

## Position Paper on the legislative proposal on plants obtained by New Genomic Techniques

- **The Commission's proposal on New Genomic Techniques (NGTs) has the potential to enable all actors, including SMEs and public researchers, to bring more resilient and sustainable plants to the EU market. This supports investment in plant breeding innovation in the EU and enhances competitiveness and sustainability of European agriculture.**
- **An enabling EU framework must provide clear and science-based criteria to determine the equivalence between NGT-derived plants and their conventional counterparts; a simplified verification process allowing all actors to commercialise products; and proportionate authorisation requirements, especially for products for which a detection method cannot be developed.**
- **The European agricultural sector urgently needs a proportionate and science-based regulation on NGTs. Allowing their uptake in the EU will facilitate the transition towards a more sustainable and resilient agriculture. Achieving this requires swift action from the European Parliament and Council.**

### Context

With more targeted genetic changes in comparison to earlier breeding methods, New Genomic Techniques (NGTs) enhance the precision and efficiency of plant breeding. Plant improvements that would take years through conventional breeding can now be obtained faster and more precisely with the use of modern plant breeding methods without compromising safety or quality. Potential target agronomic traits to benefit from a more efficient breeding process include disease resistance, increased stress tolerance, nutrient efficiency, and enhanced nutritional profile.

In the EU, products developed through NGTs are currently regulated under the GMO legislation<sup>1</sup>, despite the fundamental differences between NGTs and transgenic plants. NGT products which do not contain foreign genetic material, and which could be obtained via conventional breeding or naturally occurring mutations, urgently need an adapted legal framework.

In 2021, a Commission report concluded that the GMO rules were not fit for purpose for certain NGT products. This proposal<sup>2</sup> aims to address the important implementation challenges of the existing framework, the barriers it poses to innovation in NGTs in the EU, and the negative impacts on the competitiveness of EU agriculture. The proposed Regulation aims to maintain high safety standards, enable the development and commercialisation of NGT plants, and ensure the effective functioning of the internal market.

### The Commission's proposal is a step in the right direction

The Commission's proposal is an important first step towards a science-based and proportionate regulatory framework for NGT plants. The approach that some NGT plants are equivalent to

<sup>1</sup> Directive 2001/18/EC, Regulation (EC) 1829/2003, Regulation (EC) 1830/2003, Regulation (EC) No 1946/2003, and Directive 2009/41/EC

<sup>2</sup> <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=COM:2023:411:FIN>

conventionally bred plants and should not be treated as GMOs has been widely adopted by other regions. As a result, this has the potential to reduce regulatory divergence with Europe's main trading partners and support the competitiveness of EU agriculture.

To enable the development and adoption of NGTs in the EU, three factors must be addressed in the final legislation:

- 1- **Science-based criteria:** proportionate, science-based criteria to determine which NGT plants fall under category 1 (conventional-like) and can therefore be exempted from GMO requirements.

The most appropriate criterion for establishing equivalence with conventional plants is the absence of foreign genetic material in the final product. The Commission's proposal of a limit of 20 modifications to determine equivalence with conventional plants is highly conservative and more restrictive than that of most third countries.

These limitations are not representative of what can happen in a plant's genome through conventional breeding or in nature. It would restrict, for example, the development of important traits such as resistance to abiotic stresses (e.g. drought tolerance), which are complex and impacted by many genes. Moreover, crops such as wheat, which have more complex genomes, would have limited potential to benefit from NGT innovation if such a conservative limit is applied.

**Our proposal is to increase the number of modifications allowed under category 1, giving due consideration to the complexity of certain genomes, to allow different crops equal opportunities to benefit from the accelerated development of a diversity of traits in the EU.**

- 2- **Simplified verification process:** the verification process to determine a product's category must be streamlined, predictable and simplified. This will allow all actors to bring to the market diverse products needed to achieve sustainable agriculture.

The proposed verification process for category 1 products, conducted by national authorities as proposed by the Commission, remains relatively complex compared to those of other jurisdictions. Even though it has the potential to significantly reduce costs of commercialisation of NGT plants compared to GMOs, the proposal leaves the door open to potential misuse. Determining that one comment submitted by a Member State or the Commission during the verification process can trigger a comitology procedure risks unnecessary delays and politicisation of technical aspects, increasing uncertainty and costs.

**The integrity of the process can be maintained by ensuring that the verification process is carried out by national authorities, which should be responsible for handling any questions or concerns raised by Member States or the Commission.**

- 3- **Proportionate authorisation requirements:** to reap full benefits of science and innovation and to be commercially viable for farmers, the NGT category 2 products for which a detection method cannot be developed should also be exempted from GMO traceability, labelling, and coexistence requirements.

Existing challenges in the enforceability of traceability, labelling, and coexistence requirements of certain NGT products will remain unresolved if the new framework continues to apply such requirements to category 2 NGT products for which an analytical method for sampling, detection, and quantification cannot be developed. This would occur when NGT products are indistinguishable from conventional plants.

**We therefore support the exemption of category 2 NGT plants for which a detection method cannot be developed from GMO traceability, labelling, and coexistence requirements to enable their development for EU farmers and cultivation needs.**