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Submitted via Federal eRulemaking Portal

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Docket No. APHIS-2015-0057
Regulatory Analysis and Development
PPD-APHIS, Station 3A-03.8
River Road, Unit 118
Riverdale, MD 20737-1238

Re: **Docket No: APHIS-2015-0057 [RIN 0579-AE15];** ***Importation, Interstate Movement, and Environmental Release of Certain Genetically Engineered Organisms***

The National Association of State Departments of Agriculture (NASDA) appreciates the opportunity to submit the following comments on the U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service's (APHIS) proposed revisions to regulations regarding the importation, interstate movement, and environmental release of certain genetically engineered organisms (Docket No. APHIS-2015-0057), and NASDA appreciates USDA extending the comment period to allow adequate time for review and consideration of these proposed changes. NASDA further appreciates the significant outreach and listening session APHIS staff has undertaken throughout the rulemaking process.

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)[1], 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 plant breeding innovations, including genome editing, which hold enormous promise for improving the productivity and environmental sustainability of agriculture. In the field of agriculture, producers cope with the challenge of feeding an ever expanding world population while maintaining the

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

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 produces to provide more with less, while simultaneously continuing to improve the safety, quality, diversity and affordability of the food we consume.

Since APHIS began regulating genetically engineered organisms approximately thirty years ago, with the use of a plant pest as a vector or vector agent, the Agency has no evidence that using genetic material from plant pests as vectors or vector agents for other genetic material results in a genetically engineered organism that is itself a plant pest.

NASDA recognizes innovation is fundamental to U.S. agriculture and regulations should provide adequate and appropriate levels of risk-based oversight without obstructing innovation and creating unreasonable regulatory, legal, and commercial uncertainty. USDA's proposal acknowledges 30-plus years of scientific evidence and safe-use associated with genetically engineered organisms, and this proposal takes steps to bring pre-market regulatory oversight for these products into better alignment with actual risk.

NASDA strongly supports USDA's efforts to modernize these regulations to ensure they reflect and incorporate the best-available science and utilize the more than 30 years of experience USDA has in reviewing the safety of these crops. NASDA believes it is imperative USDA continue its important work to "right size" its oversight of agricultural biotechnology and other biology-based plant breeding innovations, while also providing strong leadership and vision to encourage other U.S. regulatory agencies, as well as foreign governments, to adopt consistent or compatible approaches.

The proposed revisions to USDA biotechnology regulations take some very positive steps in the right direction, and NASDA commends USDA for its strong leadership in proposing these new regulations. NASDA has also identified several areas of concern within the proposed rule, and NASDA requests USDA substantially revise the proposed rule before proceeding with any final rulemaking. NASDA stands ready to assist our federal partners to revisit, revise, and promulgate a final rule that will deliver a transparent, consistent, predictable, and science-based regulatory framework that provides the appropriate regulatory protections while minimizing unnecessary regulatory burdens and undue economic impacts.

III. Support for Regulation of GE Products; Not Production Methods

NASDA supports APHIS's overarching aim under the proposed rule to regulate products of genetic engineering rather than the methods by which those products are developed (Federal Register / Vol. 82, No. 12 / Thursday, January 19, 2017, p.7018). NASDA notes APHIS's January 19, 2017 proposed Part 340 revision will modernize the Agency's approach so that genetically engineered organisms created using a plant pest as a vector or vector agent will no longer be regulated solely because of the use of such a

vector or vector agent. Instead, the organisms would be regulated if they themselves present a known or unevaluated plant pest risk.

NASDA agrees the proposed revisions send strong, positive signals about the need to foster innovation by ensuring regulatory oversight is proportional to actual risk -- a message NASDA strongly supports. At the same time, NASDA has identified several considerable deficiencies in USDA's proposal substantial enough to warrant significant revisions to the proposed rule in order for USDA to sufficiently address them.

IV. Specific Provisions of Significant Concern

NASDA has significant concerns that the proposed rule seemingly shifts the regulatory burden from the commercialization stages to the research and development phases of product innovation. Under this proposed paradigm, each new plant variety will now have to undergo a complex risk assessment and public comment before a single plant can even be planted in a small-scale field trial.

Furthermore, the proposal will require risk assessments to be conducted for plant products, merely based upon the technology used in their production, regardless of the actual risk posed by the product. This proposed regulatory approach runs counter to USDA's 30-plus years of experience regulating products of biotechnology, and NASDA requests USDA work with the state departments of agriculture and the regulated community to revisit and revise this part of the proposed rule.

NASDA is also concerned the process outlined in the proposal does not provide sufficient transparency or clarity while also inserting an element of regulatory uncertainty in the scope of regulation. NASDA notes departing from the current regulatory system may have unintended consequence for other regulatory agencies, interstate commerce, and international markets. NASDA stands ready to assist USDA in undertaking a more thorough and robust review, 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.

V. Specific Provisions of Support

Notwithstanding the above areas of concern, NASDA supports several proposed revisions and applauds APHIS for proposing these revised improvements. NASDA appreciates APHIS identifying the following science-based revisions in the proposed rule, and NASDA requests USDA retain these changes in any final rulemaking.

NASDA supports APHIS's proposed Part 340 revision, whereby "genetic engineering" would mean techniques using recombinant or synthetic nucleic acids with the intent to create or alter a genome. Under the proposed rule, an organism created using techniques that do not fall within the scope of genetic engineering would preclude the organism from falling within the definition of GE organism. NASDA strongly supports this approach.

Further, NASDA supports APHIS excluding traditional breeding techniques (including, but not limited to, marker- assisted breeding, as well as tissue culture and protoplast, cell, or embryo fusion) or chemical or radiation-based mutagenesis from the definition of genetic engineering. NASDA understands APHIS has never considered such techniques to constitute genetic engineering, and NASDA strongly supports codifying this scientifically established approach.

NASDA also supports APHIS not subjecting newer plant breeding innovations, such as genome editing and synthetic genomics, that do not employ plant pests as donor organisms, recipient organisms, vectors, or vector agents, to regulation under part 340.

The Plant Protection Act of 2000 (PPA), in relevant part, authorizes the Secretary of Agriculture to oversee the detection, control, eradication, suppression, prevention, or retardation of the spread of plant pests. Pursuant to that broad authority, the Secretary may prohibit or restrict the importation, entry, exportation, or movement in interstate commerce of any plant pest, plant, plant product, or article capable of harboring a plant pest as necessary to prevent the introduction of a plant pest into the U.S or the dissemination of a plant pest within the U.S. and determine that certain articles, plants, and plant products are not plant pests and are not subject to prohibitions or restrictions on movement in interstate commerce.

NASDA agrees that plant varieties developed through plant breeding innovations, such as genome editing, should not be subject to pre-market regulatory review since they are indistinguishable at the DNA sequence level from varieties produced through conventional plant breeding and include no "foreign" DNA in the final plant product.

Furthermore, NASDA strongly supports ensuring trade in U.S. commodities, global seed movement and research collaborations are not hindered, and therefore, it is critical USDA provide consistent government policies for products of the latest plant breeding innovations, such as genome editing. Decisions affecting imports, exports, and interstate movement of products should be based on sound science. The U.S. has an opportunity to provide global leadership as countries around the world are currently considering their policy approaches to plant breeding innovations such as genome editing.

To facilitate global acceptance of plant breeding innovations, NASDA recommends the proposal be significantly modified to include an affirmative Federal Order clarifying the Secretary has authorized the introduction (including cultivation) of any plant or plant product derived through plant breeding innovations. Such an order should explicitly state APHIS has made a safety determination that introduction into the environment of plants and plant products derived through these breeding innovations would not pose a risk to agriculture, simply because of the means by which they were produced.

As stated previously, such an order would not alter the authority of the Secretary to act if a plant or plant product in commerce poses a plant pest risk, including plants and plant products that have previously been, or may in the future be, excluded or exempted from regulation under the PPA, or deregulated under Part 340, should a reason to believe those products pose a plant pest risk later arise.

Although APHIS has exercised its authority to issue limiting Federal Orders where there is need to restrict movement of agricultural products, federal orders need not be limited to restrictions on commercial activity. In fact, other affirmative applications of Federal Orders are designed to promote the orderly marketing of agricultural products in interstate and foreign commerce. NASDA suggests APHIS consider the use of federal orders in a broader context.

Such an affirmative Federal Order could be superseded at any time through the issuance of a new Federal Order, or the implementation of a new regulation if the Secretary has reason to believe such regulation is necessary to prevent the introduction or dissemination of a plant pest within the U.S.

VI. Conclusion

Whether food is grown conventionally, organically, or is the product of genetic engineering, NASDA members advocate for farmers and ranchers across the full scope of agriculture, and NASDA members strive to develop, foster, and assist market channels where producers can market their commodities irrespective of production methods.

NASDA applauds USDA's efforts to modernize these regulations to ensure they reflect and incorporate the best-available science and utilize the more than 30 years of experience USDA has in reviewing the safety of these crops. NASDA stands ready to assist our federal partners and the regulated community to revise and improve the proposed rule and to ensure any final rulemaking 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, Ph.D.
Chief Executive Officer