

Animals and Genetic Innovation

Innovations in animal biotechnology can improve human and animal health, make our farming and food systems more sustainable, and boost our bioeconomy. But these breakthroughs are dependent on a clear, timely, and science based regulatory approval process that provides a viable path to market.

FDA's Current Regulatory Approach Is an Impediment to Innovation.

FDA uses its “new animal drug” authority under the Food, Drug, and Cosmetics Act to assess animal biotechnologies.

- Evaluating animals under this pharmaceutical-based framework is essentially forcing a square peg in a round hole. Under this system, genetically engineered animals and their progeny could be considered “drugs” and farms and ranches could be regulated as “drug manufacturing facilities.”
- For developers, the FDA's current evaluation process is time-consuming, opaque, unpredictable, and disproportionate to the actual risk posed by the products being evaluated.
- FDA has suggested it plans to also regulate gene-edited animals under this system – even those products with edits that could have occurred naturally or through conventional breeding.

The administration's actions on animal biotechnology are inconsistent with its overall efforts to streamline biotechnology regulations, and have driven American research, jobs, and innovation overseas.

The Health of our Society and our Economy are at Risk.

- In more than two decades, the United States has approved only one biotechnology food animal for production and sale. Other beneficial products are either shelved or have moved to other countries with more predictable commercial pathways, such as Brazil, Argentina, and China.
- As animal biotechnology projects dry up in the United States and move to other countries, we also lose research, high paying jobs, start-up companies, and investment in an industry that generates an estimated half-billion dollars in revenue annually.
- Sixty percent of human diseases begin in animals. As the climate warms, zoonotic diseases such as COVID-19 are becoming more prevalent and present greater risks to animal and human health and to our economy.

In the midst of a global pandemic, climate change, and other challenges, now is the time for America to reclaim its position as an innovation leader by embracing the solutions that technology provides.

BIO Is Proposing Improvements to our Regulatory System for Animal Biotechnology.

- BIO and other stakeholders support a joint agreement between federal agencies whereby the USDA leads regulatory oversight of biotechnology-derived food animals and the FDA leads oversight of non-food and biomedical animals.
- In addition, FDA should conduct a review of its process and implement specific process changes to improve its decision-making, transparency, and timelines for reviews. Developers and other stakeholders need confidence that FDA will be held accountable for approval timelines and ensure that the pathway to commercialization is predictable, clear, consistent, and based on risk.
- To ensure America's farmers and ranchers have access to cutting-edge technologies to remain globally competitive and resilient to disease and climate change, the United States must have risk-proportionate regulations that spur biological innovations, while protecting health and environment.

Biotechnology as a Solution

Benefits for Farmers, Ranchers, and Food Production are at Stake.

Advances in animal breeding is making the production of meat, milk, and fish more sustainable; enhancing animal well-being; and increasing the accessibility of high-quality protein.

- The only GE food animal to be approved to date, the AquAdvantage salmon, grows to market weight faster and can be grown in contained facilities close to population centers – making it more environmentally friendly to produce and easier to bring fresh fish to consumers.
- There are fewer than half the dairy cows in the United States today as there were in 1950s, and average milk production per cow has nearly doubled, largely because of genetic improvements through traditional breeding. These improvements took more 60 years to accomplish, but the use of technologies, such as gene editing, could allow us to make similar improvements in a fraction of the time.
- Improvement of animal genetics will also be a critical aspect to helping livestock producers around the world adapt to climate change and helping animals tolerate extreme weather. For example, the genetics of cattle can be improved to make them heat-tolerant, potentially boosting protein production by as much as 50 percent.

Benefits for Human and Animal Health are Also at Stake.

Innovation in animal biotechnology may be able prevent, prepare for, and respond to outbreaks of infectious diseases such as coronavirus, Ebola, Zika, avian influenza (HPAI), and MERS, by creating more disease-resistant animals and supporting the development of disease treatments for humans. However, due to a lack of a viable regulatory path to market, many solutions, including those listed below, have languished:



Genetically designed cattle produce fully human polyclonal antibodies to provide treatments for infectious diseases such as COVID-19.



Researchers are working to develop pigs with genetic resistance to African Swine Fever and Foot and Mouth Disease.



Scientists have developed a chicken that is genetically resistant to contracting and transmitting avian influenza.



Biotechnology can arm dairy cows with resistance to mastitis, the top reason for antibiotic use in dairy cows.



Biotech goats can produce lysozyme, a human antimicrobial enzyme that destroys disease-causing bacteria.



Biotech mosquitoes are being deployed to reduce mosquito populations and reduce the risk of insect-borne diseases.