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Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460–0001

Re: Docket Number EPA–HQ–OPP–2019–0508

December 8, 2020

On behalf of the farmers, ranchers, cooperatives, retailers, scientists, plant breeders, seed producers and coregulators listed below, representing a broad and diverse swath of the agricultural stakeholders in the United States, we appreciate the opportunity to comment and provide feedback on the proposed rule, "Pesticides; Exemptions of Certain Plant-Incorporated Protectants (PIP) Derived from Newer Technologies." We applaud the Environmental Protection Agency's (EPA) efforts in seeking to modernize our biotechnology regulatory system by proposing to exempt qualifying ''PIPs based on sexually compatible plants created through biotechnology'' from most requirements of the Federal Insecticide Fungicide and Rodenticide Act (FIFRA), as well as the tolerance-setting requirements established by the Federal Food Drug & Cosmetic Act (FFDCA). While we appreciate the general vision of the proposed rule, we offer some recommendations that we believe will help EPA in developing a more science and risk-based final rule. We also believe our recommendations, if accepted, will help the United States maintain its global leadership position in the development of plant biotechnology.

We explain herein unified baseline recommendations for enhancing the proposed rule to meet the needs of our various stakeholders. Many of the signatories will also submit separate comments that provide more detail on specific recommendations as they pertain to individual stakeholder needs, or with recommendations that go beyond what is included in this letter.

Recent Historical Context of Proposed PIP Exemptions

It is important to understand the recent historical context prompting EPA's proposal to exempt this narrow, low-risk subset of PIPs. In July 2015, President Obama's Executive Office of the President (EOP) issued a memo raising concerns that the current biotechnology regulatory framework was in some cases imposing unnecessary costs and burdens that were preventing small and mid-sized businesses from participating in the marketplace, limiting public understanding of the regulatory process, and in essence stifling innovation.[1] The memo created an interagency working group to develop a "National Strategy for Modernizing the Regulatory System for Biotechnology Products" (*National Strategy*), which was published in September 2016. In addition to reaffirming that, "the policy of the United States Government is to seek regulatory approaches that protect health and the environment while reducing regulatory burdens and avoiding unjustifiably inhibiting innovation, stigmatizing new technologies, or creating trade barriers," the *National Strategy* directed that EPA should, "clarify its approach to pesticidal products derived from genome editing techniques." [2]

[1]Executive Office of the President of the United States. *Modernizing the Regulatory System for Biotechnology Products*. John P. Holdren, Howard Shelanski, Darci Vetter, and Christy Goldfuss. July 2, 2015. https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/modernizing_the_reg_system_for_biotech_products_memo_final.pdf.

[2] Executive Office of the President of the United States. Emerging Technologies Interagency Policy Coordination Committee. Biotechnology Working Group. *National Strategy for Modernizing the Regulatory System for Biotechnology Products*. September 2016. https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/biotech_national_strategy_final.pdf

These same concerns and the need for modernization were reaffirmed by the Trump Administration, which issued its own, "Executive Order on Modernizing the Regulatory Framework for Agricultural Biotechnology Products," (E.O.) in June 2019, which led to the promulgation of this proposed rule. It is important to note that the vision, goals, and objectives aimed at modernizing our biotechnology regulatory framework – and specifically the regulations governing PIPs – are bipartisan and transcend administrations. The subset of PIPs based on sexually compatible plants created through biotechnology that EPA would exempt from certain FIFRA and FFDCA requirements in this proposed rule are inherently low-risk. Their exemption would enable growers to farm more productively and sustainably with fewer inputs and with greater environmental outcomes. These are value-driven objectives that span the political spectrum.

Gene Editing & Conventional Breeding

While we appreciate EPA's undertaking, prompted by the Obama and Trump Administrations, as well as many of the premises on which EPA is proposing these exemptions, we give pause when considering the form of the proposed exemptions. They do not seem to reflect current Agency PIP policy or the science and risk-based principles that EPA has stated this effort is based upon. As we discuss below, we believe the approach used by EPA to arrive at the proposed exemptions are inconsistent and substantially diverge from USDA's SECURE Rule so much that they contradict the effort to achieve regulatory alignment within the "Coordinated Framework for the Regulation of Biotechnology" concept spanning across Administrations. Furthermore, we believe that adoption of the rule as proposed will result in an unnecessarily complicated regulatory structure that risks stifling innovation.

As EPA notes in the proposed rule, novel genetic innovations, such as gene editing, "allow for such precise editing of the genome, that the resulting genes can be indistinguishable from those found in a plant created through conventional breeding." EPA acknowledges in the proposal that these traits are low-risk and their "indistinguishable" quality is the basis for EPA's proposed exemption of this subset of PIPs. Conventional plant breeding has a long-standing, extensive history of safe use, and is responsible for nearly all foods we enjoy today. As the Agency noted in its 2001 final rule exempting PIPs derived through conventional breeding from sexually compatible plants, "[EPA] recognizes that plant breeding in the United States has a good record of providing a safe food supply and that plant breeders employ accepted standards of practice to maintain this record. This good record provides support to the Agency's determination that it can exempt plant-incorporated protectants derived through conventional breeding from sexually compatible plants from almost all regulatory oversight, relying only on the post-market reporting of adverse effects."[3] Gene editing offers even greater precision and a lower-risk profile than that of conventionally bred crops[4], which are already exempt from FFDCA and FIFRA (except for the adverse effects reporting requirement).

We agree with EPA on all these premises. Science has demonstrated that PIPs resulting from conventional breeding have an exceptional record of safe use and warrant exemption from FFDCA and nearly all FIFRA requirements. However, the same rationale should be applied to PIPs that are based on sexually compatible plants developed through gene editing techniques, which are far more precise than conventional breeding and result in a plant that is indistinguishable from their conventionally bred counterparts.

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[3] Environmental Protection Agency. "Regulations Under the Federal Insecticide, Fungicide, and Rodenticide Act for Plant-Incorporated Protectants (Formerly Plant-Pesticides)." *Federal Register* 66, no. 133. July 19, 2001: 37772. (Amending 40 CFR § 152 and 174). https://www.govinfo.gov/content/pkg/FR-2001-07-19/html/01-17981.htm

[4] Abdallah, Naglaa A, Channapatna S. Prakash, Alan G. McHughen. "Genome editing for crop improvement: Challenges and opportunities." *GM Crops Food* 6, no. 4. 2015:183-205. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5033222/

Equivalence with Conventional Breeding

With that in mind, this proposed rule as written creates additional and unnecessary requirements and complicated nuances to its proposed exemptions for this narrow subset of PIPs based on sexually compatible plants created through biotechnology. These novel requirements and inconsistent constructs that EPA builds into its exemptions do not appear to be based in science, they do not reflect the very low-risk of these PIPs, nor are they consistent with longstanding and accepted PIP policy that has spanned Administrations.

For example, the requirements for mandatory notification to the Agency, a data package requesting an exemption confirmation, and post-market record keeping are not requirements EPA has imposed on indistinguishable conventionally bred PIPs. These requirements place unnecessary costs and burdens on developers, and will likely prevent small and mid-sized businesses, academics, and specialty and minor use crops from using this technology and participating in the marketplace – a concern espoused by President Obama's EOP memo.

There are also concerns with ways in which the proposed rule constructs exemptions that stem from this disparity with conventionally bred PIPs. For example, by attempting to limit the proposed exemptions to PIPs derived from "native genes" and "native alleles" resulting from within a plant's own gene pool, EPA risks drawing unnecessarily complicated boundaries that could potentially preclude from exemption techniques – such as embryo rescue or mutagenesis – that have been regularly and safely used in conventional breeding for decades, and which currently fall under the Agency's PIP conventional breeding exemption. We appreciate that EPA is seeking to prevent developers from claiming the exemption of transgenes novel to a species with an unknown risk profile. However, a simpler, more science-based approach would be to simply reaffirm that these transgenes that could not have resulted from conventional breeding, will continue to be subject to EPA's existing PIP regulations, while PIPs that are indistinguishable from those that could have resulted from conventional breeding techniques are exempt. We believe that this is a much more scientifically justifiable approach and will be a simpler system for EPA to administer and for researchers and developers to operate within. Furthermore, we believe that this alternative approach will drive down development costs and speed access to new and more sustainable plant varieties for growers and allow them to continue to improve environmental resiliency and outcomes.

The "Coordinated Framework for the Regulation of Biotechnology," which has guided U.S. biotechnology policy for over three decades, is based upon the principle that regulation should focus on the end product and express neutrality towards the process through which it was created. The product-based approach like the one USDA adopted in its SECURE Rule, is risk-based and scientifically-sound, as it allows regulators to direct limited Agency resources toward products that may pose unique risks. EPA's proposed exemptions for PIPs based on sexually compatible plants created through biotechnology are not process or technology-neutral. Despite acknowledgement by EPA that this subset of PIPs is "indistinguishable" from their conventionally bred counterparts, EPA is seeking to impose additional requirements and a complex, inconsistent structure on these PIPs to which their indistinguishable counterparts are not subject.

To be clear, we appreciate the general direction of this rulemaking and the bipartisan evolution of biotechnology regulatory modernization more broadly. These genetic tools will be critical in providing new plant varieties to our nation's agricultural producers more quickly, affordably, and efficiently. In turn, these new varieties will help to improve the productivity and sustainability of agriculture at a time when we face population and environmental challenges unlike any time in global history. However, we

feel EPA could better capture this innovation-enabling vision; stand on a firmer risk and science-based foundation; and remain true to the guiding principles of the "Coordinated Framework" if the Agency seeks to establish parity between what is truly low-risk and indistinguishable. We appreciate your work and attention on this important matter, and we stand ready to assist the Agency in this vital effort.

Sincerely,

Agricultural Retailers Association
American Farm Bureau Federation
American Seed Trade Association
American Soybean Association
American Sugarbeet Growers Association
California Citrus Mutual
California Specialty Crops Council
Crop Science Society of America
Florida Citrus Mutual
Florida Fruit and Vegetable Association
Florida Sugar Cane League
National Association of Plant Breeders
National Association of State Departments of Agriculture
National Association of Wheat Growers
National Corn Growers Association
National Cotton Council
National Council of Farmer Cooperatives
National Onion Association
National Potato Council
National Sorghum Producers
Northwest Horticultural Council
Produce Marketing Association
Rio Grande Valley Sugar Growers
Society of American Florists
Texas Citrus Mutual
United Fresh Produce Association
Washington State Potato Commission
Western Growers Association