Testimony of Dr. Wayne Parrott
Professor of Plant Breeding Genetics & Genomics
University of Georgia

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Agriculture Innovation and the Federal Biotechnology Regulatory Framework
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Good morning, Chairman Roberts, Ranking Member Stabenow and members of the Committee. I am Wayne Parrott, a professor of Plant Breeding Genetics & Genomics at the University of Georgia. I'm pleased to be here today to talk about innovations in precision plant breeding. This is an exciting time to be a plant breeder, probably the most exciting time in my 30-year career. The reason is because we have an unprecedented number of tools to work with, which are enabled by our understanding of plants and how they work. Such an understanding has improved dramatically from what it was when the original Coordinated Framework for the Regulation of Biotechnology was drafted over thirty years ago. Thanks to technology, we have better tools like gene editing that build on what nature, farmers, and now breeders, have been doing for hundreds and thousands of years to enhance and improve the food we eat. Today, we can fully utilize our deeper understanding of plants to better target these improvements, allowing us to respond more efficiently to new and emerging challenges.

Why is the topic of innovation in breeding so important? Agriculture has always faced and will always face new and emerging threats from pests, diseases, and adverse growing conditions. So, agriculture must constantly adapt to continue to succeed in the future. For example, farmers face unprecedented fluctuations in drought and moisture conditions from a changing climate, as well as rapidly evolving pests and diseases. At the same time, crops must be profitable for farmers, and they must meet public expectations for sustainability while providing a larger variety of wholesome and affordable food options for consumers. This requires a collaborative effort along the agriculture and food value chain – from lab, to field, to market. In order to meet all of these demands, we need to have access to all of the tools available to develop plants that can thrive and meet societal needs.

Solving problems is what plant breeders have always done, and we have achieved significant success. Looking at USDA Economic Research Service data, U.S. output has increased 2.5 times since 1948 while crop inputs have stayed flat.[1] Improved plant varieties are the major factor behind this success. Now, plant breeders have an opportunity to address problems more quickly and precisely, just at a time when rapid advancement is needed. Innovative new precision breeding methods, many developed at land-grant universities, allow breeders to make very specific changes to a plant, resulting in an end-product

[1] USDA-ARS. 2020. Agricultural Productivity in the U.S. Summary of Recent Findings. https://www.ers.usda.gov/data-products/agricultural-productivity-in-the-us/summary-of-recent-findings/

that is often indistinguishable from a plant bred through more traditional breeding methods and done with greater efficiency—taking months instead of years.

Pre-commercial research is well underway. These include tomatoes adapted for growing in vertical farms, opening new farming opportunities in urban areas. Other crops are showing improved yields in field trials. Importantly, crops are being adapted to grow over wider areas and climates. As an example, there is a wild variety of lettuce that is capable of germinating at high temperatures in the Central Valley of California. Using new precision breeding methods, researchers have developed a lettuce variety that has the same heat tolerance as its wild relative, but with the same taste and nutritional value as the salad lettuce we enjoy today. With my colleagues at the University of Georgia, we are working on switchgrass that produces twice as much and is easier to convert to biofuels.

Plant breeding can help ensure that agriculture is a driving force in a flourishing bioeconomy. Not only can plant breeding help plants defend themselves from threats, it offers real solutions to global challenges, like building a more sustainable agriculture in the face of growing population pressure. We also envision that new crop varieties will strengthen the bioeconomy by providing a major source of raw materials for the manufacturing, bioenergy, and pharmaceutical industries.

Disease resistance is another area of promise for new breeding tools. By making the plant itself more resistant to disease, we can cut down on the use of pesticides while at the same time reducing pre- and post-harvest losses. Until now, plant breeders addressing disease resistance have mostly been limited to using traditional cross-breeding-- an inefficient method which takes years to produce the desired result, and thus is often not efficient enough to keep pace with new and rapidly evolving diseases.

Biotechnology methods in use for the past 25 years can also achieve the same goal, but these have gone mostly undeployed because the regulatory burdens and costs to use these methods prevent the majority of disease resistance products from being commercially viable. If newer tools face regulation that is disproportionate to risk, not scientifically based, and without any safety benefit, an opportunity to develop plants with resistance to major types of plant diseases, including viruses, bacteria, and fungi, will be lost.

Plant breeding has a tremendous safety record with hundreds of thousands of new plant varieties introduced over the past century, including major commodity crops developed using biotechnology. Now that we are in the era of genome sequencing, we know that it is completely natural for even two seemingly similar varieties of plants to have very different genetic make-ups. Importantly, the existence of differences at the genomic level is not an indicator of a risk. Plant breeders have well-established screening and quality management processes to evaluate newly developed varieties, regardless of the plant breeding method. All crop breeding programs assess thousands of plants in multiple locations and eliminate the vast majority because they do not meet rigid performance standards.

In order for public sector scientists to use evolving innovations now and in the future, the U.S. government needs rational and clear policies that allow developers to bring safe products to market. The benefits to growers and consumers from new breeding tools like gene editing cannot be disputed. But in order for these tools to be used, the surrounding policies must be risk proportionate. The original

Coordinated Framework written in 1986 as well as subsequent reviews and Executive Orders reaffirmed the need for regulatory policy that promotes innovation while protecting health and the environment. The *2019 Executive Order on Modernizing the Regulatory Framework for Agricultural Biotechnology Products* reiterated long-standing government policy that regulations should be flexible enough to accommodate new scientific evidence and meet regulatory objectives in the least burdensome way. In the intervening 30 years since the Coordinated Framework was operationalized, significant experience and familiarity with new plant/trait combinations has accrued. Scientists and regulators can predict more precisely which products require more or less stringent oversight, and which ones could be exempted from review altogether whenever they lack identifiable hazards from the use of biotechnology in their development.

For plants that could have been produced through more traditional plant breeding methods, a pre-market review is actually not necessary because the plant's characteristics do not go beyond the range and variability of what is found in nature already. The principles imbedded in the Coordinated Framework affirmed that similar products should be treated the same by regulatory agencies and that new products should meet the same safety standards and criteria as existing products. Any new regulations under the Coordinated Framework should focus only on those plants that present a new potential risk, when compared to similar plant/trait combinations that have a history of safe use and consumption.

The 2019 Executive Order also instructed USDA, the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) to take steps to have consistency and coordination among the three agencies and to streamline regulations. This work has yet to be completed, and it is unclear how much coordination has taken place amongst these three agencies since the Executive Order was published. USDA is nearing completion of a final rule updating its biotechnology regulations, including those for gene-edited plants. EPA has submitted a proposed rule to the White House Office of Management and Budget to update its regulations for Plant Incorporated Protectants to address new technologies, but we do not know its content. FDA published a *Plant and Animal Biotechnology Action Plan* in January 2019 in which it committed to publish guidance for industry in early 2019 on how their regulations apply to new plant varieties that use innovative breeding methods. This guidance has yet to be published.

While other countries are quickly moving forward to develop policies for plants developed using new breeding methods—and many have even sought input from the U.S.—at the moment, the United States has no coherent policy. Without a clear, consistent policy from USDA, EPA and FDA, the United States is unable to provide global leadership and it puts us at a global disadvantage. While it is fortunate that a number of countries including, Brazil, Argentina, Israel, Australia and Japan have put policies in place that are favorable for the use of gene editing in plants, U.S. developers and farmers will very soon start to lose their ability to compete as these products are brought to market by other countries.

As a public sector scientist, I am excited that these innovative new breeding tools have the potential to be readily employed by university as well as private plant breeding programs for the benefit of our consumers and farmers alike. The tools are very accessible to the science community, they can be used

across a broad range of crops, and result in more predictable outcomes than older breeding methods. However, the three federal agencies must have a coordinated approach that allows the benefits of current, and future, innovations to be fully realized. With a scientifically based regulatory environment, there is no doubt in my mind that American agriculture will meet all the challenges that the current century will bring forward.