White House Ends Its Interference in Approval of Genetically Modified Salmon

By Jon Entine | Updated Friday, Dec. 21, 2012, at 2:03 PM ET
| Updated Friday, Dec. 21, 2012, at 2:03 PM ET

Slate.com

White House Ends Its Interference in a Scientific Review

Leaks suggest politics blocked genetically modified salmon. Now the fish is on its way to approval.

An AquAdvantage® salmon Barrett & MacKay Photo/Courtesy AquaBounty Technologies.

Update, Dec. 21, 2012: On Wednesday, Slate and the Genetic Literacy Project published investigations into whether the White House was interfering in a scientific review process by the FDA. An environmental assessment of genetically modified salmon had cleared all internal regulatory hurdles and was due to be released in April, but the Obama administration put a hold on the release. Hours after the stories were published, according to FDA sources, the White House lifted its hold. Today, the FDA finally published the environmental assessment, one of the final stages in what could be the first federal approval of a genetically-modified animal in the United States.

The original article is below:

As president, Barack Obama promised to change "the posture of our federal government from being one of the most anti-science administrations in American history to one that embraces science and technology." To publicly guarantee that, the White House issued a science integrity memorandum in 2009 pledging, "Political officials should not suppress or alter scientific or technological findings and conclusions."

Except, it appears, when it comes to the fate of the first transgenic animal to be considered for federal approval—a genetically modified (GM) salmon developed by AquaBounty Technologies of Massachusetts. The so-called AquAdvantage salmon is a fish that has been modified to grow to market size in about half the usual time. It's raised in contained structures that eliminate many of the environmental effects that make farmed salmon unpopular with some environmentalists, including the generation of excess waste and the potential to spread disease or escape and compete with wild salmon.

The bioengineered salmon has been winding its way through a labyrinthine approval process for 17 years. And it's been in regulatory purgatory for more than two years since the Food and Drug Administration held public hearings—and promised a final determination within weeks.

As recently as last week, a spokeswoman for the Food and Drug Administration told me, "The application is still under review." But that's not the whole story.

The Genetic Literacy Project (GLP), which I direct, has learned that in April, the FDA completed its draft environmental assessment (EA), the final step in its scientific evaluation. The agency confirmed that the salmon is safe to eat and poses no serious environmental hazards. The approval document had made its way through every appropriate agency in an interagency review process coordinated by the Office of Science and Technology Policy (OSTP), which oversees the president's science policies and is empowered to enforce integrity guidelines.

But within days of the expected public release of the EA this spring, the application was frozen. The delay, sources within the government say, came after meetings with the White House, which was debating the political implications of approving the GM salmon, a move likely to infuriate a portion of its base.

The GLP has been leaked a confidential copy of the 159-page assessment, dated April 19, 2012, which had been circulated and approved—a summary of which we have been given permission to publish. It states that the Center for Veterinary Medicine, which has regulatory responsibility within the FDA, reached a "no effect" determination under the Endangered Species Act. That should have led to the publication of the EA in the Federal Register, paving the way for a public review period, which would have lasted 30 to 90 days. If the process had been followed, genetically modified salmon could have been on dinner tables by next year.

When asked about the holdup, FDA spokeswoman Siobhan DeLancey said, "I recommend you talk to the OMB or the White House. That's all I'm willing to say."

If, as FDA sources confirm, the scientific review is complete, the refusal to publish the draft EA in the Federal Register directly contradicts not only the president's directives, but also regulatory mandates ensuring the integrity of science at the Department of Health and Human Services, which oversees the FDA, and OSTP, which is under the executive branch.

"This shouldn't be happening," said Gregory Jaffe, director of biotechnology at the Center for Science in the Public Interest. Although cautious about biotechnology, Jaffe participated in a scientific review panel that unanimously endorsed the FDA's findings that the salmon was safe. "AquaBounty deserves regulatory due process," he added. "We need science-based decisions made in a timely fashion. The public deserves this, and there are questions whether that is what's going on in this case."

AquaBounty's fish is an Atlantic salmon with two added genetic elements: a Chinook salmon growth hormone gene and an on-off switch from the ocean pout, another edible fish. The modifications make the salmon grow through the winter, unlike conventional salmon. Only females are produced for consumption, and they are rendered sterile.

Americans consume 650 million pounds of salmon each year, with more than 530 million pounds of that imported. If allowed into the marketplace, the AquAdvantage salmon, as it is called, could lead to lower salmon prices and an increase in consumption of salmon, a heart-healthy food.

GM crops and animals are regulated under the 1986 Coordinated Framework. But while plants have a clear path to approval under guidance in place by 1992, animals must travel through regulatory no-man's land. The FDA has approved only one product, an anticoagulant derived from the milk of transgenic goats.

AquaBounty initiated its application to commercialize in 1995. By 2004, it had assembled its "data package," but its path to approval was never entirely clear. Finally in 2008, the Bush administration decided that transgenic animals intended for the dinner table would be regulated as animal drugs by the FDA's Center for Veterinary Medicine.

Anticipating environmental concerns, AquaBounty developed the salmon at a secure indoor facility in Prince Edward Island, Canada. A second facility was established in the mountains of Panama to evaluate whether the fish perform well under standard commercial conditions.

As part of its evaluation, the FDA inspected both facilities, determining the fish would be securely contained with multiple redundant systems that would prevent the salmon from escaping into the wild—one of the main concerns for people opposed to GMOs. The FDA concluded that even a catastrophic event at the Panamanian facility would not pose a threat. Lengthy expanses of warm, muddy water outside the facility would serve as a graveyard to any escaped cold-water fish. If some somehow made it to the ocean, they would die in the warm currents thousands of miles from their spawning grounds in the frigid waters of the North Atlantic.

There is no chance, independent scientists say, that released salmon would win a Darwinian war in open waters with wild salmon—the so-called Trojan gene effect. GMO opponents cite a 1999 study concluding that modified fish that grow extra large would have a competitive advantage, threatening extinction of conventional varieties. But AquaBounty engineered the salmon so it grows no larger than conventional fish. A co-author of that study, Bill Muir of Purdue University, who developed the risk assessment model for transgenic fish for the Department of Agriculture, studied the AquaBounty salmon and determined it has no fitness advantage—and now endorses it.

After years of reviews, in September 2010, the FDA released a long-awaited comprehensive guidance analysis that found the salmon environmentally benign and safe for human consumption. The agency concluded the AquAdvantage salmon is comparable to the traditional variety in every measurable way.

To underscore its commitment to transparency, the FDA's CVM convened a science advisory panel, which held public hearings a few weeks later. The scientists, including representatives from organizations skeptical of GMOs, unanimously reaffirmed the food safety report: AquaBounty salmon was materially identical to conventional salmon and posed no apparent environmental hazards.

The final step in the process—a "no effect" finding required under the Endangered Species Act—was expected within weeks, which would lead to its publication in the Federal Register and public hearings. Echoing one headline—"FDA to Approve GM Salmon Despite Strong Opposition"—everyone from the New York Times to anti-GMO activist groups was reporting that AquaBounty appeared to be on its way to producing the fish eggs that other companies could purchase to raise the quick-growing salmon.

Nothing has been released by the FDA since.

Friends of the Earth, Greenpeace, Union of Concerned Scientists, and other anti-GMO groups sent a letter to FDA Commissioner Margaret Hamburg demanding further review of whether wild salmon could face a competitive survival risk. AquaBounty's response noted the FDA's expert panel had already rejected those speculations.

Congressional politics then flared up. Forty members of Congress, most from the Pacific Northwest—whose salmon competes with Atlantic salmon—sent a letter to the FDA citing a supposed lack of transparency in the process. Whether because of the suddenly hostile political climate or renewed lobbying by opponents, the formal environmental assessment, which reporters had been told might be released any day, was never made public.

When rumors that approval was near surfaced again, in June 2011, a dozen members of the House, in a voice vote, approved a budget amendment prohibiting the FDA from approving the AquaBounty salmon. "Frankenfish is uncertain and unnecessary," said the bill's sponsor, Rep. Don Young, R-Alaska. "Should it receive approval as an animal drug, it clears the path to introduce it into the food supply; my amendment cuts them off before they can get that far." The Senate did not immediately take up the bill.

Critics cited the snail-like pace of approval as evidence that the AquaBounty application was in trouble. "If the FDA was so assured of the scientific merits of this application, they would have approved it by now," said Colin O'Neil of the Center for Food Safety. "The mere fact that it has taken this long tells me that jury is still out."

In fact, by summer 2011, by all reports, the FDA had yet again reaffirmed its finding that the salmon was ready for approval. The draft environmental assessment was prepared and circulated under an interagency review process coordinated by the president's Office of Science and Technology Policy. The two other agencies responsible for assessing the application under the Endangered Species Act, Fish and Wildlife, and the National Marine Fisheries Service, signed off on the "no effect" determination.

The review even went to the OMB at the Executive Office, which under normal circumstances would have no input on individual applications. Its authority is usually limited to reviewing new regulations. However I've been told that, because of the politicized nature of this case, the White House wanted to be involved. According to Talking Points Memo and my sources, OMB signed off on release of the EA that summer.

The approval was derailed when anti-GMO organizations circulated a report that the salmon at AquaBounty's Canadian facility had tested positive for a salmon virus two years previously. The company had reported the incident to Canadian authorities but not to the FDA—which reportedly did

not make officials happy. The FDA immediately put a hold on the release of the draft EA. It took months before the agency determined the incident had been isolated and had nothing to do with AquaBounty's technology.

While that controversy was being addressed, Food and Water Watch, Consumers Union, and the Center for Food Safety submitted a formal petition in February 2012, demanding the FDA reclassify AquaBounty's AquAdvantage salmon and its components as a food additive, setting up the possibility of a different regulatory regime that would have resulted in the process starting over at square one. The FDA stood firm, reaffirming its commitment to the evaluation by the CVM.

Finally, on April 19, 2012, the FDA circulated a draft EA that was an almost exact copy of what had been approved months before. The "approval of the AquaAdvantage Salmon," the document states, "... will not jeopardize the continued existence of the United States populations of threatened or endangered Atlantic salmon, or result in the destruction or adverse modification of their critical habitat."

For AquaBounty, the end again seemed in sight.

"It's a lengthy process, especially when you are dealing with a first-in-kind product that cuts across many dimensions," the FDA's Hamburg told the New York Times. A revised environmental assessment, she said, would be issued "very soon"—in a matter of days, weeks at most.

Then the gears of government and communication between the federal officials and AquaBounty shut down completely.

Late spring was a challenging time at the White House. The GOP primaries had just wrapped up, and Republicans were coalescing around Mitt Romney, who appeared to be a formidable candidate. The president's popularity remained lackluster. A late June Newsweek/Daily Beast poll showed that 54 percent of Americans thought Obama was doing a poor job—one of the lowest approval ratings of his presidency.

The main concern, politicos mused at the time, was a lack of enthusiasm by his political base, whose turnout would be critical if Obama hoped to squeeze out a victory during distressed economic times. Environmental activists were particularly ambivalent. They were upset about the president's unwillingness to block the Keystone pipeline and shale gas exploration using hydraulic fracturing.

And some of them were incensed about what they considered weak-kneed regulatory oversight by the FDA on chemicals and GMOs, which they believed had gotten a pass during the Bush administration. In late March, the FDA, citing "sound science," rejected a petition by the Natural Resources Defense Council to introduce tough restrictions on bisphenol A (BPA), a controversial plastic additive. "The FDA is out-of-step with scientific and medical research," the NRDC wrote in a blistering rebuke. "The agency has failed to protect our health and safety."

The last thing the Obama re-election effort needed was a messy dustup over the first genetically modified animal. But that was brewing. Union of Concerned Scientists' Margaret Mellon, a foe of bioengineering, had already publicly warned of "a firestorm of negative response" if the FDA approved the salmon.

With political opposition bubbling in Congress and anti-GMO activists mobilizing in cyberspace, AquaBounty's president and CEO, Ronald Stotish, encountered FDA Secretary Hamburg at an industry event in Boston.

"You've been great," he quoted her as saying. "You've been patient and taken the high road." She pointedly did not repeat her statement of a month before that the publication of the EA would be coming any day now.

Her comment set off alarm bells within the industry. Was there a new holdup? Stotish and Jim Greenwood, president of the biotech industry trade group BIO, met on July 11 with HHS Secretary Kathleen Sibelius' senior adviser Andrea Palm. Palm is known as a "fixer"—she coordinates policy with politics, often working directly with Valerie Jarrett, the president's most trusted adviser. Sources say the White House had been hearing regularly from anti-GMO organizations.

Palm professed to have no knowledge of the salmon controversy, according to people in the meeting. Palm promised to get back to them within a week. Five months later, dozens of calls and emails have gone unreturned. I've fared no better; Palm did not respond to my request for a statement.

Sources within the FDA have repeatedly asserted that the scientific review process is complete and the agency is not the source of the holdup. The media office says the application itself has not been formally approved. DeLancey referred me to the executive branch, to the White House and OMB. The OMB referred me back to the FDA. The White House declined to respond to requests for comment.

The regulatory foot-dragging sparked a letter sent to the White House in late September from more than 50 scientists and interested parties concerned about the delay.

"There is much more at stake here than just a fish," the letter asserted. "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."

China has launched an $800 million public-private investment into transgenic animals, and genetically modified animals are being developed in India, New Zealand, and across Latin America, including in Cuba. But North America has become a dead zone.

James Murray, an animal scientist at the University of California–Davis has developed goats that make milk with diarrhea-preventing lysozyme, a bacteria-fighting protein that could save children's lives. With no government or private money on the horizon, he's set up his lab in Brazil, a more biotech-friendly locale. "When you don't have a regulatory pathway forward and the government doesn't support research in this area, what company will invest in this field?" he asked. "None. The AquaBounty situation is just confirmation of a hopelessly politicized process."

The future of animal genetics is so dire, universities are killing off courses. "My program started off doing genetic engineering," said Alison Van Eenennaam, a University of California–Davis animal scientist who co-authored a scathing article for Nature Biotechnology on the broken approval process.

"I couldn't get any government funding for my work in this area, so I shut the program down. Why would I train graduate students for jobs that won't exist?"

A question remains whether the White House or FDA could face legal challenges for intervening in a scientific evaluation process that is supposed to be insulated from politics. The Federal Food, Drug & Cosmetic Act requires that the Health and Human Services secretary approve the AquaBounty application within six months after compliance with Section 512. The company holds letters from earlier this year from the FDA advising that every major component of its application has been successfully addressed.

The FDA, apparently caught in the political crossfire, appears to be in violation of its own scientific integrity guidelines, adopted last February. Scientists and staffers involved in the process say they have been instructed not to discuss the application. Key provisions of the guidelines require the agency to shield its staff from "political influence" and to allow the "FDA staff to communicate their personal scientific or policy views to the public, even when those views differ from official Agency opinions."

The FDA has referred any questions about the logjam to the White House. The chief spokesperson for the OSTP, which is empowered by the executive branch to ensure that scientists are insulated from political concerns, has not responded to requests for comment.

"I think the credibility of our regulatory process is destroyed if someone at the White House or even at the FDA can essentially, arbitrarily pocket veto an application," said Stotish.

But that's what's going on, say those monitoring science policy—even those critical of the AquaBounty salmon. The Union of Concerned Scientists, which has campaigned against bioengineering, expressed its concern that the science approval process is being compromised by politics.

"If the statutes say the decision is supposed to be made based on science, and promptly, the government should follow that," Francesca Grifo, who helped craft UCS's scientific Integrity reports, told me. "Despite what the President might have said about scientific integrity, we've seen White House interference on what should be science regulatory decisions. They have a legal responsibility to follow their own guidelines."