

September 17, 2014

The Honorable Barack Obama
President of the United States
The White House
1600 Pennsylvania Avenue Northwest
Washington, DC

Dear Mr. President:

As a group of concerned international scientists and global technology company executives, we write to respectfully ask your help in resolving an issue directly impacting global and domestic food security; the ability of scientists to respond to the impacts of human and animal disease, climate change, and the spirit of invention, innovation and scientific breakthrough, all hallmarks of American ingenuity.

We write to respectfully request FDA issue its final regulatory decision on the AquaAdvantage® Salmon, developed by AquaBounty Technologies Inc., an application which has been before the agency for 19 years this month.

September 19 will mark four years since the FDA Center for Veterinary Medicine's (CVM) Veterinary Medicine Advisory Committee (VMAC) met in Washington, DC, to review the AquaBounty Technologies Inc. application and the underlying scientific submission. The VMAC formally concluded the scientific data showed the AquaAdvantage Salmon® grew faster than conventional Atlantic salmon, was nutritionally equivalent to conventional Atlantic salmon, and the genetic construct did not harm the salmon, among other positive findings.

The sponsor company has met or exceeded all federal regulatory requirements and interagency reviews, including unprecedented FDA publication of and solicitation of public comment on the firm's environmental assessment (EA), the latter action not required by federal law. In December, 2012, FDA released a finding of no significant impact (FONSI), the last step required before the agency may issue its final decision. After an extension of the original EA comment period, the agency has spent an unprecedented 16 months reviewing public comment.

Please know we do not write to simply support AquaBounty. We write because the AquaBounty New Animal Drug Application (NADA) is the first-of-its-kind formal government review of a food animal enhanced by biotechnology anywhere in the world. The obvious regulatory roadblocks AquaBounty is experiencing not only undermine our ability to meet the future food needs of the world, but seriously damage the global credibility of FDA and its objective, science-based approval process, while stifling innovation in this critical field.

The technology used to develop the AquaAdvantage Salmon is the same technology used to develop the biotech crops planted on over 350 million acres around the globe. The United States led the development

of this technology and our nation was the first to commercialize it in 1994. Biotech crops have enabled American farmers to become the most productive farmers on the planet; this technology continues to contribute to making agriculture one of the most dynamic and important sectors of our economy.

Biotechnology enables farmers to increase productivity, even in the face of adverse environmental events, such as the drought experienced across the Farm Belt in 2012. Thanks to crop biotechnology, farmers use less pesticides and herbicides, significantly reduce the environmental impact of crop production, and are better prepared to deal with the challenges of climate change recognized by your Administration's initiatives.

As you stated in your April 11, 2014, letter to Julie Borlaug on the occasion of the placement of a statue of her grandfather, Nobel Peace Prize winner and global plant genetics and world hunger champion Dr. Norman Borlaug in the Capitol's Statuary Hall:

"The technological advances pioneered by Dr. Borlaug are a model of the American spirit of innovation and ingenuity...his support of investment in education and continued research in the biotechnology field are inspirational as we pursue developing new products that can nourish the world's vast population...I share his belief that investment in enhanced biotechnology is an essential component of the solution to some of our planet's most pressing agricultural problems."

As you publicly recognize, biotechnology not only benefits Americans, but is increasingly important to farmers around the world. In 2012, more than 50% of the world's farmers planting biotech crops were smallholders in the developing world.

Your Administration has made global food security a high priority, as Secretary of State John Kerry affirmed during the first-ever African Leaders Summit in Washington, DC. Crop biotechnology and emerging animal biotechnology are critical tools in global efforts to achieve a sustainable global food production system.

We firmly believe it is time FDA action give credence to your Administration's public support of biotechnology.

The obvious value of biotechnology as a tool for agricultural development must be enabled for use in aquaculture and livestock production. As the world population grows to 9 billion people by 2050, the demand for more animal protein grows with it. Biotechnology must be a tool available to the scientists working to increase animal protein production if we hope to meet the demand for more high quality protein in an environmentally responsible manner.

The technology used by AquaBounty to develop the AquAdvantage Salmon has a 20-year track record of safety and efficacy. The genetic changes AquaBounty made to the AquAdvantage Salmon have been thoroughly and rigorously evaluated and clearly pose no safety or environmental risks. Protests by anti-technology interests are, we believe, the root cause of the unconscionable delays in FDA approval. These groups' criticisms are based on misplaced economic/marketplace concerns and reactionary fears of people who either don't understand or choose not to understand the science behind the AquAdvantage Salmon.

Failing to approve the AquAdvantage Salmon NADA will inflict serious damage on the global credibility of FDA and on the historic United States' claim its regulatory system is based on objective science. The

inexplicable regulatory bottleneck encountered by the AquaAdvantage Salmon gives credence to those who publicly contend FDA regulation is based on politics and public opinion rather than science. Further, it lays open every decision made by FDA to be questioned by the public. It simultaneously undermines your Administration's on-going efforts to encourage our trading partners to adopt science-based regulation to ensure free trade of American agricultural products.

Dr. Calestous Juma, professor at Harvard University's Kennedy School of Government and the respected former executive secretary of the United Nations' Convention on Biological Diversity, testified before Congress, stating:

"It is not this particular fish that is at stake... it sends the message to the rest of the world that 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 the United States stay the course it has set in not letting politics interfere with its science-based regulatory system, a system that is truly the envy of the world."

Mr. President, the saga of AquaAdvantage Salmon is clear evidence of a seriously damaged regulatory process. Domestic and global distrust of this system is leading American scientists and businesses to take their projects and business ventures away from the United States to countries where there is reasonable expectation for rational and predictable regulatory outcomes. This distrust also calls into serious question whether the United States will maintain its position as a global leader in science, innovation and the fight to establish a safe and sustainable global food supply.

The political forces aligned against the approval of the AquaBounty Salmon are the same groups who decry the failure of others to recognize the scientific facts underpinning evidence that human activity does impact global climate change. Selective use of science to further a parochial cause is a slippery slope. Your Administration's oft-stated commitment to sound science and the rule of law will only ring true if it is followed by prompt regulatory action, including actions that may not be politically popular in some circles.

Therefore, we respectfully request you instruct FDA to move as efficiently as possible to conclude the regulatory review of the AquaBounty NADA, a review that has now lasted nearly two decades. Issues ancillary to the approval of this application are philosophical and marketplace issues, and must not be allowed to further undermine the credibility and trust of FDA.

The American people, and indeed all people everywhere, are best served by a trusted objective regulatory process truly based on sound science, a system which can be counted upon to evaluate and act on the applications it receives without fear of political interference.

Any further unexplained delay in moving forward with the FDA regulatory process of this precedent-setting application diminishes existing and future U.S. investment and innovation across the entire range of agriculturally important animals and the needed foods they produce. Animal biotechnologies have the potential to help address the challenges of global food security, mitigate livestock and poultry greenhouse gas (GHG) emissions, and create jobs at a time when the United States and other countries of the world could greatly benefit from such innovation.

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

Sincerely,

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