# AAVMC / APLU GENE EDITING IN AGRICULTURE TASK FORCE REPORT

**An issue and policy analysis produced by the American Association of Veterinary Medical Colleges and the Association of Public and Land-grant Universities**

The American Association of Veterinary Medical Colleges (AAVMC) and the Association of Public and Land-grant Universities (APLU) began collaborating on this project in early 2019.

The two organizations stepped forward to help following Congressional inquiries with the Food & Drug Administration regarding current regulatory processes affecting gene editing in animal agriculture. In September 2019 a symposium entitled "Gene Editing in Livestock: Looking to the Future" was presented in Washington, D.C. featuring stakeholders from the government, agricultural production, regulatory and scientific communities.

Symposium participants concluded that work with animal and plant genomes has vast potential for limiting disease and increasing productivity, but agreed that appropriate regulatory processes should be thoroughly considered and structured to support progress and advancement.

In June 2020, the AAVMC and the APLU recruited a panel of experts and created the Gene Editing in Agriculture Task Force. That group was periodically convened for almost a year. After careful analysis of the issue and the opportunities, the group has produced this report.

From the development of artificial insemination as a breeding tool for enhancing access to desirable genetics to feed additives that improve average daily gain and reduce methane emissions to genetic marker assisted selection, the U.S. has been providing leading edge innovation in animal agriculture for nearly 100 years. The next frontier in devising strategies to effectively feed a growing global human population will be defined by genetic enhancement; gene editing technologies are a key component in this endeavor.

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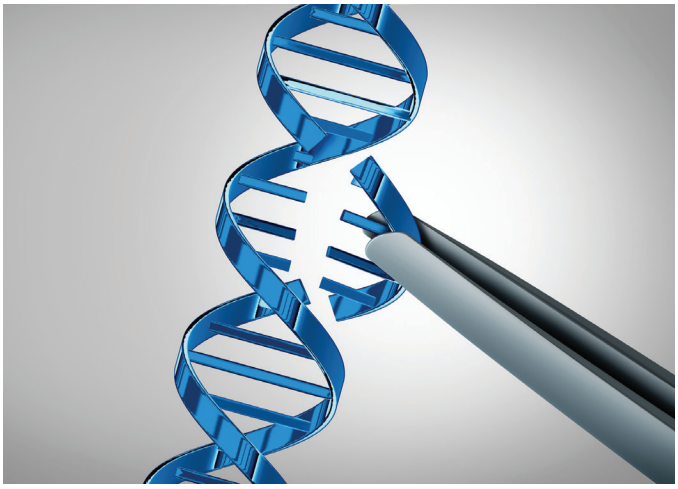
Perspectives on Modernizing the Regulatory Framework for Gene Editing of Livestock in the U.S.

## INTRODUCTION

**Food security is a critical global issue for continuity of the human race. The United Nations Population Division projects that there will be 9.8 billion people on earth by the year 2050. Providing food at sufficient quantity and nutritional quality for this number of people will require major improvements in production efficiency for both plant and animal agriculture so that sufficient outputs for human consumption are generated from minimal inputs.**

Humans have been engineering the genetics of food animals for over 10,000 years through selective breeding to improve the efficiency of protein production. The impacts, both positive and negative, of selective breeding can be observed in all livestock sectors and while gains in traits can still be made, the pace and precision needed to elevate production efficiency for providing animal protein for 9.8 billion people is not achievable with this strategy alone. With the advent of gene editing technologies, a new frontier has been launched for livestock production by providing a scientific strategy to tailor the traits of animals for optimized growth, resiliency, and performance for different environments within months to years rather than the generations that selective breeding requires.

Development and widespread adoption of innovation in livestock, poultry and fish production can have significant positive impacts on the strength of the food supply as well as economic prosperity of the U.S. Indeed, George Washington once wrote that, "I know of no pursuit in which more real and important services can be rendered to any country than by improving its agriculture, its breed of useful animals, and other branches of a husbandman's cares." For the promises of applying gene editing in livestock to be realized, federal regulatory approval and monitoring processes that are rooted in science and streamlined with the pace of development, as well as public acceptance of food derived from gene edited animals, are essential. These aspects are intimately linked, but at present neither is in a state amenable to advancing gene editing applications from the research lab to the public domain. By integrating the considerations of academic thought leaders and scientists, federal regulators and policy makers, livestock producer and industry representatives, a fact-based public narrative and streamlined, cost-effective regulatory landscape can be developed that will allow the potential of gene editing in livestock to be actualized, thereby addressing real world challenges with food security now and over the next 100 years.



## BACKGROUND

Originating with the domestication of dogs, poultry, and livestock, humans have been engineering the genomes of animals by way of selective breeding for over 10,000 years to produce more desirable phenotypes. With livestock, a central purpose of this practice has been to shape traits that lead to production of products for human consumption more efficiently and with better quality. In recent years, there have been calls for humans to reduce their intake of animal-sourced protein due to perceptions that livestock production has a significant negative impact on the environment. According to data collected by the Environmental Protection Agency (EPA), agriculture accounts for only 10% of greenhouse gas emissions in the U.S. with more than half of this production coming from crop farming.

In addition, improvements in production efficiency over the last 70 years have led to a significant decline in the carbon footprint of generating animal protein for the human diet even in the face of increased demand. In fact, the global demand for animal protein increased by ~80% between the years 1970 and 2000 according to the United Nations Food and Agricultural Organization (FAO), and this trend is expected to continue concomitant with human population growth. Moreover, livestock-based products possess an amino acid pattern and digestibility that makes the protein generally of higher quality for the human body, and they provide several essential nutrients that are not readily obtained from a plant-based diet, such as vitamin B and iron. Livestock can also graze land that cannot easily produce plants for human food. For these reasons, livestock products are and will likely continue to be a major source of protein in the human diet.

Genetic makeup is an intrinsic variable of plants and animals that influences traits driving production efficiency and resiliency. Although selective breeding has been used for >10,000 years to produce animals with genetic potential for

enhanced growth and resilience, positive impact on physical traits is often incremental, taking several generations and many decades to manifest. The modern-day approach of selective breeding via screening for DNA variations to identify potential breeding stock that are predicted to drive a desirable phenotype, is simply that – a prediction – and does not solve the bottleneck of needing multiple generations to realize a significant outcome. Moreover, selection of animals based on predictions and breeding for multiple generations produces an inherent risk of genetic drift and unintended negative genetic combinations being brought together. Therefore, neither traditional nor genome screening approaches to selective breeding are sufficient to meet the food security demands of an exponentially expanding human population.

For several decades, the science of animal biotechnology has held great promise as a modern-day complement to selective breeding for the shaping of livestock traits that will improve the nutritional quality of animal protein for human consumption and the efficiency by which it is produced. Indeed, the diverse field of biotechnology is widely regarded as a key aspect of the ongoing fourth industrial revolution. Although much of the animal side of the biotechnology sector is still in a research and development phase, the advent of gene editing technologies and their rapid deployment as tools in the animal research arena has led to several applications in livestock that are poised for entry into the marketplace.

A conventional use of biotechnology for genetic engineering of livestock has been the integration of genetic information found in other organisms, typically in the form of recombinant DNA. As such, these genetic changes could not arise in nature and therefore are a form of transgenesis. These applications have resulted in transgenic livestock being labeled “genetically modified organisms” or GMOs.

Public attitudes to GMOs have tended to be negative. The 2019-2020 Pew Research Center’s International Science survey reported that 27% of Americans thought GMOs were generally safe to eat, 38% responded they were unsafe to eat, and 33% said they did not know enough about the topic to say. This negative perception of food derived from GMOs has presented a major impediment for advancing biotechnology applications to improve livestock production in the public domain.

At present, the leading edge of biotechnology application for genetic engineering of livestock has moved from using transgenesis to gene editing. Both the technical science and intended outcomes of gene editing are substantially different compared to transgenesis. As such, regulatory statutes should not be applied as a “one size fits all” model; rather, contextual categorizing of the genetically altered animals that allows for fluidity and applying logic-based decision making, while still ensuring safety, is needed.

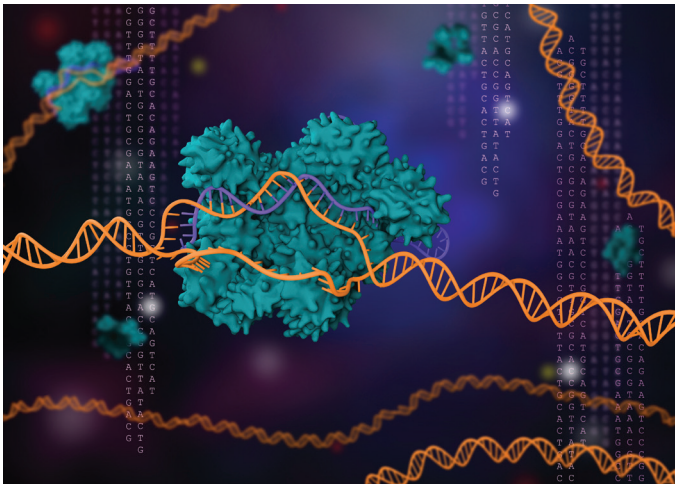
## A CALL TO ACTION

The AAVMC/APLU Taskforce on Gene Editing of Livestock was assembled as an effort to generate a blended, yet cohesive, perspective on how applications of gene editing in livestock, poultry and fish could be regulated while addressing the mutual interests of the developer, federal regulatory entities, animal, and consumer. To this end, a group of academicians with international recognition as experts in the science of animal genetic engineering, commercial sector representatives, animal engagement specialists, and animal bioethicists were assembled as a thinktank; the output of melding perspectives voiced by these groups are recommendations that may be of value for federal regulators when envisioning what a modernized and progressive framework for the regulation of gene edited livestock in the U.S. should be.

# TASK FORCE RECOMMENDATIONS

From the development of artificial insemination as a breeding tool for enhancing access to desirable genetics to feed additives that improve average daily gain and reduce methane emissions to genetic marker assisted selection, the U.S. has been providing leading edge innovation in animal agriculture for nearly 100 years. The next frontier in devising strategies to effectively feed a growing global human population will be defined by genetic enhancement; gene editing technologies are a key component in this endeavor. For the U.S. to remain a global leader in shaping how livestock products are produced in sufficient quantity to be cost-effective sources of protein in the human diet and of high quality to provide essential nutrients, the federal regulatory landscape for approving and monitoring of genetic engineering applications must evolve. The recommendations made below reflect the AAVMC/APLU Task Force considerations for devising a process of regulating gene editing applications in animals intended for agricultural production that aligns with the interests of developers and consumers.

- The science and technology of genetic engineering and potential applications in domestic animals is complex, ranging from generation of novel biomedical models to gene therapy to enhancing traits for the improvement of animal agriculture. As such, assigning federal regulatory jurisdiction to a single agency is challenging and has potential to elicit conflict that thwarts innovation. The current state of FDA regulatory framework for evaluating, approving, and monitoring of intentionally genetically altered animals is based on processes established for transgenic technologies which do not align well with the state-of-the-art gene editing technologies. In addition, the processes are viewed by many developers of genetic engineering applications in livestock as ambiguous, glacial in pace, and cost-prohibitive. Thus, a remodeling of the federal regulatory landscape is needed for the US to sustain its place as a global leader and innovator in the animal agriculture sector and keep pace with the exponentially expanding global human population. A coordinated assessment and approval process between the USDA and FDA is essential to establish a framework that is streamlined, cost-effective, and ensures safe food, with the decision-making process anchored on logic and fact.
- The technical aspects of creating mutated versions of genes via gene editing and the intended outcomes of such genetic alterations are distinctly different than transgenic approaches. Thus, the Task Force recommends an evidence and logic-based decision-making process such that gene editing applications that could have arisen in nature (e.g. insertions, deletions, rearrangements, and single nucleotide polymorphisms) and be propagated via selective breeding are regarded and regulated separately from traditional GMOs that involve integration of recombinant DNA into the genome.
- Considering the myriad applications in which gene editing could be employed in animals generated for agricultural purposes, the Task Force recommends that customization be inherent in a modernized regulatory framework. In particular, the Task Force recommends a logic-based, streamlined assessment and approval processes that categorizes gene editing applications based on: a) the type of genomic change being created (e.g. insertion-deletion mutation, nucleotide(s) swap, interspecies DNA introgression, recombinant DNA insertion), b) the method used for creating the genomic change (e.g. CRISPR-Cas9 ribonucleoproteins, plasmid-based expression, etc.), c) impact on the welfare of the animal, and d) potential for negative impact on the environment.
- Humans have been consuming animal products with mutations in DNA that arose naturally and were propagated by way of selective breeding for thousands of years. Thus, the Task Force recommends that full consideration be given to developing a regulatory channel for approval of animals possessing gene edits that could have arisen in nature (e.g. insertions, deletions, rearrangements, and single nucleotide polymorphisms) as safe for human consumption. This approval process could be streamlined by focusing assessment on impacts to the welfare of the animal rather than the process of creating a genetic alteration. The process would also be cost effective and subject to limited post approval oversight.



## OPERATIONALIZATION & CONTINUED TASK FORCE ENGAGEMENT

The members of the AAVMC/APLU Taskforce on Gene Editing of Livestock fully appreciate that for these recommendations to have impact, a well-designed implementation plan is needed. Thus, the Task Force suggests that the following strategies be put into action:

- Establish a National Coalition of scientific experts, bioethicists, and engagement specialists from APLU and AAVMC member institutions to serve as a sounding board and think-tank on ongoing issues related to modernization of the federal regulatory framework for gene editing applications in livestock and other food animals.
- Engage with federal legislators, staffers, and the White House OSTP to inform on key issues related to regulatory approval and monitoring processes for gene editing applications in livestock.
- Distribute this Task Force report to interested organizations including U.S. land-grant universities, the FDA and USDA, the Food and Agricultural Organization of the United Nations, the Gates Foundation, and others.
- Establish a University Research Consortium of scientific experts developing gene editing applications in livestock from AAVMC and APLU members institutions that will facilitate collaborative research and educational initiatives.

## CONCLUSION

The U.S. farming community needs all of the tools at its disposal to remain competitive in an increasingly globalized market. Harmonization of the regulatory processes beyond the U.S. is key to realizing the potential of the next generation breeding tools. The regulatory community across the globe looks towards the U.S. for stewardship and leadership. In this regard, the APLU/AAVMC Gene Editing task force recommends that the USDA and FDA come together and shape a harmonious, transparent, evidence based, and forward-looking regulatory process in step with the current scientific progress. This collaboration will ensure that global food security, safety, and sustainability goals can be met.

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## ABOUT THE AAVMC

The member institutions of the American Association of Veterinary Medical Colleges (AAVMC) promote and protect the health and wellbeing of people, animals and the environment by advancing the profession of veterinary medicine and preparing new generations of veterinarians to meet the evolving needs of a changing world. Founded in 1966, the AAVMC represents more than 40,000 faculty, staff and students across the global academic veterinary medical community. Our member institutions include Council on Education (COE) accredited veterinary medical colleges and schools in the United States, Canada, Mexico, the United Kingdom, Europe, Asia, Australia, and New Zealand as well as departments of veterinary science and departments of comparative medicine in the U.S.

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## ABOUT THE APLU

APLU is a research, policy, and advocacy organization dedicated to strengthening and advancing the work of public universities in the U.S., Canada, and Mexico. With a membership of 244 public research universities, land-grant institutions, state university systems, and affiliated organizations, APLU's agenda is built on the three pillars of increasing degree completion and academic success, advancing scientific research, and expanding engagement. Annually, member campuses enroll 5.0 million undergraduates and 1.3 million graduate students, award 1.3 million degrees, employ 1.3 million faculty and staff, and conduct $49.2 billion in university-based research.

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