

CropLife Europe's Position Paper on the use of New Genomic Techniques in plants

Key Messages

- **New Genomic Techniques (NGTs) can contribute to the Green Deal objectives by enabling and accelerating the development of resilient plant varieties for sustainable food production.**
- **In the EU, the regulatory framework for NGT products is not fit for purpose. The current rules hinder the development and availability of NGT products for European farmers, and negatively impact EU innovation and competitiveness.**
- **CropLife Europe calls on the European Commission and EU policymakers to drive forward an enabling and science-based regulatory framework for plants developed through NGTs by establishing a process to determine their regulatory status on a case-by-case basis.**

Context

Techniques used to alter the genetic material of an organism are defined as genomic techniques. The European Commission refers to these techniques as “new” if they have been developed after 2001, when the EU’s legislation on genetically modified organisms (GMOs) was adopted.

In the EU, products developed through new genomic techniques (NGTs) are regulated under the GMO legislation.¹ In its recently published study on NGTs², the European Commission concluded that this framework is not fit for purpose for some NGTs and their products, resulting in clear implementation challenges and negatively impacting innovation in NGTs in the EU.

A new approach with focus on plants will therefore be proposed by the European Commission to address existing shortcomings and enable the development and uptake of NGTs in the EU, while ensuring the protection of human and animal health and the environment.

NGTs improve the efficiency of plant breeding

NGTs enhance the precision and speed of plant breeding thanks to more targeted genetic changes in comparison to earlier breeding methods. Plant improvements that would take decades to be achieved through conventional breeding may now be obtained faster with the use of new techniques.

The improvements in breeding made possible by NGTs do not imply different outcomes. NGTs can produce similar plants with similar risk profiles as those resulting from conventional breeding, as concluded by the European Food Safety Authority (EFSA)³ and the European Federation of Academies of Sciences & Humanities (ALLEA)⁴. In fact, the current EU framework has faced significant implementation and enforcement

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

² https://ec.europa.eu/food/system/files/2021-04/gmo_mod-bio_ngt_eu-study.pdf

³ Applicability of the EFSA Opinion on site-directed nucleases type 3 for the safety assessment of plants developed using site-directed nucleases type 1 and 2 and oligonucleotide-directed mutagenesis: <https://www.efsa.europa.eu/en/efsajournal/pub/6299>

⁴ ALLEA Symposium report: Genome Editing for Crop Improvement. October 2020. https://allea.org/wp-content/uploads/2020/10/ALLEA_Gen_Editing_Crop_2020.pdf

challenges related to the detection and differentiation of NGT products that do not contain any foreign genetic material.

To meet the Green Deal objectives, a complete toolbox is needed

NGTs have great potential to contribute to sustainable agri-food systems, in line with the Green Deal objectives. Ambitious reduction targets for fertiliser and crop protection use, and the rapid erosion of available conventional crop protection products, present EU farmers with big challenges, create competitive disadvantages, and reinforce the need for reliable alternatives such as NGTs.

New genomic techniques could allow breeders to obtain resilient varieties more quickly and affordably. The target traits include pest resistance, increased stress tolerance, nutrient efficiency, and enhanced nutritional profile. The development of resilient plant varieties allows a more sustainable use of crop protection products as well as other inputs, delivers more stable yields under climatic changes, and contributes to healthy diets.

Innovation in plant breeding continues to gain international prominence in light of the advances in science, the growing population, climate change, and increasing scarcity of natural resources such as arable land and water. EU agriculture requires access to a complete toolbox to face such challenges and meet the Green Deal objectives.

The current framework hinders the development and uptake of NGTs in the EU

In the EU, NGTs are currently regulated under the GMO legislation. This means that plants developed through NGTs must undergo a stringent assessment even in cases where they are identical, or similar, to conventional plants, which are not subject to such risk assessment requirements.

Applying different regulatory oversight to similar products with similar risk levels is not justified. The existing policy hinders the development and uptake of NGTs due to the delays and regulatory burden placed on developers and operators, without offering gains on safety grounds. The current framework puts EU farmers, academics and research institutions at a competitive disadvantage vis-à-vis their counterparts in other countries and jeopardises the EU's sustainability goals.

CropLife Europe calls on the European Commission and EU policymakers to take action and drive forward an enabling and science-based regulatory framework for plants developed through NGTs in the EU.

A future-proof framework can only be science-based

The regulation of products developed through NGTs should be proportionate to the risk such organisms pose to human and animal health, and to the environment. As concluded by ALLEA⁵ and the European Academies Science Advisory Council⁶, a plant's regulatory status should be based on the plant's features, rather than the technique used to generate them.

CropLife Europe calls for the establishment of a process to determine the regulatory status of plants developed through NGTs based on their characteristics. This would enable a proportionate regulatory oversight that excludes from the GMO legislation plants obtained with NGTs if these are similar to those obtained by traditional breeding or spontaneous processes. Such a case-by-case approach is needed to bring EU regulation in line with that of other geographies. It would reduce the uncertainty and regulatory burden for food and feed chain operators while ensuring consumer safety. It would also enable access to innovative technologies and products for breeders, farmers, processors, traders and scientists in Europe. A future-proof framework must be based on science and ready to accommodate its continuous progress.

⁵ <https://allea.org/academies-report-reviews-debate-on-genome-editing-for-crop-improvement/>

⁶ https://easac.eu/fileadmin/PDF_s/reports_statements/Genome_Editing/EASAC_and_New_Plant_Breeding_Techniques_July_2018_final.pdf
CropLife Europe - Position Paper on Plant Breeding Innovation