



Biotechnology Innovation Organization
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February 16 2022

Ms. Shalanda Young, Acting Director
Office of Management and Budget
Executive Office of the President
725 17th Street, NW
Washington, DC 20503

Re: U.S. Oversight of Animals Derived from Biotechnology

Dear Madam,

The Biotechnology Innovation Organization (BIO) writes this letter to urge the Biden Administration to take specific and immediate steps towards modernizing U.S. oversight of animals derived from biotechnology, especially those intended for agricultural use. Specifically, we ask that the Office of Management and Budget (OMB) allow the Food and Drug Administration (FDA) to promptly publish a draft guidance document for stakeholder notice and comment on proposed changes to FDA's regulatory framework for animal biotechnology. BIO is the world's largest trade association representing nearly one thousand biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO's member companies represent global leaders in the use of biotechnology in animals.

The use of biotechnology to improve the genetics of animals used in agriculture has the potential to address a broad array of societal issues important to this Administration— adapting to climate change; increasing the sustainability of animal agricultural production; improving animal health and welfare; improving human health and nutrition; and responding effectively to zoonotic disease. The success of these innovations is critically dependent on regulatory systems that incentivize development and commercialization of innovation.

FDA's Center for Veterinary Medicine (CVM) currently regulates "intentional genomic alterations" in animals utilizing the new animal drug authority under the Federal Food, Drug, and Cosmetics Act (FFDCA), as described in draft "Guidance for Industry #187" (GFI 187).¹ In recent years, BIO and a wide range of stakeholders have expressed concern over FDA's approach to oversight of animal biotechnology. To date, that approach has significantly reduced the likelihood that such animals will

¹ <https://www.fda.gov/media/74614/download>



be grown by producers or products derived from them accepted by consumers and is therefore having real and immediate impacts on our members and the U.S.'s ability to remain the leader in animal biotechnology.

BIO strongly believes that an effective regulatory framework for the oversight of biotech animals intended for agricultural use should be based upon the following principles:

- 1) Oversight must protect animal health and welfare, ensure the safety of food and feed derived from the animals, and consider the possible impacts of the animals on the environment.
- 2) Implementation of oversight must be clear, transparent, efficient, predictable, timely, and based upon the best available science.
- 3) Risk assessment must be proportionate to the actual risk posed by the specific species/trait combination. Lower-risk, more-familiar traits, including traits that impart health benefits to humans and animals, should be given a more expedited review than traits for which there is less familiarity or greater uncertainty.
- 4) Once all appropriate safety reviews are completed, the approved animals should be allowed to be treated as any other farm animal in production and commerce. Ongoing post-market regulatory requirements imposed on such animals, even after they have been determined to be as safe as conventional animals, strongly disincentivizes development and commercialization of farm animals with improved traits.

In late 2020, the U.S. Department of Agriculture (USDA) proposed an alternate framework for oversight of certain animals modified or developed through genetic engineering built upon various USDA food safety and health inspection authorities.² BIO submitted comments on the proposal.³ BIO appreciated USDA's initiative to develop a new framework based on USDA's overlapping regulatory authorities to address stakeholder concerns with FDA's process. But as noted in BIO's comments, the framework would give rise to certain challenges, not the least of which relates a lack of clarity regarding support for the USDA framework by FDA, which would continue to have a role in regulating animal biotechnology under that proposal.

² 85 Fed. Reg. 84269-84275 (December 28, 2020).

³ <https://www.regulations.gov/comment/APHIS-2020-0079-2275>



CVM leadership and staff should be strongly commended for their willingness to have an open, fruitful dialogue with stakeholders like BIO. While CVM has expressed an openness to consider creative, collaborative refinements to their oversight program, they are unfortunately constrained in their ability to adopt impactful change without making significant revisions to their existing GFI 187. Therefore, we believe it is in the interest of improving U.S. oversight of animal biotechnology for OMB to **allow CVM to promptly publish a revised draft of GFI 187 in the *Federal Register***. Doing so would give all stakeholders an ability to review, analyze, and comment on changes FDA has proposed to its process for animal biotechnology based on stakeholder feedback to date.⁴ Such a public comment period could further inform whether a regulatory role for USDA is helpful or necessary, given significant proposed changes at FDA.

We would be pleased to meet with you in the near future to discuss this matter further.

Yours Sincerely,

A handwritten signature in black ink, appearing to read "MMH", written over a white background.

Michelle McMurry-Heath, MD, PhD
President and Chief Executive Officer
Biotechnology Innovation Organization

cc: The Honorable Xavier Becerra, Secretary, U.S. Department of Health and Human Services
The Honorable Thomas Vilsack, Secretary, U.S. Department of Agriculture
The Honorable Robert Califf, Commissioner, Food and Drug Administration

⁴ Because needed revisions to GFI 187 are likely substantial and may relate to issues upon which the agency did not solicit input previously, BIO does *not* support publication of a revised GFI 187 as final guidance at this time.