GMO salmon two months from introduction: AquaBounty fights anti-biotechnology misinformation as it gears up for April launch of fast-growing, sustainable AquAdvantage salmon



quaBounty's genetically engineered, fast-growing salmon could be sold at US restaurants and grocery stores as soon as this April. The debut would end a 26-year saga during which the development of the AquAdvantage salmon faced challenging science, foot-dragging by federal regulators, intense lobbying by anti-biotechnology groups and flagging salmon demand in the

wake of COVID-19.

CEO Sylvia Wulf told reporters on February 23 that efforts to commercialize its AquAdvantage salmon are moving forward despite these hindrances. The company plans to produce 100 metric tons of fish per month at its Indiana facility.



Sylvia Wulf

Will consumers buy GM fish?

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.

Salmon is America's second favorite seafood, trailing only shrimp. Americans consume about 794 million pounds of the pink fish each year, about 2.4 pounds per person. More than 650 million pounds of US-consumed salmon is imported, a huge sustainability drag say many environmentalists, noting the fossil fuels used to import the fish. Besides its ecological advantages, the AquAdvantage salmon could lead to lower salmon prices and an increase in consumption of the heart-healthy food.

85 grocery chains, seafood companies, restaurants, and food service companies, including distribution giant Aramark, <u>have pledged</u> not to sell AquAdavantage salmon, fueling speculation that were would be no market for the new fish. Wulf responded that many of those pledges <u>go back to 2013</u> and cited recent survey data showing that seven out of 10 consumers were open to purchasing GM salmon after learning about its sustainability benefits.



Credit: AquaBounty

The company has stressed its commitment to transparency, a theme Wulf emphasized throughout her presentation. She said AquaBounty would label its salmon as a genetically engineered product so consumers could make an informed choice. But, she noted, "consumers need to make an informed choice based on accurate information."

AquaBounty takes environmental concerns about its fish very seriously, Wulf maintained. The company says it has taken extensive measures to prevent escape from its land-based facilities, one on Prince Edward Island in Canada and another in Indiana. "In 20 years, we've never had an escape," she added. According to the Food and Drug Administration (FDA), both facilities are outfitted with "more than adequate" security measures:

Containment measures can include the use of mechanical devices, either stationary or moving (e.g., tanks, screens, filters, covers, nets, etc.), or in some cases, the use of lethal

temperatures or chemicals to prevent uncontrolled escape. All production units in the facility will have a minimum of five independent levels of physical containment (i.e., barriers) preventing escape of eggs or fish via effluent flow paths to the outside environment and some of the production units will have six or seven barriers in place. This number of containment levels is more than adequate and greater than the number at most fish production facilities.

Regulatory and advocacy group hurdles

Environmental activists have targeted AquaBounty for years, launching their opposition just after the company initiated its application to commercialize in 1995. By 2004, it had assembled its "data package," but the 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.

In an attempt to derail approval, GMO opponents cited a <u>1999 study concluding</u> that modified fish that grow extra large would have a competitive advantage, threatening extinction of conventional varieties. But AquaBounty didn't engineer the salmon to grow larger than conventional fish; rather it grows faster, reducing input costs and its environmental footprint. 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. After years of review, in September 2010, the FDA released a long-awaited comprehensive guidance analysis that found the salmon environmentally <u>benign and safe</u> for human consumption. The agency concluded the AquAdvantage salmon is comparable to the traditional variety in every measurable way.

Follow the latest news and policy debates on sustainable agriculture, biomedicine, and other 'disruptive' innovations. Subscribe to our newsletter. SIGN UP

For nearly two years, AquaBounty held its breath, anticipating the FDA green light. The regulatory logjam finally broke in December 2012 after an investigative report by GLP's Jon Entine, published simultaneously in <u>Slate</u> and the GLP, revealed the FDA had green lighted the fish the prior April. The agency had given the salmon a preliminary "finding of no significant impact" on the environment, but advocacy groups had successfully, and illegally, convinced White House officials to put a hold on releasing the stamped report.

"Within days of the expected public release of the EA [environmental assessment] this spring, the application was frozen," wrote Entine. "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." <u>According to Slate</u>, which updated its report after the White House dropped its illegal hold:



SCIENCE 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.

BY JON ENTINE DEC 19, 2012 • 3:14 PM

Hours after the stories were published, according to FDA sources, the White House lifted its hold. On December 23, two days after the exposé appeared, the FDA finally released 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.

An extended public consultation and numerous court filings delayed the final approval for almost another decade. The FDA ultimately approved AquAdvantage salmon in 2015. Federal regulation pushed by Alaska Senator Lisa Murkowski, which she claimed was necessary to protect Alaska fishermen, even though the different types of salmon are not seen as competitors, further slowed the approval process. The Center for Food Safety [read GLP profile of CFS here], which has led the activist opposition for two decades, further slowed the progress to commercialization. A 2016 import alert prohibited AquaBounty from bringing salmon eggs into the US from its first salmon farm, a 90,000 square foot facility in Canada on Prince Edward Island, until early 2019, after the USDA released its GMO labeling guidelines. AquaBounty opened its second farm, a 122,000 feet farm in northeast Indiana, last year.

In November 2020, a federal judge in the suit <u>brought by CFS</u> "ordered the agency to reconsider the environmental assessment for the salmon," ruling that the FDA had failed to fully assess the risk of the fish escaping, though he <u>did not withdraw</u> the agency's original approval. Wulf said the FDA is currently reviewing its environmental assessment, but AquaBounty doesn't expect the process to hinder its April launch date.

Wulf reiterated that the salmon are all sterile females, a trait the company <u>can test for</u> before a commercial batch of eggs leaves its farming facility on PEI. AquaBounty deliberately chose to pursue a business model, she added, and has no plans to build ocean-based fish farms. From start to finish, she said, the company's production process is "safe, secure, sustainable."



Credit: AquaBounty

The salmon will hit markets later than anticipated only last year. Following the outbreak of COVID-19 in early 2020, demand for salmon dropped, eliminating the need for another supplier and pushing the company's harvest back a year. But AquaBounty doesn't anticipate any further delays, and this week began harvesting the first samples of its salmon for 8-10 customers who have expressed interest in the product.

Cameron J. English is the GLP's managing editor. BIO. Follow him on Twitter @camjenglish

Jon Entine is the executive director of Genetic Literacy Project. Follow him on Twitter @JonEntine