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## Lawsuit Challenges FDA's Right to Approve Genetically Modified Animals

## Environmental groups say agency overstepped its authority in approving a modified salmon



**SENLARGE** 

This undated 2010 handout photo provided by AquaBounty Technologies shows two same-age salmon, a genetically modified salmon, rear, and a non-genetically modified salmon, foreground. Environmental groups have filed suit against the Food and Drug Administration for legalizing these fish and other animals as food. Photo: Associated Press

By Jacob Bunge Updated March 31, 2016 3:51 p.m. ET 30 COMMENTS

Environmental groups filed a lawsuit against the U.S. Food and Drug Administration Thursday, challenging the agency's authority to approve genetically modified animals used for food.

The lawsuit is seeking to <u>overturn the FDA's November approval</u> of a modified salmon that grows twice as fast as wild versions, and block its jurisdiction over a range of new biotech animals under development, such as a fast-growing trout and hornless dairy cows.

The lawsuit, filed in U.S. District Court for the Northern District of California, accuses the FDA of overstepping its authority in approving the salmon, developed by <u>AquaBounty Technologies</u> Inc., a unit of <u>Intrexon</u> Corp. The fish was the first genetically modified animal cleared for human consumption.

The groups said the FDA's regulation of such technology under the Federal Food, Drug and Cosmetic Act—regulating genetic modification under provisions covering animal drugs—goes beyond the law's scope.

"Congress never intended that law to cover these novel, man-made, genetically engineered animals," said George Kimbrell, senior attorney for the Center for Food Safety, which filed the lawsuit along with Friends of the Earth, the Center for Biological Diversity, and other groups.

An FDA spokeswoman said the agency doesn't comment on pending litigation.

The legal challenge is the latest front in an expanding debate over the use of genetically modified organisms, or GMOs, in food production.

In the U.S., where more than 90% of corn and soybean acres are sown with biotech crops resistant to bugs and herbicides, major food companies are beginning to roll out labels denoting GMO ingredients, in response to a Vermont law set to take effect in July.

Proponents of the technology say that adding non-native genes to plants helps farmers raise sturdier crops using less pesticides. In the case of the salmon, backers argue that genetic engineering can help produce filets using 20%-25% less feed.

Critics say that GMO crops rely on weedkillers that, when used heavily, contribute to the development of herbicide-resistant weeds that can choke out GMO and organic crops alike.

The groups behind the lawsuit over the AquaBounty salmon warn it could escape and threaten wild salmon populations, a risk AquaBounty officials have downplayed.

Other GMO food animals are in the works.

AquaBounty officials said in a February regulatory filing that the firm is working on a modified trout that adds weight faster than conventional rainbow trout, and is preparing studies for regulatory review.

Minnesota-based Recombinetics Inc. has been using gene-editing technology to develop dairy cattle that don't grow horns, which typically are cut off to ensure the animals don't injure workers or one another, a process that has drawn criticism from animal welfare groups.

The FDA has jurisdiction over animals genetically engineered for other purposes.

The agency in March sought public comment on a plan by Oxitec Ltd., another Intrexon subsidiary, to test genetically modified mosquitoes in Florida as a pesticide-free way to cull populations that could carry the Zika virus.

Mr. Kimbrell said the groups' lawsuit is aimed at GMO animals raised for food production, though it could "indirectly affect" the FDA's jurisdiction over other modified animals.

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