

September 15, 2012

The President
The White House
1600 Pennsylvania Ave NW
Washington D.C. 20500

Dear Mr. President:

We greatly appreciate the time and attention you and your Administration are giving to global food security. You have focused the entire world on this critical issue. From your comments on USDA's 150th anniversary celebration on May 15th, to the National Bioeconomy Blueprint to the Camp David Declaration, we support this effort.

In recent weeks, USDA has made a number of important regulatory decisions on plant biotechnology which we applaud. The current drought has brought home yet again the importance of doing all we can to follow modern technology and sound science when it comes to agriculture production. Seeds that are resistant to drought and require less water are critical to all of humanity.

Mr. President, we are writing today as a group of scientists, developers and investors to follow up and urge the Administration to make the same bold commitment to animal agriculture as it has to plant agriculture. A decision on genetically modified salmon has been pending at FDA for years. We are hoping you would urge the FDA to move forward on this important decision. The inexplicable regulatory bottleneck that has been encountered by the "AquAdvantage" salmon suggests that the FDA's science-based regulatory review process for the products of animal biotechnology has no predictable timeline and is holding up the development of an industry that promotes economic growth, innovation, competitiveness, and job creation in the United States.

The genetically modified salmon at issue reaches market weight in approximately half the time as does a conventional salmon. Approval would provide aquaculture farmers an environmentally sustainable land-based alternative to conventional net pen salmon farming. Faster animal growth translates to improved efficiency and a reduced environmental impact per pound of salmon produced. After well *over a decade* of scientific review and inquiry, the FDA in September, 2010 issued a detailed public report in which the agency concluded that the salmon was not only as safe to eat as any other salmon, but also indistinguishable from conventional Atlantic salmon¹.

¹ AquAdvantage Briefing packet. Food and Drug Administration, Center for Veterinary Medicine, Veterinary Medicine Advisory Committee. September 20, 2010
<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM224762.pdf>

The only remaining step precluding an FDA final decision on the salmon is the publication of an environmental assessment detailing the conditions under which AquAdvantage salmon could be grown so as to avoid any possibility of a negative impact on the marine environment, and to invite comments from the public that would be taken into account in a final ruling.

In May, 2012 the Commissioner of the FDA, Dr. Margaret Hamburg went on record as stating that the FDA would issue the environmental assessment (EA) “very soon”², indicating that the document had been reviewed and completed by the FDA. We therefore urge that the EA be published as soon as possible.

The Administration’s often-stated commitment to sound science will only ring true if it is followed up prompt regulatory action. Delay in the EA decision sends a chilling message to scientists, entrepreneurs and the investors who provide the required capital for this innovative industry. We are sensitive to the transformative nature of animal biotechnology but are concerned that the United States stands to lose this budding industry, with its many jobs, if the regulatory process is not based on peer-reviewed science.

Last year, Dr. Calestous Juma, professor at Harvard’s Kennedy School of Government and the former Executive Secretary of the United Nations’ Convention on Biological Diversity testified before Congress that *“It is not this particular fish that is at stake... it sends the message to the rest of the world that the science-based regulatory oversight as embodied in the FDA review process is subject to political intervention. Furthermore, it signals to the world that the United States may cede its leadership position in the agricultural use of biotechnology. . . I believe it is imperative that the United States stay the course it has set in not letting politics interfere with its science-based regulatory system that is truly the envy of the world”*³. It is for this reason that the pending decision is being watched by all of animal agriculture and the entire scientific community.

Therefore, we request that you instruct FDA to continue to the next step of the new animal drug regulatory review process as required by law and immediately publish the findings of its environmental risk assessment of the AquAdvantage salmon. Any further unexplained delay in moving forward with the regulatory process of this precedent-setting case diminishes existing and future investment and innovation across the entire range of agriculturally important animals. Animal biotechnologies have the potential to help address the challenges of food security at a time when the United States and the other countries of the world could greatly benefit from such innovation.

Thank you for your attention to this matter. There is much more at stake here than just a fish.

² Pollack, A. 2012. An Entrepreneur Bankrolls a Genetically Engineered Salmon. New York Times. May 21st, 2012. <http://www.nytimes.com/2012/05/22/business/kakha-bendukidze-holds-fate-of-gene-engineered-salmon.html?pagewanted=all>

³ C. Juma, 2011. Agricultural Biotechnology. Benefits, Opportunities and Leadership. <http://agriculture.house.gov/sites/republicans.agriculture.house.gov/files/pdf/hearings/Juma110623.pdf>

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