

# Frequently Asked Questions

#### WHAT DO PLANT BREEDERS DO?

Plant breeders have been working to improve plant varieties for several thousand years—long before breeding existed as a formal breeders refer to as genetic diversity) and exploited this variability by saving and planting seed from plants that exhibited more seeds, shorter plants, sweeter fruits and other characteristics that improved quality and quantity. In fact, most, if not all, modern food crops including wheat, maize, carrot and tomato bear little resemblance to their wild progenitors. Plant breeders improve the quality and performance of existing field resistance or drought tolerance, or to improve consumer The continued development of new varieties is vital to consumers and the agricultural industry as there are constant challenges to meet market requirements, consumer demands, resistance to evolving diseases and pests, and to increase the productivity and durability of existing commodity crops. Most professional plant breeding today is done by private entities and public institutions.

## HOW HAS PLANT BREEDING CHANGED?

While the goals of plant breeders have not changed, the tools and information at their disposal have significantly evolved. Historically, plant breeders focused solely on "phenotype" the observable characteristics of the plant—and how to improve on the phenotype, such as increasing yield or creating disease resistance. Since breeders were looking to improve observable characteristics, their most valuable tools to select improved plants were their sense of sight, taste and smell. Today, with an increased understanding of genetics, the capability to sequence plant genomes and the ability to link a specific gene(s) to a specific characteristic, plant breeders are able to improve a plant's phenotype more precisely and, as well by efficiently focusing on the underlying genetics. Using genetic markers, breeders can now identify and bring together defined pieces of genetic material that are responsible for the desired characteristic(s), instead of combining the whole genomes of two plants, which transfers both wanted and unwanted genes. Breeders can also make very specific changes in existing plant genes in a way that mimics the changes that occur in nature.



#### WHAT ARE NEWER BREEDING METHODS?

Newer breeding methods (sometimes referred to as new breeding techniques) comprise a collection of tools and methods that allow plant breeders to change a specific plant gene (to induce genetic variability), to silence (turn down or stop) expression of a specific plant gene or to introduce a specific gene from a wild relative or older variety into a modern, commercial plant variety. An underlying common denominator for these techniques is that they more rapidly and precisely achieve the same result that could be achieved through more traditional plant breeding methodologies. In other words, breeders are utilizing the plant's (or its wild relative's) own genetic makeup to create genetic variability, leading to improved or characteristics new to the plant, but not necessarily to the plant species. Particularly those techniques sometimes referred to as "gene editing", can result in a plant variety that does not contain any "foreign" DNA from a non-sexually compatible species.



#### WHAT ARE THE BENEFITS OF USING THESE NEWER BREEDING METHODS?

The overriding benefit of using these newer breeding methods to plant breeders, farmers and consumers is time. Timing is particularly important when breeding for resistances to disease or, pests or tolerance to stresses like drought or salinity. For breeders, it is essentially a race against the rapid evolution of diseases and pests or changing climate. Breeding efficiency is also important for those crops that have longer generation times, such as forages, fruits and vines, and for more complicated traits controlled by many genes such as yield.

In addition to these newer methods being efficient and economical, they are also accessible to both public and commercial plant breeders in developed and developing countries and can be used across all agriculturally important crops, including food, feed, fiber and fuel crops.





# DO NEW PLANT VARIETIES NORMALLY GO THROUGH A PRE-MARKET REVIEW AND CLEARANCE PROCESS BY THE GOVERNMENT?

Most new agricultural plant varieties are introduced without a specific pre-market safety review by the government, given the long history of safe use of the underlying varieties used for breeding and the safe application of the methods breeders have historically used to develop these new varieties, which are well understood by researchers and regulators alike. The 1986 Coordinated Framework for the Regulation of Biotechnology acknowledged this by focusing on those plants that presented a potential risk to health or the environment, when compared to similar plant/trait combinations that have a history of safe use and consumption. Newer breeding methods allow breeders to more precisely and rapidly produce the same types of genetic improvements that are achieved through more traditional breeding methods.

#### WHAT ABOUT UNINTENDED CHARACTERISTICS?

The possibility of unintended characteristics due to genetic changes is not new to plant breeders as evidenced by the process that lines under development go through before new varieties are selected (see question above). Plant genomes are not static; each individual has a unique genetic makeup. Spontaneous genetic variation occurs continuously at specific rates—something plant breeders have historically used to identify new, desirable characteristics as a result of this spontaneously occurring variation. Indeed, the genetic diversity that allowed domestication of crop plants and further varietal improvement ultimately depends upon an available range of diversity from past, present and future mutations. Breeders have also historically induced genetic variation using various methods such as mutagenesis and tissue culture, again screening for the desired characteristic and eliminating those lines with undesirable characteristics. Newer, more precise methods of inducing or introducing genetic variation can reduce the possibility of unintended characteristics. Where such characteristics do occur, they will be identified through the intensive assessment of the new plants in multiple performance trials, where individual plants exhibiting undesirable traits are eliminated.



"Regardless of the particular combination of techniques used, the development of a new plant variety typically will require many site-years (number of sites x number of years of plant testing) of performance trials before introduction into agricultural practice. These range from as few as 10 to 20 site-years for some plants to 75 to 100 site-years for others (some 5 to 10 years). The time of evaluation and the size and number of sites will vary as necessary to confirm performance; to reveal vulnerabilities to pests, diseases, or other production hazards; to evaluate stability of the phenotype; to evaluate characteristics of the food; to evaluate environmental effects; and to produce the required amount of seed before the new plant variety can be grown commercially by farmers. In the course of this intensive assessment, individual plants exhibiting undesirable traits are eliminated."

—FDA 1992 Policy Statement

## WHAT DO PLANT BREEDERS DO TO MAKE SURE NEW PLANT VARIETIES ARE SAFE?

Plant breeding has been driven by the need to ensure the availability of a safe, nutritious and economical food supply. Modern breeders continue the tradition of using genetic diversity to introduce desired traits and have developed many tools and innovations to improve the breeding and selection process. These include genetics, statistics, molecular biology, plant pathology, entomology, agronomy, and computer modeling. Using this information, breeders have been able to develop precise knowledge of the relationships between genes and plant characteristics and how they interact with their environments. In addition, breeders often seek to introduce new genetic diversity to existing plants to obtain new and improved characteristics.

The majority of new plant varieties are derived by selection after iteratively crossing existing varieties together to create new genetic combinations. Importantly, these existing varieties are in turn derived from varieties with a long history of safe use. Nonetheless, a key feature that defines modern breeding is extensive and rigorous testing starting early in the breeding process and continuing until the final product is commercially available. Breeders test for a range of characteristics to meet the demands of consumers and the marketplace. These can include taste, mouth feel, color and texture. Breeders also test for characteristics that are less obvious to consumers such as yield, uniformity, stress tolerance, resistance to pests and storability. Specific tests are also applied to those plant species that are known to inherently produce toxicants or anti-nutrients. Specialized varieties that are intended for specific food or industrial use undergo additional testing to ensure that these trait "targets" are indeed maintained consistently in the final variety. Because the environment can influence the expression of certain characteristics, breeders typically evaluate pre-commercial varieties in multiple environments and across several years and generations to ensure consistency of performance.

The development of a new plant variety generally requires the evaluation of thousands of plants, ultimately resulting in the selection of a few new varieties that show the desired characteristics. Throughout this process, breeders eliminate those plants that show undesired characteristics—called "off-types". The scrutiny breeders routinely apply to new variety development is well established and has been the foundation for a food supply that is safe, nutritious and diverse. All plant varieties go through this process regardless of the method used or source of genetic variability. The plant breeding process is a well-established, rigorous screen for stability and performance of plant-derived products. A description of this process from the Food and Drug Administration (FDA) is given in the box at left.



# IF MOST NEW PLANT VARIETIES DO NOT GO THROUGH A PRE-MARKET REVIEW AND CLEARANCE PROCESS BY THE GOVERNMENT, ARE THEY REGULATED AT ALL?

All foods derived from plants are regulated in the United States by the Food and Drug Administration under the Food Drug and Cosmetic Act. Additionally, plants and seeds are comprehensively regulated by the U.S. Department of Agriculture (USDA) under at least two federal statutes. The Federal Seed Act (FSA) regulates the interstate shipment of agricultural and vegetable seeds. The FSA requires that seed shipped in interstate commerce be labeled with information that allows seed buyers to make informed choices. Seed labeling information and advertisements pertaining to the seed must be truthful and cannot be misleading. The FSA helps promote uniformity among State laws and fair competition within the seed trade.

The Plant Protection Act (PPA) provides USDA with sweeping authority to regulate the movement of any plant or seed if necessary to prevent the introduction or dissemination of a plant pest or noxious weed that might harm agriculture, the environment, or the economy of the United States.



# WHAT ARE THE INTERNATIONAL IMPLICATIONS TO GOVERNMENT POLICY?

The seed industry and agriculture in general is a global business so there is a clear need for consistent government policies. Consistent and science-based policies enable farmers and consumers around the world to benefit from the most precise and efficient breeding methods. The newer plant breeding methods are increasingly becoming the subject of policy discussions internationally, in individual countries and in even in regional governmental organizations. A key issue for both public and private plant breeders is working toward consistent government policies that maintain high safety standards and facilitate seed innovation globally.

Lack of consistent government policy endpoints will result in serious consequences for trade in commodities produced from these plant varieties, for the global movement of seed and for research collaborations. Public breeding programs and smaller private breeding programs will lose the incentive to work with these important technologies. The ultimate result will be that farmers, consumers and societies will not benefit from the wide array of improved varieties that can be produced more efficiently and predictably, using these technologies.





#### WHAT IS THE COST OF NOT ENABLING PRECISION BREEDING?

If adopted policies result in a high regulatory cost for these products, there will be both short- and long-term consequences. In the shorter term, it will mean that smaller companies and universities will not be able to support this regulatory burden, stifling their research programs or forcing them to partner with larger companies. The technologies will be limited to large-acreage crops that can justify a return on investment sufficient to cover the regulatory costs. The regulatory costs in the United States will not be the only factor to consider. If there is a repeat of the current, inconsistent global policies for Genetically Engineered (GE) crops, the regulatory hurdles and potential trade implications will further impede the use of these valuable breeding tools.

Longer term, the trajectory of plant breeding research will be affected. Other countries will be able to move ahead of the United States with respect to these new technologies. Marker-assisted breeding and genome sequencing will continue to be used in breeding programs, but without the use of tools such as gene editing, it will be difficult for our breeders to efficiently and economically compete, and in particular, to achieve new characteristics that are determined by many genes (called multi-genic characteristics). Plant characteristics that are geared toward the consumer (called output traits) are often multi-genic and difficult to achieve through traditional breeding methods.

Regulatory policies, both here in the United States and globally, will in large part shape the direction of plant breeding in the future and thus affect the ability of agriculture to support healthy populations with environmental and economic security.





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