

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>

Sincerely,

C. S. Prakash
Professor, Crop Biotechnology
Tuskegee University
Editor-In-Chief, GM Crops & Food

Alison Van Eenennaam, PhD
Cooperative Extension Specialist
Animal Genomics and Biotechnology
Department of Animal Science
University of California, Davis

Dr. Nina Fedoroff
Evan Pugh Professor
Huck Institutes of the Life Sciences
The Pennsylvania State University

John Bonner, CEO
Council for Agricultural science and Technology
Ames, IA

John Connelly, President
National Fisheries Institute
Washington DC

Chris Lischewski, CEO
Bumble Bee Foods LLC
San Diego CA

Fred Craves, Managing Partner
Bay City Capital
San Francisco, CA

Dr. Jim Sartin, President
American Society of Animal Science
Champaign, IL

Andrew Baum, CEO
Arborgen Inc
Ridgeville, SC

Dr. Mark Westhusin
Professor, College of Veterinary Medicine
Texas A&M University

Kenneth R. Bondoli
Dr. Daniel Dupree Professor of Animal Sciences
School of Animal Sciences
Louisiana State University

Pablo J. Ross, PhD
Assistant Professor
Department of Animal Science
University of California, Davis

Dr. James D Murray
Professor
University of California, Davis

Scott C. Fahrenkrug, Ph.D.
CEO & Chairman
Recombinetics, Inc.
Saint Paul, Minnesota

Dr. Bob Petters
Professor of Animal Science
Director of Graduate Programs
Department of Animal Science
North Carolina State University

Daniel H. Putnam, Ph.D.
Extension Agronomist and Forage Specialist
Department of Plant Sciences
University of California

Elizabeth A. Maga, Ph.D.
Associate Research Biologist
Department of Animal Science
University of California, Davis

Eric M. Hallerman, Professor
Head, Department of Fisheries and Wildlife Sciences
Virginia Polytechnic Institute and State University

William Muir, Ph.D.
Professor Genetics
Department of Animal Sciences
Purdue University and
Department of Medicine
Indiana University

Bruce Chassy Ph.D.
Professor Emeritus of Food Safety
Professor Emeritus of Nutritional Sciences,
University of Illinois at Urbana-Champaign

Dr. Val Giddings
President, Prometheus LLC
Washington DC

Eddie J. Sullivan, Ph.D.
President
Hematech, Inc.
Sioux Falls, South Dakota

Drew L. Kershen
Prof of Law
University of Oklahoma

Terry D. Etherton, PhD
Department Head & Distinguished Professor of Animal Nutrition
The Pennsylvania State University

Steve Strauss, Professor
University Distinguished Professor
Oregon State University

Kevin D. Kephart
Vice President for Research
South Dakota State University

Thomas Parker Redick
Global Environmental Ethics Counsel, LLC
Clayton, Missouri

John R. Swart, Ph.D.
President
Exemplar Genetics
Sioux Center, Iowa

Daniel A. Sumner
Director, University of California Agricultural Issues Center

Frank H. Buck, Jr.
Professor, Department of Agricultural and Resource Economics
University of California, Davis

Christine M. Bruhn, PhD
Director, Center for Consumer Research
Department Food Science and Technology
University of California, Davis

Peggy Lemaux, Ph.D.
Department of Plant and Microbial Biology
University of California, Berkeley

Richard Michelmore PhD
Professor and Director
The Genome Center, University of California, Davis

Roger Beachy
President Emeritus, Donald Danforth Plant Science Center
St. Louis, Missouri

Dr. Gilbert Ross
Executive Director
American Council on Science and Health (ACSH)
New York, New York

Gregory Conko
Senior Fellow
Competitive Enterprise Institute
Washington, DC

Gary Anderson
Distinguished Professor Emeritus
University of California, Davis

Ruth Kava, Ph.D., R.D.
Senior Nutrition Fellow
American Council on Science and Health (ACSH)
New York, New York

John Diekman, PhD.
Managing partner
5AM Ventures

Robert H. Poppenga, DVM, PhD, DABVT
CAHFS Toxicology Laboratory
School of Veterinary Medicine
University of California, Berkeley

George E. Seidel, Jr.
Professor
Animal Reproduction and Biotechnology Laboratory
Colorado State University

Wayne Parrott, PhD
Professor
University of Georgia

Dr. Shanthu Shantharam
Professor
Seed Technology Center, BIGMAP
Iowa State University
Ames, IA

David G. McLaren
Director of Research
Genus plc

Jon Entine
Senior Fellow
Center for Health & Risk Management
George Mason University

Martin B. Dickman, Ph.D.
Christine Richardson Professor of Agriculture
Director, Institute for Plant Genomics and Biotechnology
Department of Plant Pathology and Microbiology
Texas A&M University

Dr. Mark Walton
Recombinetics
Saint Paul, Minnesota

Charles R. Long, Ph.D.
Associate Professor
Texas A&M University

Bruce N. Ames, Ph.D.
Senior Scientist
Children's Hospital Oakland Research Institute
Nutrition and Metabolism Center
Professor of the Graduate School
University of California, Berkeley

Gary Marchant, Ph.D., J.D.
Regents' Professor and Lincoln Professor of Emerging Technologies, Law & Ethics
Faculty Director, Center for Law, Science & Innovation
Sandra Day O'Connor College of Law
Professor, School of Life Sciences
Senior Sustainability Scientist, Global Institute of Sustainability
Arizona State University

Denneal Jamison-McClung, PhD
Associate Director
Biotechnology Program
University of California, Davis

David Conley, MSc
Senior Consultant, Founding Partner
Aquaculture Communications Group, LLC
Novi, Michigan

Dr. Guy A. Cardineau
ASASU Centennial Professor
The School of Life Sciences and
The Sandra Day O'Connor College of Law
Arizona State University
Tempe, AZ

Dr. Jerry Taylor
Curators' Professor
Wurdack Chair in Animal Genomics
University of Missouri, Columbia

Fred S. Conte, PhD
Department of Animal Science
University of California, Davis

Jeff W. Davis
International Seafood Partners
Senior Managing Partner
Naples, FL

cc: John Holdren, OSTP
Kathleen Sebelius, Secretary of Health and Human Services
Margaret Hamburg, FDA Commissioner
Thomas Vilsack, Secretary of Agriculture
Hillary Clinton, Secretary of State
Ron Kirk, USTR