ISSUES & INSIGHTS
Regulation of Gene-Edited Animals

SITUATION

There is no statutory requirement that the Food and Drug Administration (FDA) regulate gene editing in food-producing animals, much less that they do so as an “animal drug.” The FDA’s proposed regulatory framework is the result of a decades-old administrative decision, based on older transgenic biotechnology. This regulatory path will result in a lengthy and expensive approval process, and functionally make any gene edited animal a living animal drug—and every farm raising them a drug manufacturing facility. It does not allow for a risk-based approach that takes into consideration the familiarity or complexity of the genetic changes, and the fact that they could be achieved through conventional breeding techniques (though at the expense of time and genetic improvement from decades of animal breeding). The FDA has also indicated that only the descendants of the animals studied in the approval process will be approved, rather than granting approval for the edit to be used on the entire species (as they allow for true animal drugs). In other words, even if FDA determines that an edit is “safe” in one lineage of a breed or strain, its use in any other strain—even within the same breed—would need to go through its own approval process. Under the current FDA plan, there are only three possible outcomes: drastic loss of genetic diversity as producers move towards the few approved lineages of animals; an FDA bogged down by hundreds or thousands of costly and lengthy approval applications for each livestock breed, strain, or even herd or flock; and/or U.S. livestock farmer abandonment of this promising technology while international competitors enjoy its benefits. None of these are acceptable outcomes.

The Animal Plant Health Inspection Service (APHIS) already regulates gene editing in plants under the Plant Health Protection Act. They have a proven track record in risk-based, pro-science regulation of biotechnology. This regulatory framework can be readily adopted to animals under the Animal Health Protection Act. NPPC does acknowledge that some products of gene edited animals may be appropriately regulated by the FDA as human or animal drugs or devices—but not the animals themselves.

NPPC POSITION

NPPC strongly supports moving regulatory oversight of gene editing in animals from the FDA to USDA’s APHIS, which already regulates gene editing in plants, can ensure proper, risk-based regulatory review under the Animal Health Protection Act. Regulation of gene editing in animals by the FDA as an “animal drug” will result in U.S. innovators moving offshore to Argentina, Brazil, Canada, China and other nations which are taking a science based approach to the issue. That loss of technological leadership will erode the competitiveness of the U.S. pork industry and result in reduced sales opportunities and lower U.S. employment.

FAST FACTS

• Gene editing is making simple changes or deletions within the pig’s native genome.

• Gene editing holds the significant promise to:
  o Improve the health and welfare of their pigs.
  o Further strengthen food safety.
  o Lessen the need to use antibiotics.
  o Reduce environmental impact.

• Realizing this promise relies, in part, on a sound, risk-based and pro-innovation regulatory review process.

• Currently, FDA is seeking to regulate gene editing as an animal drug, stalling development of this promising technology, ceding it to other countries and weakening U.S. agriculture’s competitive position.

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