Gene-edited animals face uncertain future under proposed FDA regulations

Editor's note: The comment period for these regulations — as well as those proposed by the USDA — opened on Jan. 19 in an apparent attempt to coordinate oversight of gene editing. The comment period runs through April 19. Read the FDA's proposal here.

Researchers transforming animals with the latest genome-engineering tools may be disappointed by draft rules released by the US Food and Drug Administration (FDA) on 18 January — two days before US President Barack Obama leaves office. It is not clear how the administration of incoming president Donald Trump will carry the proposals forward, however.

The most controversial of three proposed regulations declares that all animals whose genomes have been intentionally altered will be examined for safety and efficacy in a process similar to that for new drugs

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Alison van Eenennaam, an animal geneticist at the University of California, Davis, calls the draft FDA proposals "insane".

"The trigger for their regulation is whether the animal was intended to be made, and what does intention have to do with risk?" she says. "The risk has to do with the attributes of the product."

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Others welcomed the Obama administration's last-minute overture. "The public is leery of genetic engineering of animals, in particular," says Jennifer Kuzma, a social scientist at North Carolina State University in Raleigh.

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"Because of measures like this, almost everything in genetic engineering will have to be done by huge multinational companies," [van Eenennaam said].

The GLP aggregated and excerpted this blog/article to reflect the diversity of news, opinion, and analysis. Read full, original post: Gene-edited animals face US regulatory crackdown