



European Plant Science Organisation
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Statement

Crop Genetic Improvement Technologies

Brussels, 26.2.2015, updated 18.12.2015 and 12.1.2017

Crop genetic improvement technologies for a sustainable and productive agriculture addressing food and nutritional security, climate change and human health

EPSOs request to the European Commission

The European Plant Science Organisation welcomes the outcome of the majority opinion of the Member States expert working group (the “New Techniques Working Group”) report (1) and asks the European Commission as a matter of urgency to provide a guideline document that follows these recommendations to provide legal certainty for science and industry concerning the application and exploration of New Plant Breeding Techniques (NPBTs).

Since an increasingly number of new breeding techniques will be developed, a more detailed and comprehensive discussion on a new approach for the regulation of new plants is required. This new approach might be based on the new characteristics of a product/trait and should take the following into account:

- a. A clear and reliable definition, based on scientific evidence, of what constitutes a novel plant trait, and thus needs to be assessed by an appropriate body (legal certainty);
- b. The need to avoid overregulation whereby an unwarranted number of processes and products will have to undergo expensive and lengthy authorization procedures (disadvantage for SMEs and scientists);
- c. The need to uncouple the question of environmental risk and safety assessment from the question of labeling (consumer acceptance).

Contribution of the EU agriculture sector

The EU agriculture sector makes a vital contribution to building the Knowledge-Based Bio-Economy, to meeting the challenges of food security and safety, to mitigating the effects of climate change, to ensuring sustainable agriculture and to maintaining employment in Europe. The EU plant breeding sector is a strategic sector which has responded to several major global challenges over the past 100 years. It has contributed, and continues to contribute, to the creation of benefits for the EU economy and society as a whole: these positive effects can only be achieved if plant breeders can deploy all appropriate tools which include conventional breeding, genetic engineering, the New Plant Breeding Techniques and other emerging technologies. Additionally, the plant breeding sector should be supported by continuous funding opportunities for fundamental research as well as a clear, workable legislative framework.

Crop genetic improvement technologies are progressing rapidly

Crossing of superior plants followed by selection of improved progeny has, for a long time, been the basis for crop improvement. Such traditional breeding techniques have been complemented since the last century by chemical or radiation mutagenesis, translocation breeding and intergeneric crosses leading to a more sophisticated exploitation of natural genetic variation by plant breeders. The emergence of genetic engineering in the 1980s allowed the development of transgenic plants as an additional approach to complement plant

breeding techniques. These breeding techniques are complementary, not mutually exclusive and are essential tools to meet the challenges of agriculture. From the beginning, the potential risks of transgenic techniques were analysed and a complex GMO regulatory system was put in place. Since then, the development of breeding techniques has continued to progress rapidly resulting in even more sophisticated methods to create plants with new traits. Collectively, these techniques are summarized as New Plant Breeding Techniques (NPBTs). Among them, site directed nucleases (SDN) and other genome editing and modification techniques such as oligo-directed mutagenesis (ODM), allow the introduction of sequence-specific changes in the plant genome. Thus precision-based mutation approaches can now be used which, unlike chemical or radiation mutagenesis, do not create hundreds of additional mutations throughout a genome.

Current European legislation neither reflects the progress made in new crop genetic improvement approaches nor the positive economic, social or environmental impact of the resulting biological outcomes

The current EU GMO-legislative framework is focused on the technique used to produce a new plant, and not on the final trait/product. As some of the NPBTs require an intermediate transgenesis step, the plants obtained by these techniques may be considered as GMOs. This legislation is not reflecting the progress made in the development of new techniques. It also does not reflect the evidence accumulated by thousands of GMO biosafety studies clearly demonstrating that GM technology *per se* does not carry any greater risk of a negative impact on health and the environment than any other technology used in plant breeding**. Therefore, it would be more evidence- and science-based to evaluate the crop genetic improvement technologies including genetic engineering and the NPBTs and other future ones according to the potential impact of the resulting end product/trait rather than the technique used. (2)

The European Commission should create favourable regulatory conditions for the European plant breeding sector

The European Commission's delays in clarifying the legal status of the NPBTs weaken the competitiveness of the EU plant breeding sector. It is clear that for the plant breeding sector and the farming community at large, the status quo on this dossier is not an option and would have a significant negative impact on the current situation for EU farmers. EU farmers already suffer unfair competition from primary producers in other regions of the world regarding access to all appropriate tools including genetic engineering and NPBTs. It is important that the European Commission creates favourable regulatory conditions for the European plant breeding sector to maintain its position of worldwide leadership in the area of research and innovation.

The European plant science community calls upon policy makers to implement a science-based policy as a priority

The European plant science community is following the current debate on the legislative classification of NPBTs along the lines of European GMO legislation with great interest and concern. We are concerned that more and more processes and products will have to undergo expensive and lengthy authorization procedures, even in cases where no foreign DNA is contained in the resulting end product or where these products are completely indistinguishable from traditionally bred crops. We support the conclusions of the New Techniques Working Group (1) that the legal definition of a GMO does not apply to most of the NPBTs and that these techniques either fall under the exemptions already established by the legislation*** or should be exempted as they do not differ from plants obtained by traditional breeding. We support the requests of the Plant ETP (3) based on the reports of several scientific bodies that have assessed and evaluated NPBTs. The European plant science community calls upon policy makers to implement a science-based policy as a priority. For a new start in Europe, the plant science community encourages the new Commission President and his team of Commissioners and policy makers in the Member

States to work towards balanced support for all crop genetic improvement technologies that allow the plant science sector to address the Grand Challenges facing our planet.

EPSO acknowledges the interpretation of the EU GMO legislation as both process and product based and considers that this could help to clarify the legal status of the New Plant Breeding Techniques

17.12.2015: This additional chapter to the original EPSO statement from 26.2.2015 was agreed at the December 2015 EPSO Agricultural Technologies Working Group Meeting and amended 12.1.2017 to include recently published reports

The European plant science community is following the current debate on the legislative classification of New Plant Breeding Techniques along the lines of European GMO legislation with great interest and concern. Over the years, the EU regulatory framework for GMOs has become increasingly dysfunctional in the sense that:

- decisions are often not taken within the legal time frames, and often not on the basis of scientific evidence and risk assessment;
- information requirements and risk assessments have not been differentiated based on gained knowledge, but instead increased and galvanized without scientific justification;
- uncertainty is created about the applicability of the regulatory framework on organisms developed through new crop genetic improvement techniques such as genome editing.

EPSO has highlighted in an earlier statement (4) that one of the causes of this situation is that in the implementation of the regulatory framework there is a disproportionate focus on the genetic improvement technique used. This has led to the following misinterpretations:

- GMOs are merely defined by the use of certain techniques. This is incorrect. Whether or not the resulting organism is a GMO depends entirely on the fact if a novel combination of genetic material has been produced beyond the natural barriers of mating and recombination. This is for example not the case for point mutations obtained by genome editing (5, 6, 7, 8).

In the present debate on the GMO legislation an increasing number of competent authorities, risk assessment bodies, and stakeholders interpret the EU GMO legislation as both process and product based. EPSO acknowledges this interpretation and considers that this could help to clarify the legal status of the New Plant Breeding Techniques.

Recent publications provide evidence on the power of the technologies discussed:

- Major resources are used to control the powdery mildew disease in cereals which would otherwise cause decrease in yield. With the precision breeding technologies resistant wheat plants have been developed leading to reduced pesticide use.
- With precision breeding technologies barley and corn have been improved to a significantly better utilization of seed phosphorus and minerals in feed and food leading to less undigested phosphorus going back to nature and an optimized use of this critical raw material.

Therefore, as a matter of urgency, EPSO reiterates its request to the European Commission to provide legal certainty for science, industry and farmers concerning the application and exploration of New Plant Breeding Techniques and to work towards balanced support for all crop genetic improvement technologies that allow the plant sector to address the Grand Challenges facing our planet.

** to avoid misinterpretation: this does not imply that conventional breeding should be restricted by similar regulations

*** techniques that are not considered to result in genetic modification (Annex I, Part B of Directive 2009/41/EC and Annex IA Part 2 of Directive 2001/18/EC) or yield organisms that are excluded from the Directive (Annex II Part A of Directive 2009/41/EC and Annex IB of Directive 2001/18/EC)

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Useful links

- (1) New Techniques Working Group (2012) Final Report of the European Commission
 - (2) EASAC Report "[Planting the Future](#)"
 - (3) Plants for the Future ETP: [Statement on New Breeding Technologies](#), September 2012
 - (4) EPSO Statement on Crop Genetic Improvement Technologies, 26.2.2015
www.epsoweb.org/file/2038
 - (5) BVL Opinion on the legal classification of New Plant Breeding Techniques, in particular ODM and CRISPR-Cas9, October 2016
www.bvl.bund.de/SharedDocs/Downloads/06_Gentechnik/Opinion_on_the_legal_classification_of_New_Plant_Breeding_Techniques.pdf;jsessionid=9A8AE3A96D9EDD1DA8D39B19544B34A9.2_cid322?_blob=publicationFile&v=3
 - (6) Swedish Board of Agriculture, CRISPR/Cas9 mutated Arabidopsis, 2015
www.upsc.se/documents/Information_on_interpretation_on_CRISPR_Cas9_mutated_plants_Final.pdf
 - (7) VIB Opinion "When is an organism subject to the provisions of the EU GMO legislation? An in-depth analysis", November 2016
www.vib.be/en/about-vib/organization/Documents/rc_bvl_2016_00533%20GMO%20definition%20legal%20analysis_final.pdf
 - (8) Italian Societies on Agricultural Genetics and Plant Biology: Position on genome editing techniques applied to agriculture, April 2016
www.epsoweb.org/file/2257
- EPSO Working Group on Agricultural Technologies: www.epsoweb.org/agricultural-technologies-wogr
Statements drafted by this group and approved by the EPSO representatives are for instance:
- EPSO statement on Crop Genetic Improvement Technologies, 26.2.2015
 - EPSO statement on Plant Breeders' rights and patent rights, 26.2.2015
 - EPSO statement on GMO cultivation – national opt-out, 26.2.2015
- EPSO [Science Based Policy](#), 1.9.2013
EPSO member institutes and universities: www.epsoweb.org/membership/members
EPSO representatives: www.epsoweb.org/membership/representatives

About EPSO

EPSO, the European Plant Science Organisation, is an independent academic organisation that represents more than 200 research institutes, departments and universities from 28 European countries, Australia and New Zealand, and 3.200 individuals Personal Members, representing over 27 000 people working in plant science. EPSO's mission is to improve the impact and visibility of plant science in Europe, to provide authoritative source of independent information on plant science, and to promote training of plant scientists to meet the 21st century challenges in breeding, agriculture, horticulture, forestry, plant ecology and sectors related to plant science.
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