Plants generated by new genomic techniques: Update

EU paves way for new regulation applying in 2028

On 4 December 2025, after a long and rocky road and under the stewardship of the Danish presidency of the Council of the European Union (EU), the Council of the European Union and European Parliament reached a provisional agreement in trilogue negotiations on rules establishing a legal framework for new genomic techniques. The agreement was subsequently endorsed by the member states on 19 December 2025 and opens the way for some NGT plants in the EU market while preserving the possibility to patent NGT plants and plant material.

Background

At stake in trilogue negotiations was a new legislation that would differentiate between two categories of plants obtained by new genomic techniques (NGT), which include gene editing using CRISPR/Cas. These categories are:

- **Category NGT 1 plants**, defined as NGT plants that could also occur naturally or by conventional breeding, would be exempt from the strict requirements of the genetically modified organism (GMO) legislation.[1]
- **Category NGT 2 plants**, defined as all other NGT plants, would continue to be subject to the current GMO legislation. That is, they would be subject to risk assessment and authorization prior to market approval, and would have to be traced and labelled as GMOs.

The European Parliament entered the trilogue negotiations with a proposal that would require a public online list of all NGT 1 plants, implement strict labelling requirements on all NGT 1 plants and plant materials, and, crucially, **ban all patenting** of NGT plants, plant material, parts thereof, genetic information, and the process features they contain, regardless of which of the two new categories they may belong to. All protection would have had to be obtained via variety protection, where a full breeder's exemption applies and where NGT plants would face the developing and somewhat unclear rules on essentially derived variants (EDVs).

The Council of the EU on the other hand came to the trilogue negotiations with a draft that would **permit patenting**, but would require an applicant wishing to obtain NGT 1 status for a plant or plant material to provide **a written statement identifying both product patents and process patents covering or confirming an absence of patents covering the plant**. The Council's proposal did not intend for labelling requirements, but also envisioned a public online list of all NGT 1 plants.

Details on both proposals can be found in MAI*insight* volume 2[2] and in a side-by-side comparison of the EU Commission's (original), Council of the EU's, and European Parliament's drafts in track changes at *https://data.consilium.europa.eu/doc/document/ST-7448-2025-INIT/en/pdf*.

Trilogue negotiations began on 6 May 2025 and did not go smoothly, with the positions of the European Parliament and Council of the EU diverging significantly on such key points as labelling and patenting of NGT plants. Indeed, a trilogue meeting scheduled for 30 June 2025 had to be postponed after a group of members of the European Parliament, led by French Social Democrat Christophe Clergeau, withheld approval in the lead Committee on the Environment, Climate and Food Safety (ENVI) and accused both the Council and Commission of refusing to consider concessions on product labelling and a patenting ban for NGT plants.

Nevertheless, when Denmark took on the presidency of the Council of the EU on 1 July 2025, it set itself the ambitious goal to see trilogue negotiations through to success within its six months term. Yet the Danish presidency prevailed and managed to conclude the trilogue negotiations with a provisional agreement at 1:30 am on 4 December 2025.

The Committee of Permanent Representatives of EU Member States approved the agreed upon text on 19 December 2025 with a qualified majority. Germany abstained, while Belgium, Bulgaria, Croatia, Austria, Romania, Slovenia, Slovakia, and Hungary opposed the deregulation. The eleven countries supporting the agreed upon text represent about 67 % of the EU member states and about 66 % of the EU population.

The agreed upon proposal

The agreed upon text strongly resembles the Council's proposal[3]. If implemented in the agreed upon form, as in the original drafts, NGT plants would be divided into two distinct classes that would create **two distinct pathways to the EU market**.

NGT 1 plants (which could also occur naturally or by conventional breeding and which must comprise less than 20 genetic modifications resulting from NGT) would be **subject to a verification procedure to be performed by national authorities**, based on set criteria. There would be a list of intended traits that would be excluded from the NGT 1 category, which list would include tolerance to herbicides and *»production of a known insecticidal substance«*. Even if an NGT plant containing such traits could occur naturally or by conventional breeding, it would automatically be treated as an NGT 2 plant. Given the rather limited number of scenarios in which such exclusion traits could be created in a plant while meeting the other NGT 1 criteria, the exclusionary list may however not have too great an impact on eligibility of candidate plants.

Provided that they meet the verification criteria and are not excluded by the exclusion criteria, the NGT 1 plants would be treated like conventional plants, i.e., would be **exempt from the rather strict requirements of the GMO legislation of the EU**. Offspring of the once verified NGT 1 plants would not require further verification rounds. NGT 1 plants would however remain prohibited in organic farming.

[1] *https://food.ec.europa.eu/plants/genetically-modified-organisms/gmo-legislation_en*
[2] MAIinsight Vol. 2, 2025, p.3-7.
[3] *https://data.consilium.europa.eu/doc/document/ST-6426-2025-INIT/en/pdf*

There would be **no general GMO labeling requirement for NGT 1 plants and products**, while NGT 1 seeds and other plant reproductive material would have to be labelled.

Under the agreed upon text, there would be **no patenting ban for NGT plants, plant material, parts thereof, genetic information, and the process features they contain**. This follows the release of the long-awaited 149 page long report on the impact of patents on plants by the EU Commission[4], which determined that a patenting ban *»could weaken Europe's scientific base in knowledge-intensive key technologies and pose a serious threat to Europe's long-term competitiveness in plant breeding«* (see page 117, first full paragraph of the report).

However, when an applicant wishes to register an NGT 1 plant or product, it would be required to submit information on all relevant existing patents and pending patent applications, including those by third parties, and this information would have to be included in a publicly available database. It would therefore seem that extensive freedom-to-operate (FTO) analyses would be necessary before applying for exemption.

Applicants would also be able to voluntarily share details on licensing intentions under fair conditions.

It would fall to the EU Commission to oversee transparency and licensing practices related to patents, and provide guidance where needed. The Commission would also assess the impact of patents on breeders' access to genetic material and on farmers' access to plant varieties, with a view to proposing follow-up measures if necessary. To this end, a patenting expert group would be created. The expert group would focus on the effect of patents on NGT plants, composed of experts from all EU member states, the European Patent Office, and the Community Plant Variety Office. The results of the expert group's study would have to be published one year after entry into force of the regulation, although it remains to be seen whether the results would differ from those just published by the EU Commission. The study would also propose follow-up actions and legislation if considered necessary in view of the study results.

All other NGT plants would be considered NGT 2 plants and, **as is the current status quo, would be subject to the strict requirements of the current GMO legislation**, i.e., would have to undergo risk assessment and an authorization procedure before they could be put on the market. NGT 2 plants would also require tracing and GMO labelling (including the option to include a voluntary label to

[4] *https://single-market-economy.ec.europa.eu/document/download/e57a1a6d-9ea7-4f95-8dfd-5c9c36881f78_en?filename=NGT-patent-study.pdf*
[5] Currently, only a single transgenic crop, MON810, a Bt expressing maize conferring resistance to the European corn borer, is approved for commercial cultivation in the European Union, while other GMOs may be imported only for food and feed purposes. MON810 was approved in the EU in 1998.
[6] *https://www.martin-haeusling.eu/artikel/deregulierung-der-neuen-gentechnik-druck-im-trilog-waechst-parlamentsmandat-droht-missachtet-zu-werden?filter_tag[0]=182*
[7] *https://www.europarl.europa.eu/news/en/press-room/20251201IPR31710/new-genomic-techniques-deal-to-support-the-green-transition-in-farming*
[8] *https://euroseeds.eu/news/member-states-endorse-new-genomic-techniques-agreement/*
[9] *https://www.leibniz-hki.de/en/news/dfg-welcomes-eu-agreement-on-new-plant-breeding-techniques.html*
[10] *https://croplifeeurope.eu/ngt-agreement/*
[11] *https://ec.europa.eu/commission/presscorner/detail/en/ip_25_2912*

indicate the purpose of the genetic modification). EU member states would have the option of opting out from the cultivation of NGT 2 plants on their territory even if approved under the GMO legislation and of taking measures to avoid the unintended presence of NGT 2 plants in other products. Given the extremely sparse use of this path to market so far[5], it can be expected that a development focus in Europe would be on NGT 1 plants.

Reactions

The agreed upon text, which does not retain much of the Parliament's diverging positions, has been hard-fought. Some members of the European Parliament feel that the leading negotiator for the Parliament, Jessica Polfjärd from the center-right European People's Party (EPP), *»fail[ed] to defend her mandate with sufficient determination«*[6]. Polfjärd herself however appears quite satisfied with the outcome, stating *»This is a historic day. The EU is taking its first step towards giving farmers access to new, Nobel Prize-winning technology. Technology that will allow them to grow crops that can withstand climate change and deliver higher yields on less land. This is crucial for strengthening our food security. Today's agreement is a breakthrough that boosts not only our farmers' competitiveness, but also Europe's position in research and innovation.«*[7]

While there has been criticism from organic farmers and environmental groups, the agreed upon text has received widespread praise from the general breeding and seed sector as well as from agricultural companies. Garlich von Essen, Secretary General and CEO of Euroseeds, considers the agreed upon text *»a very welcome and encouraging development«* that *» shows that Europe is determined to advance in support of innovation, sustainability and competitiveness.«*[8] The Deutsche Forschungsgesellschaft (DFG) similarly welcomes the NGT agreement, calling it a *»political breakthrough«* that *»strengthens Europe as a research location and opens up new avenues for climate-resilient and resource-efficient agriculture.«*[9] CropLife Europe similarly considers the agreed upon text *»an important milestone in advancing innovation and strengthening the resilience of European agriculture«*.[10]

Outlook

The regulation will be submitted to the European Parliament's Environment Committee in January 2026. If approved as is, it would then be presented for a vote to the European Parliament at large on 9 March 2026. Should the European Parliament adopt the regulation, it would then enter into force on 29 March 2026 and start applying two years later, i.e., on 29 March 2028. According to the Council of the EU, the regulation's implementation will be supported by a monitoring program of economic, environmental, and social impacts of NGT.[11]

It is likely that this new regulation, if adopted, will spur increased innovation in the NGT, and specifically NGT 1, sector in Europe to position breeders and agricultural companies for the opening of the market in 2028. It will be key to bolster new NGT 1 plant products with strong IP portfolios that may include both patents and protected varieties while also monitoring the patent landscape extensively to ensure compliance with the regulations on providing patenting information when applying for NGT 1 status.

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