



VIA ELECTRONIC SUBMISSION

January 13, 2021

Mr. Lorren Walker
Acting Under Secretary
Marketing and Regulatory Programs
United States Department of Agriculture
1400 Independence Avenue, S.W.
Washington, D.C. 20250-0268

Mr. Paul Kiecker
Administrator
Food Safety and Inspection Service
United States Department of Agriculture
1400 Independence Avenue, S.W.
Washington, D.C. 20250-0268

Re: Docket No. APHIS-2020-0079, Regulation of the Movement of Animals Modified or Developed by Genetic Engineering

Dear Acting Under Secretary Walker and Administrator Kiecker:

The National Pork Producers Council (NPPC) strongly supports the USDA's Advance Notice of Proposed Rulemaking proposing a critically needed new regulatory framework for genetically engineered livestock and poultry. NPPC conducts public-policy outreach on behalf of its 42 affiliated state pork association members. U.S. pork producers see tremendous potential in gene editing to address significant animal health issues, as well as assisting the industry in making continuous improvement in areas such as food safety, animal welfare, responsible antibiotic use, and sustainability. An appropriate and practicable regulatory environment is critical to ensuring that this promise can be realized.

The USDA's proposed pathway will foster innovation, allow for producer access to this technology, and preserve the preeminence of American agriculture globally. This new regulatory framework will achieve this by addressing the following:

- **The U.S. critically needs a cohesive regulatory approach to the use of genetic technologies in agriculture under a single department.** The U.S. is unique in the world in having vastly different regulatory structures under different agencies for evaluating, approving and regulating the use of genetic technologies in plants and animals—especially when it comes to agricultural applications. The rest of the world is moving forward with integrated agricultural approaches to genetic technologies that allow for consistent regulation across agricultural uses; that recognize that while there are

obviously differences between plants and animals, an overall cohesive regulatory framework is both possible and advantageous.

Currently, primary oversight for agricultural applications of genetic technologies in plants is housed within the USDA under the Plant Protection Act (PPA). Agricultural applications of genetic technologies in plants has flourished. There is a robust research and development pipeline constantly feeding new innovations to plant producers that can use and enjoy the benefits of this technology. Current primary oversight for agricultural and other applications of genetic technologies in animals is housed at the FDA under Food, Drug and Cosmetic Act (FDCA). There is no concurrent history of fostering innovation and application in agricultural animals. In fact, there is the direct opposite.

The USDA's proposal to regulate agricultural applications of animal genetic technology under the Animal Health Protection Act (AHPA), the Federal Meat Inspection Act (FMIA), and the Poultry Products Inspection Act (PPIA) is very sound and critically needed. It will allow the USDA to bring the full breadth of its expertise and authority to bear in ensuring their safe and appropriate use in animals while fostering these new technologies as it has done for plants for years. The AHPA contains all the tools necessary to effectively regulate agricultural animals bred utilizing new genetic technologies. The FMIA and the PPIA contain all the tools needed to ensure that the meat products they produce are safe and wholesome (the USDA can partner with FDA to ensure the safety of dairy and egg products under that agency's primary purview).

The FDCA does not have the same tools—nor the FDA the same expertise across the agricultural production chain—to effectively regulate agricultural applications of this technology. This is reflected in their continued reliance on regulation through guidance documents that fail to meet the needs of agriculture—and the failure to date to have any meaningful commercialization of agricultural animals bred using genetic technologies.

A unified, cohesive, and workable regulatory framework for addressing all applications of genetic technologies to agriculture is long past due. The USDA is clearly well placed to achieve this through this proposed regulatory action.

- **The U.S. needs to stop ceding advantage to foreign competitors.** As noted above, no other country is attempting to regulate agricultural applications of genetic technologies in animals under a drug paradigm. Instead, many of our competitor nations have or are moving towards common sense, risk-based regulatory models that capture all agricultural applications and that offer clear pathways to commercialization. Major competitors such as Argentina, Australia, Brazil, Canada, and China are moving forward while the U.S. lags behind. Even the European Union, long viewed as a bastion against agricultural genetic innovation, is having meaningful discussion about accessing the benefits of gene editing. This is already placing U.S. livestock and poultry producers at a disadvantage. This disadvantage will be more acute if these countries approve the significant gene edits that we know are on the horizon long before the U.S. is able to do so. We simply cannot allow U.S. farmers and ranchers to lack the same animal health and food safety advantages as producers in other countries.

- **The U.S. needs a regulatory framework that encourages, not hinders, innovation.** The current U.S. regulatory framework is also having a chilling effect on research and development of agricultural animal applications of gene editing technology. Public and private agricultural research institutions and innovators are hesitant to conduct work in this area—both because the costs of doing research under the “new animal drug” paradigm are too high, and because they do not see a path forward to commercialization. Meanwhile, they see opportunities in other countries. American agricultural research institutions are being sidelined; research investments and expertise are being driven overseas. The USDA proposal will have a major rejuvenating effect. It proposes the very regulatory climate that numerous scientists have called for in multiple forums.
- **The U.S. needs to position itself to vigorously promote American agricultural products in international markets.** The disparate regulatory systems for plant and animal products of genetic technology has already created unnecessary barriers to effective promotion of U.S. agricultural products in global markets. Important advocates for U.S. agricultural products such as the USDA’s Foreign Agricultural Service and the Office of the United States Trade Representative will be much better served by a unified and cohesive U.S. approach to regulation of agricultural applications of genetic technology. A unified approach under one department will streamline all aspects of global trade facilitation and allow for common sense dialogue with other countries vis-à-vis respective requirements for entry, labeling and so forth. None of this is currently possible, as the FDA’s approach of regulation under drug authority is a global outlier.
- **Researchers, developers, producers, and markets need regulatory certainty.** A clear, prescribed, and durable regulatory framework is critical to ensuring that livestock and poultry producers have access to new and existing genetic technologies. It is also desperately wanted by the scientific and animal breeding sectors. FDA is currently asserting regulatory authority over all applications of genetic technology in animals under loose and shifting guidance documents. Moreover, guidance documents that are subject to continuous revision. This does not promote any sense of confidence to the scientific community, technology developers and multipliers, or producers that requirements are fixed, and that applications can move forward under security of a clear approval pathway. It does promote a sense that at any moment any provision of the FDCA can be brought to bear; that any aspect of animal and subsequent food production can be treated as the distribution of a drug. FDA’s stated intent to use “regulatory discretion” to waive any such drug distribution requirements does not inspire confidence as any such discretion can be unilaterally changed or revoked by the FDA without consultation or notice.

In contrast, the USDA is proposing to actually regulate this technology through a public rulemaking process. This will absolutely provide the clarity, consistency, and durability that is needed to ensure that investments in these technologies can move forward.

- **A risk-based regulatory approach that understands and appreciates the different applications of new genetic technologies is critically needed.** Gene editing offers the animal agriculture community incredible promise to rapidly disseminate desirable characteristics through animal populations. Gene edits that are familiar either mimic

genetic sequences known to exist in the species of interest or are very reasonably likely to exist or to develop through mutagenesis with or without selection pressure. These genes could be propagated without gene editing techniques—though at a much slower rate and not in isolation thereby compromising years of selective breeding—throughout the species.

Given the known nature of this genetic material—or in the case of a deletion the high predictability of the result—there is no new or novel element being introduced into the genome of the species. There is therefore no new or novel risk or threat to animal health, human health and food safety, or the environment. The use of gene editing in this context should not be viewed in a regulatory capacity as any different from those already in use developed over millennia of domestication. The proposed USDA pathway recognizes this, while still providing regulatory review to ensure no novel genetic material will allow for adoption across a species. This is especially important when looking at special populations of agricultural animals, such as rare breeds, that are numerically small. Under current FDA regulation, they are virtually prohibited from being able to use these new technologies as the cost of approval for each of these subpopulations is too high. Animal breeders will have to choose between sacrificing genetic diversity or foregoing use of genetic technology under FDA regulation.

- **The Secretary of Agriculture has clear authority to regulate genetic technology in agricultural animals and, crucially, better authority to address potential issues post-approval.** NPPC wholeheartedly supports the USDA’s authority to regulate this technology under the AHPA, FMIA, and PPIA. These bodies of law are robust and well-able to address concerns about application of genetic technologies to livestock and poultry populations used for the production of food. Furthermore, it must be acknowledged that the Secretary of Agriculture has far better authorities to control the movement and marketing of animals and animal products should the need arise. The USDA has a long history of working with state and tribal animal health and food safety authorities, and industry, to address situations concerning the health of animals, and the safety or wholesomeness of food products. In the unlikely event that an approved (or for that matter unapproved) application of a genetic technology leads to a negative consequence, the USDA is well poised to take any necessary actions. The FDA is not—it is not reasonable to presume that they could effectively manage such situations under drug recall authority.
- **The status quo, regulation by the FDA under the “animal drug” paradigm, is untenable.** We have already pointed out several disadvantages to the current FDA regulation of agricultural animal applications of genetic technologies under the FDCA. There are many more. The FDA regulates genetic alterations by considering the actual altered DNA in the animal as a drug under the FDCA. The animal, and the products it produces, are indivisible from its DNA. In addition to grave domestic concerns with agricultural animals and animal products subject to consideration under the FDCA throughout the production chain, it raises the clear threat of trading partners invoking their own body of drug regulations as a bar to U.S. agricultural animal products. It places farms and ranches—as well as packers, food processors, grocery stores, agricultural

research facilities, livestock markets, and all other facilities touching agricultural animal production or animal food products—under potential designation as or being subject to the requirements of drug manufacturing or distribution facilities. Not to mention requirements concerning adverse reaction reporting, general drug withdrawal requirements, recall authority and all other aspects of drug regulation under the FDCA. All of these ramifications are again subject to constant changes under the FDA mechanism of regulation through “guidance to industry” with no public participation.

In summary, the USDA’s proposal addresses all current needs for ensuring a viable pathway to adoption of new genetic technologies in animal agriculture. It will ensure that producers have access to these needed new tools, that society will be able to enjoy the benefits, and that the U.S. will be well-positioned on the global stage. The alternative—regulation remaining at the FDA—will do the opposite.

Thank you for your consideration of these comments. Please do not hesitate to contact NPPC staff should you have any questions or require further clarification on our position.

Sincerely,

A handwritten signature in blue ink that reads "Howard A. Roth". The signature is written in a cursive style with a long, sweeping underline.

Howard “A.V.” Roth
President
National Pork Producers Council

The Global Voice of the U.S. Pork Industry

10676 Justin Drive ★ Urbandale, IA 50322 ★ 515.278.8012 ★ Fax: 515.278.8014
122 C Street NW, Suite 875 ★ Washington, DC 20001 ★ 202.347.3600 ★ Fax: 202.347.5265