

Congress of the United States
Washington, D.C. 20515

October 07, 2021

The Honorable Thomas J. Vilsack
Secretary
United States Department of Agriculture
1400 Independence Avenue SW
Washington, DC 20250

The Honorable Janet Woodcock, M.D.
Acting Commissioner
United States Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Secretary Vilsack and Acting Commissioner Woodcock,

As you know, several challenges facing the agriculture industry and our communities have emerged or intensified in recent years. Zoonotic disease, climate change, and a growing global population require us to consider new solutions to protect our food supply and sustainably meet demand. Ongoing research and existing innovations in animal genetics show great promise in addressing these challenges. However, an efficient, risk and science-based regulatory system that can create a safe, predictable path to market is imperative to capitalizing on these solutions. We believe the existing U.S. regulatory process for the review of animals developed or improved through biotechnology requires significant improvement to meet that standard, and we encourage the U.S. Department of Agriculture (USDA) and Food & Drug Administration (FDA) to continue working with each other and with other relevant federal partners to appropriately modernize this important process.

For thousands of years, genetic improvements have been a hallmark of agriculture. Over the last century, organized research and formal plant and animal breeding programs have rapidly advanced the success and sustainability of agricultural production. Since the 1950s, [milk production](#) in the United States has nearly doubled while using half the number of cows, reducing both the environmental footprint and costs of production. However, many of the challenges we face today will not afford us another 70 years to make similar incremental improvements. Zoonotic disease risks like SARS-CoV-2 or [recent avian influenza spread to humans in Asia](#), could be greatly mitigated by [disease-resistant livestock](#). Animals improved to reduce [methane emissions](#) or [improve heat tolerance](#) could play an important role in our efforts to address climate change and achieve more resilient supply chains.

Unfortunately, the existing regulatory system is not conducive to the timely adoption of these sorts of innovations. In the past 25 years, only two animals intended for agricultural purposes have been approved for use domestically by FDA. One of these innovations is primarily [intended for biomedical applications](#), and both took decades to achieve regulatory approval. A costly, protracted regulatory system will continue to stifle important agricultural innovations.

Efforts to modernize the regulatory environment for products of biotechnology have transcended administrations and party lines—a tradition we hope to see continued. In 2015, President Obama's Executive Office of the President (EOP) issued [a memo](#) initiating a process to modernize the Federal regulatory system for products of biotechnology with the objective of

ensuring public confidence, preventing unnecessary barriers to future innovation, and continuing to protect health and the environment. These are sound objectives, and we support efforts to continue exploring improvements in our regulatory system, such as USDA's publication of an Advance Notice of Proposed Rulemaking (ANPR) regarding whether to establish regulations for the movement of certain animals modified or developed using genetic engineering. We were heartened by the decision to extend the ANPR's comment period to ensure ample opportunity for thoughtful input from the public.

With the ANPR comment period now closed—and as the Administration decides how to best navigate this vital modernization effort—we encourage USDA and FDA to carefully consider the feedback provided by stakeholders. The challenges facing our food supply and society demand an improved regulatory approach, and we are hopeful that this Administration will rise to the occasion and empower agriculture with the tools necessary to be a part of the solution.

Sincerely,


STACEY E. PLASKETT
Member of Congress


JAMES R. BAIRD
Member of Congress

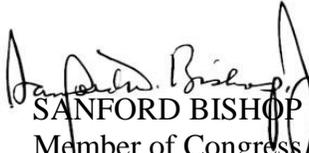

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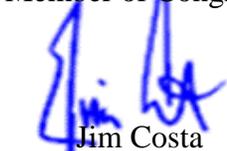

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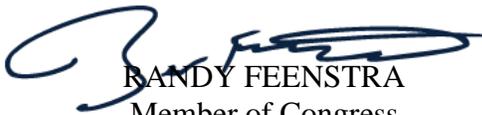

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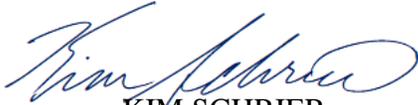
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