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Re: Docket No. APHIS-2018-0034-0037: Movement of Certain Genetically Engineered Organisms

The Society of American Florists (SAF) greatly appreciates the opportunity to comment on USDA's proposal regarding the, "Movement of Certain Genetically Engineered Organisms," which would modernize the Department's biotechnology regulations. SAF is a national trade association representing the floriculture and greenhouse industry. Its 7,000 small business members include growers, wholesalers, retailers, importers, suppliers, researchers, students and related organizations located in communities nationwide and abroad. The industry produces and sells cut flowers and foliage, foliage plants, potted flowering plants and bedding plants, which compete in the international marketplace.

The floriculture industry dwarfs all other sectors of agriculture in the number of new varieties and cultivars that are brought to market each year. Customers are always seeking new flower colors, attractive shapes, improved longevity, better fragrance and other intriguing attributes. Crop innovation holds great promise for the future of floriculture, and farmers recognize how these advancements not only improve farm profitability but also hold benefits for the entire supply chain and its customers. We believe advances in plant breeding technology will allow growers to supply high quality ornamental crops desired by domestic and global customers. New breeding innovations, from the use of marker-assisted selection to precision breeding techniques to genetic engineering, provide growers with higher yields, better quality and value-added products, include the potential for improved environmental profiles. SAF is supportive of a regulatory system that makes innovation and technology improvements in our crops available to the full breeder community.

General Comments

SAF is largely encouraged by USDA's proposal and supports the Department in moving forward as swiftly as possible to finalize the rule. SAF recognizes the need and importance of updating the nearly 30-year-old 7 CFR 340 regulations and appreciates efforts by the agency to reduce regulatory burdens and alter their approach through "lessons learned" regarding plant pest risk given APHIS's years of experience regulating these crops. Our greatest interest in utilizing new techniques like gene editing is to develop plant products that could also be achieved through traditionally breeding. However, the new techniques will allow for more efficient development, saving valuable time and resources.

SAF sees the advances in breeding techniques as an opportunity to more precisely and efficiently bring new traits to market that improve the ornamental quality, reduce input needs like water and fertilizer and impart pest and disease resistance, thus reducing reliance on pesticides. While technology and innovation cannot remove all uncertainties, they can provide confidence of improved crops and reduced environmental impacts.

Exemptions from Regulation

Secretary Perdue's March 28, 2018 statement¹ on biotechnology clearly identified a series of plant breeding approaches that are currently pursued through traditional breeding practices – such as induced or somaclonal mutagenesis, tissue culture, protoplast, cell or embryo fusion, wide and bridging crosses, or haploid induction – but can now be accomplished much faster and more precisely using gene editing. For these plant products, the statement rightly indicated that, "such products of biotechnology are likely to pose no greater plant pest risk than their traditionally bred comparators, which APHIS does not regulate."

In keeping with the Secretary's statement, under the proposed § 340.1 (b)(1) through (4) USDA would exempt GE crops that meet the following criteria from regulation:

- The genetic modification is solely a deletion of any size; or
- The genetic modification is a single base pair substitution; or
- The genetic modification is solely introducing nucleic acid sequences from within the plant's natural gene pool or from editing nucleic acid sequences in a plant to correspond to a sequence known to occur in that plant's natural gene pool; or
- The plant is an offspring of a GE plant and does not retain the genetic modification in the GE plant parent.

We agree with USDA in that the risk posed by the gene edited plant product that meets the proposed exempted criteria is identical to that of the conventionally bred crop, which has never been regulated under CFR 340. The emphasis on evaluating risk from the perspective of

¹ <https://www.usda.gov/media/press-releases/2018/03/28/secretary-perdue-issues-usda-statement-plant-breeding-innovation>

“product” instead of the “process” is an important one, as it does not impart a negative connotation of any breeding method and appropriately places the evaluation of risk on the resulting product. The National Academy of Sciences shared this perspective in their 2016 report².

Floriculture producers are largely reliant on small breeder companies, academic institutions and other publicly funded researchers to pursue new traits and we are encouraged by the potential gene editing offers. The exemptions for plant products that differ from conventionally bred crops, only in that gene editing was used, are vital to the democratization of plant breeding and will allow the scientific community to rapidly pursue traits to address our production and sustainability goals.

However, SAF would like USDA to consider expanding the exemption pertaining to a single base pair substitution to be more reflective of the types of genetic changes achieved in the traditional breeding method of mutagenesis, particularly with radiation-based methods. While viable plants resulting from chemical mutagenesis are typically the product of single base pair changes, radiological methods can create additional and more complex polymorphisms³. We believe it is possible for USDA to augment this particular exemption to make it more consistent with the genetic changes observed through mutation breeding while preserving the expectation of low risk associated with traditional breeding.

Regulatory Status Review

As stated above, SAF supports the exemptions proposed and USDA’s acknowledgement of the inherently low risk profile of plant products that are the result of gene editing to accomplish what could otherwise have been done through conventional breeding. We believe that, just as there are no regulatory obligations or oversight for crops bred using conventional methods, plant products that meet the exempted criteria should also be free from regulatory obligations. However, USDA plays a critical role in the Coordinated Framework for the Regulation of Biotechnology and must work and coordinate with Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) to ensure clear roles, responsibilities and provide regulatory streamlining.

Based on numerous conversations with EPA regarding traits that provide pest and disease resistance, and an analysis of their approach to Plant Incorporated Protectant⁴, we have determined that some kind of notification from the breeder/innovator to USDA may be necessary to achieve the goal of regulatory streamlining, even when the exemptions described in the USDA

² National Academies of Sciences, Engineering, and Medicine. 2016. Genetically Engineered Crops: Experiences and Prospects. Washington, DC: The National Academies Press. doi: <https://doi.org/10.17226/23395>.

³ Sikora P et al. 2011. Mutagenesis as a Tool in Plant Genetics, Functional Genomics and Breeding. International Journal of Plant Genomics. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3270407/>

⁴ <https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/overview-plant-incorporated-protectants>

proposal are met. SAF sees the benefits of one set of standards and a notification requirement that meets the needs of USDA, EPA and FDA, perhaps under a memorandum of understanding (MOU) or equivalent.

We believe the notification requirement for plant products that fall within gene editing exemptions should be simple and straightforward likely requiring no more than a single-page attestation. The information required should be limited to the plant of interest, the desired trait, brief description of the trait benefit and the method used to introduce the edit. In addition, the attestation document must allow the breeder to protect confidential business information. To avoid hampering early-phase research and alerting potential competitors, the attestation should only be necessary a short period of time before marketing of the plant or plant product.

Conclusion

SAF commends USDA in their efforts to modernize the biotechnology regulations by emphasizing decision-making based on actual risk rather than process or breeding techniques used. A final rule that largely maintains the approach proposed would better position floriculture farmers to meet production goals, reduce inputs and compete in the global marketplace. Again, we thank the USDA for the opportunity to comment on APHIS-2018-0034-0037 and urge the Department to move forward thoughtfully, transparently and rapidly toward the publication of a final rule.

Sincerely,



Drew Gruenburg
Chief Operating Officer
Society of American Florists