Plants generated by new genomic techniques

The slow move toward a new regulation for the EU

On 7 February 2024, the European Parliament approved a proposal to **support the cultivation of some plants generated by new genomic techniques** (NGT) in the European Union, **but to ban patents for all plants obtained by such means**.

Under the stewardship of the new Polish presidency, the Council of the European Union, more than a year later, finally succeeded in negotiating with its members on what a resulting law may look like. On 14 March 2025, a qualified majority of the member states approved a new approach that would reinstate the possibility to patent NGT plants that the European Parliament sought to remove.

The NGT proposal accepted by the European Parliament

The proposal accepted by the European Parliament in February 2024 differentiates 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, provided they meet certain criteria in a verification procedure, be treated like conventional plants and be exempt from the requirements of the genetically modified organism (GMO) legislation. A public online list of all NGT 1 plants is intended.
- **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.

Crucially, the accepted proposal would **exempt NGT 1 plants from the strict requirements of the GMO legislation of the European Union**. Currently, only a single NGT 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.

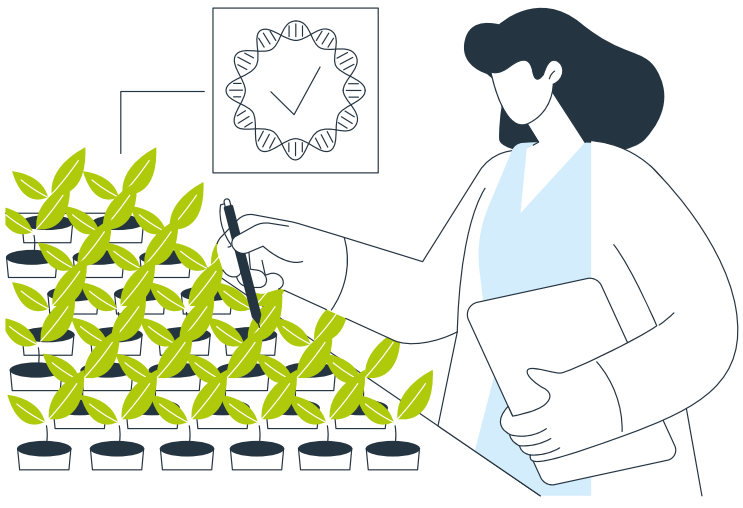
Equally crucially, however, **all patenting would be banned** for NGT plants, plant material, parts thereof, genetic information, and the process features they contain, regardless of which of the two new categories they may belong to.

The European Commission has stated that the accepted proposal not only aims to maintain a high level of protection of health and the environment but also to steer developments towards making a contribution to sustainability goals in a wide range of plant species, especially for the agrifood system, and create an enabling environment for research and innovation, especially for small and medium-sized enterprises (SMEs).

In stark contrast thereto, the accepted proposal – via an amendment introduced during the parliamentary process by the Committee on the Environment, Public Health and Food Safety of the EP – would also establish a ban on all patenting for ›NGT plants, plant material, parts thereof, genetic information and the process features they contain,‹ regardless of which of the two new categories the NGT plants in question may belong to. The accepted proposal also outlines an according amendment to the Biotech Directive 98/44/EC. A report on the impact of patents on breeders' and farmers' access to plant reproductive material, as well as a legislative proposal to update the EU rules on intellectual property rights accordingly, are due by June 2025 (but may well be delayed). The European Parliament has stated in a press release that the ban on patenting intends to ›avoid legal uncertainties, increased costs and new dependencies for farmers and breeders.‹

Outside criticism of the European Parliament's accepted proposal

The accepted proposal, especially the ban on patenting, has drawn ample criticism. Amongst others, Garlich von Essen, the secretary general of the seed industry association Euroseeds and epi, the Institute of Professional Representatives before the European Patent Office, have pointed out that a complete lack of protection for NGT plants in the EU may prevent European companies from investing in the development of NGT plants, because they would not be able to rely on a period of exclusivity in which to recoup their significant development investments.



The Council of the European Union's struggle to gain approval from the member states

For a proposal accepted by the European Parliament to be implemented as new legislation, the Council of the European Union must further approve the proposal in question. After the acceptance of the NGT proposal by the European Parliament, however, the Council of the EU struggled for over a year to make any headway in negotiating the proposal's adoption.

Facing opposition to a patent ban from multiple member states, Belgium, which held the Presidency of the Council of the EU in the first half of 2024, when the proposal was accepted by the European parliament, proposed to **limit the ban on patenting to NGT 1 plants only**. Despite this suggested amendment softening the patent ban, the Council did not reach a majority vote to move the regulatory package forward.

In the second half of 2024, Hungary, a known sceptic of NGT plants, took over the Council Presidency. The Hungarian Presidency's focus seemed to be on slowing any progress of the regulatory package. Instead of discussing the proposed patenting ban (and not mentioning the Belgian presidency's amendment thereof to NGT 1 plants only), this Presidency instead sought changes to the definition of NGT 1 plants due to apparent concerns about, to name just a few, safety, compliance, and labelling requirements. Another apparent concern of the Hungarian presidency was the burden the intended verification process for NGT 1 plants would put on the member states. Whether this was intended as a delaying tactic or not, the Hungarian Presidency succeeded in, once again, preventing a majority vote.

In January 2025, the Presidency of the Council of the EU passed on to Poland, which sought to regain the steam lost under the Hungarian Presidency. Still in January, the Polish Presidency squarely addressed the issue of the patenting ban, which was the key point that had prevented the formation of a majority, with fresh amendments to the NGT regulatory package. A revised draft taking into account feedback from Member States was published on 7 February 2025 and adopted on 14 March 2025.

The initial amendments of the Polish Presidency

Initially, the new amendments proposed by the Polish Presidency **no longer envisioned a patenting ban** (whether for NGT 1 plants only or for all NGT plants) but instead planned to introduce a verification system for the patenting status of plant reproductive material (PRM) of NGT 1 plants. It appeared that, since this verification system would only have been implemented for plant reproductive material only, e.g., harvested material imported into the EU for food and feed purposes would not have to be so verified. Similarly, the verification system would not have applied to other plants, including NGT 2 plants.

The proposed verification system would have required that plant reproductive material of NGT 1 plants covered by patents, whether owned by the party planning to market the PRM or by a third party, be marked accordingly, likely including in the database already envisioned in the regulatory package. The verification system would also have **differentiated between patents covering basic technologies and patents covering plants and processes resulting in a specific plant trait**.

NGT 1 plant reproductive material that is not covered by any patents could have been, upon request, exempted from the marking requirements and placed on the market without further restrictions. Given that exemption would have required a declaration by the party intending to market the PRM, and given that such a declaration would have had to pertain not only to that party's own patent portfolio, but to third party patents as well, extensive freedom to operate (FTO) analyses would likely have been required before applying for exemption.

On the other hand, NGT 1 PRM either protected by patents or not requested to be exempt despite a lack of patent coverage would not have been generally banned from the marked, but the initially proposed amendments foresaw local restriction options. Any individual member state of the EU that so wished could have **either restricted or completely banned commercial cultivation of the respective NGT 1 plants**.

The revised, adopted proposal

The amended draft, published just over a month after the initial version, and adopted five weeks thereafter, simplified the Polish Presidency's approach further:

Instead of the previously envisioned verification process, the party wishing to obtain NGT 1 status for a plant now would have to provide **a written statement identifying both product patents and process patents covering or confirming an absence of patents covering the plant**:

›The requester shall submit a written statement (patent information):

(a) identifying patents for products claiming modifications of biological material resulting in particular traits; or

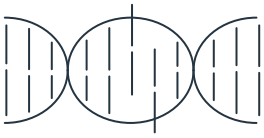
(b) identifying patents for processes claiming modifications of biological material resulting in particular traits; or

(c) confirming the absence of patents referred to in letters (a) and (b).‹

In the same declaration, the party could also indicate a willingness to grant licenses:

›The requester may submit a written declaration of a patent holder confirming his willingness to licence the protected subject under fair, reasonable and non-discriminatory conditions, which is applicable within Union territory (licence declaration).›

However, in the adopted proposal, patent information would have to be provided **for any NGT 1 plant material, not only for plant reproductive material**. That is, information would apparently have to be provided even when importing material for food and feed purposes. This still appears to include even third party patents and applications.



The labelling requirement also was struck from the proposal, but, as also previously intended, **patent information would have to be recorded in the database of NGT 1 plants** maintained by the European Commission.

The adopted proposal also states that tolerance to herbicides cannot be one of the traits for NGT 1 plants. That is, plants with such traits would remain subject to the authorization, traceability and monitoring requirements for NGT 2 plants.

Perhaps most strikingly, the adopted proposal **no longer includes provisions that would enable individual Member States to restrict or ban the sale of NGT 1 PRM locally except in specific organic farming areas with specific geographical conditions**. The Council thus seems to aim at stimulating innovation in the European Union by recognizing the importance of patents.

The adopted proposal has been met with widespread approval by interested parties. Euroseeds' Garlich von Essen called the adopted proposal ›*balanced*‹ and ›a significant step forward‹. Plants for the Future stated in a press release that they ›*applaud this historic milestone*‹ and the European potato trade association Europatat considers the adopted proposal ›*a major step forward in advancing agricultural innovation*‹.

Outlook

Thanks to the Polish Presidency's new approach, the Council of the EU has finally adopted a proposal as of 14 March 2025 and there is a real chance of advancing the NGT regulatory package. On 6 May 2025, the Council of the EU and the European Parliament now need to enter final negotiations (so-called ›trilogue negotiations‹) to arrive at a final proposal that both institutions can adopt before the new regulation can enter into force.

The proposal as adopted by the Council would not ban patenting of NGT plans, but instead require including information on relevant patents or the absence thereof in a central database. Non-patented NGT 1 plant material would be able to enter the market without the strict GMO legislation requirements currently in force in the EU.

The European Parliament however was in favor of a patent ban for genetically modified plants, their genetic information, and their process characteristics. Similarly, the Parliament wants strict labeling requirements on all NGT 1 plants instead of just seeds. Nevertheless, it is possible that the final law may be more similar to the Council's adopted proposal than to the proposal adopted by the Parliament, as the European elections that occurred in June 2024 have changed the Parliament's composition and, possibly, the inclination of its majority. In the same vein, Swedish MEP Jessica Polfjärd from the center-right European People's Party (EPP), a group broadly supportive of biotech innovation, will lead the trilogue negotiations for the European Parliament's side. The Polish Presidency will negotiate for the Council.

A side-by-side comparison of the EU Commission's (original), EU Council's, and EU Parliament's drafts in trackchanges is available at: https://data.consilium.europa.eu/doc/document/ST-7448-2025-INIT/en/pdf

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