International Seed Federation
Seed is Life

Plant Breeding Innovation: Consistent Criteria for the Scope of Regulatory Oversight

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OBJECTIVE

To achieve alignment among governments on the criteria used to assess whether plants developed through plant breeding innovations should be subject to regulatory oversight under existing Genetically Modified Organism (GMO) regulations for plants.

BACKGROUND & CURRENT CONTEXT

Internationally, there is a patchwork of national GMO regulations. Some countries regulate specific technologies through GMO definitions. Other countries regulate based on the characteristics of the final product. Additionally, definitions for 'GMO', 'biotechnology', 'genetic engineering' and 'bioengineering' are not consistent across countries. Due to these differences, products developed through the latest plant breeding methods may be subject to different requirements for pre-market assessments and other requirements, such as labeling. Across countries this is negatively affecting research collaborations and hindering the movement of seed globally. As a consequence, commodity trade disruption will occur and agricultural development and food security will be impeded. Enforcement issues are likely to increase because seeds and commodities developed with the aid of some the latest plant breeding methods are indistinguishable from those derived from traditional plant breeding methods or natural occurring genetic variation.

Consistent policies among governments for products of the latest plant breeding methods, such as gene editing, would facilitate the development and uptake of advanced, innovative breeding applications by both private and public breeders in developed and developing countries. Plant breeders need legal certainty so they can reliably plan their breeding programs, their product development and market potentials. Disproportionate regulatory hurdles mean higher costs, especially for registration and approval which limit the access of small and medium sized enterprises (SME) and public plant breeding institutions to the latest plant breeding innovation tools. Furthermore, such government policies will impede the availability of a diversity of crops and varieties for farmers, including speciality crops and crops with niche markets.

The seed sector is therefore focused on achieving a consistent approach among governments to the scope of regulatory oversight for products of plant breeding innovation. The first step in this process is agreement among countries on the criteria that would be used to determine the scope of regulatory oversight. Once countries agree on the criteria, they may need to implement them differently, given the differences in current regulations around the world. For example, some countries may need to interpret definitions and others may need to redefine regulatory triggers.

PLANT BREEDING

Plant breeding is a product-oriented, science-based discipline for improving plants. Plant breeding is rooted in population development, selection theory, quantitative genetics, statistical analysis and an increasing number of support technologies. It involves generating genetic variation, selecting desirable plants, stabilizing inheritance of desirable characteristics, testing in multi-locations over many years, and multiplying the best performing plants.

Plant breeders have always used the creation of new variations of plant characteristics to provide solutions for resistance to plant diseases and pests, to increase tolerance to environmental stress, to improve quality and yields, and to meet consumer expectations. Plant breeding depends upon genetic variability within and across related species as a basis for developing new plant varieties with improved characteristics. To create a new plant variety, plant breeders have generally relied on two sources of genetic variation as a basis for new characteristics: the inherent diversity in a plant's gene pool and new, naturally occurring variants of existing genes.

Breeders often make crosses between plants of diverse genetic makeup to produce new combinations of genetic characteristics which result in diverse morphological or quality characteristics in the progeny plants. The natural diversity of different sources of germplasm within a species or its close relatives is a primary source of genetic variation.

Genetic variation can also be increased by using mutations – changes in the DNA sequences of the plants. Natural and induced mutagenesis can introduce different classes of mutations, one of which is the point mutation. A point mutation results in a change of one, or a few, DNA base pairs in a gene's nucleotide sequence. Point mutations include substitutions and insertions and deletions of basepairs. Since the 1950s, well over 3200 crop varieties have been directly developed by induced mutations.

Some examples of the successes of mutation breeding include:

- High-yielding and short barley for brewing industry
- Heat tolerance and early maturity in cotton
- Seedless watermelon
- Multiple disease resistances in tomato.
- Ruby Red grapefruit
- Gold Nijisseiki Japanese pear which is disease resistant
- Peanuts with tougher hulls
- Semi-dwarf rice with higher yields
- Virus resistant cocoa plants
- Canola with healthy fatty acid composition

Breeders have historically integrated the latest technologies in plant biology and genetics into their methodologies to efficiently use existing variation, and to induce new genetic variation. Plant breeders continue to develop precise yet flexible methods to safely increase specificity and efficiency of breeding, decrease development time and cost, and increase genetic diversity for breeding programs. These the

latest breeding tools can be used to precisely target a change to (a) specific gene(s) in a plant's genome to create the desired plant trait. They can also be used to identify a gene in a plant's gene pool (e.g., in wild relatives) and to precisely and efficiently introduce the desired version of this gene into an existing, high-performing commercial variety. By applying these the latest methods, plant breeders can make the same desired changes with greater precision and in a much shorter time than was possible with earlier breeding methods. Because these new methods are efficient and economical, they are accessible to public and commercial plant breeders in developed and developing countries and can be used across all agriculturally important crops, including field, vegetables and specialty crops.

There is inherent variation in many characteristics considered to be important by plant breeders and the expression of a trait is influenced by growing conditions. The development of a new plant variety normally involves many performance trials in different environments before introduction as a new commercial variety. Prior to the release of a new plant variety to farmers, plant breeders use well established, intensive assessments across growing conditions across locations and over multiple years to eliminate plants with undesirable characteristics, to ensure stability of the desired trait and to confirm performance. This evaluation is intended to not only confirm the performance of the new variety, but also to evaluate the variety's characteristics and eliminate those characteristics that are undesirable. 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. Plant varieties developed through the latest breeding methods are subject to the same critical performance evaluations and processes that breeders have used for many decades to create new plant varieties that are safe to grow and eat.

CONSISTENT CRITERIA FOR THE SCOPE OF REGULATION

When considering the criteria for the scope of regulatory oversight, the question is not whether there is adequate regulation of foods and plants but rather the extent to which a specific pre-market review and clearance process is justified for plant varieties developed using certain plant breeding methods.

An underlying principle for determining these consistent criteria is:

Plant varieties developed through the latest breeding methods should not be differentially regulated if they are similar or indistinguishable from varieties that could have been produced through earlier breeding methods.

Therefore, the international seed industry proposes the following:

The genetic variation in the final plant product would not be covered under the scope of existing biotech/GMO regulations for plants if:

a) there is no novel combination of genetic material (i.e. there is no stable insertion in the plant genome of one or more genes that are part of a designed genetic construct), or;
b) the final plant product solely contains the stable insertion of inherited genetic material from sexually compatible plant species, or;
c) the genetic variation is the result of spontaneous or induced mutagenesis.