american seed trade association

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U.S. Department of Agriculture
1400 Independence Ave SW
Washington, D.C. 20250

RE: Docket No. AMS-TM-22-0025
Competition and the Intellectual Property System: Seeds and Other Agricultural

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

Ms. Nian,

The American Seed Trade Association (ASTA) is pleased to provide these comments to the U.S. Department of Agriculture (USDA) Agricultural Marketing Service (AMS) in response to its request for public comment on *Competition and the Intellectual Property System: Seeds and Other Agricultural Inputs.*

Founded in 1883, ASTA is one of the oldest trade organizations in the United States. Its membership consists of nearly 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 membership includes approximately 85% of all private U.S. seed companies operating in the U.S. Ninety-five percent of ASTA's active members are small businesses that report annual sales of less than $15 million. ASTA values and promotes diversity of membership, in terms of company size, products and geographic area served. Quality seed products from ASTA members support farmers of conventional, genetically engineered, and organic crops to produce food and farm commodities in the U.S. and around the world.

ASTA's comments will focus on the following key areas: 1) the U.S. seed industry profile and the seed production process; 2) domestic and international regulatory systems impacting the U.S. seed industry; and 3) importance of intellectual property rights (IPR) to the U.S. seed industry. ASTA believes strongly that fair and open competition benefits farmers, consumers, the agriculture industry, and society at large.

About the U.S. Seed Industry

The U.S. seed industry is highly specialized and diversified with hundreds of varieties per crop species, involving hundreds of regional and independent seed companies doing business across the country, producing seed for all sectors of the industry, including row crops, flowers, vegetables, grasses, forages and turf. The U.S. seed market was valued at $14.51 billion in 2020, representing about 25% of the global seed market.[1] In 2021, U.S. planting seed exports exceeded $1.6 billion to a total of 144 countries. The U.S. seed industry enjoys the global reputation of providing seed with the highest quality assurance standards, the most innovative technologies and broadest genetic resources. It is one of the most dynamic and innovative sectors in the world, developing and commercializing thousands of new products annually.

Given its advanced leadership role in the world when it comes to plant breeding research and development, the U.S. seed industry continuously integrates modern, sophisticated breeding techniques to develop new plant varieties, not only for the U.S. marketplace, but also for an ever-growing number of countries worldwide. The U.S. seed industry is intimately linked to the global seed industry. Numerous foreign seed businesses have established a presence in the U.S., and similarly, U.S. seed companies invest in and establish research, seed production facilities and commercial operations in overseas markets.

The Seed Production Process

The development and production of seeds has high commercial value and is a unique and specialized business. U.S. seed companies produce high quality seeds by employing strict quality management practices, with stringent targets for genetic purity and viable seed quality. This process begins with advanced research and breeding programs, proceeds with production practices ranging from large-scale crops to hand-pollinated varieties, and concludes with conditioning, treatment and testing of seed quality and purity prior to commercial sale. The process from research to final sale may take place in multiple countries, as companies take advantage of each different regions' climate and available workforce. Leveraging multiple growing seasons per year is a common practice for most seed crops, accelerating the rate of both research and seed production activity. As a result, some seed moves between as many as six countries for testing, evaluation and multiplication before it is planted by a farmer.

U.S. seed companies strive to provide variety choice and performance for America's growers, gardeners and landscape managers to ensure the best seed is available for the market. The vast array of choices meets the needs of the wide range of environments, soil types and management practices. Just like other agriculture producers, seed producers shoulder the same pressures of increased costs along the value chain – from inputs, to labor, to transportation, to cost of land. Furthermore, seed companies are often making seed planting and production decisions two growing seasons in advance of seed sales. This creates additional constraints for

[1] *Mordor Intelligence: Global Seeds Market (2021-2026*)

seed companies to respond to last minute changes in demand. Despite these challenges, the U.S. seed industry consistently meets market demands. This has been demonstrated clearly in recent months as the U.S. seed industry continued to meet producer demand for high quality seed at the right place at the right time, despite a global pandemic, supply chain challenges and regional unrest.

Seed companies, down to the local level, make significant investments in the development of local varieties, as well as physical and business infrastructures, that ensure the production and distribution of seed to the farmer. All of these factors play a key role in the long-term viability and competitiveness of the global seed industry.

Another key factor in producing seed for today's farmers is the time and cost of growing, multiplying and distributing improved seed varieties. The process of breeding and commercializing a particular plant variety takes from several years to more than 10 years for some varieties. This requires seed companies to invest in research, in close coordination with customers, for many years in advance to develop new variety breeding strategies, to predict which characteristics will become important to farmers, consumers, and the overall food value chain. It is a constant and recurring process with ongoing selection within a particular species germplasm which is necessary to adjust for changing market demands, environmental fluctuations, and constantly evolving agricultural pests and plant diseases. During the plant breeding process, up to hundreds of thousands of plants are meticulously tested, cross-bred, re-tested, and winnowed down to a handful of plants with the desired characteristics. These plants are then evaluated in different growing environments with different environmental conditions, over many growing seasons, requiring years of investment to develop commercial varieties. The best performers are then multiplied to scale for commercial seed sales.

Companies generally produce specific seed varieties for local and regional markets, depending on specific agronomic issues facing the growers in those areas. This requires companies to analyze numerous varieties in order to determine which are most appropriate for the agronomic make-up of the surrounding soils and climatic conditions. This analysis has been improved through new testing methods and computer analytical tools that enable companies to evaluate varieties at a much earlier stage and determine the best varieties to use in their breeding programs to enhance the seeds for local and regional production. The seed production and multiplication cycle often take place here in the U.S. and in other countries to take advantage of counter seasonal production throughout the year. This enables seed companies to bring seed to market in a more expeditious manner, to deal with pressures from changing climate events, and meet the quality and purity demands of farmers.

While food and commodity prices have recently been on an upward trend, it's worth noting that according to USDA's Economic Research Service (ERS),[2] "seed expenses [for farmers] are expected to remain unchanged" while most other production inputs are continuing to rise.

[2] *2022 Farm Sector Income Forecast, released Feb. 4, 2022*

Similarly, according to a recent study from Purdue University,[3] "of the input prices examined, only seed and wages had a rate of change during the last 12 months that was lower than the rate of change for general inflation." Over the past 10 years, seed prices only increased at an average annual rate of 1.3%.

The relative stability of seed prices contrasts with the tremendous value gained by farmers from planting professionally-produced improved varieties. The value of improved seed over the years has been estimated to have contributed between 50% - 70% of increased on-farm yields over time, with the remaining 30% a result of environment and agronomic management.[4] It is estimated that farmers get a $6 benefit for each $1 invested by private sector in seed research.[5]

A recent example in corn-yields showcases the tangible benefits of seed research investments and planting professionally produced improved varieties. Despite increased weather variability--2019 was one of the wettest farming years on record and 2012 was one of the driest in the Midwest—overall crop yields continue to trend upward over time. According to data from Corteva Agriscience,[6] the almost seven-fold increase in average corn yields achieved in North America since 1920 means we've grown millions of additional bushels of grain without putting a corresponding number of acres into agricultural production. Innovation in plant breeding over the last century has increased corn yields from an average of 25 bushels per acre to 170 bushels per acre.

Further, if the top 20 world corn-producing countries improved their production levels to those found in the U.S. 20 years ago, it would be the equivalent of adding another 100 million acres of farmland. USDA ERS date on commodity costs and returns shows that the yield (in bushels per planted acre) for corn in the U.S. grew from 118 in 2012 to 184 in 2021—a 56% increase; for soybeans, the yield grew from 42 to 54 bushels during the same period—a 29% increase.[7]

Similar genetic improvement was also observed in non-row cops. For example, yields of processing tomatoes have steadily increased, from 35 tons per acre in 2006, to 49.5 tons per acre in 2020.[8] This yield increase is due to a combination of improvements in hybrid processing tomato seed as well as improved production practices.

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[3] *Trends In General Inflation and Farm Input Prices, April 2022*

[4] *The economic, social and environmental value of plant breeding in the EU. HFFA Research, 3/18/2016*

[5] Lence S, Hayes D & Goggi S. 2009, Returns from Private Sector Seed Research. Study by Iowa State University. http://www.beyondtheseed.org/commitment.asp

[6] *www.corteva.com/resources/media-center/corteva-agriscience-says-advanced-plant-breeding-shows-path-to-greater-climate-resilience-and-food-security.html*

[7] https://www.ers.usda.gov/data-products/commodity-costs-and-returns/commodity-costs-and-returns/#Historical%20Costs%20and%20Returns:%20Corn

[8] https://www.nass.usda.gov/Statistics_by_State/California/Publications/Specialty_and_Other_Releases/Tomatoes/2022/PTOMInt_0122.pdf

The Regulatory Systems
Phytosanitary hurdles

The U.S. seed industry must be able to move seeds and genetic material globally to innovate and meet grower demands. The U.S. has one of the world's most extensive phytosanitary systems, supported by scientific literature on seed-borne diseases. Unfortunately, some countries have prohibitive non-science-based phytosanitary import requirements for U.S. seed, which increases the cost and time to move seed, making seed production and multiplication more expensive. Examples of these requirements include testing for pathogens that are not seed-borne or known to occur within the species, region, or country of production.

In other cases, a seed company cannot comply with the host country's phytosanitary import requirements, because there are no seed-testing laboratories and/or field inspection protocols available for certification or because the cost of preparing a science-based risk assessment for all seed-borne pathogens of concern to an importing country is cost prohibitive. USDA should invest in efforts to advance transparent, predictable, and harmonized seed testing methodologies, particularly for new diseases and viruses, between the U.S. and partner countries. This would minimize the costly rejection or destruction of U.S. seed lots due to discrepancies in test results.

In addition, USDA APHIS phytosanitary restrictions, as well as the limited capacity of its plant germplasm quarantine limit the ability of U.S. plant breeders, public and private, from importing novel germplasm to enhance U.S. plant breeding programs. For example, recent updates to the NAPPRA listing restricted importation of wheat seed from countries where it has been previously allowed; and USDA's regulation of all pospiviroids on imported tomato seed delayed farmer access to the latest hybrid seeds.

ASTA and its member companies believe strongly in the USDA APHIS mission of protecting U.S. agriculture and natural resources from risks associated with the movement of plant pests and noxious weeds. We ask that USDA APHIS work collaboratively with the plant breeding community to ensure that phytosanitary restrictions are based on the best available science. Further, we look to collaborate on solutions to safely increase the capacity of the USDA APHIS plant germplasm and post entry quarantine to improve the ability of the plant breeding community's access to exotic germplasm. These challenges impact U.S. seed companies of all sizes and crops because of the global nature of the industry. Seed production is largely dependent on counter-seasonal production and often crosses several borders before reaching its final destination. Larger companies have more employees working directly on international phytosanitary issues, while smaller companies struggle to clearly understand import requirements from certain countries, which increases costs, is very time consuming, and typically results in those companies choosing not to do business in those countries.

Strong and consistently applied regulatory frameworks that are transparent, based on scientific principles, and risk proportionate are critical for the international movement of American seed

products. The U.S. should proactively enforce these long-standing sanitary and phytosanitary principles through free trade agreements and other bilateral and multilateral fora.

Biotechnology

In a 2011 study conducted by Phillips McDougal for CropLife International, the cost of bringing a new biotechnology trait through the research, development, regulatory and commercialization process was estimated at $136 million.[9] A recent study reported that this cost has decreased to $115 million in the last five years.[10] It is important to recognize that these estimates do not account for the large investments of seed industry research into biotechnology traits that either were not accepted into certain markets after regulatory investment, or simply did not result in commercial varieties due to the biotechnology trait not being fully efficacious.

The recent study also examined the costs and timelines for bringing a biotechnology trait to market in 2008-2012 as compared to 2017-2022. While the cost of research and development has decreased by $29.1 million, the cost and time of regulatory compliance has significantly increased. Regulatory expenses increased from $35.1 million in 2008-2012, to $43.2 million in 2017-2022. Furthermore, the study showed an increase in the amount of time spent in the regulatory approval process, from 86 non-consecutive months for each trait in 2008-2012, to 204.5 non-consecutive months in 2017-2022.[3]

While other costs of research and development may vary between companies and plant species, the cost and time of regulation is applied equally regardless of the size of the company, the plant species, commercial market potential, or even the safety risk assessment of the gene target(s). The history of safe use of the crop species and the gene families being utilized are often not taken into account by global regulatory agencies. Since 1986, more than 180 genetically engineered plants have been approved under the U.S. and international regulatory systems. Not one has been found to cause harm to food or environmental safety. Despite this safety record, the regulatory hurdles and costs in the U.S. and internationally have not diminished. In the current regulatory environment, it is untenable for small and medium sized entities, public or private, to bring varieties with biotechnology trait improvements to the marketplace, especially for lower acreage crops and perennial plant species.

Plant Breeding Innovation

As plant breeding innovation continues at a rapid pace, seed companies and public plant breeding entities are seeking to leverage the increased understanding of plant genomes and emerging tools, such as genome editing, to improve plant species more effectively and efficiently. Whether these innovations lead to growth of new seed companies, and growth and

[9] Phillips McDougall. 2011. The cost and time involved in the discovery, development and authorization of a new plant biotechnology derived trait: A consultancy study for CropLife International. Midlothian, UK: Phillips McDougal.
[10] https://croplife.org/plant-biotechnology/regulatory-2/cost-of-bringing-a-biotech-crop-to-market/

diversification of types of improved plant varieties commercially available and accessible to U.S. farmers depends in part on modernizing and reforming the policy and regulatory approaches in the U.S. and foreign markets to reduce unjustified barriers to entry.

In this area, USDA has made positive strides in revising 7 CFR part 340 and should continue to implement the final rule consistent with its intent to reduce regulatory burdens. USDA should also work with other U.S. regulatory agencies to adopt consistent policies across the U.S. Government. In addition, the U.S. Government should take a leadership position and actively engage with other governments, particularly among its trading partners, with the goal of working toward internationally consistent, science-based and risk proportionate policies with regards to varieties developed using plant breeding innovation.

ASTA strongly supports science-based and risk-proportionate regulatory approaches which recognize the long and safe track record of plant breeding and biotechnology, foster innovation, and value the environmental and societal benefits that agriculture can achieve using plant breeding innovation. As evident from the experience with plant varieties improved with biotechnology traits, unduly burdensome and costly regulatory policies are barriers to entry for small- and medium- sized entities, especially for those working in specialty crops, fruit trees and vines species.

Intellectual Property Rights

Continuing innovation in the plant breeding and seed sectors requires sustained investment. The public sector, through national and international research systems, invests significantly in plant breeding and development. This public investment is complemented by private sector investment. On average, 15% of ASTA member seed companies' revenue is spent on research and development.

Both public and private sector supported agricultural research benefit from strong intellectual property protection In the U.S. and internationally. The U.S. has a long history and tradition of entrepreneurship founded on successful systems of technology transfer from the public sector to the private sector. Especially true for low acreage crops, public and private partnerships are essential in deploying the strengths of both sectors to bring improved varieties to the marketplace. Strong intellectual property protection will encourage the investment needed to benefit agriculture and society through new products and to maintain the continued increase in crop productivity required to sustainably feed the world.

One of the key drivers of innovation within any industry is the capital that is invested in research and development. R&D investments in plant breeding are generally long-term, require significant amounts of capital resources and involve substantial risks. The level of investment in the seed industry is directly correlated to the effectiveness of the intellectual property protection available in the U.S. and internationally. In order to attract the size and scope of investment necessary to develop and bring to market improved plant products, there must be

an opportunity for investors, plant breeders and product developers to earn competitive returns on their original investments in products such as varieties, hybrids, biotechnology-traited products, or products developed from the use of new breeding tools such as genome editing.

Markets or countries that provide weak intellectual property protection have been shown to attract substantially less investments for the research and development of new plant varieties. In addition, these environments make it more challenging to bring new, innovative seed varieties to growers in those countries.

High-quality germplasm is the foundation of the seed industry, and the improvement of crop germplasm is an essential activity of plant breeding. Robust intellectual property systems provide strong support for efforts to improve germplasm and increase genetic diversity, which are critical for meeting increasing challenges to food security. In recent decades private companies have invested heavily in plant breeding and seed production to develop improved cultivars and hybrids. Additionally, the advent of innovations in plant breeding, such as gene editing, have facilitated the entry of start-up companies into the agricultural arena, and the subsequent development of crops that can be efficiently and precisely improved will contribute even more to agricultural productivity.

There are multiple ways that intellectual property resulting from such investment and risk-taking can be protected by an inventor. We highlight the following: trade secrets, Plant Variety Protection (PVP), and utility patents[11].

- Trade secret protection can be coupled with either licenses or use agreements. Unlike other forms of protection, as long as trade secrets are maintained, the intellectual property never enters the public domain. In the seed business, the trade secret mechanism is generally insufficient protection when companies are distributing the seeds of varieties which can easily be reproduced and mis-acquired. Even hybrid seed with today's technologies can be reverse engineered to make close copies.
- Plant Variety Protection, through the 1991 Convention of the International Union for the Protection of New Varieties of Plants (UPOV) and the U.S. Plant Variety Protection Act, provide exclusive marketing rights for varieties, their harvested material, and, optionally, for products made directly from them. These rights extend for a fixed period of not less than 20 years from the date of the grant of the right. Importantly, PVP also provides exceptions for experimental use by third parties for the purpose of plant breeding and new variety development. An optional exception in the PVP Act permits farmers to save seed for propagation on their own holdings within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder.

[11] Plant patents are available in the US for non-sexually propagated materials. We did not highlight plant patents since the RFI is focused on seed.

- Utility patents, which are granted for a term of 20 years from application, provide a broad and strong form of protection that in many ways is preferential to license or technology use agreements. As a result, utility patents generally encourage investments in all facets of plant breeding, including germplasm, specific traits or genes and technologies more than any other form of intellectual property available to breeders and investors. Plant varieties are only eligible for utility patent protection in the U.S., Japan and Australia. In some countries, such as Mexico, utility patents are available, but patent examination has not been implemented for plant varieties.

IP protection through the U.S. system of patents and PVP certificates rewards risk-taking and investment with a limited period of exclusivity, after which the claimed intention moves to the public domain. This is no different than intellectual property protection in other sectors, and is easily and affordably leveraged by both the private and public sectors of the plant breeding community.

In almost all cases, the patent application is made by the organization when it determines the plant variety and or biotechnology trait has positive marketing capabilities. The seed varieties are then taken through the final research and evaluation stages, and then move to multiplication for commercial sale. This part of the process can often take 2 – 5 years, depending on plant species, therefore, seed in the commercial market are well into their patent protection term. In the case of plant varieties improved with biotechnology traits, the mean duration from discovery to commercial launch is 16.5 years. This does not include the time required to develop and obtain regulatory approval for stacked trait varieties, which are typically the final product in most crops. Therefore, by the time a plant variety with a biotechnology trait is introduced into commerce, a significant part of the patent life has passed.

Under the U.S. IP systems, applicants need to provide seed in order to obtain protection. The seed, which is deposited to satisfy both the patent and PVP IP system requirements, becomes available without additional restrictions after the protection period ends. The usefulness of germplasm after IP expiration, as well as biotechnology traits whose patents have expired create opportunities for seed businesses to provide additional planting choices for farmers. For seeds, in particular those improved with biotechnology traits, it is important to ensure that the U.S. regulatory framework, as well as regulatory policies of major trading partners, encourage and incentivize post-IP use scenarios. The AgAccord was established by the U.S. seed industry in 2014 to facilitate the smooth transition to post-patent biotechnology traits in commercial markets.[12] The AgAccord established mechanisms to ensure compliance with global regulatory commitments for post-patent products that may be developed in the U.S.

[12] http://www.agaccord.org/

Strong IP policies promoting continued developments in innovation have been critical to advancing research into improved seed to support on-farm resilience and climate mitigation in recent years. The level of investment in cutting-edge breeding tools like gene editing is directly related to the effectiveness of the intellectual property protection available. In order to attract the size and scope of investment necessary to develop improved products, either varietal, hybrid, or from the use of new innovative breeding methods, seed companies and investors must have the opportunity to earn competitive returns on their original investment. Markets or countries that provide weak protection are unlikely to attract substantial investments for research and development and are most likely not going to receive the newest innovations from those investments in a timely fashion.

Conclusion

As evidenced by ASTA's own membership profile, there are hundreds of seed suppliers that currently operate in the U.S., including those with local, regional, national, and international footprints. ASTA members are committed to investing in plant breeding, seed development and production to bring to market improved seed year upon year. ASTA's members need the U.S. government's support in building a pro-innovation environment for investment, innovation and growth.

It is vitally important that the U.S. government advances science-based regulatory approaches that are risk proportionate and predictable at both the domestic and international levels. In addition, the U.S. must continue to advocate for strong, enforceable IPR, domestically and internationally, to encourage continued risk-taking and investment by U.S. companies and entrepreneurs. These effects must be coupled with strong public sector research investments in the plant sciences. Promotion of strong intellectual property protection is critical from the smallest of start-up companies to the largest multi-national companies. If their research and development investment cannot be realized through strong protection mechanisms, progress in development of improved seed products that provide reliable food, feed, fuel, and fiber production in ever changing growing environments will be greatly diminished.

U.S. agriculture has been successful thanks to a long-standing public and private commitment to science and research that brings new discoveries to farmers and consumers. The seed industry plays an active role in this partnership. We look forward to continuing to work to accelerate innovation in the years ahead, as the seed industry strives towards a more sustainable and secure future for food and agriculture.

Sincerely,

A. W. LaVigne

Andrew W. LaVigne
President & CEO