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## Lawsuit Challenges FDA's Approval of Genetically Engineered Salmon

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A coalition of environmental, consumer, and commercial and recreational fishing organizations has sued the Food and Drug Administration (FDA) for approving the first-ever genetically engineered (GE) food animal, an Atlantic salmon engineered to grow quickly.



The man-made salmon was created by AquaBounty Technologies, Inc. with DNA from three fish: Atlantic salmon, Pacific king salmon, and Arctic ocean eelpout.

It marks the first time any government in the world has approved a GE animal for commercial sale and consumption.

“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. “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.”

In approving the GE salmon, FDA determined it would not require labeling of the GE fish to let consumers know what they are buying, which led Congress to call for labeling in the 2016 omnibus spending bill. FDA’s approval also ignored comments from nearly two million people opposed to the approval because the agency failed to analyze and prevent the risks to wild

salmon and the environment, as well as fishing communities, including the risk that GE salmon could escape and threaten endangered wild salmon stocks.

AquaBounty's GE salmon will undertake a 5,000-mile journey to reach U.S. supermarkets. The company plans to produce the GE salmon eggs on Prince Edward Island, Canada.

The GE salmon will then be grown to market-size in a facility in Panama, processed into fillets, and shipped to the U.S. for sale.

AquaBounty has publicly announced plans to ultimately grow its GE fish in the U.S. rather than Panama, and sell it around the world.

Despite this, FDA's approval only considered the current plans for the far-flung facilities in Canada and Panama, leaving the risk of escape and contamination of U.S. salmon runs unstudied.

[The lawsuit challenges FDA's claim](#) that it has authority to approve and regulate GE animals as "animal drugs" under the 1938 Federal Food, Drug, and Cosmetic Act.

Those provisions were meant to ensure the safety of veterinary drugs administered to treat disease in livestock and were not intended to address entirely new GE animals that can pass along their altered genes to the next generation.

The approval of the GE salmon opens the door to other genetically engineered fish and shellfish, as well as chickens, cows, sheep, goats, rabbits and pigs that are reportedly in development, the coalition said.

The lawsuit also highlights FDA's failure to protect the environment and consult wildlife agencies in its review process, as required by federal law. U.S. Atlantic salmon, and many populations of Pacific salmon, are protected by the Endangered Species Act and in danger of extinction. Salmon is a keystone species and unique runs have been treasured by residents for thousands of years.

Diverse salmon runs today sustain thousands of American fishing families, and are highly valued in domestic markets as a healthy, domestic, "green" food.

When GE salmon escape or are accidentally released into the environment, the new species could threaten wild populations by mating with endangered salmon species, outcompeting them for scarce resources and habitat, and/or introducing new diseases.

Studies have shown that there is a high risk for GE organisms to escape into the natural environment, and that GE salmon can crossbreed with native fish. Transgenic contamination has become common in the GE plant context, where contamination episodes have cost U.S. farmers billions of dollars over the past decade. In wild organisms like fish, it could be even more damaging.

The world's preeminent experts on GE fish and risk assessment, as well as biologists at U.S. wildlife agencies charged with protecting fish and wildlife heavily criticized the FDA decision for failing to evaluate these impacts. FDA ignored their concerns in the final approval.

“FDA has not answered crucial questions about the environmental risks posed by these fish or what can happen when these fish escape,” said Earthjustice attorney Brettny Hardy and co-counsel for plaintiffs. “We need these answers now and the FDA must be held to a higher standard. We are talking about the mass production of a highly migratory GE fish that could threaten some of the last remaining wild salmon on the planet. This isn't the time to skimp on analysis and simply hope for the best.”

The coalition, jointly represented by legal counsel from Center for Food Safety and Earthjustice, includes Pacific Coast Federation of Fishermen's Associations, Institute for Fisheries Resources, Golden Gate Salmon Association, Kennebec Reborn, Friends of Merrymeeting Bay, Ecology Action Centre, Food & Water Watch, Center for Biological Diversity, Friends of the Earth, Cascadia Wildlands, and Center for Food Safety.