July 30, 2020

Mr. Stephen Censky,
Deputy Secretary, United States Department of Agriculture.

Solicitation of Input from Stakeholders on Agricultural Innovations
Submitted via Federal eRulemaking Portal

Dear Mr. Censky,

The FASS - Science Policy Committee (SPC) appreciates the opportunity to respond to the United States Department of Agriculture (USDA) solicitation for comments and suggestions on objectives and opportunities leading to research goals and informed product goals to facilitate transformative breakthroughs to enable U.S. agriculture to meet the Department’s goal of increasing agricultural production by 40 percent to meet the needs of the global population in 2050 while cutting the environmental footprint of U.S. agriculture in half.

While we recognize the importance of all four of the innovation clusters identified in the National Academies of Sciences, Engineering, and Medicine report “Science Breakthroughs to Advance Food and Agricultural Research by 2030”, we would specifically like to focus on the Genome Design cluster, and more specifically on what we consider to be a regulatory barrier that needs to be addressed as it relates to the application of genome editing in food animal species.

The FASS SPC considers that the FDA’s proposed approach to regulate intentional genome alterations in food animals as drugs is a regulatory hurdle that will disadvantage uniquely both U.S. researchers and animal agriculture. The FASS SPC encourages the USDA to work to harmonize the regulation of genome editing in food species, especially for plants and animals that could otherwise have been developed through traditional breeding techniques. Having a much higher and disparate regulatory barrier for genome edits in the animal kingdom is not scientifically justifiable from a risk perspective, and needlessly disadvantages both U.S.-based animal genetic researchers, and more generally American animal agriculture. We believe USDA APHIS (Animal and Plant Health Inspection Service) is a more appropriate agency to oversee genome editing in plants and animals for agricultural purposes that could otherwise have been developed through traditional breeding techniques. We consider that it is unlikely that the genome design innovation solutions developed by animal geneticists will be applied in the U.S. livestock industry unless this regulatory barrier is addressed. This works to the advantage of livestock industries in other countries with technology agnostic, risk-based regulatory approaches

FASS specializes in providing services to science-focused organizations and is a 501(c)(3) organization. The purposes of FASS are: 1) promote education and research including bringing together scientists and educators in animal agriculture and animal sourced foods. 2) facilitating the dissemination of scientific and technical information through publications and scientific meetings; and 3) serving in other capacities in which supported societies can function more efficiently as a group than as individual units.
Through SPC, FASS provides science-based information to public policy makers and regulators on issues pertaining to humane, sustainable, safe, and bountiful food animal production and animal origin foods.

The National Academies of Sciences, Engineering, and Medicine report “Science Breakthroughs to Advance Food and Agricultural Research by 2030”, noted that in America “livestock and poultry production account for approximately $100 billion per year in agricultural cash receipts.” The report continues to note that the “genetic improvement and adoption of optimized nutritional programs, along with innovations to maintain and improve animal health status, have reduced the costs of production, lowered prices for consumers, decreased resources used (resulting in lower greenhouse gas [GHG] emission intensities per unit of production), and increased the competitiveness of American products internationally, benefiting both local and national economies.”

Improved genetics has dramatically decreased the environmental footprint of animal-source foods. The adoption of genomic selection methods, from research investments in sequencing livestock genomes, has more than doubled the rate of genetic gain in dairy cattle breeding programs in the past decade. The FASS SPC recognizes the potential that genomics and precision breeding have to explore, control, and improve traits of agriculturally important organisms. Improved genetics is key to increasing the resilience of food animal populations and thereby decreasing the environmental footprint of animal sourced foods in the next 10- to 30-year timeframe. The development of disease-resistant livestock, for example, would improve all three pillars of sustainability: economic (reduced morbidity and improved production), environmental (reduced use of chemicals and antibiotics to treat sick animals and decreased mortality), and social (improved animal well-being and welfare).

There are some exciting developments in the field of genome editing, such as the porcine reproductive and respiratory syndrome (PRRS) virus-resistant pigs first developed at the University of Missouri. PRRS is one of the costliest pig diseases globally. Annual production losses in breeding and growing-pig herds from PRRS was estimated to be around $663 million in the US alone. There is no foreign transgene or recombinant DNA (rDNA) present in these gene knock-out pigs, meaning that they do not fit the classical definition of a transgenic or genetically engineered animal.

In 1986, the White House, Office of Science and Technology Policy (OSTP) published the Coordinated Framework for Regulation of Biotechnology. This document states, “This framework has sought to distinguish between those organisms that require a certain level of federal review and those that do not. This follows a traditional approach to regulation. Within agriculture, for example, introductions of new plants, animals and microorganisms have long occurred routinely with only some of those that are not native or are pathogenic requiring regulatory approval.” The document goes on to clarify that regulatory review should be confined to organisms deliberately formed to contain an intergeneric combination of genetic material from sources in different genera, subsequently known as “transgenic” organisms.

In March 2018, the USDA announced that it had no plans to evaluate gene-edited plants for health and environmental safety prior to commercial release if they could otherwise have been developed through traditional breeding, so long as the crop is not a plant pest or developed using plant pests. Under this ruling, genetic deletions, single base-pair substitutions and the insertion (introgression) of nucleotide sequences from related plants that could potentially have come about through crossbreeding, are all outside the scope of USDA regulation.

This stands in stark contrast to FDA’s guidance whereby all intentional genomic alterations in animals, irrespective of their nature, are going to be subject to mandatory premarket regulation as a new animal drug. This is a departure from the approach that was outlined by OSTP in the 1992 policy
announcements. There it is stated that, “Exercise of oversight in the scope of discretion afforded by statute should be based on the risk posed by the introduction and should **not turn on the fact that an organism has been modified by a particular process or technique**”. Additionally, it was clarified that “(O)versight will be exercised only where the risk posed by the introduction is unreasonable, that is, when the value of the reduction in risk obtained by additional oversight is greater than the cost thereby imposed.”

In a rare rebuke, the scientific journal Nature, wrote in a 2020 editorial article “**The US Food and Drug Administration is sticking to its plan to carry out mandatory premarket review of all gene-edited livestock, irrespective of trait risk. It should rethink.**” The article continues, “A cautious, process-based regulatory route keeps the FDA out of trouble and lowers litigation risks for CVM’s lawyers.” And while that may be true, it is not consistent with risk-based regulation, nor does it consider the opportunity cost of precluding the adoption of innovative technology. This regulatory hurdle will effectively thwart the development of genome edited food animals by the public sector and small companies.

The FDA regulatory approach puts the animal breeding industry, and animal agriculture in America, at a significant disadvantage relative to other countries that do not differentially regulate genome edited products between the plant and animal kingdom. Genome edited products containing novel DNA sequences, like the PRRS pigs, would be not be regulated as a GMO (e.g. Argentina, and Australia). Again the FASS SPC urges USDA to utilize the most appropriate mechanism to address this regulatory barrier so that U.S. agriculture will be able to benefit from this important new technology.

**REFERENCES**


