FOR IMMEDIATE RELEASE
Wednesday, July 24, 2013

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LEADING SCIENTISTS FIND US FDA PROCESS FOR APPROVING GENETICALLY MODIFIED FOOD AND ANIMALS SO ONEROUS THAT IT TIES HANDS OF SCIENCE-BASED AGENCIES

FDLI's Food and Drug Policy Forum Article:
No Product Could Withstand This Level of Non-Science-Based Scrutiny, Say Independent Experts

A paper published in today's Food Drug Law Institute's Food and Drug Policy Forum, by three respected scientists with long U.S. Food and Drug Administration relationships, finds the process used by the US FDA to regulate products from genetically modified animals is so rigorous that it goes far beyond the legally required scientific analysis of food and environmental safety.

The paper – the authors include a member for the independent advisory panel that reviewed the data for the world's first genetically modified food animal and two noted PhDs who testified at the FDA's public hearings on the topic – says the scrutiny required by this process forces the agency to respond to non-science-based claims and fall victim to political interference. The scientists say in the paper:

> *"Science is the basis for the FDA's considerations of all products… Lacking the background to interpret the science associated with GE [genetically engineered] animals as presented, activists often offer biased interpretations of the data and criticize the process by which the regulatory decision making goes forward. Further, elected officials criticize agency actions on the basis of perceived risks to narrow constituencies. Regulatory actions…should be based exclusively on science."*

The paper confirms facts previously released many times by the US FDA, namely fish grown from AquAdvantage® Salmon eggs:

> *"is as safe as food from conventional salmon"* and that these salmon *"will not have any significant impacts on the quality of the human environment of the United States … when grown and produced under the conditions of use for the proposed action."*

The authors also say unaccountable delays have jeopardized the FDA's ability to regulate rDNA animal products and have started to force these technologies offshore, despite their benefits. They quote Dr. Calestous Juma, Harvard's Kennedy School of Government, that this nearly 20-year process:

"…sends a 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."

The paper also points out that when the science-based process is ignored, regulation can be influenced by those who don't understand basic biology and have financial interests. For example, Rep. Don Young (R-AK) told the *Washington Post* his objective was to "put the company out of business" even though, the researchers drily note, it is biologically impossible for Atlantic salmon to mate with Pacific salmon – even if they were able to overcome infertility, escape multiple redundant containment systems and swim hundreds, if not thousands, of miles to his state.

The authors make four policy recommendations to help protect the US FDA from non-science-based meddling as follows:

- Maintain and *strengthen a science-based regulatory review system* for the evaluation of GE animals and continue formal consultation with all agencies with relevant expertise.
- Require *hypothesis-driven studies for regulatory evaluation detailing the biologically relevant issue(s)* based upon the novel traits or phenotype(s) associated with the species/gene/insertion event combination.
- Focus risk assessments *on those unique risks associated with the GE animal application* and evaluate them in relation to known risks associated with existing production systems.
- Following submission of all pre-defined required data, *impose finite response times* for agency decisions at each point in the evaluation process to provide developers and investors with a predictable regulatory timeline for GE animals.

This paper, by noted research scientists, was written in response to a piece in the same issue of the FDLI journal written by a staff researcher at Food & Water Watch, a non-profit organization known to be opposed to biotechnology of any kind. This piece by Food & Water Watch recycled claims previously disproven and dismissed by the academic community and the regulatory agencies themselves.

The three authors include internationally respected experts who receive no money or other support from industry or non-profits that meddle in policy. Alison Van Eenennaam, Ph.D., University of California-Davis, is a member of US FDA's Veterinary Medicine Animal Committee, the independent body of experts that reviews applications at the request of the agency's Center for Veterinary Medicine. William Muir, Ph.D. is a professor of animal science at Purdue University. Eric Hallerman is a professor of wildlife and fisheries at Virginia Tech University. Muir and Hallerman thoroughly reviewed the data and both presented at the public FDA Forum on the AquaBounty application.

Ronald L. Stotish, Ph.D., CEO of AquaBounty Technologies, stated: "The delay associated with our approval has damaged the credibility of the FDA as an independent science-based regulatory agency. The influence of politicians and those philosophically opposed to biotechnology on what is

supposed to be an evidence-based process is creating an environment of ‘regulation by referendum’ – a disservice to the health and safety of the American people.”

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