National Pork Producers Council®

The Global Voice for the U.S. Pork Industry

National Pork Producers Council
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Dockets Management Staff
Food and Drug Administration
5630 Fishers Lane
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Commissioner Califf,

The National Pork Producers Council (NPPC), which represents the interest of more than 66,000 U.S. pork producers, submits the following comments on FDA CVM's guidance document, *GFI #187B Heritable Intentional Genomic Alterations in Animals: The Approval Process*.

U.S. pork producers see tremendous potential in gene editing as a tool to address ongoing animal health issues, as well as assisting the industry in making continuous improvement in areas such as animal welfare, responsible antibiotic use, and sustainability. A science-based, practicable regulatory environment that offers opportunity, not obstruction, is critical to ensuring continued growth and advancement for all of livestock agriculture.

NPPC supports the Food and Drug Administration's (FDA) efforts to clarify regulatory requirements for developers of intentional genomic alterations (IGA) in animals, as well as efforts clarifying that downstream producers choosing to invest in this technology will be exempt from regulatory oversight (GFI #187A). However, we do not believe the updated guidance (GFI #187B) offers any significant improvement to the burdensome regulatory process historically imposed on developers of IGAs. The following comments will focus on the unchanged regulation of genetically engineered swine under the Federal Food, Drug and Cosmetic Act (FD&C Act).

Previously, NPPC encouraged FDA to look to the 2017 National Academies of Sciences, Engineering and Medicine publication *Preparing for the Future Products of Biotechnology* (NAS Report) as direction. The NAS Report offers a clear pathway, consistent with the Coordinated Framework for the Regulation of Biotechnology, that the FDA can utilize to determine what, if any, approval under the FD&C Act is required for gene edited animals not intended to produce biopharmaceuticals or medical devices. This regulatory approach would utilize the NAS Report's classification system of new biotechnology products as "familiar and noncomplex," "unfamiliar or complex," and "unfamiliar and complex."

Unfamiliar +/- complex classifications may be the proper subject of regulation under the FD&C Act, like that proposed by the FDA in the draft guidance.

However, familiar and noncomplex edits are not the proper subject of regulation under the FD&C Act. The nature of a familiar and noncomplex gene edit is such that it either corresponds to a genotype found in the subject or a sexually compatible species and could reasonably occur in the subject species through mutagenesis. Animals derived from gene edits that fall into this category would have a genome indistinguishable from non-genome edited animals that share the relevant genotype through inheritance or mutagenesis. The subject and products they produce pose no novel risks.

Section 201(g) of the FD&C Act-

- defines drug as: "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals," and;
- describes "articles (other than food)" as: items intended to affect the structure or any function of the body of man or other animals.

FDA Guidance 187 qualifies its authority on the basis that "altered genomic DNA in an animal is a drug within in the meaning of section 201(g) of the FD&C Act because such altered DNA is an article intended to affect the structure or function of the body of the animal, and, in some cases, intended for use in diagnosis, cure, mitigation, treatment, or prevention of disease in the animal. However, the FDA's logic fails when applied to situations where gene editing techniques are utilized to delete DNA and when DNA that would naturally be found or is reasonably likely to be found in the species' genome, is inserted. The FD&C Act's definition for "drug" is inherently premised on the idea that an "article" is foreign and distinct from the recipient and, therefore, is a necessary addition to induce a change to the structure or function of man or animal. When gene editing techniques are utilized to delete DNA, there is no distinctive article added to cause the resulting change to the structure or function of the animal. Thus, the inserted or deleted genetic sequences, or the resultant genome, cannot be defended as an "article" under the FD&C Act.

In the updated guidance to which we are providing comment, FDA specifically calls out disease resistance- currently, an area of focus in the swine industry. FDA does not expect developers to submit applications or get approval to market IGAs in food animals where […] (3) the intended use of the alteration does not include any effect on animal disease, human disease, or other health outcome […]. In other words, an alteration that results in an effect on animal disease (disease resistance as an example), which we know could reasonably occur in the subject species through mutagenesis, is still subject to the burdensome regulatory process under FD&C Act.

In summary, gene editing offers a tremendous opportunity for the U.S. pork industry, but continued regulation under FDA and the FD&C Act creates insurmountable barriers to utilization by industry and

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is not in keeping with federal policy and precedence—and indeed global regulatory trends—concerning the use of biotechnology in agriculture. NPPC will continue to advocate for the transfer of regulation from FDA to the U.S. Department of Agriculture (USDA). USDA has already established the right regulatory framework for reviewing potential genetic changes in plants. It easily could adapt that approach for livestock and regulate gene-edited animals under the Animal Health Protection Act. We will continue to urge FDA to relinquish its current proposed oversight of gene edited animals on farms and instead place that authority where it belongs, at USDA.

Thank you for your consideration.
Sincerely,

Bryan Humphreys
CEO