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# EU legal proposal for genome-edited crops hints at a science-based approach

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**The European Commission (EC) recently published a legislative proposal that hints at a science-based approach to the regulation of genome-editing applications in crops in the EU. This would be in line with legislation in an increasing number of countries worldwide, but further science-based advice on implementation will be essential.**

## The European Commission acknowledges the potential of genome editing for sustainable and resilient food systems

On 5 July 2023 the EC published its legislative proposal on plants derived from new genomic techniques (NGTs) to enable the potential of genome editing for crop improvement to contribute to sustainable food systems. The proposal hints at a more science-based and differentiated approach for the regulation of genome-editing applications in crops in the EU by proposing to categorize NGT plants resulting from targeted mutagenesis and cisgenesis into two distinct categories: 'conventional-like' and 'genetically modified organism (GMO)-like'. The EU regulatory approach would be more in line with the regulatory guidelines and legislation in an increasing number of countries, and creates a framework that would more readily allow 'conventional-like' NGT crops to be placed on the market in the EU. However, the impact of some legal aspects and details remains unclear, and science-based advice on the implementation will be essential for the legal proposal to deliver its objectives.

With the European Green Deal and the Farm to Fork Strategy, the EC set out an ambitious political agenda to facilitate the transition towards more sustainable and resilient agri-food systems in Europe that could become an international reference[i]. This is more important than ever owing to the climate challenges that agricultural production is facing, resulting in crop failures and reduced yields. The current worldwide situation has demonstrated the fragility of globalized food systems and the need to make agriculture more climate-resilient. Several interlinked aspects such as advances in research and technology on the one hand, followed by public perception and societal awareness on the other, finally leading to policy decisions, will determine how these challenges will be tackled over time.

Plant breeding innovation has shown its ability to contribute to more sustainable agriculture through the development of improved plant varieties and shortening the development time for new plant varieties. Plant breeding practices have evolved over time, and new plant breeding techniques are helping plant breeders to increase their efficiency in reaching specific plant breeding goals. Genome editing is one of these new plant breeding techniques that enables the efficient, precise, and time-saving introduction of desired genetic variation encoding specific beneficial characteristics in plants [1]. As a result, some genome-edited crops are more resistant to pests and diseases, have improved tolerance to stressful weather conditions, give higher yields, or have improved nutrient- and water-use efficiency, which are all beneficial to the environment, farmers, and consumers.

In 2018, however, the Court of Justice of the EU (CJEU) ruling in case C-528/16 confirmed that all organisms resulting from mutagenesis are GMOs, and that only organisms resulting from mutagenesis techniques that have conventionally been used and have a history of safe use are exempted from the GMO directive. The EC interpretation of this ruling is that organisms resulting from modern targeted forms of mutagenesis are subject to the GMO provisions. The current EU GMO legislation *de facto* blocks the cultivation and marketing of GM crops in the EU, and field trials of genome-edited crops are very limited owing to the current, complex regulatory process. Under this GMO legislation, genome-edited crops are considered to suffer the same fate, leading to a situation in which a crop with a genetic change produced by a conventional breeding technique, including random mutagenesis, is exempted from the provisions of the GMO legislation, whereas a crop with the same genetic change obtained through targeted mutagenesis is confronted with an insurmountable GMO regulatory hurdle. This is considered to be a scientifically unjustified discrimination that limits the potential of genome editing for the development of improved plant varieties in Europe.

The EC has acknowledged that the GMO legislation is not fit for purpose for some plants derived from NGTs and needs to be adapted to reflect scientific and technological progress because some new plant varieties have the potential to contribute to sustainable agri-food systems. Based on its detailed study, the EC therefore proposed in 2021 to initiate a policy action on plants produced by targeted mutagenesis and cisgenesis, aiming for appropriate regulatory oversight of the plants and plant products concerned while ensuring a high level of protection of human and animal health and the environment, and also enabling innovation[ii].

## The European Commission's legal proposal envisages two new regulatory categories for plants derived from genome editing

After a robust impact assessment, the EC published on 5 July 2023 its long-awaited legislative proposal for the regulation of plants derived from NGTs[iii]. The proposed regulation, which would be applicable in all member states, could be considered a *lex specialis* because it creates a derogation for NGT plants without changing the current GMO legislation. In contrast to plants resulting from conventional random mutagenesis, NGT plants are not exempted from the GMO legislation. Instead, specific provisions are introduced that make a distinction between two NGT plant categories: 'conventional-like' (category 1) and 'GMO-like' (category 2), as summarized in Table 1.

Category 1 NGT plants are 'conventional-like' NGT plants harboring genetic changes that could also occur spontaneously or by conventional breeding, including random mutagenesis. These plants will be subject to a verification procedure based on 'conventional-like' criteria and will be exempted from the requirements of the GMO legislation, and no further risk assessment or detection methods will therefore be required. For a field trial, the verification procedure is performed by the relevant national authority. Should another EU member state raise an objection to the proposed verification decision by that national authority, then the verification decision is lifted to the EC level. To ensure transparency, category NGT plants will be listed in a public database and in the EC Common catalogue of varieties of agricultural plant species and of vegetable species (https://food.ec.europa.eu/plants/plant-reproductive-material/plant-variety-catalogues-databases-information-systems_en), and seed bags will need to be labeled appropriately to enable freedom of choice by farmers.

Category 2 NGT plants are all other NGT plants that do not fulfill the 'conventional-like' criteria. For these plants, the requirements of the current GMO legislation would still apply. This implies that they are subject to risk assessment, including traceability and labeling requirements. Authorization would require a proportionate and adapted risk assessment on a case-by-case basis, and a unique detection method will not be mandatory if it is demonstrated that it is not possible to develop such a method. Interestingly, incentives would be offered to applicants who are small- and medium-sized enterprises (SMEs) or if the traits would contribute to sustainability for category 2 NGT plants, including a fee waiver for the validation of detection methods and more extensive pre-submission advice. Furthermore, member states will not be able to use the 'opt-out' option to disallow cultivation of this category of plants on their territory. On the other hand, for category 2 NGT plants, member states are required to formulate measures to prevent the unintentional presence of such plants in products that are not subject to the GMO legislation.

The proposal hints at a more science-based and differentiated approach to the regulation of genome-editing applications in crops in the EU. It would create a regulatory environment that would more readily allow 'conventional-like' NGT crops to be developed, cultivated, and marketed in Europe. The EU legislation would also become more in line with legislation in other parts of the world, thereby avoiding large problems in international trade. For 'GMO-like' category 2 NGT plants, the main bottlenecks remain strict food and feed safety testing, labeling, and traceability requirements according to the GMO legislation which are likely to block the development, cultivation, and marketing of these category 2 NGT plants in

Table 1. Regulatory categorization of plants in the EU including the NGT legal proposal

| | Conventional plants | NGT category 1 plants: 'conventional-like' | NGT category 2 plants: 'GMO-like' | GMOs 'transgenic' | Annex IB GMOs 'exempted' |
|---|---|---|---|---|---|
| Process/product | Classical breeding techniques | Equivalent to conventional plants (cf. conventional-like criteria) | Not equivalent to conventional plants | Transgenesis | Mutagenesis (and other GMO Annex IB techniques) |
| Risk assessment | No[a] | No | Adapted GMO risk assessment | Full GMO risk assessment | No |
| Labeling | No | Seed bag labeling | GMO labeling and traceability | GMO labeling and traceability | No |
| Detection method | No | No | Yes (if a unique method is available) | Yes | No |
| Variety testing and registration | Yes | Yes | Yes | Yes | Yes |
| Organic farming | Yes | No | No | No | Yes |
| Cultivation opt-out | No | No | No | Yes | No |
| Coexistence measures | No | No | Yes | Maybe allowed | No |

[a]Verification procedure.

the EU, despite the SME and sustainability incentives that apply to this category.

## Response of stakeholders to the legal proposal and the way forward

The plant science network European Sustainable Agriculture through Genome Editing (EU-SAGE) and many other actors in the agri-food value chain welcome the EC proposal as a reasonable starting point for a new regulatory framework, even though the introduction of the two additional categories of plants creates a relatively complex regulatory situation. There are also outstanding questions regarding several details in the proposal, including the interpretation of the 'conventional-like' criteria, among others. The interactive, publicly accessible EU-SAGE database (https://www.eu-sage.eu/genome-search) of genome-edited crop plants as described in peer-reviewed scientific publications has revealed that most of the genome-editing applications in crops are small genetic changes which belong to the so-called SDN-1 (site-directed nuclease 1) category. This needs to be further studied, but presumably most of the plants generated using SDN-1 technology would fall into category 1 NGT plants [2].

The fact that for category 1 NGT plants the number of genetic changes would be restricted to 20 has consequences particularly for polyploid crops in which each alteration to an allele of a gene is counted as one, instead of counting all alterations to a single gene as one. In addition, low-gluten, celiac-safe wheat developed through genome editing would be regulated as a category 2 NGT plant because it has alterations in many gluten-related genes, thereby limiting its benefit for consumers because of the regulatory burden[iv]. In addition, the EC also proposes to consider off-target genetic changes under the limit of 20 genetic changes, even though the European Food Safety Authority (EFSA) concluded that off-target effects are of the same nature as genetic changes resulting from conventional breeding [3].

There is a need to clarify and interpret the conventional-like criteria in a science-based manner and to see that this is uniformly applied. Given that genome editing has been used in 70 different crops, and most of the introduced traits improve food and feed quality, agronomic aspects, or disease resistance, the differentiated regulatory framework should allow a wider diversity of genome-edited crops and traits to be developed for European agriculture (Figure 1). Scientists will have an important role in the upcoming period to provide science-based advice to decision makers on the potential and practicalities of plant genome editing and the legal framework.

The publication of the legal proposal by the EC is only a first step. According to the legislative process, the European Parliament and member states represented through the European Council are in a position to discuss, adapt, and potentially put a proposal to vote, which will still take a considerable amount of time. However, in view of the challenges of climate change and the lengthy process of developing and releasing a new plant variety to the market, there is no time to waste for policy makers. Europe should join the increasing number of countries that follow a differentiated, science-based, and efficient regulatory approach.

The EC legal proposal on NGTs could have a considerable impact on the European plant research and breeding sector, seed companies, farmers, and vegetable growers. The EU is now at a critical juncture to choose which innovative technologies will be available to help farmers to meet the challenges of climate change, to improve sustainability, and to protect biodiversity while leaving no one behind. The upcoming policy decisions in Europe will determine how genome editing in plant breeding can contribute to the green transition.

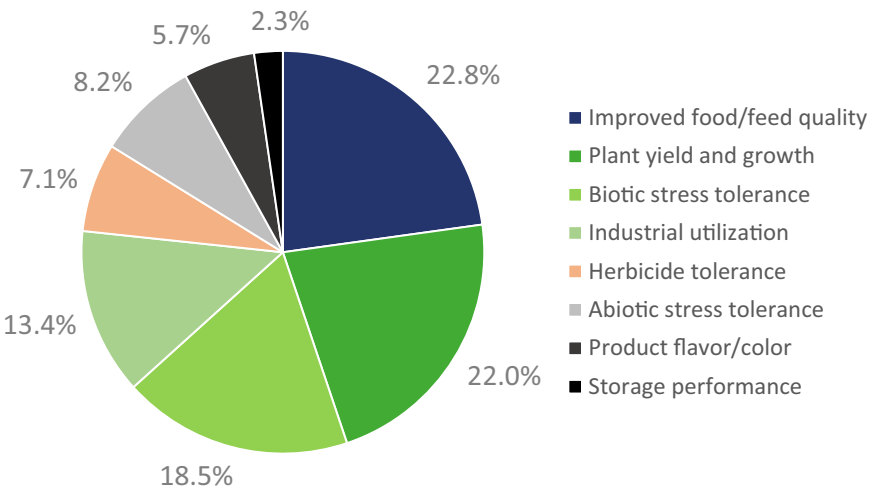


Figure 1. Distribution of traits of genome-edited crops in the European Sustainable Agriculture through Genome Editing (EU-SAGE) database. Status: September 2023. *N* = 784 research studies.

## Declaration of interests

The authors declare no competing interests.

## Resources

[i]https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal_en

[ii]https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques_en

[iii]https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023PC0411

[iv]https://data.europa.eu/doi/10.2760/280847

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