



European Plant Science Organisation  
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*First reaction*

## **On the ECJ Ruling regarding mutagenesis and the Genetically Modified Organisms Directive**

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*Brussels, 26.7.2018*

**The European Plant Scientists express their disappointment with regard to the ruling of the European Court of Justice (ECJ) in case C-528/16 which classifies plants obtained by recent techniques such as CRISPR-Cas9-mediated genome editing as genetically modified organisms (GMO) that are subject to extensive pre-market risk evaluations laid down in EU Directive 2001/18/EC. It is contrary to scientific evidence and as it stands now it very likely will prevent the use in Europe of such technologies to address food and nutritional security and a more positive impact of agriculture on the environment.**

Whereas the ruling maintains the exemption accorded to mutants obtained by methods existing before 2001 due to their history of safe use, it explicitly excludes mutants obtained by more recent techniques like genome editing from the exemption. This very rigid, process-based interpretation of EU Directive 2001/18/EC did not follow the more subtle, largely product-based opinion of the Advocate General published in January. It is regrettable that the ruling does not take into account scientific evidence that genome edited plants contain more precise modifications of the genome and less off-target effects than plants that underwent irradiation or chemical treatment.

Therefore, EPSO reiterates its updated statement on [Crop Genetic Improvement Technologies](#) from 12.01.2017:

- **The 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 European Commission should create favourable regulatory conditions for the European plant breeding sector**
- **The European plant science community calls upon policy makers to implement a science-based policy as a priority**

EPSO fears that the current status following from the ruling of the ECJ will prevent research and innovation in plant breeding aiming to adapt future agriculture to (i) the reduction of pesticides and fertilisers, (ii) the increase of quality and yield of plant production, the basis for nutritious and healthy food as well as non-food products, and (iii) the challenges of the climate change and a biobased economy. This will impact research, companies, farmers and the public at large. It may also have a negative impact on the international cooperation between the EU and countries deregulating genome editing and thus result in a competitive disadvantage of European research, innovation

and farming. While the judgement does not directly concern the use of genome editing as a research tool in confined environments the lack of linkage to an option of broad application may considerably reduce future research efforts in Europe.

Therefore, EPSO scientists offer their expertise to develop now an appropriate regulation addressing the issue of how much a product of modern biotechniques differs from those achieved with other breeding approaches in order to balance potential benefits and risks. EPSO will support efforts enabling new technologies to be used by public sector, small and medium sized companies and farmers to contribute to food and nutritional security and to reduce the environmental impact of agriculture.

*This first reaction was developed by Frank Hartung, Ralf Wilhelm and Peter Rogowsky based on the discussions in the EPSO Agricultural Technology Working Group and in the EPSO Board upon request of the EPSO General Meeting 2018.*

*EPSO will publish first reactions from individual members during this week and is working on a more detailed statement and offer for collaboration with policy makers in upcoming weeks.*

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#### Useful links

Court of Justice of the EU: Judgment in Case C-528/16, 25.7.2018. English Press Release:

<https://curia.europa.eu/jcms/upload/docs/application/pdf/2018-07/cp180111en.pdf>

Ruling in English:

<http://curia.europa.eu/juris/document/document.jsf?text=&docid=204387&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=949807>

Court of Justice of the EU: Advocate General's Opinion in Case C-528/16, 18.1.2018. English Press Release: <https://curia.europa.eu/jcms/upload/docs/application/pdf/2018-01/cp180004en.pdf>;

Opinion in English:

<http://curia.europa.eu/juris/document/document.jsf?text=&docid=198532&pageIndex=0&doclang=EN&mode=req&dir=&occ=first&part=1&cid=780899>

Court of Justice of the EU: Case C-528/16

<http://curia.europa.eu/juris/document/document.jsf?text=&docid=186771&pageIndex=0&doclang=EN&mode=req&dir=&occ=first&part=1&cid=780899>

EC: Explanatory Note on New Techniques in Agricultural Biotechnology from EC's High Level Scientific Advice Mechanism, 28.4.2017

[https://ec.europa.eu/research/sam/pdf/topics/explanatory\\_note\\_new\\_techniques\\_agricultural\\_biotechnology.pdf#view=fit&pagemode=none](https://ec.europa.eu/research/sam/pdf/topics/explanatory_note_new_techniques_agricultural_biotechnology.pdf#view=fit&pagemode=none)

EC news alert Commission's top scientific advisers publish explanatory note on new techniques in agricultural biotechnology, 28.4.2017

<http://ec.europa.eu/research/index.cfm?pg=newsalert&year=2017&na=na-280417>

[www.epsoweb.org](http://www.epsoweb.org)

EPSO Working Group on Agricultural Technologies: [www.epsoweb.org/agricultural-technologies-wogr](http://www.epsoweb.org/agricultural-technologies-wogr)

Statements drafted by this group and approved by the EPSO representatives are for instance:

- EPSO updated statement on [Crop Genetic Improvement Technologies](#), 12.01.2017
- EPSO: [First reaction on the Advocate General's Opinion regarding mutagenesis and the Genetically Modified Organisms Directive](#), 18.1.2018
- EPSO: [Opinion on the SAM Explanatory Note on New Techniques in Agricultural Biotechnology](#), 15.9.2017
- EPSO: [Synthetic Biology should not be confused with the application of new breeding techniques](#), updated statement, 30.8.2017
- EPSO: [Comment on the report of the Ad Hoc Technical Expert Group on Synthetic Biology](#), 8.3.2018, [original report of the AHTEG and all submitted comments](#).

