

June 15, 2022

Melissa Bailey, Ph.D.
Associate Administrator
Agricultural Marketing Service
U.S. Department of Agriculture
1400 Independence Avenue, S.W.
Washington, DC 20250-0201

Submitted electronically via Federal eRulemaking Portal

RE: Competition and the Intellectual Property System: Seeds and Other Agricultural Inputs (AMS-AMS-22-0025-0001).

Dear Associate Administrator Bailey:

As stakeholder groups who represent growers, retailers, cooperatives, plant breeders, developers, among others, we write to express our strong support for the U.S. Department of Agriculture (USDA, or the Department) and other federal agencies increasing access to genetic innovation in agriculture as a means of promoting competition in the seed industry. Traditional technologies, such as recombinant biotechnology, have both historically and currently bring great value to American agriculture, consumers, and our environment. Novel genetic techniques, such as gene editing, have transformative potential for bringing enormous value to our food supply chain, including seed markets, so long as we continue to advance a pro-innovation regulatory strategy.

The need for having access to the most innovative breeding technologies is particularly salient now, as the industry (and the world) is looking for opportunities to minimize and mitigate the effects of climate change. Furthermore, consumer, retailers, and regulators are seeking crops produced with fewer inputs. It is clear growers need access to the broadest set of tools for growing food that meets demands of domestic and global consumers. As USDA contemplates competition in the seed market, we strongly encourage the Department to consider the below recommendations which have great potential to remove market barriers to innovation and thus promote greater trait development and advanced breeding in seed markets.

Plant Breeding and Biotech Seed Development

Agricultural producers are constantly seeking improved genetics for their crops. Whether varieties are sought with greater crop yield, enhanced disease-resistance, improved flavor or nutritional profile, reduced input and operational cost potential, or improved marketability, growers are constantly seeking better seed genetics. In recent years, growers have added reduced environmental footprint to this list of much sought-after traits. This producer demand has been a central underpinning to the plant breeding industry for more than a century, where innovation and improved varieties have enabled market opportunity and greater competition.

For more than 25 years, recombinant biotechnology has offered great benefits for growers of several crops through plant trait development. A recent study found that in 2018, biotech varieties of corn and soybeans boosted global yields by more than 3.1 billion bushels on 50.4 million fewer acres than would

be required by conventional varieties.¹ Domestically, benefits of biotech crops have boosted U.S. farm incomes by \$96 billion from 1996 through 2018.²

Our environment has also been a significant benefactor of biotech crop adoption. These crop varieties have helped to reduce or optimize certain input needs, such as fuel, water, fertilizer, and pesticides, while enabling certain conservation practices, such as tillage reductions. In turn, these practices have reduced soil erosion, nutrient losses to watersheds, greenhouse gas emissions, among other benefits. A recent estimate suggests in 2018 alone, global biotech crop production helped to remove the equivalent greenhouse gas emissions of 15.27 million cars from roadways.³

Given these immense impacts, it should come as no surprise the vast majority of producers have opted to transition to varieties containing biotech traits when available. For example, in 2020, more than 90 percent of all U.S.-grown canola, corn, cotton, soybeans, and sugarbeets were all biotech varieties (largely insect-resistant and herbicide-tolerant varieties)⁴ due to the significant value they offer producers and their customers when compared with conventional varieties.

The Current Impact of Regulation in the Seed Market

Despite more than 25 years having passed since their U.S. debut and an indisputable success for producers, markets, and the environment, biotech varieties remain largely limited to a handful of large acre commodities. The significant costs of regulation have served as a great barrier to biotech trait commercialization and limited access mostly to larger row crop markets where costs can be more easily recouped. Not only have these barriers limited market participation, but they have deprived specialty and minor use crops the opportunity of accessing these valuable technologies.

One of the greatest challenges biotechnology faces in expanding these benefits to other producers, consumers, and our environment continues to be regulation. A 2011 study found that, from 2008-2012, bringing a new biotech crop trait to market cost on average \$136 million and took more than 13 years. At that time, regulatory science and compliance alone cost \$35.1 million, or 25.8 percent of the total costs of commercialization, and required 4.8 years, or 36.7 percent of the time necessary for commercialization.⁵ These are not insignificant costs that can serve as a market barrier.

Interestingly, a just-released, 2022 reassessment analyzing biotech trait commercialization costs and timeframes from 2017-2022 found overall commercialization costs have decreased to \$115 million, largely driven by improvements in discovery and new efficiencies in genetic event construction and

¹ Brookes, Graham and Peter Barfoot. July 24, 2020. "GM crop technology use 1996-2018: farm income and production impacts." *GM Crops & Food*. Vol. 11, Iss. 4. P. 242-261. <https://www.tandfonline.com/doi/full/10.1080/21645698.2020.1779574>

² Ibid.

³ Brookes, Graham and Peter Barfoot. July 24, 2020. "Environmental impacts of genetically modified (GM) crop use 1996-2018: impacts on pesticide use and carbon emissions." *GM Crops & Food*. Vol. 11, Iss. 4. P. 215-241. <https://www.tandfonline.com/doi/full/10.1080/21645698.2020.1773198>

⁴ United States Department of Agriculture. Economic Research Service. Last updated July 17, 2020. "Biotechnology." Accessed May 11, 2022. <https://www.ers.usda.gov/topics/farm-practices-management/biotechnology.aspx>

⁵ McDougall, Phillips. September 2011. *The cost and time involved in the discovery, development and authorisation of a new plant biotechnology derived trait*. <https://croplife.org/wp-content/uploads/2014/04/Getting-a-Biotech-Crop-to-Market-Phillips-McDougall-Study.pdf>

testing.⁶ This should be positive news, especially for specialty crops and small developers seeking to enter the market. Unfortunately, regulatory costs in the time between the two studies grew to \$43.2 million, or 37.6 percent of commercialization costs, and overall timeframes for commercialization grew to 16.5 years, of which 8.4 years or 51.1 percent of the total time was regulatory.⁷

In summary, over the course of a decade, the cost of regulation for biotech trait commercialization grew by more than 23 percent while regulatory timeframes grew by 75 percent. This is not a trend conducive to promoting healthy, vibrant trait development and seed markets.

A 2015 memo from President Obama's Executive Office agreed that regulation is a concern. "While the current regulatory system for the products of biotechnology effectively protects health and the environment, in some cases unnecessary costs and burdens associated with uncertainty about agency jurisdiction, lack of predictability of timeframes for review, and other processes have arisen. These costs and burdens have limited the ability of small and mid-sized companies to navigate the regulatory process and of the public to understand easily how the safety of these products is assured; and, accordingly, they have the potential to reduce economic growth, innovation, and competitiveness."⁸ This memo initiated a regulatory modernization process which, while incomplete to date, has signaled great optimism to the market and holds significant potential for improving access to genetic innovation in agriculture and supporting a vigorous seed market.

Right-Sizing Regulation to Increase Competition

The advent of gene editing holds enormous potential to democratize access to genetic innovation in agriculture and promote a robust seed development market, possibly even more than traditional recombinant biotechnology. In particular, the ability of CRISPR systems and other gene editing platforms to quickly make precise edits to a plant or other organism's genome in a way that can replicate genetic outcomes that occur naturally or through conventional breeding has cut years off the breeding process and greatly driven down costs for research. There are other advantages as well, such as greatly reducing risks of linkage drag that has for centuries plagued plant breeding, ensuring new varieties can be optimized to meet the needs of growers, consumers, and the environment.

However, the opportunities possible with agricultural applications of gene editing were not and are still not a given. As discussed, shackling these nascent technologies with legacy regulations that are neither science-based nor risk-proportionate will not only suppress a new generation of much-needed agricultural innovation, but prospects for promoting trait development and plant breeding as well.

With that in mind, we applaud steps USDA has taken to date to adopt science-based, risk-proportionate, pro-innovation regulation for certain varieties developed using these new tools. The principle that plants containing edits that could have occurred naturally or through conventional breeding pose no greater risk than conventional varieties and therefore should be exempted from regulation is a scientifically-sound concept. This foundational principle in USDA's May 2020 SECURE Rule is supported by a long history of

⁶ AgbioInvestor. April 2022. *The cost and time involved in the discovery, development and authorisation of a new plant biotechnology derived trait*. <https://croplife.org/wp-content/uploads/2022/05/AgbioInvestor-Trait-RD-Branded-Report-Final-20220512.pdf>

⁷ Ibid.

⁸ 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

safe use and has already spurred great investment into research and development of new traits and plant varieties. While we appreciate these efforts, we remain concerned some unnecessary regulatory barriers have been maintained for gene editing of polyploid crops including wheat, canola, potatoes, cotton, and peanuts. We urge USDA to expeditiously implement exemptions supporting work with these crops such as for changes resulting from cellular repair of multiple DNA breaks occurring at similar locations on two or more homeologous chromosomes.

All things considered, however, one need not look far to see how USDA's leadership on this matter, which has inspired similar actions from many of our trade partners, has both reduced regulatory market barriers and encouraged a significant number of start-ups and inflows of venture capital into trait development and seed markets.^{9,10,11,12,13} The trait development and seed industries are currently like a promising crop approaching harvest. We are hopeful that over the next several years recent regulatory modernization efforts of USDA and other regulators, with some additional improvements, will yield a bountiful market in the trait development and plant breeding industries.

Additional Action Necessary

As previously noted though, the work is not yet complete. There remain several risks which could prevent these promising technologies from realizing their full production, market, and environmental potential. In recent years, USDA has postured itself as a leader to advance access to these tools within the Department, with coregulators, and internationally. We urge USDA to pursue additional actions which are likely to have a greater impact for promoting competition in the seed industry, perhaps even more than any other opportunity available to the Department.

Implementation of the SECURE Rule

In its promulgation of the SECURE Rule, USDA exempted three types of genetic edits that are known to occur naturally or through conventional breeding. We appreciate these scientifically-sound exemptions, however we believe there are additional types of edits that can and do occur naturally and through breeding that USDA should consider exempting. For example, there are a host of polyploid crops referenced above that do not benefit from the SECURE rule as currently drafted. Maintaining the science-based approach USDA has advanced necessitates inclusion of further exemptions that address edits to multiple homeologous chromosomes as are evident in polyploid crops. By expanding the list of scientifically-justifiable exemptions, the Department could offer more tools to developers and breeders that would enable a greater array of new possible crop varieties.

⁹ Burwood-Taylor, Louisa. August 9, 2018. "Flagship's latest venture Inari raises \$40m Series B to 'transform plant breeding'." *AFN*. <https://agfundernews.com/flagships-latest-venture-inari-raises-40m-series-b-to-transform-plant-breeding>

¹⁰ Burwood-Taylor, Louisa. March 28, 2017. "Benson Hill Biosystems Raises \$25m Series B, Reveals CRISPR 2.0." *AFN*. <https://www.iselectfund.com/benson-agfundernews/>

¹¹ Doering, Christopher. February 4, 2021. "Pairwise raises \$90M to develop new fruit and vegetable varieties using CRISPR." *Food Dive*. <https://www.fooddive.com/news/pairwise-raises-90m-to-develop-new-fruit-and-vegetable-varieties-using-crispr/594467/>

¹² Marston, Jennifer. December 16, 2021. "Phytoform bags \$5.7m to boost crop resilience through genome edits." *AFN*. <https://agfundernews.com/phytoform-bags-5-7m-to-boost-crop-resilience-through-genome-edits>

¹³ Ellis, Jack. June 3, 2020. "Tropic Biosciences banks \$28.5m in Temasek-led Series B for gene-editing, RNAi approach." *AFN*. <https://agfundernews.com/uks-tropic-biosciences-banks-28-5m-in-temasek-led-series-b-for-novel-gene-editing-rnai-approach>

Urge Action from Coregulators

Under the *Coordinated Framework for Regulation of Biotechnology*, USDA is only one of three coregulators of genetic innovation in the U.S. federal government. Both the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) have important roles to play related to food and feed safety and the regulation of plant incorporated protectants (PIP), respectively. While FDA has made promising, pro-innovation statements about agricultural gene editing applications, it has yet to issue guidance regarding its approach to these tools. EPA has published a draft rule exempting certain PIPs that could occur naturally or through breeding from certain regulations under FIFRA but has yet to finalize its rulemaking.

Regulatory clarity from these coregulators would not only strengthen confidence in the market and further drive investment in innovative start-ups, but it will also allow the U.S. federal government to engage in a cohesive manner with trade partners to advance a coordinated regulatory approach to gene editing internationally. We urge USDA to engage with these coregulators to advance these much-needed regulatory actions. Importantly though, USDA should strive to coordinate these additional regulatory actions with the pro-innovation approaches taken by the Department to minimize burdens on market participants.

Engaging with Trade Partners

We appreciate and applaud the efforts USDA has taken to hold our trade partners accountable to transparent, science-based regulation for products of biotechnology. The work of Secretary Vilsack and the Department to prioritize the normalization of the biotech approval processes in Mexico has been extremely valuable.

Much work remains to be done in driving more appropriate regulation for biotechnology abroad though. We urge USDA to continue to prioritize improving biotech approval processes with key markets, such as China, Europe, and Mexico. Moreover, we also strongly encourage USDA to drive our trade partners to adopt consistent, pro-innovation policies for agricultural gene editing that will facilitate U.S. exports. Creating export opportunities for new gene edited crop varieties will further promote healthy, vibrant trait development and plant breeding industries.

Conclusion

A strong seed market is one that will continue to meet grower, consumer, and environmental needs through improved traits, varieties, and germplasm. For more than 25 years, recombinant biotechnology has been successful in meeting many of these needs, though we believe genetic innovation holds far greater potential. Unfortunately, the significant costs of regulation have historically limited the use of biotechnology in trait and seed development. We think we can do better, and we believe we are on the cusp of something better.

The introduction of gene editing in the breeding and seed development industries has sparked excitement for greater opportunities far beyond the decades of success that legacy recombinant technologies have provided. These new technologies and others have significantly reduced the costs and time needed for discovery and development, but we need regulation to follow suit. Thankfully, USDA and other regulators to date have signaled applications of these technologies will be treated in a scientific,

risk-proportionate manner, which has opened the doors for great investment and start-ups in the industry.

Further action is needed to cement these promising developments. Renewed efforts from USDA to further implement its own rulemakings, drive pro-innovation policies from coregulators, and press for an international regulatory framework conducive for trade and swift, science-based regulatory decisions will spur further innovation and development unlike any other action the Department can take. We hope to partner with USDA to advance these efforts to ensure a healthy supply of innovative solutions will be available to meet the needs of farmers, consumers, and our environment for decades to come.

Sincerely,

Agricultural Retailers Association
American Farm Bureau Federation
American Seed Trade Association
American Soybean Association
American Sugarbeet Growers Association
Biotechnology Innovation Organization
Crop Science Society of America
International Fresh Produce Association
National Association of Wheat Growers
National Corn Growers Association
National Cotton Council
National Council of Farmer Cooperatives
National Sorghum Producers
U.S. Canola Association
U.S. Wheat Associates