



October 22, 2019

Office of Science and Technology Policy

Re: RFI Response: Bioeconomy

Submitted Via Email: MBX.OSTP.WHBioeconomy@ostp.eop.gov

To whom it may concern:

The American Seed Trade Association is pleased to provide comments on the Office of Science and Technology Policy's (OSTP) Request for Information on the Bioeconomy. Founded in 1883, ASTA is one of the oldest trade organizations in the United States. Its membership consists of over 700 companies involved in seed production and distribution, plant breeding, and related industries in North America. ASTA members research, develop, produce and distribute all varieties of seeds – including grasses, forages, flowers, vegetables, row crops, and cereals. These seeds support agricultural production in the United States and around the world.

We commend OSTP for recognizing the important role that government plays in promoting scientific innovation. Plant breeding innovation is based on an increased understanding of plant genomes, refinements in breeding techniques, and identification of new characteristics so that farmers have a wide array of high quality, high producing seed varieties available when making their planting choices. Such innovation is crucial for both the U.S. seed sector and global food security, particularly at a time when the global population continues to grow rapidly. Stability of food production and expanding food choices will continue to be a priority for all nations.

Domestic Regulatory Policy

For more than three decades, numerous administrations¹ have agreed on the principles and policies that provide the foundation for effective and efficient regulatory oversight. In 2011-12,

¹ EO 12866 (Sept.30, 1993) *Regulatory Planning and Review*. <http://www.archives.gov/federal-register/executive-orders/pdf/12866.pdf>; OECD. 1995. Recommendation of the Council on Improving the Quality of Government Regulation. <http://acts.oecd.org/>

[Public/Info.aspx?lang=en&infoRef=C\(95\)21/FINAL](http://www.oecd.org/gov/regulatory-policy/2391768.pdf); OECD.1997. Report on Regulatory Reform. <http://www.oecd.org/gov/regulatory-policy/2391768.pdf>; APEC-OECD. 2005. Integrated Checklist on Regulatory Reform <http://www.oecd.org/regreform/34989455.pdf>

OECD. 2005. Guiding Principles for Regulatory Quality and Performance. <http://www.oecd.org/fr/reformereg/34976533.pdf>; Middle East and North Africa-OECD.2009. Regional Charter for Regulatory Quality. <http://www.oecd.org/mena/governance/45187832.pdf>; OECD. 2012.

two Executive Orders and a memo on appropriate regulation of emerging technologies² reaffirmed the principles that were clearly articulated in the 1993 Executive Order on regulatory development and review:

- Regulate only when there is a significant problem that is best solved by regulation.
- If regulation is warranted, it should be designed to be cost-effective: the benefits of regulation should justify the costs, and the degree of regulation should be commensurate with the risk.
- Base regulatory decisions on the best available scientific and technical information.
- Provide sufficient flexibility to accommodate new evidence and learning, and review regulations on a regular basis to ensure they meet the regulatory objectives in the least burdensome way.
- Use clear language and provide opportunity for stakeholder and public involvement.
- If possible, regulation should promote innovation while protecting health and the environment.
- Avoid interagency duplication and inconsistency.
- Promote international coordination to minimize trade impacts.

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, was consistent with the principles described above. It additionally set forth a number of principles specific to Federal regulation of the products of biotechnology.

A fundamental principle articulated in the Coordinated Framework was the use of existing Federal laws to regulate biotechnology research and products. These laws provide authority to various agencies to regulate particular products and product uses. Because the uses and potential risks posed by products developed through modern biotechnology would be the same as existing products otherwise developed with similar traits, the developers of the Coordinated Framework rightly determined that existing laws would provide adequate oversight for protecting the public and the environment. The use of existing laws helped ensure adherence to other central regulatory principles: that similar products be treated the same by regulatory agencies, and that new products meet the same safety standards and criteria as existing products. Thus, a new food crop must be as safe to grow and as safe to eat as those food crops already on the market.

Recommendation of the Council on Regulatory Policy and Governance

<http://www.oecd.org/regreform/regulatory-policy/49990817.pdf>

² EO 13563 (January 18, 2011) *Improving Regulation and Regulatory Review* <http://www.whitehouse.gov/the-press-office/2011/01/18/executive-order-13563-improving-regulation-and-regulatory-review>; EO 13610 (May 10, 2012) *Identifying and Reducing Regulatory Burdens* <http://www.whitehouse.gov/the-press-office/2012/05/10/executive-order-identifying-and-reducing-regulatory-burdens>; Memorandum (March 11, 2011) *Principles for Regulation and Oversight of Emerging Technologies*

³ OSTP. 1986. Coordinated Framework for Regulation of Biotechnology. 51 *Fed. Reg.* 23302, 23304

These principles were reaffirmed in a review of the Coordinated Framework in early 2017.⁴

Most recently, reforms were described that will promote agricultural innovation in accordance with the report of the Interagency Task Force on Agriculture and Rural Prosperity⁵ and the June 11, 2019, Executive Order on Modernizing the Regulatory Framework for Agriculture Biotechnology Products.⁶ In particular, ASTA notes the instructions in the 2019 Executive Order regarding regulatory streamlining and review of existing authorities, regulations and guidance with the goal of removing undue regulatory burdens for smaller developers and public researchers developing genome edited plants. The 2019 Executive Order also instructed USDA, the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) to take steps to have consistency and coordination among the three agencies. Additionally, the order reiterates the importance of trade and international engagement.

In order to maximize the benefits of innovations in plant breeding across the seed sector, there needs to be a rational path to commercialization that does not include unnecessary duplicative requirements or processes among the U.S. regulatory agencies. The benefits to agriculture that have resulted from, and will continue to result from, the development and commercialization of innovative plant products, including crops developed using genome editing and other precision breeding methods, should be available to all of our nation's farmers.

International Policy and Trade

The U.S. seed industry is the largest in the world. Unnecessary and unjustified hindrances to seed movement have an economic impact throughout a seed product's lifecycle—from early research and development, commercial seed production and seed trade through harvesting, processing, final production and consumption. The structure of the seed industry and the process used by commercial plant breeders to bring new seed varieties to market means that seed movement across national borders is an integral and essential part of variety development and deployment of new technologies and genetics. Seed movement is critical for the development of foundation and breeder seed lines used in research and development, for parental seed and stock seed production, for commercial seed production and for processing and packaging of commercial seed.

Therefore, the global policy around plant breeding innovations will be critical for the U.S. to remain a leader in this area. Other countries, most notably South and Central America and Japan, are currently putting in place policies around plants developed through innovative

⁴ https://www.aphis.usda.gov/biotechnology/downloads/2017_coordinated_framework_update.pdf

⁵ <https://www.usda.gov/sites/default/files/documents/rural-prosperity-report.pdf>

⁶ <https://www.whitehouse.gov/presidential-actions/executive-order-modernizing-regulatory-frameork-agricultural-biotechnology-products/>

methods such as gene editing. The U.S. has historically played a key international role in advocating for science and risk- based policies that both maintain high standards of safety and facilitate continued innovation. Failure to achieve alignment around these goals across countries will have a negative impact on research collaborations and trade in seed and agricultural commodities.

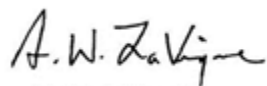
While the U.S. enjoys a robust system for protecting intellectual property rights (IPR), the same does not hold true in many countries. ASTA encourages the U.S. Government to continue advocating for strong IPR systems globally, particularly as it relates to enforcement.

Investment in Research

The seed industry is fueled by innovation, and funding for agriculture research is critical. A strong federal investment in research is vital to ensuring the success of U.S. farmers and a thriving bioeconomy. An area of federal investment that is not well-known but critically important is the USDA Agricultural Research Service National Plant Germplasm System which collects and stores unique plant germplasm from around the world. Plant breeders use these plant materials to help bring forth new varieties that can resist pests, diseases and environmental stresses. Additional investment in the NPGS would undoubtedly help researchers uncover new sources of food, fuel and fiber within the 584,000 samples of 15,000 plant species currently stored within the system. Ultimately, public investments in pre-commercial research and development facilitates public/private partnerships and creates a climate for increased applied research by the private sector.

ASTA appreciates the opportunity to comment on the OSTP's Request for Information on the Bioeconomy.

Sincerely,

A handwritten signature in black ink, appearing to read "A.W. LaVigne". The signature is fluid and cursive, with a long horizontal stroke at the end.

Andrew W. LaVigne
President & CEO