US universities push for fewer hurdles on gene editing farm animals

Veterinary schools lead campaign protesting regulatory obstacles applied to an array of food-related genomic research

July 26, 2021

Paul Basken (/author/paul-basken)

Twitter: @pbasken (https://twitter.com/pbasken)

A coalition of US veterinary schools and public colleges is pressing the federal government to remove obstacles to gene editing in farm animals that they say are blocking hundreds of critical food-related research projects.

Source: iStock

The US has several dozen agricultural and veterinary colleges, and nearly all of them could push ahead needed research on hundreds of projects if regulatory processes were improved,

the academic associations are insisting in a new analysis (https://www.aavmc.org/wp-content/uploads/2021/07/AAVMC-Gene-Editing-Report-12.pdf).

“It’s been such a roadblock for years,” said Noelle Cockett, president of Utah State University (https://www.timeshighereducation.com/world-university-rankings/utah-state-university), who led the just-concluded review for the American Association of Veterinary Medical Colleges and the Association of Public and Land-grant Universities.

The hundreds of projects worthy of research, but which are largely frozen by fear of regulatory chaos, include improving the ability of meat-producing animals to also deliver good-quality milk or wool and improving their disease resistance, Dr Cockett said.

A chief argument of the university groups is that researchers and industry have been using gene-editing insights to cross-breed animals of the same species for decades, yet the rules appear to be getting tougher just because the technical methods of accomplishing the same basic tasks have grown more sophisticated.

Advances including CRISPR-Cas9, the newest and most advanced gene-editing tool, have “so much potential” in such areas, Dr Cockett said, but much of it is stifled “because no university is going to bet on getting this into production at this point”.

Experts warn, however, that the universities are being pulled by the lure of corporate partnerships into a political minefield that’s brought heavy controversy since gene-editing techniques were first developed in the 1970s.

The US Food and Drug Administration (FDA) has primary responsibility for approving genetically modified foods, and it does have a tough approval process, said Jennifer Kuzma, professor of public and international affairs at North Carolina State University (https://www.timeshighereducation.com/world-university-rankings/north-carolina-state-university).

But that's not unwarranted given the complexities and potential implications of genetic changes that could become permanent and spread across the food supply, said Professor Kuzma, a co-founder and co-director of the Genetic Engineering and Society Center at NC State.

Research delays attributed to the FDA may be upsetting some universities but could benefit them in the long run if it prevents a dangerous mistake, Professor Kuzma said.

A textbook cautionary tale has been the attempt to breed dairy cattle without horns. The horns are dangerous in farm settings, and their physical removal is hard on the animal.

Researchers at the University of California at Davis have developed genome-edited dairy bulls that don't grow horns, but their commercial partners haven't been able to win FDA approval for their use in milk production.

For Dr Cockett, the case is an example of why regulatory authority for such work should be moved from the FDA to the US Department of Agriculture, which handles many federal laws related to farming and has a much simpler approval process.

"We're not proposing that there be no regulation," she said in an interview. But cattle without horns do occur naturally, and there's no obvious harm in using genetic techniques to make the condition more widespread, she said.

Opponents, however, cite the case of Recombinetics, a gene-editing company that made its own hornless cattle. A subsequent review by the FDA found that its genetic alteration also created antibiotic resistance in their animals and the company apologised for missing that fact (https://www.technologyreview.com/2019/08/29/65364/recombinetics-gene-edited-hornless-cattle-major-dna-screwup).

That unexpected alteration may not have been harmful to anyone, but it showed the benefit of rigorous FDA oversight, Professor Kuzma said.

It is also wrong to believe that a genetic manipulation that occurs in nature is automatically safe to repeat on a large scale with more advanced gene-editing methods, said Greg Jaffe, director of the Project on Biotechnology at the Center for Science in the Public Interest.

“What should drive the risk assessment is the final product”, not just the pathway for getting there, he said.

Corporate partners and their motivations may also bring a level of risk that academic scientists might not create on their own, said Jaydee Hanson, policy director at the Center for Food Safety.

“One of the challenges, frankly, is that the companies don’t want to do what they’re asked to do, and they don’t do it well,” he said.

FDA officials said in an interview that their agency recognised such concerns in academia and has been trying both to lessen the regulatory burden and to better explain the processes to researchers.

The FDA does have an expedited process for relatively low-risk genetic alterations in farm animals, where approval can be granted within a few months, said Heather Lombardi, director of the Division of Animal Bioengineering and Cellular Therapies at the FDA's Center for Veterinary Medicine.

FDA officials started a campaign a few years ago to meet researchers at conferences and other events to describe such options, although the pandemic greatly hindered that outreach, Dr Lombardi said.

“We need to do a better job of reaching people in academia, in explaining our process a bit better," she said. The report by the university groups, she said, “helps us realise we need to do a better job not only reaching out to academia, but a lot of our different types of stakeholders.”

paul.basken@timeshighereducation.com (mailto:paul.basken@timeshighereducation.com)

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