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G6 Statement on the European Commission's proposal for a regulation on Plants obtained by certain new genomic techniques

On 5 July 2023, the European Commission proposed a major revision of the regulation of plants obtained by certain new genomic techniques (NGT). The six major research organisations of the G6 network very much welcome this proposal, particularly its focus on state-of-the-art scientific evidence and a proportionate risk benefit approach. NGT plants derived through either targeted mutagenesis or cisgenesis provide opportunities for European scientists to advance basic understanding while addressing major environmental challenges in Europe and beyond. Here, G6 experts provide additional scientific context to their earlier 14 July 2023 G6 statement[1].

We welcome the European Commission proposal since it will restore the capacity and competitiveness of European plant science to again contribute to strategically important areas by using NGT plants, examples of which include:

- **Advancing fundamental knowledge of plant biology**. Our ability to exploit plants as our principal food source will critically depend on an increased understanding of biological processes (the capacity to routinely conduct field trials being an essential component of it).
- **Ensuring food security in a time of climate change.** NGT plants have the potential to address food insecurity caused by accelerated changes in abiotic conditions like fluctuations in rainfall and changes in temperature, accompanied by increased incidences of drought, salinity, floods, and heat stress.
- **Increasing sustainability**. NGT crops have the potential to contribute to the important goal of reducing the use of fertilizers (through improved efficient nitrate and phosphate use) and pesticides. Drought tolerant crops could also play a major role in conserving water while maintaining agricultural yields.

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[1] https://www.helmholtz.de/assets/g6/Downloads/202307_G6_Task_Force_NGT_Statement.pdf

- **Improving the lives of citizens through the generation of speciality crops.** The capacity to efficiently and precisely develop crops for groups of citizens with particular needs could greatly improve the lives of consumers e.g. the 1.0%[2] of EU citizens that suffer from celiac disease. Further examples include NGT varieties with reductions in allergens and toxins.

Compared to conventional breeding methods, NGT approaches are faster, more precise and prevent unnecessary modifications of the genomes, thus enabling the necessary rapid and targeted development of new plant varieties and products with improved performance.

Definition of NGT1 plant category

Annex 1 is at the core of the proposed regulation, as it defines the key Category-1 NGT (NGT1). While being supportive of the Commission's proposal, the G6 sees a strong evidence base indicating that its utility could still be significantly enhanced without negatively impacting safety.

The limitation of NGT1 to 20 modifications lacks a scientific basis, given the magnitude of modifications (hundreds or even thousands) routinely introduced by natural spontaneous events, already permitted by biotech approaches (e.g. tissue/protoplast culture) or untargeted induced mutagenesis (ionization and chemical techniques). This is particularly the case for polyploid plant species that contain multiple copies of the same chromosome and where a targeted modification will introduce a change not at two sites like in diploid species but at 4, 6, or 8 depending on the ploidy[3]. Moreover, failing to expand the limit of 20 modifications will restrict the capacity to manipulate traits controlled by large numbers of genes simultaneously, limiting the effectiveness of NGT1 plants to combat conditions such as celiac disease[4] or drought tolerance.

NGT1 should be expanded to include cisgenic plants obtained by untargeted gene introduction, but which show no interruption of endogenous genes. As these plants do not bear any additional risk compared to hybridization within the breeders' gene pool5, they should be considered comparable to conventional plants.

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[2] Mustalahti, K. et al. (2010): The prevalence of celiac disease in Europe: Results of a centralized, international mass screening project https://doi.org/10.3109/07853890.2010.505931

[3] For example, commercial strawberries are octoploid and have 8 copies of each chromosome, so targeted modification of a single gene would currently count as 8 modifications. This means that only a maximum of 2 genes in a strawberry variety could be modified (3 x 8 is greater than 20), while in a soya plant which has only two sets of chromosomes 10 distinct modifications would be permitted.

[4] Sánchez-León, S. et al. (2018): Low-gluten, nontransgenic wheat engineered with CRISPR/Cas9 https://doi.org/10.1111/pbi.12837

[5] EFSA Panel on Genetically Modified Organisms (GMO) (2012): Scientific opinion addressing the safety assessment of plants developed through cisgenesis and intragenesis https://doi.org/10.2903/j.efsa.2012.2561

Detectability and identification of NGT plants

There are methods available to detect NGT plants or products thereof whose genetic modifications at the DNA level are known. This holds true even for single-nucleotide polymorphisms[6]. However, such methods are more complex than those for transgenic plants and they need to be optimized for each relevant genome editing event. Due to the biological equivalence with untargeted induced or spontaneous mutations, legally reliable proof of the use of NGT is only conceivable for exceptional cases with large insertions or where very closely and exclusively linked polymorphisms are present. Plants with unknown genetic modifications are at present neither detectable nor identifiable as NGT events, which entails a lack of control of these modifications with consequences on labelling and trade issues to be discussed elsewhere.

The role of field trials for science and crop improvement

The ability to conduct experimental field trials beyond the confinement of greenhouses is currently obstructed by the existing regulatory system. Field trials are essential for a realistic evaluation of the performance of a new trait in real-world conditions. They are not only necessary to develop new commercial varieties, but are also crucial for scientists to expand their understanding of fundamental plant biology. The dynamic and changing conditions in the open environment, such as temperature fluctuations, soil types, and pest pressures, help researchers gain insights into the intricate relationships between genes, traits, and environmental factors. They also provide a more accurate representation of the trait's stability and consistency and help generate more robust and adapted plant varieties, ensuring that the traits function optimally and reliably in real-world agricultural settings.

Since 2015, only 71 trials have been permitted in the EU, whereas the corresponding number in the USA is 4312[7]. This difference of 60 times more trials in the USA represents a substantial loss of innovation potential for Europe. The USA is already benefiting from the kind of regulatory changes proposed by the Commission that streamline the permit application for low-risk scenarios.

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[6] Pallarz, S. et al. (2023): Reproducibility of next-generation-sequencing-based analysis of a CRISPR/Cas9 genome edited oil seed rape. https://doi.org/10.1016/j.fochms.2023.100182.

[7] For data concerning the number of field trials in the EU, please see: List of SNIFs submitted to the Member State's Competent Authorities under Directive 2001/18/EC, accessable via https://webgate.ec.europa.eu/fip/GMO_Registers/GMO_Part_B_Plants.php For the corresponding data from the USA, please see: https://www.aphis.usda.gov/brs/data/BRS_public_apps.csv

NGT plants compared to conventionally bred plants

Genetic modifications occur naturally billions of times in the wild, on farmland through natural reproduction and in breeding facilities and typically lead to new varieties. The unexpected and the unknown are already accepted as inherent outcomes of standard plant propagation. Compared to conventional breeding using untargeted induced mutagenesis, plants modified through NGT do not pose any greater risks. Therefore, we encourage policymakers and consumers to embrace the possibilities offered by these techniques. Potential risks to the environment and human health are determined by the traits produced and how they interact with the environment. Thus, risk assessment should be based on the features of the organism itself rather than of the techniques leading to its generation.

NGT and organic farming

In Article 5 and elsewhere in the proposed regulation it is indicated that no NGT plants, unlike plants obtained by random mutagenesis, can be used in organic farming[8]. However, the current state of science neither indicates an elevated risk as stated above nor negative impacts of NGT on farming. Conversely, the restriction of their use would preclude organic farmers from the benefits arising from their deployment (e.g., better control of new diseases and abiotic stresses, reduction of the use of highly polluting copper-based antifungal compounds or targeted improvement of local and traditional varieties). This would contribute to the increase in productivity of organic agriculture production and support the Farm to Fork Strategy's target of 25% of agricultural land under organic farming by 2030.

In any case, the decision on the use of such plants should be left to organic operators and any provision in this regard would be better placed in the specific sector regulation together with other provisions.

NGT impact on ecosystems

The possibility to incorporate newly developed NGT varieties that more efficiently utilize soil nitrate and phosphate would reduce the need to apply excess fertilizers. This would also include reducing pollution of waterways and contributing to the 2030 target of reducing fertilizer use by at least 20%. Considerable progress has already been made using NGT1 permissible techniques, to develop crops with reduced susceptibilities to pathogenic fungi, nematodes, viruses, and bacteria. Such crops can simultaneously reduce disease risks for farmers while contributing to the 2030 target of a 50% reduction in pesticide application.

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[8] These concerns have been expressed by the majority of the organic sector regarding compatibility of NGT with the current concept of organic production as can be found in the regulation (EC) 2018/848 and current consumers' perception of organic products.

Consequently, a flexible EU legislation for research on NGT would strongly promote the political efforts to reduce soil pollution and detrimental environmental effects on ecosystems and to reach the goals of the EU Soil Strategy 2030.

NGT contribution to the entire agricultural (innovation) system

NGT offer significant advantages in accelerating the exploitation of genetic diversity to address major challenges of today and in the future. The new regulation of NGT would be a major step forward, but will only be effective, if Europe continues and enhances a full innovation landscape for sustainable agriculture. The G6 network is confident that NGT will play a substantial role in securing a future-proof, agile and climate-resilient agricultural system based on the best genotypes, particularly if the parts of the proposal ensuring the flexibility to incorporate future scientific developments into regulations are retained.

The G6 network (http://www.g6-research.eu) unites six large multidisciplinary European Research Performing Organisations with a total annual budget of 15.6 billion euros and over 140,000 employees: the Consiglio Nazionale delle Ricerche, the Centre National de la Recherche Scientifique, the Consejo Superior de Investigaciones Científicas, the Helmholtz Association, the Leibniz Association, and the Max Planck Society.