

THE NATIONAL LAW REVIEW

FDA Holds Ground in Challenge over GE Animal Regulatory Authority

Friday, July 12, 2019

As previously reported on this [blog](#), on June 11, the President issued [Executive Order Modernizing the Regulatory Framework for Agricultural Biotechnology Products](#), ensuring coordination across federal regulatory agencies for biotechnology products. Referring to gene-edited crops and animals, the executive order told regulators to use their existing powers “to exempt low-risk products of agriculture biotechnology from undue regulation.”

Currently, FDA regulates these animals under the “new animal drug” provisions of the Federal Food, Drug, and Cosmetic Act and FDA’s implementing regulations for new animal drugs. FDA has only approved one GE animal, the [AquAdvantage Salmon](#) in 2015 after determining that it met the statutory requirements for safety and effectiveness under the Federal Food, Drug, and Cosmetic Act.

Shortly after the release of the June 11 Executive Order noted above, the National Pork Producers Council (NPPC) put out a “[Keep America first in agriculture](#)” platform that states that “under FDA regulation, gene editing [in American livestock] faces an impractical, lengthy and expensive approval process.” The NPPC has called for regulatory oversight of GE animals to shift to USDA, arguing that it already has a review process in place for genetic editing in plants under its Animal and Plant Health Inspection Service.

As [reported](#), FDA has pushed back against the NPPC call for USDA to take control over the regulation of GE animals. Steve Solomon, director of FDA’s Center for Veterinary Medicine, said the agency has the right framework and expertise after decades of reviewing biotech applications and building teams that are steeped in the science. Whether and how the hog industry continues to challenge FDA’s authority over the regulation of GE animals remains to be seen.

© 2019 Keller and Heckman LLP

Source URL: <https://www.natlawreview.com/article/fda-holds-ground-challenge-over-ge-animal-regulatory-authority>



Article By
[Food and Drug Law at Keller and Heckman](#)
[Keller and Heckman LLP](#)
[The Daily Intake](#)
[Biotech, Food, Drug](#)
[Administrative & Regulatory](#)
[All Federal](#)