

# Plant breeding innovation: Consistent criteria for the scope of regulatory oversight

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## CONTEXT

Plant breeding is the art and science of improving crops to meet the ever-changing needs of the value chain, from farmers to consumers. Plant breeders develop plant varieties in response to global challenges, such as emerging plant diseases and pests, and environmental stresses. Today's plant breeding methods are based on the same principles that farmers and plant scientists have been using for thousands of years. Scientific advances have enabled the development of precise methods to safely improve the efficiency of breeding, and increase genetic diversity for breeding programs. Countries currently have different systems to evaluate and regulate products entering the market, as for example Genetically Modified Organisms (GMOs). This creates a patchwork of national regulations: some countries regulate specific technologies, while others regulate based on the characteristics of the final product or both. Furthermore, definitions for 'GMO', 'biotechnology', 'genetic engineering' and 'bioengineering' are not consistent across countries.

## THREATS TO INNOVATION

If different national regulations are applied to products developed through the latest plant breeding methods, such as gene editing, there may be different requirements for pre-market assessments and labelling, for example. This will limit the capacity of the industry to innovate; reduce the diversity of genetic resources; negatively affect research collaborations; and hinder the movement of seed globally. In addition, 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 of the latest plant breeding methods are indistinguishable from those derived from traditional plant breeding methods or naturally occurring genetic variation.

## POSITION

ISF believes that the adoption of science-based, consistent policies for products of the latest plant breeding methods, such as gene editing, would facilitate the development and uptake of advanced, innovative breeding applications by private and public breeders in developed and developing countries.

ISF calls for legal certainty and predictability to enable plant breeders to reliably plan their breeding programs, their product development and market potentials.

ISF rejects disproportionate regulatory hurdles to avoid higher costs, especially for registration and approval, which limit the access, especially by small and medium sized enterprises (SME) and public plant breeding institutions, to the latest plant breeding methods.

ISF advocates government policies that enable the availability of a diversity of crops and varieties for farmers, including specialty crops and crops with niche markets.

ISF promotes a consistent approach to the scope of regulatory oversight for products of the latest plant breeding methods among governments. The first step towards consistency is agreement among countries on the criteria that would be used to determine the scope of regulatory oversight.

## CRITERIA FOR THE SCOPE OF REGULATORY OVERSIGHT

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 through the latest plant breeding methods. An underlying principle for determining these consistent criteria is:

Plant varieties developed through the latest plant breeding methods should not be differentially regulated if they are similar or indistinguishable from varieties that could have been produced through earlier plant 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 biotechnology/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 genetic material from sexually compatible plant species, or;
- c) The genetic variation is the result of spontaneous or induced mutagenesis.

## PROCESS FOR DETERMINING REGULATORY STATUS

Once countries agree on the criteria, there may be differences in how they incorporate these criteria into current policies and regulations. For example, some countries may need to interpret definitions and others may need to redefine regulatory triggers.

The second essential factor affecting the predictability of the policy approach is the process used to determine whether a product is within or outside the scope of existing biotechnology/GMO regulations. The process should be predictable and timely, taking into account existing regulatory mechanisms for improved plant varieties, such as variety registration and national seed laws and regulations. Alignment across countries can be facilitated through alignment of:

- (a) definitions
- (b) standard information requests needed to make determinations
- (c) timelines
- (d) recognition of other countries' scope decisions

Countries should take into account the global impacts that different processes may have on global seed movement, exchange and access to germplasm globally, agriculture, trade and research collaborations.