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## This Genetically Altered Salmon Is No Fish Story

Inching toward FDA approval, AquaBounty's mega-fish stir critics

By Molly Peterson

For 15 years, AquaBounty Technologies has tried to win U.S. approval to sell a genetically modified salmon that can reach full size up to twice as fast as its naturally occurring brethren. Now the effort by the Waltham (Mass.) company may be drawing to a close. U.S. Food and Drug Administration advisers last week held what may be the agency's final hearing on whether AquaBounty's salmon is safe to eat.

The FDA hasn't set the timing of a final decision. Its staff, though, has already agreed that the meat from the altered fish is safe and has no biologically relevant differences from that of the naturally occurring variety. So AquaBounty's fish finally may be headed for American kitchens. FDA approval could make the salmon the first in a series of animals with mix-and-match DNA that have the potential to change the U.S. food chain.

AquaBounty's Atlantic salmon contain a growth gene implanted from another variety of salmon that's activated by DNA from an eel-like creature called the ocean pout. The altered fish can grow to "market weight" of as much as 13 pounds in two or three years, compared with three to four years required for natural salmon, says Chief Executive Officer Ronald L. Stotish.

The company would sell its AquAdvantage brand salmon eggs to fish farms isolated from the ocean that then could see their catch reach supermarkets in about two years. Stotish says the enhanced fish could "increase the availability of a high-quality product that is indistinguishable from the traditional food."

Not everyone is firing up their grills just yet. Groups opposed to genetically modified foods on Sept. 16 held a protest in Washington. "Today it's a fish that we're talking about. But very soon it will be genetically engineered pigs, chicken, and our beloved cows," Ben & Jerry's CEO Jostein Solheim told protesters.

Critics say they're particularly miffed that the FDA is reviewing AquaBounty's altered fish as a veterinary drug rather than creating a new review process for gene-altered foods. FDA spokeswoman Siobhan DeLancey says the genetic material used in the AquaBounty fish meets the statutory definition of a veterinary drug because it alters the structure and function of the animal. She says veterinary drug approval is stringent: "The review of the AquAdvantage salmon, conducted under that process, includes a rigorous analysis of food safety and application of a stringent safety standard: 'reasonable certainty of no harm.'"

The FDA's decision, critics say, allows some testing data reviewed by regulators to be kept confidential, as trade secrets. "They're obviously using this veterinary designation to keep the data confidential," says Wenonah Hauter, executive director of Food & Water Watch, an environmental and food-safety group in Washington. "I think they're afraid of the public reaction."

Alaska Senators Mark Begich and Lisa Murkowski, whose state harvested 163 million commercial salmon last year, are also against AquAdvantage. "Let's call this genetically engineered fish for what it is: Frankenfish,"

Begich said in a statement. "Approval of genetically modified salmon, the first such hybrid to be considered for human consumption, is unprecedented, risky, and a threat to the survival of wild species."

The modified fish, all female, are sterile, so they can't reproduce with regular salmon, Stotish says. "People who take the time to look" at the regulatory data "will satisfy themselves that the FDA has taken a very cautious, very robust regulatory approach," he says.

Stotish says 97 percent of the total tonnage of salmon now consumed in the U.S. is imported. Almost 427,000 tons, valued at \$1.39 billion, was imported last year from countries led by Chile, Canada, and Norway, according to Agriculture Dept. data. Although he says it's too early to project the sales potential of AquaAdvantage eggs, Stotish says the fast-growing salmon could help domestic fisheries gain a larger share of the market.

The genetically engineered salmon eggs are produced at an AquaBounty facility in Prince Edward Island, Canada, and the fish are grown to market weight at an AquaBounty farm in Panama. If the FDA approves the aquaculture company's salmon, another company would sell the Panama-grown fish in the U.S., Stotish told reporters at a Sept. 20 FDA advisory panel meeting. He declined to identify the company because the product hasn't been approved yet. "AquaBounty does not plan to be in the fish business," he said. "We're a technology company."

**The bottom line:** *Although genetically modified crops have been used for 20 years, AquaBounty's gene-altered salmon is facing fierce scrutiny and protests.*

*Peterson is a reporter for Bloomberg News.*

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