

USDA, Health and Human Services reach agreement to bring US animal gene-editing rules 'into the 21st century'



S. Secretary of Agriculture Sonny Perdue issued the following statement after signing a [Memorandum of Understanding](#) with the Assistant Secretary for Health and Head of the Public Health Service Admiral Brett Giroir, M.D., establishing a regulatory environment at the Department of Agriculture for agricultural animal biotechnology innovation:

[Jan. 19's] Memorandum of Understanding clears a path to bring our regulatory framework into the 21st century, putting American producers on a level playing field with their competitors around the world. In the past, regulations stifled innovation, causing American businesses to play catch-up and cede market share," said Secretary Perdue. "America has the safest and most affordable food supply in the entire world thanks to the innovation of our farmers, ranchers and producers. Establishing a new, transparent, risk and science-based regulatory framework would ensure this continues to be the case.

Background:

[On January 19], the U.S. Department of Agriculture (USDA) announced the finalization of a Memorandum of Understanding (MOU) with the U.S. Department of Health and Human Services' Food and Drug Administration (FDA) outlining responsibilities concerning the regulation of certain animals developed using genetic engineering that are intended for agricultural purposes (such as human food, fiber, and labor). This MOU complements USDA's issuance of an Advanced Notice of Proposed Rulemaking (ANPR) on the Movement of Animals Modified or Developed by Genetic Engineering on December 28, 2020.

Agricultural biotechnology holds tremendous potential to improve animal health, enhance farm productivity, improve nutrition, and even reduce the need for some animal health measures. USDA and FDA have a long history of delineating the review of products with overlapping jurisdictional authority between the two agencies to promote regulatory clarity and reduce duplicative review. USDA and FDA are committed to working together to foster safe use of this promising technology and encourage innovation.

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The terms of the MOU support USDA's ANPR outlining a contemplated regulatory framework that would apply to certain animals (cattle, sheep, goats, swine, horses, mules, or other equines, catfish, and poultry) developed using genetic engineering intended for agricultural purposes. Under this framework, USDA would safeguard animal and human health by providing end-to-end oversight from pre-market reviews through post-market food safety monitoring for certain farm animals modified or developed using genetic engineering that are intended for human food.

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Editor's note: FDA Commissioner Stephan Hahn Tweeted Jan. 19 that his agency opposes this MOU with the USDA. Read the entire [Twitter thread here](#).[/su_panel]

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The MOU also allows for the transition of portions of FDA's pre-existing animal biotechnology regulatory oversight to USDA. USDA would continue to coordinate closely with FDA to fulfill oversight responsibilities and provide the appropriate regulatory environment, ensuring the safety of products derived from new technologies and fostering innovation at the same time. As always, FDA would continue its review of intentional genomic alterations intended for any purpose other than agricultural use, such as biopharma and non-heritable genomic alteration, and the regulation of dairy products, table and shell eggs, certain meat products, and animal food (feed) derived from animals developed using genetic engineering.

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