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U.S. FDA's approval of AquaBounty's GMO salmon as food challenged

'AquaBounty is confident that the approval will stand,' CEO says in written release

By Gail Harding, <u>CBC News</u> Posted: Mar 31, 2016 10:26 AM AT Last Updated: Mar 31, 2016 4:43 PM AT



AquaBounty says once its genetically-modified salmon is harvested it cannot be distinguished from regular salmon. (AquaBounty)

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A group of environmental, consumer, and commercial and recreational fishing organizations say in a press release they have filed a lawsuit against the United States Food and Drug Administration (FDA) for approving AquaBounty Technologies's genetically modified salmon as food.

"FDA's decision is as unlawful as it is irresponsible," said George Kimbrell, senior attorney for Center for Food Safety and co-counsel for the plaintiffs, in the press release.

"This case is about protecting our fisheries and ocean ecosystems from the foreseeable harms of the first-ever GE fish, harms FDA refused to even consider, let alone prevent. But it's also about the future of our food: FDA should not, and cannot, responsibly regulate this GE animal, nor any future GE animals, by treating them as drugs under a 1938 law."

The lawsuit challenges the FDA's approval of genetically modified salmon for human consumption "without considering or fully disclosing the environmental and other risks of this unprecedented decision."

The lawsuit alleges the possible risks include:

- The salmon will escape from the facilities where they're being grown and interbreed with wild endangered salmon, compete with those salmon for food or pass on infectious diseases.
- The impacts on salmon fisheries, and the economic well-being of those who depend on them.
- The risks to eco-systems from the introduction of what the lawsuit calls invasive species.

The lawsuit asks the court to issue an injunction requiring the FDA to withdraw its assertion of jurisdiction over genetically modified animals.

In a written statement, AquaBounty CEO Ron Stotish said, "AquaBounty is confident that the approval will stand, and that the FDA has been extraordinarily thorough and transparent in the review and approval of our application."

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- Genetically-modified salmon production appealed to Federal Court
- AquaBounty genetically-modified salmon approved by FDA

Approval in November

AquaBounty Technologies, based in Massachusetts, <u>received approval from the FDA</u> in November 2015 to sell the first genetically modified food animal in the world.

"The FDA has thoroughly analyzed and evaluated the data and information submitted by AquaBounty Technologies regarding AquAdvantage Salmon and determined that they have met the regulatory requirements for approval, including that food from the fish is safe to eat," said Bernadette Dunham, director of the FDA's Center for Veterinary Medicine, in a news release in November, 2015.

AquaBounty has asked Health Canada to be allowed to sell the fish as food in Canada. That request is still under review.

The eggs for the salmon are raised in a facility in the eastern P.E.I. community of Bay Fortune and exported to Panama, where they're grown out in above-ground tanks.

AquaBounty Technologies first sought approval for its salmon 20 years ago.

The plaintiff group includes Pacific Coast Federation of Fishermen's Associations, Institute for Fisheries Resources, Golden Gate Salmon Association, Kennebec Reborn, Friends of Merrymeeting Bay, the Halifax-based Ecology Action Centre, Food & Water Watch, Center for Biological Diversity, Friends of the Earth, Cascadia Wildlands, and Center for Food Safety.

All are being represented in the lawsuit by legal counsel from the Center of Food Safety and Earthjustice.

In an email response, a spokesperson for the FDA said, "As a matter of policy, the FDA does not comment on pending litigation."

Corrections

• A previous version of this story said Health Canada has approved the salmon. In fact that request from Aquabounty is still under review.

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