April 28, 2022

The Honorable Sanford Bishop, Jr.
Chairman
Subcommittee on Agriculture, Rural Development, Food and Drug Administration, Administration, and Related Agencies
U.S. House Committee on Appropriations
Washington, DC 20515

The Honorable Tammy Baldwin
Chairwoman
Subcommittee on Agriculture, Rural Development, Food and Drug and Related Agencies
U.S. Senate Committee on Appropriations
Washington, DC 20510

The Honorable Andy Harris
Ranking Member
Subcommittee on Agriculture, Rural Development, Food and Drug Administration, Administration, and Related Agencies
U.S. House Committee on Appropriations
Washington, DC 20515

The Honorable John Hoeven
Ranking Member
Subcommittee on Agriculture, Rural Development, Food and Drug and Related Agencies
U.S. Senate Committee on Appropriations
Washington, DC 20510

Dear Chairman Bishop, Chairwoman Baldwin, Ranking Member Harris, and Ranking Member Hoeven,

U.S. livestock producers face many urgent challenges, such as zoonotic disease, climate change, and helping to feed 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. Unfortunately, as bipartisan members of the House Agriculture Committee noted in their October 2021 letter to the U.S. Department of Agriculture (USDA) and the U.S. Food and Drug Administration (FDA) regarding gene editing in livestock, "the existing system is not conducive to the timely adoption of these sorts of innovations." We share these concerns and write to request report language in FY2023 Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations legislation supporting a more risk- and science-based regulatory pathway for agricultural applications of these technologies at USDA.

The FDA's current regulatory approach – one 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 regulates the DNA of animals as "animal drugs" and makes 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 21st 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. As your committees begin work drafting FY2023 Agriculture,

Rural Development, Food and Drug Administration appropriations legislation, we respectfully request you include report language directing USDA and FDA to implement a more appropriate pathway for agricultural applications of these innovations under USDA.

Sincerely,

American Farm Bureau Federation
American Sheep Industry Association
American Soybean Association
National Association of State Departments of Agriculture
National Cattlemen's Beef Association
National Council of Farmer Cooperatives
National Milk Producers Federation
National Pork Producers Council
National Turkey Federation