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Submitted via Federal eRulemaking Portal

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: **Docket No: FDA-2008-D-0394; *Regulation of Intentionally Altered Genomic DNA in Animals; Draft Guidance for Industry; Notice of Availability***

The National Association of State Departments of Agriculture (NASDA) appreciates the opportunity to provide comments on the Food and Drug Administration's (FDA) draft guidance for industry (GFI) #187, entitled *Regulation of Intentionally Altered Genomic DNA in Animals*[1]. This draft guidance revises GFI #187 entitled "Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs" (current GFI #187)[2].

I. About NASDA

NASDA represents the Commissioners, Secretaries, and Directors of the state departments of agriculture in all fifty states and four U.S. territories. State departments of agriculture are responsible for a wide range of programs including food safety, conservation, and fostering the economic vitality of our rural communities. Combating the spread of disease and environmental protection are also among our chief responsibilities.

NASDA supports agricultural biotechnology and recognizes the important role this technology plays in both meeting growing global demand for food and helping farmers and ranchers address the sustainability of their land and operation for generations to come. Further, NASDA supports the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework)[3], established as a formal policy by the Executive Office of the President, Office of Science and Technology Policy (OSTP) in 1986.

II. General Comments

NASDA supports the use of biotechnology, including genome editing, which hold enormous promise for improving the productivity and environmental sustainability of agriculture. In the field of agriculture,

[1] Draft GFI #187
https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM113903.pdf
[2] GFI #187 Regulation of Genetically Engineered Animals Containing Heritable rDNA constructs.
https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052463.pdf
(document now archived on FDA website)
[3] OSTP. 1986. Coordinated Framework for Regulation of Biotechnology. 51 *Fed. Reg*. 23302, 23304

producers cope with the challenge of feeding an ever expanding world population while maintaining the highest safety, quality, diversity and affordability in the global food supply. Biotechnology plays a critical role in meeting a number of producer, consumer, and societal needs. From the earliest experiments with agriculture to present time, producers have been growing, cross–breeding, and fundamentally altering crops and livestock in order to meet the growing demand and standards for a safe and affordable food supply. As these needs have evolved, so has the use of technology. Each technological development has enabled producers to provide more with less, while simultaneously continuing to improve the safety, quality, diversity and affordability of the food we consume. If applied to livestock, poultry and fish, these tools could help producers control diseases, improve food safety, enhance animal welfare, facilitate the responsible use of antibiotics and decrease the environmental impact of animal agriculture.

NASDA submitted comments on USDA's proposed revisions to regulations regarding the importation, interstate movement, and environmental release of certain genetically engineered organisms (Docket No. APHIS-2015-0057) supporting APHIS's underlying effort to send strong, positive signals about the need to foster innovation by ensuring regulatory oversight is proportional to actual risk. NASDA supports USDA's recognition to exclude genome editing from the definition of genetic engineering, and NASDA is concerned with any actions FDA may pursue in conflict with this long-standing, science-based approach to regulating these important technologies.

NASDA supports FDA's longstanding, science-based approach to reviewing and regulating these tools based on risk a certain product may pose rather than the process in which it is produced, and NASDA is concerned the proposed revisions to GFI #187 will significantly impede U.S. producers' access to these critical tools.

III. Specific Areas of Concern & Request for Clarifying Statements

NASDA is concerned that FDA's proposed revisions to GFI #187 focuses quite specifically on the process of genome editing, while excluding products made with other genetic modification processes, such as chemical mutagenesis, from the pre-market oversight requirements.

The proposed revisions to GFI #187 also seem to be rooted in the assumption that all animals developed with genome editing techniques pose significant risks and, therefore, pre-market oversight of all genome edited animals would be warranted. NASDA opposes this approach, and NASDA notes this assumption of risk, based solely on the use of a certain technique, runs counter to the scientific consensus first articulated in the late 1980's by the OECD report, *Recombinant DNA Safety Considerations*[4] the National Academy of Sciences report[5]. Although those documents focused on the newest genetic improvement technology at that time, which was recombinant DNA technology, or genetic engineering, the same reasoning is applicable to genome editing:

- There is no evidence that unique hazards exist in the use of rDNA organisms or in the transfer of genes between unrelated organisms; and

[4] OECD. 1985. Recombinant DNA Safety Considerations. https://www.oecd.org/sti/biotech/40986855.pdf
[5] National Academy of Sciences. 1987. Introduction of DNA-Engineered Organisms into the Environment: Key Issues

- The risks associated with rDNA organisms are the same in kind as those associated with unmodified organisms or organisms modified by other genetic techniques.

The great majority of the animals created through genome editing will be essentially the same as the animals that farmers and ranchers currently raise, except they will have a new characteristic, such as disease resistance. Often times that new characteristic could have been obtained through cross breeding. Genome editing makes the same kind of modifications as breeding and mutagenesis, but it does so much more specifically. Therefore, the risks of both the intended and unintended effects of genome editing will be significantly less than the use of the excluded techniques.

As co-regulators with the FDA, USDA and EPA, NASDA members have significant concerns with FDA's seeming reversal of policy FDA appears to be proposing in this updated guidance and the lack of risk-based justification for expanding the scope of the guidance to include genome edited animals. NASDA requests FDA provide state departments of agriculture and the regulated community an explanation clarifying: (1) why such a change in policy has been contemplated; and (2) how this conforms to the stated policy of the administration to reduce regulatory barriers and facilitate innovation. NASDA requests FDA provide these responses before proceeding further with any final changes to GFI 187 at this time.

IV. Call for Enhanced Coordination

NASDA is further concerned by the apparent lack of coordination between FDA and its sister agencies in the Federal government. NASDA urges FDA to adhere to the principles, set forth originally by OSTP in the 1986 Coordinated Framework[6]; clarified in the 1992 OSTP Policy, *Exercise of Federal Oversight within the Scope of Statutory Authority*[7] (the Scope Policy); and reaffirmed most recently in the 2016-17 Update to the Coordinated Framework[8].

NASDA notes the Coordinated Framework charges the agencies to focus on only those biotechnology products that present a potential risk, when compared to similar products that have a history of safe use and consumption. This principle is consistent with the Scope policy, which notes the purpose of government regulation of biotechnology is to limit unreasonable risks and requires the agencies to show discretion in using their authorities for regulating biotechnology products. In keeping with the regulatory principles articulated above, the Scope policy sets forth a risk-based approach that outlines how agencies should exercise their oversight authority within the scope of discretion afforded by statutes.

NASDA calls on FDA to initiate additional outreach and coordination with its sister agencies under the Coordinated Framework before proceeding further with any final changes to GFI 187 at this time.

[6] OSTP. 1986. Coordinated Framework for Regulation of Biotechnology. 51 Fed. Reg. 23302, 23304

[7] OSTP. 1992. 57 FR 6753. Exercise of Federal Oversight within Scope of Statutory Authority: Planned Introductions of Biotechnology Products into the Environment. https://www.whitehouse.gov/sites/default/files/microsites/ostp/57_fed_reg_6753__1992.pdf

[8] https://www.epa.gov/sites/production/files/2017-01/documents/2017_coordinated_framework_update.pdf and https://www.epa.gov/sites/production/files/2016-12/documents/biotech_national_strategy_final.pdf

V. Comments on FDA's Specific Request for Input

NASDA raises concerns on the two following questions FDA is seeking public input under the draft GFI 187:

> **Question 1:** *In the first, we seek the public's input on how to refer to these animals. In the past, FDA has used the term "genetically engineered" to refer to animals containing recombinant DNA constructs intended to alter the structure or function of the body of the animal. For this draft revised guidance, we have used the phrase "animals whose genomes have been altered intentionally." Other terms that could be used include "genome edited animals," "intentionally altered animals," or expanding the term "genetically engineered" to include the deliberate modification of the characteristics of an organism by manipulating its genetic material. The public is encouraged to suggest other phrases that are accurate and inclusive.*

NASDA opposes the suggestion that FDA can create an alternative means of identifying animals based on the method by which they are bred. NASDA asserts the Agency has not documented an inherent risk that needs to be addressed through regulation, nor has it provided any justification for differentiating animals resulting from breeding innovations including genome editing. NASDA cannot identify any basis upon which the Agency should seek to differentiate animals resulting from these methods. NASDA also notes Congress has clearly spoken on the definition of bioengineering by defining the term, or any similar term with respect to food, as that which "contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature."[9] Congress clearly excluded techniques such as genome editing from the bioengineered food disclosure standard, and NASDA recommends FDA not solicit recommendations or seek to adopt guidance in contradiction to Congressional intent and long-standing science-based policies.

> **Question 2:** *The second set of questions for which we seek public input is on whether there is any existing empirical evidence demonstrating that certain types of genome editing may pose minimal risk, with particular emphasis on the following:*
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> > *c. Is there empirical evidence to demonstrate that there are degrees of introduced changes (e.g., insertions or deletions of any size or single nucleotide substitutions) that are likely to pose less risk than other changes? If so, what is that evidence?*

NASDA notes there has been considerable debate between the U.S and several of our trading partners in regards to regulation of products of agricultural biotechnology. In some instances, our trading partners have adopted a policy shifting the burden of proof to regulated entities to demonstrate the absence of risk, while at the same time failing as regulators to demonstrate any quantifiable harm. The question posed by FDA seems to follow a similar path in asking innovators to prove a negative. NASDA encourages FDA to carefully consider the implications such an approach would have on our regulatory

[9] 7 U.S.C. 1621, *et seq.*

programs, and instead, NASDA requests FDA present evidence to demonstrate what the Agency believes to be the risk of genome editing and why this breeding innovation should be regulated.

VI. Conclusion

NASDA supports our federal agency partners' willingness to revisit, revise, and improve regulations or guidance to better reflect modern technologies and to facilitate an informed and efficient regulatory framework.

NASDA requests FDA undertake a more thorough and robust review of the proposed changes to GFI 187, in conjunction and consultation with partner agencies responsible for regulating products of biotechnology and the agricultural community, to enhance continued alignment, agency roles and responsibilities, and improve communication between the federal, state, and agricultural stakeholders. NASDA is concerned with any proposed changes to regulations or guidance that may be inconsistent with the spirit and intent of the Coordinated Framework.

NASDA stands ready to assist our federal partners to revise and improve the proposed GFI 187 changes and to ensure any final guidance reflects and incorporates the best available science, provides a consistent regulatory framework, facilitates innovation, and enables our producers, growers, and other agricultural stakeholders to continue to produce our nation's food, fiber, and fuel in a collaborative and productive manner.

Thank you for your consideration, and we appreciate this opportunity for comment. Please contact Dudley Hoskins (dudley@nasda.org) if you have any questions or would like any additional information.

Sincerely,

Barbara P. Glenn

Barbara P. Glenn, Ph.D.
Chief Executive Officer