



THE CENTER FOR FOOD SAFETY

August 1, 2011

Dr. Bernadette Dunham
Director
Center for Veterinary Medicine
Food and Drug Administration

Cc: President Barack Obama

Secretary Kathleen Sebelius, U.S. Department of Health and Human Services
Dr. Margaret A. Hamburg, Commissioner, U.S. Food and Drug Administration
Dr. Jane Lubchenco, Administrator, National Oceanic and Atmospheric Administration
Nancy Sutley, Chair, U.S. Council on Environmental Quality
Daniel M. Ashe, Director, U.S. Fish and Wildlife Service
Dr. Larissa Rudenko, Center for Veterinary Medicine, FDA

Attached: Moreau et al. (2011); Pennington, K.M. and A.R. Kapuscinski (2011).

RE: Additional Comments; New Scientific Materials on Risks of GE Salmon Must be Considered

Dear Members of the Veterinary Medicine Advisory Committee and FDA:

The Center for Food Safety respectfully submits additional comments to the U.S. Food and Drug Administration (FDA) and its Veterinary Medicine Advisory Committee (VMAC) on Docket ID. FDA-2010-N-0001-0094. Newly released scientific studies indicate that genetically engineered (GE) growth enhanced salmon are able to and will breed with wild salmon in the event of intended or unintended release. To date the issue of genetic contamination of wild species has not been studied in papers released by either the FDA or AquaBounty Technologies. FDA's announcement regarding GE salmon is the first of its kind, for any GE food animal. FDA and the VMAC recognize that whether or not to approve the first GE animal for use as food is a critical and precedent-setting decision. As such, it would be arbitrary and capricious for the agency not to take fully into account this new scientific information. Please see below a brief summary of the Center's concerns to date and the new scientific information available to the agency.

Background

On August 25, 2010, 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 (AA Salmon) produced by AquaBounty Technologies. We testified at both of the public meetings the FDA held in September to discuss the AA Salmon. The first FDA meeting convened the Veterinary Medicine Advisory Committee (VMAC) on September 19-20 to consider issues regarding the safety and effectiveness of the transfer of genes from two fish species into an Atlantic salmon as a "new animal drug" (NAD) that is the subject of the GE fish new animal drug application (NADA).¹ Unlike other animal drugs, which are expected to be at negligible levels before the food is consumed by humans, these new "drugs" are designed to remain in every cell of the animal while it is eaten. The

second meeting was a public hearing on September 21 to present the public with FDA's existing legal framework for food labeling, and to receive public input on whether food from GE Salmon should be labeled.²

Regrettably, the decision-making process chosen by FDA failed to provide the public with sufficient time or available data that would have allowed for full and meaningful participation prior to the VMAC and labeling meetings. The exceedingly short timelines for public comment were exacerbated by the lack of transparency. AquaBounty filed a New Animal Drug (NAD) application for AquaAdvantage salmon with FDA in 2001, yet the agency chose not to disclose any data relating to its decision until just 10 working days before the public meeting.

Food Safety and Environmental Data Gaps

The data FDA provided to the public on food safety is altogether deficient given that the FDA has had 10 years to review the product. Additionally, the Environmental Assessment (EA), a less comprehensive review than an Environmental Impact Statement, compiled by AquaBounty for the FDA is inherently flawed and does not take into account the full and broad range of impacts the approval of the GE salmon will have on the environment. The study on changes in the morphology of the new GE salmon involved only 12 fish. The limited study on possible allergic reactions involved only six fertile GE fish and six infertile fish. The fact that such an inadequate study still found possible allergic reactions from the fertile GE fish argues for a much larger study and a full review of the potential health and safety problems with these fish before they are grown commercially.

The VMAC raised a number of concerns surrounding inadequate sample sizes,³ incomplete data,⁴ questionable culling practices,⁵ troubling physical abnormalities,⁶ and poor environmental and scientific assessments.⁷ Speaking to the general safety of the GE fish, one Committee member state, "I do not have adequate information to give an answer that -- to be able to answer that the data cause me to believe that it is safe."⁸ This was followed by his colleague who said "the short answer as a professor is I don't know." In light of the numerous unknowns raised throughout the Sep. 19-20 meeting, FDA officials announced that any approval would require post-market review and data requirements. Yet the VMAC expressed its concerns with FDA's plan to require post-market reviews as sufficient for gaps in current safety data. Post-market review is not an adequate substitution for proper regulation and safety assessments. Moreover, it is completely impossible without labeling at every step of the production and consumption chain.

Environmental and Human Health Impacts

FDA announced at the VMAC meetings that the EA provided to the public and the VMAC was merely a draft. FDA said it plans to publish the final environmental assessment (EA) as well as issue a notice in the Federal Register establishing a 30-day public comment period on the EA. However, the current EA is very narrow in focus and if by approval of supplemental application the FDA opens the door to open water pens at a later date, transgenic salmon will be among the millions of salmon that currently escape every year, possibly delivering the final blow to wild salmon stocks and concomitantly the thousands of men and women who depend on salmon fishing for their livelihoods. Similarly, salmon are a species that travels between inner waters and ocean waters, so "inland water" containment will present novel threats to our nation's lakes, rivers, and estuaries, many of which are already under attack by invasive fish species like the Asian carp and Northern snakehead. Approving genetically engineered salmon is a sharp contradiction to the agreements the United States has signed at the meetings of the North Atlantic Salmon Conservation Organization (NASCO), where transgenic salmonids are considered a serious threat to wild salmon.

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 salmon into a wild population of 60,000 would lead to the extinction of the wild population in less than 40 generations. While the company claims it will produce only sterile fish, the data FDA shared show that up to 5% of the fish will be fertile and able to reproduce. In 2002, the National Academy of Sciences issued a report saying that GE fish could cause significant environmental and food safety problems.⁹ More recently, a 2009 study commissioned by the European Union revealed that fish engineered to grow faster have a resultant high tolerance to environmental toxins.¹⁰ The study's authors expressed concerns that both toxins and growth hormones had a

high potential to end up in consumers' bodies, calling for further tests to determine safety. Dr. Gary Thorgaard, the only member of the VMAC with expertise on fisheries, called on FDA to conduct a full Environmental Impact Statement, a sentiment echoed by other members of the Committee during the public meeting.

The scientific data reviewed by FDA were developed by the company-applicant that has engineered the fish. Numerous concerns were raised by both FDA and the VMAC,¹¹ including inadequate safety testing, incomplete safety data,¹² questionable culling practices,¹³ troubling physical abnormalities,¹⁴ and poor environmental and scientific assessments.¹⁵ Some of the test results consisted of too-small sample sizes – as few as six fish – and reliable conclusions cannot be drawn from the tests.¹⁶ Furthermore, the standard for scientific reviews – random sampling – was not used; instead, healthy looking fish were deliberately chosen and deformed fish were culled from the analysis.

Pennington and Kapuscinski Study

In its briefing packet for the VMAC, FDA noted that the fish studied were raised at Prince Edward Island, while the actual planned location to raise the fish is in Panama. The agency concluded that “the culture (e.g., water temperature, pH, alkalinity, etc.) were likely to be significantly different from the facility at PEI as a result of differences in, among others, water surface, facility design, and environmental factors due to geographic location....**the effect of the difference between the PEI and Panama facilities, especially temperature, on the resulting AquaAdvantage phenotype is unknown.**” This point is even more relevant in light of a recent study published by Kelly M. Pennington and Anne R. Kapuscinski¹⁷ that focuses on developing risk assessment approaches that incorporate the genetic backgrounds and environmental conditions that are likely factors in a real escape of GE fish. This study stresses the importance of testing likely environmental conditions rather than merely extrapolating results from unrelated scenarios – something FDA properly criticized AquaBounty for.

Moreau et al. Study

The risks of genetic contamination of wild stocks has been raised numerous times by members of the public, VMAC, scientific community and Congress. In a recently released study, Canadian researchers concluded that if GE Atlantic salmon were to escape from captivity they could succeed in breeding and passing their genes into the wild.¹⁸ The authors note:

This study provides the first empirical observation on the breeding of and potential for transgene introgression by GH transgenic male Atlantic salmon, including that of alternative reproductive phenotypes... Although transgenic males displayed reduced breeding performance relative to non-transgenics, both male reproductive phenotypes demonstrated the ability to participate in natural spawning events and thus have the potential to contribute genes to subsequent generations.¹⁹

In the current absence of company-applicant data on mating abilities of its AquaAdvantage salmon, FDA should use the Moreau et al. study as an indicator that breeding between wild and GE salmon can occur and therefore should be taken into account as a foreseeable risk in its evaluation.

Conclusion

FDA has maintained unbroken silence on the status of the AquaAdvantage salmon application after its public meeting in September. In the absence of agency dialogue, it would be arbitrary and capricious for the agency not to take fully into account this new scientific information.

Respectfully submitted,

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- ¹ Federal Register / Vol. 75, No. 165 / Thursday, August 26, 2010 / Notices/ pp. 52605. (Public VMAC Meeting)
- ² Federal Register / Vol. 75, No. 165 / Thursday, August 26, 2010 / Notices/ pp. 52602. (Public Meeting on Labeling)
- ³ Veterinary Medicine Advisory Committee Meeting Transcript, Center for Veterinary Medicine, Food and Drug Administration. Recorded by Audio Associates at the Double Tree Hotel in Rockville, MD, Sept. 20, 2010, p. 193, 351.
- ⁴ Transcript p. 168, 170, 187.
- ⁵ Transcript p. 170, 173.
- ⁶ Transcript p. 92, 343, 354, 359, 386.
- ⁷ Transcript p. 86, 336, 337, 340, 341, 343, 355.
- ⁸ Transcript p. 343.
- ⁹ National Research Council of the National Science Foundation. (2002) "Animal Biotechnology: Science-Based Concerns." National Academies Press, Washington, D.C.
- ¹⁰ Centre for Aquaculture and Environmental Research. (2009) "Ecological Risk Assessment of Transgenic Salmon." Study commissioned by the European Union, the Swedish Research Council Formas and the University of Gothenburg. Vancouver, Canada.
- ¹¹ Veterinary Medicine Advisory Committee, Briefing Packet – AquAdvantage Salmon, at 26, *available at* <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM224762.pdf> (last visited Nov. 17, 2010). (Herein after "VMAC")
- ¹² Id at pg. 92, 343, 354, 359, 386.
- ¹³ Id at pg. 168, 170, 187.
- ¹⁴ Id at pg. 170, 173.
- ¹⁵ Id at pg. 86, 336, 337, 340, 341, 343, 355.
- ¹⁶ Id at pg. 26, 193, 351.
- ¹⁷ Pennington, K.M. and A.R. Kapuscinski (2011) "Predation and Food Limitation Influence Fitness Traits of Growth-Enhanced Transgenic and Wild-Type Fish." *Transactions of the American Fisheries Society*, 140:2, 221-234. (attached for your convenience)
- ¹⁸ Darek T. R. Moreau, Corinne Conway, Ian A. Fleming. (2011) "Reproductive performance of alternative male phenotypes of growth hormone transgenic Atlantic salmon (*Salmo salar*)." *Evolutionary Applications*, Blackwell Publishing, Ltd. (attached for your convenience).
- ¹⁹ Id at pg. 8