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Joint Hearing of the U.S. House of Representatives Subcommittees on:
Biotechnology, Horticulture, and Research; and
Subcommittee on Livestock and Foreign Agriculture

AGRICULTURAL BIOTECHNOLOGY: 21ST CENTURY ADVANCEMENTS AND APPLICATIONS
October 26, 2021

Good morning, Chairwoman Plaskett, Chairman Costa, Ranking Member Baird, Ranking Member Johnson, and members of the Subcommittees. I am Fan-Li Chou, Vice President of Scientific Affairs and Policy at the American Seed Trade Association (ASTA). Prior to joining ASTA, I served for over a decade at USDA, including as the Agricultural Biotechnology Advisor to the Office of the Secretary and in positions with the Foreign Agricultural Service and the Animal and Plant Health Inspection Service. I am pleased to be here today to discuss *Agricultural Biotechnology: 21st Century Advancements and Applications.*

Founded in 1883, the ASTA represents nearly 700 member companies involved in seed production and distribution, plant breeding, seed treatment and related industries in North America. The U.S. seed industry is highly specialized and diversified with hundreds of varieties per crop species. ASTA's member companies produce everything from grass and turf seed to row crop seed, to vegetable, ornamental and flower seed, to true potato seed – for conventional, genetically engineered, and organic seed markets.

My remarks today will focus on plant breeding's impact to each of us, to our economy and to our environment. The importance of plant breeding innovations, including agricultural biotechnology such as genome editing; and actions needed to fully realize the real-world benefits of plant breeding innovation.

Plant breeding is not new, it dates back thousands of years to when people first domesticated wild plant varieties. Over time, plant breeders have accumulated an impressive collection of tools, such as cross breeding, selection, hybridization, induced mutagenesis, biotechnology and molecular markers to unlock the genetic potential of plant crops. Using these breeding tools, the plant breeding community, both the public and private sides, have safely and reliably introduced to the food system hundreds of thousands of new plant varieties over the past century. To be commercially released, new plant varieties, regardless of the breeding tools used, are subjected to strict, multiyear, multi-location evaluation and assessment for quality and performance.

We have all benefited from, and continue to benefit from, the innovations of plant breeding. The food we eat, the clothes we wear, the fuel that powers our cars—all these things and more start with a seed in the ground. New plant varieties have enriched our lives, by increasing our food choices, for example seedless grapes, easy-peel citrus, tastier tomatoes of all sizes and shapes, and snackable peppers; by beautifying our landscapes with ornamental varieties adapted to all seasons and geographies.

New varieties developed from plant breeding allow our farmers to produce more using fewer inputs. According to USDA Economic Research Service's report on Agricultural Productivity in the U.S., since 1948, domestic agriculture productivity nearly tripled. While some of the gains can be attributed to better management practices, some experts estimate that improved varieties account for more than a 50 percent productivity gain. This is because new varieties are bred to be more productive, more disease and pest resistant, and better adapted to environmental stresses such as drought and excess water.

Our economy has benefited and continues to benefit from plant breeding. The U.S. seed market was valued at $14.51 billion in 2020, which is about 25% of the global seed market. In 2020, U.S. planting seed exports exceeded $1.6 billion to 144 countries. Our industry enjoys the global reputation of providing seed with the highest quality assurance standards and the most innovative technologies and genetic resources.

In the 21st century, we are facing the convergence of critical challenges to the agricultural food system: climate change, rapidly growing global population, expansion of the global middle class, environmental degradation, and biodiversity loss. The need for improved plant varieties is more pressing than ever. Thankfully, plant breeders have an unprecedented number of tools to work with. The most exciting of late is gene editing.

In agriculture, gene editing is an enabling tool, supporting, rather than supplanting, the fundamentals of plant breeding. Gene editing enables plant breeders to leverage the decades of accumulated scientific discovery and understanding of plant genetics, its natural variability, and its interaction with the environment, to increase the accuracy, precision, and efficiency of plant breeding. One of the most exciting developments around gene editing and agriculture is that we see it being used across all crops, including specialty crops, and by breeding programs of all sizes, including the public and private sectors. Plant breeders are using gene editing to create genetic variability within the plant's own genetic family, similar to what could be achieved with conventional breeding or could occur in nature.

Let me share a few examples of how gene editing could be used in plant breeding to help drive solutions to the growing pressures of climate change, food and nutritional security, and sustainability.

Bruised and browning produce are a top contributor to food waste in restaurants and grocery stores. Research shows shoppers avoid purchasing bruised produce, even if the vegetables are perfectly healthy and taste fine. And in restaurants, produce prepped before the dinner rush

often need to be thrown out at the end of the night because of their brown color. Using innovations like gene editing, plant breeders are unlocking the code to make potatoes more resistant to bruising and browning. The new non-browning characteristic could eliminate 1.5 billion pounds of wasted potatoes, translating to resources saved. The same application is being applied to other produce, from mushrooms to apples and avocadoes.

With 70% of the world's freshwater used for agriculture, reducing the amount of water needed to grow food could have a significant environmental impact. Plant breeders are using gene editing to develop new, water-efficient varieties of crops. For example, lettuce struggles in the heat. But promising research is showing that gene editing can be used to develop lettuce varieties that have the same heat tolerance as certain wild relatives, with the same taste and nutritional value as the lettuce we enjoy today. Drought tolerant varieties are also under development for wheat and rice.

Gene edited is being employed to develop plant varieties that can better support carbon capture. Gene edited crops with stronger, deeper roots can capture carbon and sequester it in the soil for longer periods of time. Gene editing and plant breeding will also expand farmer choices in cover crops, as well as developing cover crops as a source of income for farmers. With funding from the USDA National Institute for Food and Agriculture, a consortium of university researchers from Illinois, Minnesota, Ohio, and Wisconsin, as well as start-up company CoverCress, have used gene editing to develop a cover crop, pennycress, with edible oil and meal, bringing environmental, as well as economic, benefits to the farmers.

Gene edited plants can support healthy eating. Calyxt, company that was founded by a University of Minnesota professor, commercialized a variety of soybean that has been gene edited so that its oil is heart healthy, with a similar composition to olive oil. The same company is working on wheat varieties with higher protein and fiber, and less gluten. Pairwise, a startup food and tech company that uses gene editing to develop new varieties of fruits and vegetables, is part of a collaboration with USDA ARS and others to identify and characterize~~d~~ genetic diversity in berries. The outputs from this collaboration will be used to bring new and better berries to producers, and to make berries more consistent and more available to consumers.

The 21st century is an exciting time for plant breeding and for plant breeders and plant scientists. We are faced with unprecedented challenges, yet we are equipped with extraordinary tools and scientific understanding to find solutions. A continued and robust investment in public sector agriculture research is needed. The work of the public and private sectors complements each other. The public sector's role is critical in fundamental research, germplasm collection and maintenance, addressing emerging plant diseases and pests, and training of our future breeders and scientists. The strength of the seed industry is taking a promising concept to market, to shoulder the expensive and time-consuming process of delivering high performing plant products to farmers around the world.

In addition to these groundbreaking examples of public-private partnerships in gene editing, a long-standing example of public-private sector collaboration is the Germplasm Enhancement of Maize project, or GEM. GEM is a cooperative effort of the USDA ARS, land-grant universities, and the seed industry. Similarly, on the specialty crop side, the close collaboration between seed companies and University of California Davis (UC Davis), has resulted in identifying key pre-commercial research priorities. Seed Central at UC Davis provides a networking forum that facilitates the public-private collaborations often needed to shift these pre-commercial research priorities to commercial applications.

As I previously mentioned, plant breeding innovation, like gene editing, is currently being researched and used across a vast array of plants, including fruits, vegetable, and ornamentals, what we consider specialty or small acreage crops. Whether these crops—and the tremendous benefits they can provide--will become widely available will depend in part on research investment and more notably on the policy and regulatory approach.

Numerous administrations, across more than three decades, have consistently agreed on the foundational principles and policies for effective and efficient regulatory oversight. These principles were articulated in the 1993 Executive Order (EO) *Regulatory Planning and Review* and reiterated in the 2011 EO *Improving Regulation and Regulatory Review.*[1],[2] Specifically, for emerging technologies such as agricultural biotechnology, the foundational principles of effective and efficient regulatory oversight were reaffirmed in the 2011 Memorandum *Principles for Regulation and Oversight of Emerging Technologies*, the 2015 Memorandum *Modernizing the Regulatory System for Biotechnology Products*, and the 2019 EO *Modernizing the Regulatory Framework for Agricultural Biotechnology Products.*[3],***[4],[5]***

In advancing innovation in agriculture, the stated policy goals are that regulatory oversight must "ensure the fulfillment of legitimate objectives of protection of safety, health, and the environment" and "avoid unjustifiably inhibiting innovation, stigmatizing new technologies, or creating trade barriers".[3] Regulatory agencies are to, among other things:

- Identify and consider all regulatory alternatives, including the alternative of not regulating.
- Regulate only when there is a significant problem that is best solved by regulation, and where the benefits of regulation justify the costs.

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[1] https://www.archives.gov/files/federal-register/executive-orders/pdf/12866.pdf

[2] https://obamawhitehouse.archives.gov/the-press-office/2011/01/18/executive-order-13563-improving-regulation-and-regulatory-review

[3] https://obamawhitehouse.archives.gov/sites/default/files/omb/inforeg/for-agencies/Principles-for-Regulation-and-Oversight-of-Emerging-Technologies-new.pdf

[4]https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/modernizing_the_reg_system_for_biotech_products_memo_final.pdf

[5] https://www.whitehouse.gov/presidential-actions/executive-order-modernizing-regulatory-framework-agricultural-biotechnology-products/

- If regulation is warranted, it should be commensurate with the risk, and "avoid arbitrary or unjustifiable distinction across like products developed through different technology".
- 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 continue to meet the regulatory objectives in the least burdensome way.
- Use clear language and provide opportunity for stakeholder and public involvement.
- Promote interagency coordination and harmonization; avoid interagency duplication and inconsistency.
- Promote international coordination to minimize trade impacts.

With regards to products of plant breeding innovation such as gene editing, I also note the commitments for agencies to provide regulatory clarity in the 2016 *National Strategy for Modernizing the Regulatory System for Biotechnology Products* and the 2019 EO *Modernizing the Regulatory Framework for Agricultural Biotechnology Products*.[1,2]

ASTA commends the regulatory improvements USDA made in the Final Rule for biotechnology regulation, published in May 2020. The Final Rule reflects the over 30 years of regulatory experience accumulated by USDA, recognizes the longstanding safety record associated with plant breeding, and exempts types of plants that could be developed through conventional breeding or occur in nature. As USDA proceeds in implementing the various elements in the Final Rule, we believe it is imperative for the plant breeding community to be consulted to assure a smooth transition to the new processes and to mitigate against unintended barriers to smaller organizations and public sector institutions involved with the development of new crop varieties, especially specialty crops.

ASTA appreciates the proposed rule published by the Environmental Protection Agency in December 2020, proposing exemptions of certain plant-incorporated protectants derived from newer technologies that are like those developed through conventional breeding. We look forward to Administrator Regan's leadership in shepherding the proposed rule revision to finalization and implementation.

We eagerly await clarifying guidance on food derived from plant breeding innovation such as gene editing by the Food and Drug Administration. It is critical that these three agencies are consistent and coordinated in their policy approaches.

[1] https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/biotech_national_strategy_final.pdf
[2] https://www.federalregister.gov/documents/2019/06/14/2019-12802/modernizing-the-regulatory-framework-for-agricultural-biotechnology-products

One of the exciting things about gene-editing tools is the potential for widespread access across breeding programs of all sizes, including the public and private sectors, across all crops, and across farming operations of all sizes, production methods, and geographies. Federal and global policies will play a huge role in access to these products. It is important that policies be clear, and risk- and science based; it's also important that there is harmonization across global policies -- otherwise, innovation will be limited to very few crop varieties, and the benefits will never be fully realized across the agriculture sector. Appropriate policies can incentivize investments in plant breeding innovation, such as gene editing, creating new jobs and market opportunities, and boosting sustainability throughout the agriculture and food value chain.

In conclusion, the 21st century food and agriculture system faces unprecedented challenges, from climate change to a growing population, and rapidly evolving pests and diseases. In order to maintain the U.S.' position as an economic world-leader in innovation, and to enable long-term economic, social and environmental sustainability, we must make strong investments in plant-breeding research and ensure the alignment of science-based policies, at the domestic and global levels. Thank you for the opportunity to testify before you today. I'll be happy to take your questions.