



## **EC roadmap regarding the legislation for plants produced by new genomic techniques (NGTs)**

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25.10.2021

EPSO submitted to the DG SANTE public consultation to the Roadmap (Inception Impact Assessment, IIA) regarding the legislation for plants produced by certain new genomic techniques (NGTs).

EPSO has previously contributed to the European Commission (EC) study on new genomic techniques (published on 29 April 2021) [1] and agreed with the general conclusions made in the study. EPSO welcomes the initiative taken by the Commission to adjust the regulation on NGT and promote NGT for plant breeding in the European Union (EU). Taking into account recent and ongoing research activities, EPSO would like to provide the following feedback to the Inception Impact Assessment (IIA):

- **Criteria for sustainability should refer to all techniques and approaches, and not only NGTs.**
- **Risk assessment for NGT products should be proportionate**
- **Labelling and requirements for detection methods should not be barriers in the approval process.**

**Criteria for sustainability should refer to all techniques and approaches, and not only NGTs.**

EPSO agrees with the EC conclusion that plant products obtained from certain NGTs have the potential to contribute to the objectives of the European Green Deal, particularly the related Farm to Fork and Biodiversity strategies and the United Nations' Sustainable Development Goals for a more resilient and sustainable agri-food system. Recent surveys of public opinion in different European countries also indicate considerable support for NGT products that contribute to sustainable development (see e.g. Annex 1, pages 2-3). However, a pre-market sustainability assessment should apply to all products and services to be introduced into the agri-food chain, and not focus on breeding techniques, or NGTs in particular. EPSO is partner of and takes part in the stakeholder consultations run by the EC funded Chicory Innovation Consortium (CHIC) [2]. Experiences from that project show that a detailed pre-assessment of sustainability may pose additional administrative burdens and costs that SMEs will have difficulty affording. Also, a pre-market sustainability assessment requires a market authorisation procedure, which would differ from the regulatory approaches in the rest of the world and therefore would not contribute to international harmonisation.

## **Risk assessment for NGT products should be proportionate**

The European Food Safety Authority (EFSA) has concluded that plants produced by NGTs do not necessarily pose new hazards than plants produced with mutagenesis and conventional breeding techniques [3-5]. EPSO thinks that the risk assessment must be based on scientific evidence and triggered by the quality of the modification (trait) rather than the technology to ensure proportionality; mere speculation should not guide the authorisation process. Even a GMO-lite version that singles out NGTs would cause disproportionalities and cannot solve problems of law enforcement.

## **Labelling and requirements for detection methods should not be barriers in the approval process.**

The European Network of GMO Laboratories and others concluded that it will be challenging to develop event-specific and quantitative detection methods for genome-edited plants with known mutations, and virtually impossible for genome-edited plants harbouring unknown mutations [6, 7]. Also, requirements for detection methods mustn't become a new barrier in the approval process. As pointed out by the starch company Lyckebý, labelling requirements of NGT-products could become a severe hindrance to marketing in the EU (See Annex 1, pages 4-5). Therefore, any labelling requirements should be neutral, fair and proportionate. Opinion surveys indicate that the public wants information about the breeding method, irrespectively of techniques, suggesting that the public opinion does not warrant specific labelling requirements for NGTs only (See Annex 1, pages 2-3).

Web-links and scientific publications referred to:

- 1) [https://ec.europa.eu/food/plants/genetically-modified-organisms/new-techniques-biotechnology/ec-study-new-genomic-techniques\\_en](https://ec.europa.eu/food/plants/genetically-modified-organisms/new-techniques-biotechnology/ec-study-new-genomic-techniques_en)
- 2) Levi, Sebastian (2022): Living standards shape individual attitudes on genetically modified food around the world. In: Food Quality and Preference 95, S. 104371. DOI: 10.1016/j.foodqual.2021.104371.
- 3) David L. Ortega, Wen Lin, Patrick S. Ward, Consumer acceptance of gene-edited food products in China, Food Quality and Preference, Volume 95, 2022, 104374, ISSN 0950-3293, <https://doi.org/10.1016/j.foodqual.2021.104374>
- 4) Chicory as a multipurpose crop for dietary fiber and medicinal terpenes' <http://chicproject.eu>, <https://cordis.europa.eu/project/id/760891>
- 5) <https://www.efsa.europa.eu/en/efsajournal/pub/2561>
- 6) <https://www.efsa.europa.eu/en/efsajournal/pub/2943>
- 7) <https://www.efsa.europa.eu/en/efsajournal/pub/6299>.
- 8) <https://gmo-crl.jrc.ec.europa.eu/doc/JRC116289-GE-report-ENGL.pdf>
- 9) Grohmann, L., Keilwagen, J., Duensing, N., Dagand, E., Hartung, F., Wilhelm, R., Bendiek, J. and Sprink, T. 2019 Detection and identification of genome editing in plants: Challenges and opportunities. Frontiers in Plant Sci: DOI: 10.3389/fpls.2019.00236

*This submission was developed by Jens Sundström with the EPSO Representatives and the EPSO Agricultural Technologies Working Group, based on a dedicated discussion at the EPSO General Meeting July 2021.*

EPSO looks forward to engaging as a major stakeholder with the European Commission, Member States and the European Parliament to achieve a well-balanced policy action on plants derived from targeted mutagenesis and cisgenesis. EPSO will

continue providing scientific input in the course of the consultations with the EC and other stakeholders.

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### Useful links

EC: [Roadmap \(inception impact assessment\) on new genomic techniques](#), 24.9.2021  
EC: [Study on new genomic techniques](#), 29.4.2021  
Court of Justice of the EU: Judgment in Case C-528/16, 25.7.2018. [EN Press Release](#); [Ruling in EN](#):  
Court of Justice of the EU: Advocate General's Opinion in Case C-528/16, 18.1.2018. [EN Press Release: Opinion in English](#)  
Court of Justice of the EU: [Case C-528/16](#)  
EC: [Explanatory Note on New Techniques in Agricultural Biotechnology](#) from EC's High Level Scientific Advice Mechanism, 28.4.2017  
EC [news alert](#) Commission's top scientific advisers publish explanatory note on new techniques in agricultural biotechnology, 28.4.2017

EU Green Deal EC: [A European Green Deal](#), 11.12.2019 → strategies relevant to the plant sector:

- EC: [Farm to Fork Strategy](#), 20.5.2020
- EC: [Biodiversity Strategy for 2030](#), 20.5.2020
- Biodiversity partnership [DRAFT SRIA](#), January 2021
- EC: [EU Forest Strategy for 2030](#), adopted by the 16.7.21 → EC [Press release](#)

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

EPSO Statements on agricultural technologies and on the EU Green Deal are for instance:

- EPSO: [Genome editing – Improving legislation and starting flagships to better address climate, environmental, food and health challenges](#), Report 4<sup>th</sup> informal science and policy meeting, 4.10.2021
- EPSO: [Repurposing agricultural support to transform food systems' FAO, UNDP and UNEP Report – will be discussed at EPSO concepts workshop 26 October 2021](#), 16.9.2021
- Opinion paper: [Designing the Crops for the Future: The CropBooster Program](#) – mobilize the European plant research community and all interested actors in agri-food research and innovation to face the challenge, 30.7.2021
- EPSO: [Genome editing – Improving legislation and starting flagships to better address climate, environmental, food and health challenges](#), Report 3<sup>rd</sup> informal science and policy meeting, 16.2.2021
- EPSO: [Statement on the Draft Strategic Research and Innovation Strategy by the Biodiversity Partnership Consortium](#), 29.1.2021
- EPSO statement [Nobel Prize awarded to E Charpentier and J Doudna for genome editing](#), 7.10.2020
- EPSO statement ['Detecting a point mutation does not clarify its origin'](#), 9.9.2020
- EPSO statement [EFSA draft opinion on directed mutagenesis](#), 25.6.2020
- EPSO: [Statement on the Farm to Fork Strategy by the European Commission](#), 2.6.2020
- EPSO statement [EC study on New Genomic Techniques \(NGTs\)](#), 27.5.2020
- EPSO: [Contributions from plant science towards Nutritional Security and human health](#), Draft Statement, 11.5.2020
- EPSO statement [Farm to Fork Strategy by the European Commission](#), 2.6.2020
- EPSO statement on the [French draft decree on mutagenesis](#), 8.7.2020
- EPSO [Submission to the EC consultation on EU research and innovation missions \(FP9\)](#), 30/03/2018, based on the [Mazzucato report](#), welcoming the mission concept and offering to help further develop and implement it as it highlights similar principles we proposed in the [EPSO position on FP9](#) (19.9.2017). EPSO suggest three mission ideas: 1) 1001 Crops – diverse crops for diverse diets and human health and sustainable production, 2) Planty Food – Sustainable agriculture for sustainable food, and 3) Green Bio-Factories – New bioactives for pharma, cosmetics, food and fine chemicals. [Completed online questionnaire. Online questionnaire](#)

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

EPSO member institutes and universities: [www.epsoweb.org/membership/members](http://www.epsoweb.org/membership/members)

EPSO representatives: [www.epsoweb.org/membership/representatives](http://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 32 countries, mainly from Europe, and 2.700 individuals Personal Members, representing over 26 000 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 including science advice to policy, 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. <https://epsoweb.org> | EU Transparency Register Number 38511867304-09