

April 14, 2022

The Honorable Tom Vilsack  
Secretary  
U.S. Department of Agriculture  
1400 Independence Avenue, SW  
Washington, D.C. 20250

Dear Secretary Vilsack:

We write to express our continued support for the U.S. Department of Agriculture's ongoing process to develop a modern regulatory structure related to gene editing in livestock. U.S. livestock producers face many urgent challenges, such as zoonotic disease, climate change, and a growing global population, which require us to consider new solutions to protect our food supply and sustainably meet demand. Gene editing is one technology that holds tremendous promise to help America's food and agricultural producers address these challenges. Producers need these tools to continue to sustainably produce an abundant, affordable food supply for America and the world. Unfortunately, as the House Agriculture Committee noted in its October 2021 letter to USDA and the U.S. Food and Drug Administration (FDA), "the existing system is not conducive to the timely adoption of these sorts of innovations."

The FDA's current regulatory approach – an approach that producers, other stakeholders, and Congress have repeatedly expressed concern with – will only stifle U.S. producers' access to much-needed innovations. Under the status quo, FDA regulators make case-by-case decisions on innovations to determine their regulatory pathway, data requirements, and ultimate market opportunities. The decades-long approval process for these technologies is based on FDA exercising enforcement discretion under agency guidance rather than through rulemaking. This is an untenable way to regulate. Academics, developers, and investors are unlikely to make the significant investments needed to research and develop agricultural innovations if they do not have clear, predictable criteria to achieve enforcement discretion and reasonable market access.

Gene editing technology offers livestock producers the opportunity to address the serious sustainability, animal health, and food security challenges facing our food supply in the 21<sup>st</sup> century. However, this potential can only be achieved if we have federal policies that are risk- and science-based, and that permit the meaningful adoption of these products by producers, supply chains, and consumers. We support USDA's ongoing efforts to modernize regulations governing these technologies, as proposed under the advanced notice of proposed rulemaking (ANPR) for the Regulation of Movement of Animals Modified or Developed by Genetic Engineering (APHIS-2020-0079). We strongly urge USDA to continue this rulemaking process to ensure U.S. agriculture is sufficiently equipped with the tools needed to address our food production challenges in the future.

Sincerely,

American Farm Bureau Federation  
American Soybean Association  
American Sheep Industry Association  
National Association of State Departments  
of Agriculture  
National Cattlemen's Beef Association

National Corn Growers Association  
National Council of Farmer Cooperatives  
National Milk Producers Federation  
National Pork Producers Council  
National Sorghum Producers  
National Turkey Federation