Animals and Genetic Innovation

Innovations in animal biotechnology can improve human and animal health, make our farming and food systems more sustainable and resilient, 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.

The health of our society and our economy are at risk.

- In more than two decades, the United States has approved only two biotechnology-enhanced food animals for production and sale. The prolonged and unclear regulatory path is forcing innovators to shelve beneficial applications in animals or shift R&D towards genetic improvements for animal production in other countries with more predictable commercial pathways, such as Brazil, Argentina, and China.

- The United States risks losing research, high-paying jobs, start-up companies, and investment in an industry that generates an estimated half-billion dollars in revenue annually.

- More than 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 wake of a global pandemic and the increasing threat of climate change, now is the time for America to reclaim its position as an innovation leader.

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 are regulated as if they contain "drugs" and farms, and ranches could be regulated as "drug manufacturing facilities."

- For developers, the FDA's current evaluation process is time-consuming, opaque, and unpredictable for the products being evaluated.

- FDA uses this system even for those products with genetic improvements that could have occurred naturally or through conventional breeding.

> The United States actions on animal biotechnology are inconsistent with the country's overall efforts to streamline biotechnology regulations, and empower American research, job growth, and innovation.

BIO is proposing improvements to the U.S. regulatory system for animal biotechnology

- BIO is calling on the White House to provide leadership to FDA and USDA in establishing an improved, coordinated framework for oversight of animal biotechnology that is efficient, transparent, predictable, and risk proportionate.

- In 2020, USDA issued an Advance Notice of Proposed Rulemaking (ANPR) on whether to establish its own regulatory system for oversight of biotech livestock animals intended for food; however, without the support of FDA, this proposed USDA framework is largely redundant.

- FDA should conduct a thorough review of its premarket review process and post-market-oversight system and implement specific changes to improve its decision-making, transparency, and timelines to ensure that its oversight does not unintentionally disincentivize innovation and market adoption. Developers and other stakeholders need confidence that FDA will be held accountable for overhauling its oversight and providing a pathway to commercialization that is predictable, clear, consistent, and based on risk.

Biotechnology Innovation Organization

Benefits for farmers, ranchers, the environment, and food production are at stake.

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

- After 20 years of review, FDA approved the first bioengineered food animal—the AquAdvantage salmon—in 2015. The salmon is environmentally friendly because it grows to market weight with fewer resources compared to other salmon farmers and can be grown in contained facilities close to population centers.

- There are fewer than half the dairy cows in the United States today as there were in the 1950s, and average milk production per cow has nearly doubled, largely because of genetic improvements through traditional breeding. These improvements took more than 60 years to accomplish, but the use of technologies, such as gene editing, could allow us to make similar improvements to produce more protein with fewer animals in a fraction of the time, which means less land, feed, water, and emissions.

- 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 to 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. Examples of innovations in animal biotechnology that benefit the animals, people, and planet include:

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 Porcine Reproductive and Respiratory Syndrome Virus or PRRS

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.