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Plant Breeding Innovation

Applying the latest Plant Breeding Methods for the benefit of sustainable Agriculture, Consumers and Society

Reconciling sustainability with agricultural productivity relies strongly on the development of stable, high-yielding crops of superior nutritional value that can be grown more resource-efficiently. Therefore, innovation in plant breeding has gained unprecedented importance. For a competitive and sustainable EU agriculture, the following is crucial:

- *plant varieties developed through the latest breeding methods should not be subject to different or additional regulatory oversight if they could also be obtained through earlier breeding methods or result from spontaneous processes in nature.*
- *policy makers should foster a high-performing, innovative and diversified European plant breeding sector, enabling agriculture to become more sustainable.*
- *regulators should actively support a practical and science based approach towards the latest breeding methods, both in regulation and public debate.*

In light of the rapidly-growing world population, climate change and increasing scarcity of natural resources such as arable land and water, progress in plant breeding has gained unprecedented importance. High-yielding crops of superior nutritional value that can be grown more resource-efficiently are increasingly becoming the cornerstone of a sustainable, yet highly-productive agriculture[1]. In addition, crops need to become more pest- and disease-resistant as well as more tolerant to adverse conditions such as drought, heat, submergence and salinity.

Continuous advances in science and technology have provided precise and robust tools to plant breeders that stimulate innovation and allow for the development of improved varieties more quickly and efficiently.

[1] The economic, social and environmental value of plant breeding in the European Union, 2016 http://www.plantetp.org/system/files/publications/fileshffa_research_paper_03_16_final_unprotected.pdf

Plant breeding depends upon genetic variability within crops and their relatives as a basis for developing new plant varieties with improved characteristics. Plant breeders are continuously integrating the latest methods in plant biology and genetics into their breeding toolbox to efficiently use existing diversity but also to induce new genetic variation. Over the past years ever more precise and efficient plant breeding methods have been developed. This plant breeding innovation leap is based on an in-depth understanding of plant genomes and refinement of breeding methods, enabling more efficient, more precise and faster progress in achieving the desired breeding goals. Consequently, plant breeding innovations are rapidly being developed and utilised internationally and across the seed sector, public and private research, plant species and markets.

Providing legal certainty

Europe's seed sector, technology developers and public researchers are global leaders in developing improved plant breeding methods[2]. The sector is highly innovative and invests up to 20% of its turnover in research and development, to constantly provide farmers with the best varieties that fit the needs of a highly productive and sustainable agriculture as well as consumer demands. The ruling of the European Court of Justice (ECJ) in case C-528/16 confirmed that:

- organisms obtained by all means of mutagenesis must be considered to be GMOs as defined in article 2(2) of Directive 2001/18 (GMO Directive),
- the mutagenesis exemption only applies to organisms obtained by methods of mutagenesis which have conventionally been used in a number of applications and have a long safety record,
- the mutagenesis exemption cannot be interpreted as preventing Member States from legislating in that area. Member States are entitled to subject such organisms to the obligations laid down in the GMO Directive or to other obligations as long as such obligations comply with EU law and in particular with the rules on the free movement of goods.

ESA considers that the consequences of this ruling present unacceptable socio-economic risks for European plant breeding, for the wider agri-food chain, for consumers and for our European environment.

The prohibitive compliance requirements of the GMO Directive relative to the value of commodity crops effectively cut Europe's breeders off from scientific progress and puts them as well as farmers, processors, traders and consumers at a competitive disadvantage to regions with more enabling regulations. Moreover, it will not allow Europe to advance the development of new, better adapted plant varieties that are both high-performing and resilient, contribute to healthy diets to mitigate the effects of climate change and innovate for a more sustainable agri-food system at the pace that is urgently needed.

Furthermore, as it will create severe uncertainties among all stakeholders from primary processors to consumers, Member States should not adopt specific rules on plants resulting from conventional, random mutagenesis.

ESA maintains its position that plant varieties and seeds are subject to a respected and robust regulatory regime. The development of new plant varieties requires up to 15 years before they can be marketed. It is therefore crucial for companies that their investments in the latest plant breeding methods can be based not only on sound science, but also on confidence that the market access of their improved varieties will not be subject to an uncertain outcome of politicised regulatory procedures.

[2] JRC Report New Plant Breeding Techniques: State of the art and prospects for commercial development, 2011

If plants resulting from the latest plant breeding methods are, without differentiation, be subjected to the requirements of Directive 2001/18/EC on the deliberate release of GMOs in the environment, achieving the EU's goals of increased sustainability of EU agriculture and of the bio-based economy will be put at risk, because

- the associated regulatory costs, cumbersome approval processes and long timelines would prevent most of Europe's plant breeding companies from developing and using these methods, thereby eroding their competitiveness and ultimately leading to a less diversified plant breeding sector;
- similarly, breeding with these latest methods on a wide range of species and diverse characteristics, targeting also speciality uses and niche markets, could not be envisaged as the small size of these markets would not justify the regulatory approval costs;
- excessive costs and unpredictable decisions as for GM authorisations will result in a further exodus of innovative breeding companies from Europe. European scientific excellence, at both private and public levels, related jobs, innovation and consequently economic growth will be once more driven out of Europe;
- the incentives for innovative plant breeding activities in Europe will decrease significantly which will give a competitive advantage to those plant breeding industries competing outside Europe;
- the portfolio of products developed in and for the Common Market will be reduced, which means less choice in products specifically targeted to the needs of Europe's farmers, growers, processing industries and consumers.

ESA and its members therefore commit to further engage with policy makers, stakeholders and all interested parties and work for constructive change. Our goal is to obtain practical and science-based rules for the latest breeding methods that foster public confidence and trust and effectively unlock this great potential for a high-performing, innovative and diversified European plant breeding sector and agriculture, for Europe's consumers and its environment. The ability to continue deploying all the tools available is an important lever of competitiveness across various sectors and enhances the attractiveness of plant-related sciences and the bioeconomy in general.

Applying consistent and science based policy criteria

Like evolution itself, plant breeders have generally relied on two sources of genetic variation as a basis for developing plant varieties with new characteristics: the inherent diversity in a plant's gene pool, and naturally occurring or induced variants of existing genes (mutations). Importantly, most of the latest plant breeding methods apply molecular genetic tools within the genetic borders of a given plant species. These do result in plants that do not contain genetic material from non-plant sources or from sexually-incompatible species. They therefore generally create plant products that may also be obtained using earlier breeding methods.

This is confirmed by the vast majority of scientific and legal opinions, including a specific report by a Member States Experts Working Group[3] and an explanatory note by the EU Commission's Scientific Advice Mechanism[4, 5].

[3] Final Report of the EU "New Techniques Working Group", 2012
[4] Explanatory Note, New techniques in agricultural biotechnology, 2017
[5] https://ec.europa.eu/info/sites/info/files/2018_11_gcsa_statement_gene_editing_2.pdf

Specifically, the Member States Experts Working Group[3] report clearly stipulates that most applications of these latest plant breeding methods and the resulting products should be exempted from the EU's GM legislation. We underline that this position is not only broadly shared by scientists and experts but also increasingly adopted as principle regulatory approach by countries around the world.

ESA maintains its position that:

> ***Plant varieties developed through the latest breeding methods should not be subject to different or additional regulations if they could also be obtained through earlier breeding methods or result from spontaneous processes in nature***.
>
> ***Consequently, genetic variation and final plant products are not covered under the scope of existing GMO regulation if***
>
> 1. ***there is no novel combination of genetic material [6] (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***
> 2. ***the final plant product contains solely the stable insertion of inherited genetic material from sexually compatible plant species or***
> 3. ***the genetic variation is the result of spontaneous or induced mutagenesis.***

ESA calls upon decision makers to act swiftly in support of a high-performing, innovative and diversified European plant breeding sector by applying this science based and coherent approach towards the latest breeding methods.

The ECJ ruling shows that the existing GMO legislation no longer reflects current knowledge and scientific evidence. ESA therefore encourages Commission to apply the above-mentioned criteria and update the EU's current regulatory framework accordingly.

This will enable Europe's plant breeders to continue investing in research, development and application of these improved breeding methods, for the benefit of farmers, growers, consumers and society at large.

[6] According to the Definition of a living modified organism in Art 3 of the Cartagena Protocol to which the EU and its Member States are a party.

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Application of the agreed criteria to plant varieties

Applied method / Resulting plants which are placed on the market	Targeted Mutagenesis via SDN1[1],ODM[2]	Targeted gene edit via SDN2[3]	Transgenesis (stable integration of DNA from a non-sexually compatible specie)	Intragenesis (Cisgene[4], but novel combination of genetic material)	Cisgenesis (addition of a cisgene[4] at different location – novel combination of genetic material)	Cisgenesis *sensu stricto* (*replacement or addition[5] of allele[4] at naturally occuring location using SDN3[6]*)	RNA-induced DNA-methylation	Reverse Breeding	Grafting on GM-rootstock		Agro-Infiltration of non-reproductive tissue only	Agro-Infiltration of reproductive tissue (floral dip)	Null-Seggregants	Future techniques
1. contains 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**	√	√				√	√	√	√		√		√	
2. solely contains inherited genetic material from sexually compatible plant species **or**	√	√			√	√	√	√	√		√		√	
3. is the result of spontaneous or induced mutagenesis	√	√												
Subject to GMO Regulation	No	No	Yes	Yes	Yes/ No*	No	No	No	No fruits/ seeds	Yes entire plant	No	Yes/ No depending on kind of application[7]	No	to be assessed

*** The outcome can be different depending on whether a country is party to Cartagena Protocol and incorporated the protocol in its national/regional legislation**

[1] SDN1 = using Site directed Nucleases like Zinc-Finger, TALEN, CRISPR for the creation of unspecific mutations (small changes in DNA – base pair exchanges/ deletions/ additions) at precise location
[2] ODM = Oligonucleotide Directed Mutagenesis
[3] SDN2 = using Site directed Nucleases like Zinc-Finger, TALEN, CRISPR for the creation of specific mutations (small changes in DNA – base pair exchanges/ deletions/ additions) at precise location
[4] Cisgene = gene from a sexually compatible plant species
[5] allele addition from naturally occuring presence/absence variation
[6] SDN3= using Site directed Nucleases like Zinc-Finger, TALEN, CRISPR for the insertion of larger pieces of DNA, e.g. genes at precise location
[7] transgenesis, intragenesis, cisgenesis or cisgenesis sensu stricto