**Statement**

**EPSO statement on the European Commission’s legal proposal for a Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed ....**

*Brsussels, 5.11.2023*


The European Plant Science Organization (EPSO) welcomes the legislative proposal by the EU Commission for the regulation of New Genomic Techniques (NGTs). EPSO sees the move towards a proportionate, more product-based regulatory environment, with evaluation on a case-by-case basis, as an important step into the future. Clearly the Commission, through its Impact Assessment and consultations, has taken the views of diverse stakeholders and sectors into account in developing the proposal. EPSO acknowledges that the legal proposal constitutes a balanced compromise between different stakeholder views. If it is adopted in its current form, the legal proposal will enable Category-1 NGTs (NGT1), which cannot be distinguished from conventional plants produced by random mutagenesis, to make a substantial contribution to the Farm-to-Fork and Biodiversity Strategies under the EU Green Deal.

EPSO supports most of the proposal’s content, especially the quasi-equivalence of NGT1 plants with conventionally bred ones and the omission of additional labelling issues beyond the labelling of seeds. The new regulation will also be in line with already-existing laws based on science that are found in other countries.

EPSO has identified a few elements in the legal proposal that need further clarification or that could be refined to make the legal proposal more future proof.

1. **Criteria for determining the status of NGT1 plants**

The criteria for determining whether a plant can be classified as an NGT1-plant are specified in Annex I to the legal proposal. According to the definitions, an “NGT plant is considered equivalent to conventional plants when it differs from the recipient/parental

1 [https://epsoweb.org/download/23-07-06_epso_1st_reaction_ec_proposal_nts/?tmstv=1688649797](https://epsoweb.org/download/23-07-06_epso_1st_reaction_ec_proposal_nts/?tmstv=1688649797)
“plant by no more than 20 genetic modifications...” EPSO acknowledges that a delimitation, such as a maximum number of allowed modifications, will make it clear for both developers and the national competent authorities whether or not a plant falls in category NGT1. The proposed number, 20, is derived from estimates of how many genetic changes a breeder can expect to obtain using conventional breeding methods. However, plant genomes differ considerably in size and complexity and crop species vary greatly in their levels of genetic diversity (heterozygosity). The number of expected genetic changes that can be obtained using conventional breeding methods, moreover, will vary between different species if the number of changes is counted on the whole genome. For example, the model species *Arabidopsis thaliana* is diploid \( (n=2) \), two basic sets of chromosomes) and has a genome size of 125 megabases (Mbp). However, barley is diploid but with a genome size of 5,100 Mbp, whereas bread or common wheat (*Triticum aestivum*) is hexaploid \( (n=6) \) and has a genome size of 15,600 Mbp. The evident difference in genome size in these two species will allow for a larger total number of genetic changes to occur in bread wheat during conventional breeding using, e.g. random mutagenesis. Potato is tetraploid \( (n=4) \), resulting from two doublings to produce four highly similar chromosome sets; a maximum of 20 changes across the genome would be in practice equivalent to at most 5 per basic genome. Strawberry, however, is octoploid \( (n=8) \), derived from four distinct chromosome sets brought together by hybridization. Even in conventional breeding, 20 changes would easily be exceeded in strawberry through use of wild relatives in crop improvement.

Equally important, because selection (which is an inherent part of all conventional breeding methods) will act on two alleles in Arabidopsis or barley, but on four in potato, six in bread wheat, and eight in strawberry. Hence, the number of changes needed to achieve a favourable genetic change will also be progressively higher in each of these crops. **EPSO suggests that the maximum number of targeted genetic changes allowed in NGT1 plants (20) should be counted per basic set of chromosomes** (e.g., one of the six sets in bread wheat) to compensate for differences in genome size and complexity between different plant species.

### 2. Field trials

According to the proposed legislation, the NGT1 plant status declaration should be obtained before any deliberate release, including placing on the market or carrying out field trials in a member state (Articles 16 & 17). The verification of NGT1 status will be valid in the whole Union and includes field trials and commercial applications. The verification procedure of NGT1 plant status prior to field trials should be conducted by national competent authorities, and a decision should be taken at the Union level only if there are comments to the verification report by other national competent authorities (Article 18).

**EPSO believes that the legislation should enable a simplified approval system for field trials for scientific purposes.** Often, field trials are carried out to verify that the induced genetic changes lead to the expected traits under agricultural conditions and to establish whether additional traits appear. It is therefore important that the proposed legislation does not create additional administrative burdens when field trials are undertaken for scientific purposes. EPSO therefore proposes that the verification of NGT1 status prior to a field trial for scientific purposes and having limited temporal and spatial scale should only require a simplified procedure at the relevant national level. It should not be possible for a Member State to block field trials in other Member States if the national competent authorities in those countries have verified the NGT1 status of the lines tested. For field trials targeting e.g. the preparation of market releases, the procedure as described in the draft regulation should be followed. It is nevertheless essential that the documentation required for any field trial review process is the same
for all Member States and that the criteria for consideration of the NGT1 status of plants are strictly scientific.

3. Exclusion of NGT1 plants from organic farming practices

The suggested legislation prohibits the use of NGT1 plants in organic production (Article 23). It does not present science-based reasoning for the prohibition. NGT1 plants are considered equivalent to conventionally bred plants; many of the NGT1 traits that can be envisaged will be of direct benefit to organic farmers as well, who often lack effective plant protection alternatives. For instance, NGT1-induced resistance to late blight in potatoes could reduce the need for chemical plant protection measures by 90% in conventional agriculture and enable organic farmers to grow potatoes without substantial yield losses.

For the benefit of organic farming, EPSO strongly recommends that excluding NGT1 category plants should not be part of this legislation. Organic farming organisations may choose to abstain from using NGT1 plants, which are equivalent to conventionally bred plants, and that should be stipulated only in their own regulations, allowing a choice for organic farmers and consumers.

The exclusion of NGT1 plants from organic farming practices would have a negative effect on European agricultural research. Under the current European research-funding programme, Horizon Europe, most of the calls of relevance to plant biology and plant breeding stipulate that the funded research should be applicable to both organic and conventional agriculture. The legislative exclusion of NGT1 plants from organic farming would, in practice, discriminate against, or prevent, the use of new genomic techniques in research proposals, as the proposals would need to create two independent research streams, organic and conventional. EPSO thinks the combination of the NGT1 exclusion and the Horizon Europe call stipulations will have, therefore, a negative impact on agricultural research and innovation because it will limit the positive contributions NGT1 plants can have on the Farm-to-Fork and Biodiversity Strategies under the EU Green Deal.

This statement was developed by Jens Sundström and Alan Schulman (chairs EPSO Agricultural Technologies WG) with Odd Arne Rognli (EPSO President) and Karin Metzlaff (EPSO Executive Director), based on discussions at the EPSO General Meeting June 2023 and the EPSO Agricultural Technologies Working Group meeting April 2023.

EPSO offers to collaborate with policy makers to develop appropriate future-ready regulations that enable the European public sector, small- and medium-sized companies and farmers to contribute more comprehensively to food and nutritional security and to use all available tools to reduce the environmental impact of agriculture. Notwithstanding the technical options retained, EPSO supports a science-based revision of the present European legislation establishing a more proportionate product-based risk assessment. EPSO is also willing to contribute to the societal debate on genome editing and to communicate in a fact-based and yet accessible manner about innovative plant science and its societal role.

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^2 [https://pub.epsilon.slu.se/id/document/20416457](https://pub.epsilon.slu.se/id/document/20416457)
Useful links

EC:
- EC legal proposal for a Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed & Annexes, 5.7.2023
- Consultation on the Horizon Europe – interim evaluation (europa.eu) (1.12.022 – 23.2.2023)
- Consultation towards the impact assessment of policy options on New Genomic Techniques (NGTs) (29.4.-22.7.2022)
- High level event on "New genomic techniques – the way forward for safe and sustainable innovation in the agri-food sector", 29.11.2021
- Sustainable food system framework initiative – Inception Impact Assessment, 28.09.2021
- Roadmap (inception impact assessment) on new genomic techniques, 24.9.2021
- 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:
- Advocate General’s Opinion in Case C-528/16, 18.1.2018. EN Press Release: Opinion in English

EPSO (www.epsoweb.org) on EC strategies, Food and Nutritional Security:
- EPSO’s Tree and Forest Biology and Biotechnology Working Group – statement on Future research needs, 25.9.2023
- EPSO statement on Nutritional security and announcement 4th Workshop ‘Addressing the Nutritional Security goal in the context of climate change’ in Milano on 13-14 September 2023 – registration deadline 20.6.2023; 31.5.2023; updated 12.7.2023
- EPSO: Healthy Plants for a sustainable production – statement by the EPSO ‘Plant Health’ Working Group, 11.7.2023
- EPSO: first reaction to the EC’s legal proposal for a Regulation of the European Parliament and of the Council on plants obtained by certain NGTs and their food and feed", 6.7.2023
- EPSO: Genome editing - Improving legislation and starting flagships to better address climate, environmental, food and health challenges, Report, 7.3.2023
- EPSO: Contributions from plant research & innovation on the past, present & future of the European Research & Innovation Framework Programmes 2014-2027, 21.2.2023
- EPSO submission to the European Commission’s consultation on the impact assessment of policy options regarding the legislation for plants produced by certain new genomic techniques (NGTs), 2.12.2022 [22.7.2022 Contribution ID: ad1dcdf3-3ce9-44e9-af12-054d72d75b94]
- EPSO first reaction to the statement from EFSA regarding “Criteria for risk assessment of plants produced by targeted mutagenesis, cisgenesis and intragenesis”, 20.10.2022
- EPSO: Healthy Plants for a sustainable production – draft statement by the new EPSO ‘Plant Health’ Working Group, 5.4.2022
- EPSO submission to the EC’s consultation on the roadmap regarding the legislation for plants produced by novel genomic techniques (NGTs), 25.10.2021
- 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 welcomes the EC’s study regarding the status of novel genomic techniques (NGTs) under European Union law, 30.4.2021
- EPSO: Statement on the Farm to Fork Strategy by the European Commission, 2.6.2020
- EPSO: Statement on the EC study on New Genomic Techniques (NGTs), 27.5.2020
- EPSO: Statement on the Court of Justice of the EU ruling regarding mutagenesis and the GMO Directive, 19.2.2019
EPSO member institutes and universities: www.epsoweb.org/membership/members
EPSO representatives: www.epsoweb.org/membership/representatives

Surveys
- The Norwegian Biotechnology Advisory Board (2020).
  - Questionnaire available upon request
- First outcome from the Swedish survey was presented at our meeting - link to the report (in Swedish)
- Survey on NGTs in Finland - report: Blog
- ETH study in Switzerland: Angela Bearth, ETH / CH
  - The video of a workshop: https://geneticresearch.scnat.ch/en/events/uuid/i/4b5f727d-b532-5e04-8b79-02fd2f78c-CRISPR_and_food_production

About EPSO
EPSO, the European Plant Science Organisation, is an independent academic organisation that represents around 200 research institutes, departments, and universities from 31 countries, mainly from Europe, and 2,600 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.