

May 15, 2017

U.S. Environmental Protection Agency
Office of Regulatory Policy and Management
1200 Pennsylvania Ave. NW.
Mail Code 1803A
Washington, D.C. 20460-0001

Submitted Electronically via Federal eRulemaking Portal (<http://www.regulations.gov>)

Re: Evaluation of Existing Regulations; Docket ID No. EPA-HQ-OA-2017-0190

Dear Sir or Madam,

Founded in 1883, the American Seed Trade Association (ASTA), located in Alexandria, Virginia, 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. ASTA member seed products support agricultural producers of food products and farm commodities in the United States and around the world.

General Comments

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, 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.

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. 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*

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- Promote international coordination to minimize trade impacts.

The Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework) is 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 in the Coordinated Framework is that similar products be treated the same by regulatory agencies and that new products meet the same safety standards and criteria as existing products.

EPA'S Mission and 40 CFR Part 174

For Plant Incorporated Protectants (PIPs), EPA has consistently stated that its intent is to focus its regulatory efforts to those defense mechanisms that are new to plants and that act directly on the target pest through a toxic mechanism of action. In the 2001 final PIP rule, EPA stated that it would focus on those PIPs that are isolated from novel sources and may present novel, unknown and/or unfamiliar toxicological profiles. (66 Fed. Reg. 37782-83).

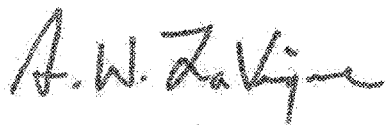
EPA further recognized the safety record of plant breeding in the United States and that plant breeders have provided a safe food supply and that they have standards of practice to maintain this safety record. Based on this safety record, EPA exempted PIPs derived through conventional breeding from sexually compatible plants from almost all regulatory oversight, except the post market reporting of adverse effects. EPA stated that it did not want to unnecessarily supplant the self-regulating aspects of plant breeding. (66 Fed. Reg. 33783)

Many of the applications of innovative plant breeding tools are and will continue in the future to be used by plant breeders to more efficiently and effectively develop disease and pest resistant plant varieties. These tools will be particularly important for creating resistance to diseases that rapidly evolve and for crops with longer generational times. These newer plant breeding tools create disease resistance through inducing genetic variability in a very targeted way using the plant's own gene pool. No "foreign" DNA is found in the final plant product. Plant varieties improved with these latest breeding methods are subjected to the same critical performance evaluations and processes that breeders have used for many decades to create new plant varieties that are safe to grow and eat.

If the plant varieties developed with the newer tools meet the same standards as those developed with earlier breeding methods, they should be subject to the same treatment under the law and are not within the mandate of EPA, something EPA has consistently recognized since 1994. This science-based approach will promote agricultural innovation while, at the same time, allowing the Agency to focus its limited resources on higher priorities.

ASTA appreciate the opportunity to engage with the agency. We look forward to working together throughout the process.

Sincerely,



Andrew W. LaVigne
President & CEO