to administer large quantities of antibiotics and vaccines to curb the spread of illness. (See Aquaculture section for more info.)

3. Aqua Bounty failed to demonstrate that producing AquAdvantage salmon is safe. It is not sound science to make conclusions about health and safety based on examining just 6-12 relatively healthy fish during a 2-week period. Unhealthy fish were excluded from the study, and even the FDA admitted that it was not possible to make any strong conclusions from this study. Several members of the FDA's Veterinary Medicine Advisory Committee also said they did not feel confident that it is safe to produce the AquAdvantage salmon. (See Animal Health section for more info.)

4. The Aqua Bounty GE salmon will set a precedent for how other GE animals will be approved. There are already several other GE animals in the pipeline, include GE pigs and GE cows. It is important that appropriate standards are set for protecting animal health, consumers, and the environment. The FDA's approach to regulating GE animals as New Animal Drugs is wholly inadequate and new regulations are needed to address concerns. (See Regulatory Process section for more info.)

5. If, somehow, the AquAdvantage salmon are approved, they absolutely must be labeled as "genetically engineered salmon." Consumers have made it clear that they care how their food is produced, particularly how animals are raised and treated. According to a Demeter Communications 2010 poll, 81% of consumers consider labels important for providing information on how a food is produced, and 68% would like labels to provide more information about animal care. Consumers are not interested in raising unhealthy, deformed animals on factory farms. (See Poll Data section for more info.)

6. Consumers are particularly interested in knowing if their food is genetically engineered: In poll after poll, 95% of Americans say they want GE fish to be labeled, and more than half of consumers absolutely would not buy GE fish. Whether or not fish is genetically engineered is a piece of information that is materially important to consumers and would affect their purchasing decisions. (See Poll Data section for more info.)

7. Consumers should not be tricked or forced into buying GE fish when they do not want to. The label "genetically engineered salmon" is factual, disclosing relevant information that is important to consumers. It is not inherently a warning label. The fact that the biotech industry perceives it that way underscores the fact that they are afraid that consumers would not willingly and knowingly buy GE salmon, and that GE salmon could only be sold if consumers could not tell they were buying it. Normal market forces should be allowed to play out, and consumers should be allowed to "vote with their dollars" to indicate their demand, or lack thereof, for GE fish.

Background Information

1. The AquAdvantage salmon is a genetically engineered fish intended to be sold for food.

- 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 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 (to contain 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.

2. The AquAdvantage salmon application sets a precedent and, if approved, would open the door to numerous other factory farmed GE animals.

- 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.

3. GE animals are regulated as drugs.

- 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.
- A New Animal Drug must be evaluated for its safety to the animals receiving it, the safety of any food derived from those animals, risks to the environment, and its effectiveness.

Animal Health Concerns

1. GE salmon are susceptible to deformities and disease, and experience high rates of mortality.

- While Aqua Bounty provided very limited, highly flawed data on the health of AquAdvantage GE salmon, the data do provide evidence that GE 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.
- AquAdvantage salmon experience "increased frequency of skeletal malformations, and increased prevalence of jaw erosions and multisystemic, focal inflammation," according to the FDA's own assessment. (VMAC Briefing Packet, P. 43)
- Ten of 12 adult AquAdvantage salmon studied had external abnormalities, and AquAdvantage salmon had over 30% more slight-moderate abnormalities than comparators in three of the five year-classes studied. (VMAC Briefing Packet, P. 25, 28)
- Less than half of AquAdvantage salmon survived in 8 of 15 groups studied. In only one group did more than 90% survive, while in another group, all but 2% of AquAdvantage died prematurely. (VMAC Briefing Packet, P. 32)
- AquAdvantage salmon are more likely to have inflamed tissues and lesions, and succumbed to disease sooner than comparators in one study, indicating that the GE salmon may be more susceptible to disease. (VMAC Briefing Packet, P. 38-41)
- Certain aquaculture conditions, procedures, and genetic backgrounds may increase the occurrence of health problems, but the FDA has failed to specify standards to promote animal health and minimize adverse outcomes. (VMAC Briefing Packet, P. 21-46; P. 30)
- Many fish are killed during the production of AquAdvantage salmon due to excessive, on-going culling to remove unhealthy individuals, "non-performing" individuals, and "excess inventory." In addition, entire lots of fish (numbering in the thousands at least) would be destroyed if they are found to be "out of specification." (VMAC Briefing Packet, P. 21, 26, 27, 31, 33, 59)
- Methods used to produce future generations of AquAdvantage salmon, including killing males to strip them of their milt (sperm) and treating fish with androgen hormone to induce sex reversal, raise additional concerns. (VMAC Briefing Packet, P. 52)

2. Aqua Bounty's studies are highly limited and poorly designed. As a result, the FDA's conclusion that genetically engineering AquAdvantage salmon is safe is completely unfounded.

- Fish who were severely deformed or unhealthy were precluded from the main study, only 6-12 relatively healthy fish were examined over a 2-week period, and very limited data were collected, making it impossible to assess impacts to animal health.

- No statistical analyses were performed to support the FDA's conclusions.
- Paradoxically, the FDA acknowledged that "...significant morbidity and mortality could be masked as a result of the rigorous culling practices..." (VMAC Briefing Packet, P. 36-37), and that it was not possible to draw any strong conclusions from the study. (VMAC Meeting Transcript, Sept. 20, 2010, e.g., P. 193, 194)

3. Several important gaps in the data on AquAdvantage salmon preclude making a complete assessment of animal health. The following data are lacking:

- Incidence of health problems, deformities, disease, medical treatment or intervention (e.g., with antibiotics), and premature death at all life stages and through the animals' entire lifespan.
- Impact of environmental conditions and genetic background on the effects of the genetic modification and animal health.
- Number, health, and fate of animals used to produce initial founder animal as well as subsequent generations.

Regulatory Process Problems

1. No approvals for genetically engineered animals should be granted using the New Animal Drug Application (NADA) regulatory process.

- Use of the NADA rubric is akin to trying to fit a square peg into a round hole. A genetic modification is conceptually different from a drug and raises novel issues.

2. The NADA process is limited in its ability to address animal health concerns associated with producing GE animals.

- 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 to the animals.
- The FDA does not consider the animal health impacts associated with production of the genetically engineered line of animals, i.e., "administration of the drug," even though this uses large numbers of animals and abnormalities and high mortality rates 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 reserved the right to waive the NADA requirements entirely for certain genetically engineered animals.

3. The FDA's review of the AquAdvantage GE salmon demonstrates the inadequacies of using the NADA rubric to regulate GE animals.

- The AquAdvantage salmon application does not meet the standards of a traditional NADA for demonstrating animal safety and sets a dangerous precedent for future applications involving GE animals. (See Animal Health section for more info.)
- The FDA has said that, instead of fully examining the health of GE salmon before granting approval, it will instead rely on post-market surveillance to determine the rate of health problems.
- Despite the FDA's statutory responsibility to ensure animal health safety, the health of GE animals has been a concern only to the degree that it affects the marketability of the animals or human food safety. The FDA has not demonstrated concern for individual animals or their welfare when evaluating NADAs for GE animals.

- The FDA has not indicated that it would be willing to withhold approval due to animal health problems that do not impact food safety, and has not required measures to promote animal health or minimize adverse outcomes.

4. The New Animal Drug regulatory process is confidential, allowing companies to withhold important information from the public, and 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 select data were made available to the public just two weeks prior to the public advisory committee meeting.
- After 10 years of review, the FDA 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.

5. An appropriate regulatory framework for GE animals (unlike the NADA framework) would:

- consider the health of all animals involved in producing the GE animals intended for commerce over their entire lifespan;
- demonstrate concern for animal health irrespective of its impact on food safety or marketability;
- provide a mechanism for weighing harms to individual animals and populations against benefits;
- provide a forum for considering ethical concerns;
- solicit broad public participation;
- involve key stakeholders;
- make use of appropriate experts, including representatives of animal welfare, without financial conflicts of interest; and
- be transparent.

Poll Data on Food Production Practices and Labeling

1. How a food is produced, in particular how animals are raised for food, is materially important to an overwhelming majority of consumers and affects their purchasing decisions. Consumers look primarily to labels on food for information on how it is produced.

- 81% of indicator consumers considered labels important or very important as a source of information regarding how a particular food is produced. 68% of consumers said they agree or strongly agree that they would like to know more about "ways to ensure animal care." (Demeter Communications SegmenTrak study, 2010: http://demetercommunications.com/wp-content/uploads/2010/04/REVFINAL.SegmenTrakExecSummary.4.28.10.pdf)
- 69% of consumers said they were willing to pay more for food that promises to be produced to higher ethical standards, with 57% willing to pay up to 10% more, and 12% willing to pay even more. 91% of consumers said that for a food to be considered ethical, inhumane treatment of animals had to be avoided. (Context Marketing Ethical Food Poll, 2010: http://contextmarketing.com/sources/feb28-2010/ethicalfoodreport.pdf)
- 68% of Americans said the humane treatment of farm animals raised for food is important to them. (Harris Interactive survey for WSPA's Finding Animal Friendly Food report, 2007: http://www.wspa-usa.org/pages/2501_download_grocery_store_report.cfm)

2. Whether a food is produced through genetic engineering is materially important to almost all consumers and affects their purchasing decisions.

- 95% of consumers think that food products made from genetically engineered animals should be labeled as such. 71% of consumers would not buy milk or meat products from genetically engineered animals if it were available. (Consumer Reports National Research Center Food-Labeling Poll, 2008: http://www.greenerchoices.org/pdf/foodpoll2008.pdf)
- 50-84% of consumers would not buy or eat GE salmon if it is approved by the FDA, according to numerous online polls done by news organizations following the FDA announcement that the agency is considering approving the GE fish. Several of these polls also reported that 95% of consumers would want GE food labeled. (For a list of polls on GE fish, see http://ge-fish.org/policy-comments/polls-on-genetically-engineered-fish/)

Aquaculture and Animal Welfare

1. Current research on fish sentience has demonstrated that not only do fish experience pain, fear, and stress, they are also capable of learning and retaining information. (Lucy Odling-Smee, *The Role of Learning in Fish Orientation*, 4 Fish & Fisheries 235 (2003))

2. Developed for rapid growth, AquAdvantage GE salmon support the industrial farming model and promote intensive confinement in U.S. aquaculture and abroad, negatively impacting animal health and welfare.

- Negative environmental conditions for fish raised in aquaculture, such as high stocking density, poor husbandry practices, poor water quality, inadequate nutrition, improper lighting, and unsuitable water temperatures, are known to have significant welfare implications, including increased aggression, injury, disease, and distress. (T. Hastein, *Animal Welfare Issues Relating to Aquaculture*, *in* Global Conference on Animal Welfare 219 (Feb. 2004))
- Natural swimming, feeding, anti-predatory and reproductive behaviors are often lacking in fish raised in aquaculture facilities. Factory farmed fish exhibit chronic stress responses including reduced immune function, growth, and reproduction and increased death. (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))

3. Raising GE fish under aquaculture conditions can further worsen the health problems they experience.

- 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. (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, Envtl. Defense Fund (1997))