Reuters Life | Thu Mar 31, 2016 4:17pm EDT <u>http://www.reuters.com/article/us-aquabounty-fda-lawsuit-idUSKCN0WX1PE</u> Related: <u>Health, Environment</u>

U.S. environmentalists sue to overturn approval of GMO salmon

CHICAGO | By Tom Polansek



An AquAdvantage Salmon is pictured in this undated handout photo provided by AquaBounty Technologies.

Reuters/AquaBounty Technologies/Handout via Reuters

U.S. health regulators are facing a lawsuit from a coalition of environmental organizations seeking to overturn the government's landmark approval of a type of genetically engineered salmon to be farmed for human consumption.

The Center for Food Safety, Food and Water Watch, Friends of the Earth and other groups allege in the lawsuit, filed on Wednesday, that the Food and Drug Administration (FDA) failed to consider all of the environmental risks of the fish when the agency approved it in November. The FDA also cleared the product, made by Massachusetts-based AquaBounty Technologies, without having the proper authority to regulate genetically engineered animals produced for food, according to the complaint.

The agency declined to comment on the lawsuit on Thursday. Its approval of AquaBounty salmon followed a 20-year review and was the first such approval for an animal whose DNA has been scientifically modified.

AquaBounty is confident the FDA's approval will stand, Chief Executive Ron Stotish said in a statement. The agency was "extraordinarily thorough and transparent in the review and approval of our application," he said.

The company has said its salmon can grow to market size in half the time of conventional salmon, saving time and resources.

However, the FDA approval process included "an extremely limited environmental assessment" that did not fully evaluate the potential for AquaBounty salmon to escape from the facilities where they are grown, among other risks, according to the lawsuit.

The legal challenge comes as the U.S. food industry is facing increased pressure from consumers to provide more information about the use of genetically engineered ingredients.

General Mills Inc and other major food companies are rolling out new disclosures on products to comply with a Vermont law that will require labels on foods made with genetically modified organisms, or GMOs.

Major retailers, including Kroger Co and Target Corp, have already said they do not plan to stock AquaBounty salmon on store shelves. It is not yet available for sale.

Activists worry the FDA's approval of the salmon will serve as a precedent for other genetically engineered food animals.

Their lawsuit seeks to prohibit the FDA from taking further action on the fish or any other genetically engineered animal for human consumption until Congress grants an agency clear authority over such products.

The case is Institute for Fisheries Resources et al v Sylvia Mathews Burwell et al, U.S. District Court, Northern District of California, No. 16-cv-01574.

(Reporting by Tom Polansek; Editing by Richard Pullin and Andrew Hay)