

Fast-growing fish may never wind up on your plate (Update)

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(AP)—Salmon that has been genetically modified to grow twice as fast as normal could soon show up on American dinner plates. That is, if the company that makes the fish can stay afloat.

After weathering concerns about everything from the safety of humans eating the salmon to their impact on the environment, Aquabounty was poised to become the world's first company to sell fish whose DNA has been altered to speed up growth.

The U.S. Food and Drug Administration in 2010 concluded that Aquabounty's salmon was as safe to eat as the traditional variety. The agency also said that there's little chance that the salmon could escape and breed with wild fish, which could disrupt the fragile relationships between plants and animals in nature. But more than two years later the FDA has not approved the fish, and Aquabounty is running out of money.

"It's threatening our very survival," says Ron Stotish, chief executive of the company. "We only have enough money to survive until January 2013, so we have to raise more. But the unexplained delay has made raising money very difficult."

The FDA says it's still working on the final piece of its review, a report on the potential environmental impact of the salmon that must be published for comment before an approval can be issued. That means a final decision could be months, even years away. While the delay could

mean that the faster-growing salmon will never wind up on dinner tables, there's more at stake than seafood.

Aquabounty is the only U.S. company publicly seeking approval for a genetically-modified animal that is raised to be eaten by humans. And scientists worry that its experience with the FDA's lengthy review process could discourage other U.S. companies from investing in animal biotechnology, or the science of manipulating animal DNA to produce a desirable trait. That would put the U.S. at a disadvantage at a time when China, India and other foreign governments are pouring millions of dollars each year into the potentially lucrative field that could help reduce food costs and improve food safety.

Already, biotech scientists are changing their plans to avoid getting stuck in FDA-related regulatory limbo. Researchers at the University of California, Davis have transferred an experimental herd of genetically-engineered goats that produce protein-enriched milk to Brazil, due to concerns about delays at the FDA. And after investors raised concerns about the slow pace of the FDA's Aquabounty review, Canadian researchers in April pulled their FDA application for a biotech pig that would produce environmentally-friendly waste.

"The story of Aquabounty is disappointing because everyone was hoping the company would be a clear signal that genetic modification in animals is now acceptable in the U.S.," said Professor Helen Sang, a geneticist at the University of Edinburgh in Scotland who is working to develop genetically modified chickens that are resistant to bird flu. "Because it's gotten so bogged down—and presumably cost AquaBounty a huge amount of money—I think people will be put off."

AGAINST THE CURRENT

The science behind genetic modification is not new. Biotech scientists

say that genetic manipulation is a proven way to reduce disease and enrich plants and animals, raising productivity and increasing the global food supply. Genetically modified corn, cotton and soybeans account for more than four-fifths of those crops grown in the U.S., according to the National Academies of Sciences.

But there have always been critics who are wary of tinkering with the genes of living animals. They say the risk is too great that modified organisms can escape into the wild and breed with native species. Not that we don't already eat genetically altered animals. Researchers say the centuries-old practice of selective breeding is its own form of genetic engineering, producing the plumper cows, pigs and poultry we eat today.

"You drive a hybrid car because you want the most efficient vehicle you can have. So why wouldn't you want the most efficient agriculture you can have?" asks Alison Van Eenennaam, a professor of animal science at University of California, Davis.

Aquabounty executives say their aim is to make the U.S. fish farming industry, or aquaculture, more efficient, environmentally friendly and profitable. After all, the U.S. imports about 86 percent of its seafood, in part, because it has a relatively small aquaculture industry. Aquaculture has faced pushback in the U.S. because of concerns about pollution from large fish pens in the ocean, which generate fish waste and leftover food.

Aquabounty executives figure that the U.S. aquaculture industry can be transformed by speeding up the growth of seafood. The company picked Atlantic salmon because they are the most widely-consumed salmon in the U.S. and are farmed throughout the world: In 2010, the U.S. imported more than 200,000 tons of Atlantic salmon, worth over \$1.5 billion, from countries like Norway, Canada and Chile.

Using gene-manipulating technology, Aquabounty adds a growth

hormone to the Atlantic salmon from another type of salmon called the Chinook. The process, company executives say, causes its salmon to reach maturity in about two years, compared with three to four years for a conventional salmon.

Aquabounty executives say if their fish are approved for commercial sale, there are several safeguards designed to prevent the fish from escaping and breeding with wild salmon. The salmon are bred as sterile females. They also are confined to pools where the potential for escape would be low: The inland pens are isolated from natural bodies of water.

And the company says that these pens would be affordable thanks to the fast-growing nature of Aquabounty's fish, which allows farmers to raise more salmon in less time. Overall, the company estimates that it would cost 30 percent less to grow its fish than traditional salmon.

TOUGH SALE

But getting the fish to market hasn't been easy.

The company began discussions with the FDA in 1993. But the agency did not yet have a formal system for reviewing genetically-modified food animals.

So Aquabounty spent the next decade conducting more than two dozen studies on everything from the molecular structure of the salmon's DNA to the potential allergic reactions in humans who would eat it. By the time the FDA completed its roadmap for reviewing genetically-modified animals in 2009, Aquabounty was the first company to submit its data.

After reviewing the company's data, the FDA said in a public hearing in September of 2010 that Aquabounty's salmon is "as safe as food from conventional Atlantic salmon." The FDA also said the fish "are not

expected to have a significant impact" on the environment.

But as the company has inched toward FDA approval it has faced increasing pushback from natural food advocates, environmentalists and politicians from salmon-producing states. In fact, following the FDA's positive review of the fish, the House of Representatives passed a budget that included language barring the FDA from spending funds to approve a genetically-engineered salmon.

"Frankenfish is uncertain and unnecessary," said Rep. Don Young of Alaska, who authored the language. The Senate did not adopt the measure.

Despite such opposition, environmental groups such as the Food and Water Watch say that FDA approval seems inevitable. "We think there is a clear bias toward approving genetically modified animals within the FDA," said Patty Lovera, assistant director of Food & Water Watch, a nonprofit that promotes environmental-friendly fishing and farming practices. "This thing is trapped in a regulatory process that is predisposed toward approving it."

But the delay could cause Aquabounty to go bankrupt before its salmon reaches supermarkets.

Aquabounty, which started in 1991 focusing on proteins used to preserve human cells, changed direction after acquiring the rights to gene-manipulation technology from researchers at the University of Toronto and Memorial University of Newfoundland. Aquabounty's Initial financing came from Boston-area investors and biotech-focused venture capital funds, but the company has burned through more than \$67 million since it started.

According to its mid-year financial report, Aquabounty had less than

\$1.5 million in cash and stock. And it has no other products besides genetically-modified salmon in development.

In February, the cash-strapped company agreed to sell its research and development arm to its largest single shareholder, Kakha Bendukidze, a former Republic of Georgia finance minister turned investor, in return for his help raising \$2 million in cash to stay afloat. Aquabounty's CEO Stotish fretted that Bendukidze, who controlled nearly 48 percent of Aquabounty's public stock, would move the company overseas. But in October Bendukidze's investment fund sold its shares to Intrexon, a biotech firm headquartered in Germantown, Maryland.

Stotish views the sale as a positive development, but he still worries that the U.S. government is unwilling to approve the technology at the heart of his company's work.

"This is about more than Aquabounty and more than salmon," Stotish says. "And shame on us if we allow this to slip away because of partisan bickering and people who oppose new technology."

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