



Written Testimony of Iowa Pork Producers
Association President Mike Paustian on behalf
of the National Pork Producers Council on

**“Agriculture Innovation and the Federal
Biotechnology Regulatory Framework”**

U.S. Senate Committee on Agriculture,
Nutrition and Forestry

March 12, 2020



Chairman Roberts, Ranking Member Stabenow, and members of the Committee, I appreciate the opportunity to discuss issues of critical importance to U.S. pork producers. I am the president of the Iowa Pork Producers Association and a hog farmer from Walcott, Iowa.

I am also here today on behalf of the National Pork Producers Council, a national association representing the interests of 60,000 U.S. pork producers.

The U.S pork industry has been built on innovation. Our commitment to continuous improvement has made the United States the world's leading supplier of high-quality, safe and sustainably produced pork. However, we are currently in danger of ceding this advantage to international competitors due to significant flaws in the current U.S. approach to regulating animal biotechnology. While countries like Canada, China, Brazil and Argentina are moving quickly to gain a competitive advantage in the market, the U.S. is falling behind.

New animal breeding tools such as gene editing, which allow for precise changes within an animal's own genome, offer tremendous promise to further improve animal health and care, and produce safer food in a more sustainable fashion. Gene editing may allow us, for example, to finally stamp out Porcine Reproductive and Respiratory Syndrome (PRRS), a highly contagious disease that costs the pork industry more than \$1 billion dollars annually. Livestock producers need access to these technologies.

I want to be very clear that we are not advocating for de-regulation of these new technologies. Farmers support scientifically sound, transparent, risk-based regulations that ensure that these new tools are effective and safe for both animals and consumers. Our concern is not if this technology should be regulated, but rather by who and under what authority.

Under the current regulatory framework, the Food and Drug Administration (FDA) has authority over all applications of genetic technologies in animals. The agency is proposing regulating new tools such as gene editing in exactly the same manner that they have regulated older transgenic technologies under the Food, Drug and Cosmetics Act (FDCA) by approving the altered genome in specific lineages of animals put forward for evaluation as a "drug." In effect, this would regulate the animal—which is indistinguishable from the genetic material in every cell of its body—as a drug under U.S. law. Furthermore, this designation would apply to all offspring of edited animals in perpetuity.

There are myriad, grave problems with this approach. I will highlight several. First, the FDA proposal does not offer a staged, risk-based approach to regulatory oversight that recognizes the important distinctions between the many tools now available to affect genetic changes, and the different types of changes that can be made. Both the Coordinated Framework itself, and the National Academies of Sciences in its review of the

document, recommend a more nuanced approach. Simply put, we need a regulatory system that recognizes that simple, familiar changes within an animal's own genome—changes that mirror natural genetic diversity and harness it in a controlled fashion—do not need to go through a lengthy drug approval process and become saddled with a drug designation that will never go away.

Second, the FDA proposal does not appear to offer any path forward for species-level approval of a given edit. Rather, any edit would have to be individually evaluated for every breed, strain, family, and flock or herd of animals that wanted to incorporate a given trait. This is untenable. Not only does it not make sense from a scientific standpoint—a gene edit should be presumed to work in any member of a species with a shared genotype of interest unless compelling evidence suggest otherwise—but it sets up this regulatory pathway for failure. It will result in three outcomes: tremendous loss of genetic diversity in our herds and flocks, as entire industries move to the few approved animal lines with highly valued edits; a regulatory system bogged down with hundreds, if not thousands, of costly and time-consuming approval applications; and farmers simply not having access to this technology because the cost and ramifications of the regulatory system are simply too great to bear. None of these are acceptable outcomes. Simply put, this approach would severely slow down regulatory approval and makes this technology inaccessible to most U.S. livestock producers who maintain their own seedstock.

Third, the FDA has not demonstrated that it understands the complexity and breadth of the U.S. animal breeding—and indeed commercial production—industries. This is very concerning given the potential scope of authority FDA would be assuming for all aspects of animal agriculture under this proposal. Given even the assumption that an animal has a gene-edited ancestor, the FDA could bring authority under the FDCA to bear against any aspect of breeding, raising or processing that animal and the distribution, marketing and consumption of any product it produces. For example, the FDA could determine that any commercial sale of semen is potentially a drug sale. The agency could determine that any farm producing animals with gene-edited ancestors is a drug manufacturing facility. FDA could make the decision that any meat products produced from these animals would have to bear drug labels. We acknowledge that the FDA has said it does not intend to do any of these things, but that doesn't mean the agency wouldn't have the authority to do so. FDA's current assurances that regulatory discretion would be used do not provide sufficient comfort to ignore the huge potential disruptions this could cause.

The final significant problem is the very real potential for the United States to lose its standing as the top producer of high-quality, healthy and affordable pork in the global marketplace. Competitor nations are advancing reasonable regulatory pathways that aren't hampered by regulatory red tape. We are already seeing investments in research and development moving overseas, and ceding our global edge in animal breeding. If we continue down this path, our country will lose its competitive advantage in all animal agriculture.

In effect, we are subjecting U.S. exports from gene-edited livestock to damaging trade barriers, as FDA has said they will be regulated as drugs. It is naïve to think that this determination will not impact trade in animal products. Trading partners may be required under their bodies of law and regulation to bring their requirements for drug importation, which are very different from those for agricultural products. There are countries who wish to exclude U.S. agricultural products on spurious grounds; this will certainly give them new ammunition. We have had extensive conversations with regulators in other countries and they are scratching their heads at what we are doing.

The FDA has insisted that farmers simply misunderstand its regulatory proposal. This is incorrect. We, along with the scientific and trade communities, have clearly stated our strong objections to FDA's proposal. Alternative strategies the FDA could pursue under its authority have been put forth by multiple stakeholders and quickly rejected, if considered at all. The agency has not addressed these concerns in any meaningful way. Inexplicably, the agency remains entrenched in its flawed approach. The FDA has been given numerous opportunities to address this fundamental issue, only to dismiss it as inconsequential and insist that additional clarification is forthcoming. We are still waiting.

It is clear we need a new approach. Fortunately, we have a model that we can look to. The U.S. Department of Agriculture (USDA) has fostered the development and application of new breeding techniques in plants for decades under the Plant Protection Act. The USDA has acknowledged the real need to make development of genetically edited crops affordable, timely and accessible to smaller producers. Their approach will ensure that this technology can be broadly researched, developed and implemented at a pace that will maintain U.S. global leadership. The USDA approach means that we are poised for a revolution in crop production that will pay huge dividends to farmers, consumers and the environment. The USDA can do the same thing for agricultural applications of animal biotechnology in animals under the Animal Health Protection Act.

The USDA has the authority and expertise available to effectively regulate gene-edited livestock, leaving the FDA to focus its attention and resources on other exciting biomedical applications under development. As they do with plants, the USDA can draw upon the expertise of other agencies, such as the FDA, to make assessments as needed to ensure a complete and trustworthy evaluation has taken place—and then approve under their authority the resulting product.

This shift will remove many of the obstacles that the current FDA approach is placing on the development of gene editing and similar technologies in livestock agriculture. It will:

- allow for research and development of these technologies to take place at American universities rather than overseas.
- let farmers adopt these new breeding techniques without the fear of losing access to international markets.
- demonstrate to the world that the U.S. is committed to a pro-innovation, risk-based approach to new technology, not a precautionary one.

In short, this approach will allow U.S. agriculture to maintain its global edge. We ask you to support moving oversight of gene-edited livestock on American farms from the FDA to the USDA.