

April 21, 2016

Regulatory Analysis and Development
PPD, APHIS, Station 3A-03.8
4700 River Road Unit 118
Riverdale, MD 20737-1238

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

Re: Docket No. APHIS-2014-0054— Environmental Impact Statement; Introduction of the Products of Biotechnology

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.

This innovation is based on an increased understanding of plant genomes, refinements in breeding techniques, and identification of new traits so that farmers have a wide array of high quality, high producing seed varieties available when making their planting choices. The continuation of such innovation is crucial for both the U.S. seed industry and global food security, particularly at a time when the global population continues to grow rapidly and many developing nations can ill-afford food shortages.

ASTA appreciates the opportunity to submit comments in response to the USDA Animal and Plant Health Inspection Service (APHIS) request for public input on the on the agency's Notice of Intent (NOI) to prepare an Environmental Impact Statement in connection with possible revisions to its biotechnology regulations (7 CFR part 340).

Principles of Regulation and Oversight of Emerging Technologies

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:

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://acts.oecd.org/Public/Info.aspx?lang=en&infoRef=C(95)21/FINAL); 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*

- 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 (e.g., food, pesticides). 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 determined that existing laws would provide adequate oversight for protecting the public and the environment. Using existing laws helped to ensure that other central regulatory principles were adhered to—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.

In agriculture, most new plant varieties are introduced without a specific pre-market safety assessment, given the long history of safe application of the methods breeders use to develop new plant varieties. Acknowledging the first principle of appropriate regulation (see above), the Coordinated Framework focused on only those plants that presented a potential risk, when compared to similar plant/trait combinations that have a history of safe use and consumption. The Coordinated Framework also recognized that regulations should evolve and be refined. In the intervening 30 years since the Coordinated Framework was operationalized, significant experience and familiarity with new plant/trait combinations has accrued. Scientists and regulators can predict more precisely which products and product uses require more or less stringent oversight and which could be exempted from pre-market review.

Plant Breeding

Plant breeding is a product-oriented, science-based discipline for improving plants. Plant breeding is rooted in population development, selection theory, quantitative genetics, statistical analysis and an increasing number of support technologies. It involves generating genetic variation, selecting desirable plants, stabilizing inheritance of desirable traits, testing in multi-locations over many years, and multiplying the best performing plants.

The goals of plant breeders have always been to create new variations of plant characteristics, to provide solutions for resistance to plant diseases and pests, to increase tolerance to environmental stress, to improve quality and yields, and to meet consumer expectations. Plant breeding depends upon genetic variability within

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

and across related species as a basis for developing new plant varieties with improved traits. To create a new plant variety, plant breeders generally have relied on two sources of genetic variation as a basis for new traits: the inherent diversity in a plant's gene pool and new, naturally occurring variants of existing genes.

Plant traits are encoded in the DNA of their genes. Sometimes many different genes can influence a desirable trait, making it difficult for plant breeders to accumulate them all into a single variety. Marker-assisted breeding allows breeders to map and trace thousands of genes and screen large populations of plants for those that possess the desirable alleles for traits of interest. The marker, or genetic tag, can be based on either DNA or proteins. Molecular markers have enabled high-throughput genotyping and accelerated the rate at which breeders can combine useful traits into new varieties.

Breeders often make crosses between plants of diverse genetic makeup or genotypes to produce new combinations of genetic traits, which then result in diverse phenotypes, or observable morphological or quality traits in the progeny plants. The natural diversity of different sources of germplasm within a species or its close relatives is a primary source of genetic variation. Genetic variation can also be increased by inducing mutations – changes in the DNA sequences of the plants. Since the 1950s, over 2,200 crop varieties have been developed by induced mutations.

Breeders have historically integrated the latest technologies in plant biology and genetics into their methodologies to efficiently exploit existing, and to induce new, genetic variation. Plant breeders are continuing to develop precise, yet flexible, methods to safely increase specificity and efficiency of breeding, decrease development time and cost, and increase genetic diversity for breeding programs. These newer breeding tools can be used to precisely target a change to a specific gene(s) in a plant's genome to create the desired plant trait. They can also be used to identify a gene in a plant's wild relative and to precisely and efficiently introduce the allele for that gene and the desired trait into an existing, high-performing commercial variety. By applying these newer methods, plant breeders are more efficient and precise at making the same desired changes that can be made over a much longer period of time through earlier breeding methods. Because these new methods are efficient and economical, they are accessible to public and commercial plant breeders in developed and developing countries and can be used across all agriculturally important crops, including field, vegetables and specialty crops.

There is inherent variation in many traits considered to be important by plant breeders, and the expression of a trait is influenced by growing conditions. The development of a new plant variety normally involves many performance trials in different environments before introduction as a new commercial variety. Prior to commercial release of a new plant variety, plant breeders use well-established, intensive assessments across growing conditions across locations and over multiple years to eliminate plants with undesirable characteristics, to ensure stability of the desired trait, and to confirm performance. This evaluation is intended to not only confirm the performance of the new variety but also to evaluate the variety's traits and eliminate those traits that are undesirable. The scrutiny breeders routinely apply to new variety development is well established and has been the foundation for a food supply that is safe, nutritious and diverse.

Plant varieties improved with the 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.

Definitions and Scope of Regulatory Oversight

Any revisions to Part 340 should be based not only on the policy principles initially articulated in the Coordinated Framework and the Executive Orders described above but, more importantly, on over 100 years of experience in incorporating scientific advances to develop improved, safe, nutritious and environmentally adapted plant varieties. APHIS has adequate authority under the Plant Protection Act to protect U.S. agriculture from the risks posed by plant pests and noxious weeds. Therefore, in determining the appropriate scope of regulatory oversight, the question is not whether there is adequate regulation of new plant varieties but rather the extent to which a specific pre-market review and clearance process is justified for plant varieties developed using certain plant breeding techniques. Having a clearly articulated scope of regulatory oversight provides developers, both public and private, with the predictability and legal certainty needed so they can reliably plan their breeding programs, their product development and market potentials.

In the NOI, APHIS proposes a working definition for “biotechnology” that would essentially define the initial scope of products that would be subject to any of the alternatives described in the Notice of Intent:

Laboratory based techniques to create or modify a genome that result in a viable organism with intended altered phenotypes. Such techniques include, but are not limited to, deleting specific segments of the genome, adding segments to the genome, directed altering of the genome, creating additional genomes, or direct injection and cell fusion beyond the taxonomic family that overcomes natural physiological reproductive or recombination barriers.

This definition is much broader than that found in current regulations and is entirely based on the process by which a new plant variety is developed. If applied to Part 340, this definition would require pre-market regulatory review of many modifications that could be achieved through conventional breeding. In light of the fact that no plant pests or noxious weeds have been identified in 30 years of regulatory oversight of transgenic plants, including every transgenic plant on the market today, this expansion of regulatory scope cannot be justified by APHIS from either a scientific or risk perspective. Nor is this proposal consistent with the Coordinated Framework principle that the focus of regulatory oversight should be on the characteristics of the product rather than the process by which it was produced. Moreover, whether a technique is “laboratory based” is not relevant to the plant pest and noxious weed statutory authorities of APHIS.

A fundamental principle for determining the initial scope for any of the alternatives proposed by APHIS should be:

Plant varieties developed through the latest breeding methods should not be differentially regulated if they are similar or indistinguishable from varieties that could have been produced through earlier breeding methods.

This principle is consistent with the well-established practice of using the conventionally bred plant counterpart as the comparator during the risk assessment process for transgenic plants⁴⁵. It also is consistent with the recognition by both the Food and Drug Administration and the Environmental Protection Agency of the quality

⁴ Organization for Economic Cooperation and Development (OECD). 1993. Traditional Crop Breeding Practices: An Historical Review to Serve as a Baseline for Assessing the Role of Modern Biotechnology. OECD. Paris, France.

⁵ Codex Alimentarius. 2009. Foods Derived from Modern Biotechnology. Food and Agriculture Organization and World Health Organization. Rome, Italy.

assurance steps plant breeders take during the development of a new plant variety as well as the safety record of plant breeding⁶⁷.

ASTA therefore recommends the following definition of “biotechnology product” as a substitute for the working definition of “biotechnology” in the NOI:

The term “biotechnology product” means a plant—

(A) that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques; and

(B) for which the modification could not otherwise be obtained through conventional breeding.

Under this definition, new plant varieties would not be subject to a pre-market regulatory review if there is no insertion and stable transmission to subsequent generations of genetic material that encodes an expressed protein. Additionally, based on over 30 years of regulatory experience, if there is insertion and stable transmission of genetic material, new plant varieties would also not be subject to a pre-market regulatory review if the inserted genetic material is from a sexually compatible plant. This regulatory scope would allow plant breeders to quickly and efficiently deliver targeted genetic improvements that would be possible, but with much greater difficulty, using earlier breeding methods. It would also facilitate the use of these newer breeding methods in a wide range of crops, including specialty crops, and by a wide range of both public and commercial plant breeders without modifying current proven and well established standards of safety.

While ASTA believes that the above definition of “biotechnology product” is scientific and risk-based, ASTA recognizes that many other countries are also reconsidering the definitions in their current regulatory frameworks for products of biotechnology. ASTA strongly encourages APHIS to actively consult with these governments before formally proposing any revisions to definitions in Part 340⁸⁹.

Proposed Regulatory Alternatives

Alternative One

Alternative One has been identified by APHIS as the “no action” alternative. “No action” is not a viable alternative. Beyond considering the viability of this alternative, there are tools under the current Part 340 that APHIS could use to modify their current regulatory process to create regulatory relief without proposing a new rule. Two possible suggestions for this approach are identified later in these comments.

Alternative Two

ASTA will concentrate its comments on Alternative Two, for which APHIS has provided the most specifics. In principle, the concepts articulated under Alternative Two could be promising and could show an innovative

⁶ Food and Drug Administration. 1992. Food For Human Consumption And Animal Drugs, Feeds, And Related Products: Foods Derived From New Plant Varieties; Policy Statement, 22984. 57 CFR 104.

⁷ Environmental Protection Agency. 2001. Plant Incorporated Protectants, 37772. 40 CFR Parts 152 and 174.

⁸ Japan New Plant Breeding Technique Study Group. 2015. Towards The Development And Practical Application Of Crops Using New Plant Breeding Techniques Such As Genome Editing.
http://www.s.affrc.go.jp/docs/committee/nbt/pdf/siryo3_en.pdf

⁹ Haut Conseil des Biotechnologies. 2016. Scientific Committee Memorandum on New Plant Breeding Techniques. Paris, France.

approach to determining which products would be subject to regulation. However, the Agency does not provide any detail on what would be involved in the new review process nor on the risk assessment model upon which this process is based. If the criteria that determine whether a product would be subject to further regulatory review and requirements are not clear and predictable, developers will be faced with such a level of uncertainty that it would result in viable and enhanced commercial products not being further developed. It is also not clear if APHIS has the resources to efficiently implement Alternative Two. This problem would be greatly exacerbated if APHIS maintains the broad working definition of “biotechnology” currently articulated in the NOI, potentially subjecting thousands of new products to an uncertain review process.

APHIS does put forward the possibility of exemptions of products of biotechnology in NOI. One possible exemption identified in the NOI is based upon plant products of biotechnology “that could reasonably be expected to be obtained through mutagenic techniques”. While it is encouraging that APHIS recognizes that this category of plants would not warrant additional APHIS regulatory review and oversight since they “lack the realistic potential to pose documented plant pest or noxious weed risks”, it is not clear why APHIS brings them in under the definition of biotechnology and therefore under the initial scope of regulatory oversight. Nor is it clear how long it would take for APHIS to promulgate the necessary exemptions. A risk-based approach would treat all DNA changes, such as deletions and base-pair substitutions, the same.

Alternative Three

Under Alternative Three, APHIS would eliminate the notification and petition processes and there would be no exemptions for any “products of biotechnology”. The Agency does not provide many specifics as to the “analysis triggers” it would use to classify plants as noxious weeds or plant pests nor does it provide any detail as to how this regulatory scheme would be implemented. On the face of it, this alternative seems to substantially increase the range of oversight by the Agency, particularly in light of the proposed working definition of “biotechnology” in the NOI. As such, this alternative would not be tenable.

Alternative Four

Under Alternative Four, APHIS would withdraw the current 7 CFR part 340 regulations and implement a voluntary consultative process for certain products of biotechnology. This alternative is consistent with the principle of the Coordinated Framework that regulation should be based on the risk posed by the product and not because a specific process was used to develop that product. Under this alternative, developers would still be responsible for compliance with all Federal and State statutes that relate to plant pests or noxious weeds. This alternative recognizes that developers of all new plant varieties have processes in place to meet the standards under these statutes. It eliminates the current double standard under which biotechnology products are subject to a different level of oversight. While there are many attractive aspects to this alternative, it would be a radical departure from the current regulatory approach of APHIS, and it may not be practical to move to such a model quickly. In considering this alternative, it would be critical for APHIS to first look at possible intermediate steps for implementation of this alternative. It would also be critical that the Agency initiate significant consultation with other countries and stakeholders well before any implementation.

Other Possible APHIS Actions

ASTA urges APHIS to give serious consideration to other actions that the Agency can take to meet the goals articulated in the NOI. Many of these actions could be taken without the need for rulemaking by using some of the Agency’s current regulatory processes. First, APHIS has published a number of letters to developers, clarifying the regulatory status of individual products. Rather than relying on this case-by-case approach, the Agency could use the conclusions provided in these letters to provide more generally applicable guidance to developers. Such an approach would provide developers with additional clarity and predictability about which products would or

would not be subject to APHIS pre-market regulatory review. Second, APHIS could continue to further develop and justifiably increase its use the existing extension process (7 CFR 340.6(e)) to achieve the goal of providing regulatory relief as expressed in the NOI. The Agency could build upon and expand the guidance that the Agency recently published on the use of the extension process.

Conclusions

ASTA commends APHIS for trying to take an innovative approach to revising its current regulatory process and approach. The direction that APHIS ultimately takes will have impacts on U.S. agricultural innovation and competitiveness and will be watched closely by governments and regulators in other countries. It is therefore important that APHIS carefully weigh these impacts and that their oversight is consistent with the principles articulated in the Coordinated Framework and builds on the experience gained over the past 30 years. It will be critical for the Agency to consult early with FDA and EPA and to be informed by the Office of Science Technology Policy's (OSTP's) review of the Coordinated Framework to assure that the framework in fact remains "coordinated" and the report to be produced by the National Academies of Sciences committee organized at OSTP's request. APHIS should broadly consult with domestic stakeholders before such dialogue and interaction is limited following the publication of a proposed rule. Given the global nature of the seed industry and the agriculture sector as a whole, it is also critical that APHIS consult with other key governments where some of the same discussions and considerations are taking place and with the Office of the U.S. Trade Representative. ASTA stands ready to provide any additional information as needed by the Agency.

Sincerely,



Andrew W. LaVigne
President & CEO
American Seed Trade Association