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Lawsuit Challenges FDA Approval of Genetically Engineered Salmon

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Product Liability and Mass Torts

Last November, we posted that the Food and Drug Administration (FDA) had approved a genetically engineered (GE) salmon: AquaBounty Techonologies' AquAdvantage Salmon. This approval marked the first time that the FDA authorized selling a genetically engineered animal for human consumption.

Immediate backlash followed the FDA's November 19, 2015 announcement from environmental and consumer advocacy groups. On March 31, 2016, environmental and food safety groups, as well as fisherman trade associations, sued the FDA and related agencies in federal court in California. The suit seeks to reverse the FDA's approval of the fish for human consumption.

The complaint alleges that the FDA failed in its statutory duty to take a "hard look" at how GE salmon will impact the environment. The plaintiffs warn that the FDA did not appreciate the risk that the farmed salmon would inevitably escape, "interbreed with wild endangered salmon, compete with them for food and space, or pass on infectious disease . . . ."

The plaintiffs also take aim at the FDA's authority to regulate GE animals under the Federal Food, Drug, and Cosmetic Act (FFDCA), arguing that, back in 1938, Congress did not expect the FDA to regulate genetically engineered animals for human consumption: "GE animals present enormously different risks and impacts than drugs, requiring different expertise, analyses, and regulation than were contemplated when Congress enacted the FFDCA."

Whether additional lawsuits will follow this one remains to be seen. In our November post, we predicted that consumers could sue to challenge the labeling of the GE fish. Although the FDA initially determined that AquaBounty would not need to label its salmon as GE, a provision in December's 2016 Omnibus Appropriations Bill required the FDA to ban GE salmon imports until it published labeling guidelines for the fish. In February, the FDA issued that ban and announced its plans to establish labeling guidelines.

Even if AquaBounty puts FDA-approved labeling on its product, consumers still may sue under failure to warn and related legal theories. The food industry has had some success defending state law food labeling claims based on federal preemption. But the federal Nutrition Labeling and Education Act exempts claims based on the adequacy of safety warnings unless the FDA has actually considered a risk and determined that no warning is necessary. So, the key question in any consumer personal

injury suit involving GE salmon likely will be whether the FDA considered the risk of the alleged harm in implementing its new labeling guidelines.

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