Proposal on new genomic techniques

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EU reaches agreement on regulating new genomic techniques

Proposal for a Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625

Annexes to the Proposal

[The text above is the European Commission's original proposal. The provisional agreement is not yet publicly available.]

European Commission (2025) Commission welcomes provisional agreement on new genomic techniques for plants. Press release, 4 December.

Update

New European Union (EU) rules have been agreed on the marketing of crops produced using certain new genomic techniques (NGTs) that change genetic material in plants (European Commission 2025). The new rules classify NGTs in two categories:

- Category 1 NGT plants – that could occur naturally or by conventional breeding – will not be considered as genetically modified organisms (GMOs). They will only have to undergo a verification procedure, and will not need to be risk-assessed and authorised.
- Category 2 NGT plants – where changes to the plant could not occur naturally or through conventional breeding – will have to comply with the GMO rules, including risk assessment and authorisation.

This has been provisionally agreed by the Council of the EU and the European Parliament, and will have to be formally approved.

What is changing?

Scope

The Regulation that has provisionally been agreed applies to plants produced using certain NGTs that do not insert genes from other plants (known as "NGT plants"). The relevant techniques are targeted mutagenesis and cisgenesis (see Background for more detail).

Two categories of NGT plants

The Regulation will establish two categories of plants and related products from NGTs.

Category 1 NGT plants and products

These are considered to be equivalent to plants produced by conventional breeding. They are not considered to be GMOs, and therefore do not have to comply with the general GMO rules (Directive 2001/18/EC and Regulation 1830/2003). For non-EU suppliers, commodities that are category 1 NGT plants may be placed on the EU market in the same way as conventional commodities.

Category 1 NGT plants/products do not require specific labelling or traceability – with the exception of seeds and other plant reproductive materials, which must be labelled as NGT-1 plants.

Products of NGT-1 plants placed on the EU market for the first time must undergo a verification procedure that checks the status of the plant/product, including its equivalence to conventionally bred plants. This procedure does not involve risk assessment or risk management. The European Commission plans to establish a public database that lists decisions on the status of NGT-1 plants.

Plants that are tolerant to herbicides or have known insecticidal effects will **not** be included in category 1. These products will fall under category 2, and thus will be subject to authorisation, traceability, and monitoring (Council of the EU 2025).

Category 2 NGT plants and products

NGT plants that are not equivalent to those produced by conventional breeding must be risk-assessed and authorised under GMO legislation. The Regulation provides some flexibility around risk assessment requirements to take into account the wide variety of NGT plants.

EU Member States are permitted to prohibit the cultivation of NGT-2 plants on their territory. They are also allowed to take specific “coexistence” measures to ensure that non-GMO products do not contain traces of NGT-2 plants by accident (Council of the EU 2025).

Organic production

GMO crops and products may not be produced in organic production. NGT-1 plants are prohibited in organic production. However, the accidental and technically unavoidable presence of NGT-1 plants in organic products would not disqualify them from being considered organic. The European Commission will further assess whether this Regulation creates any administrative, economic, or practical burdens for the organic sector (European Parliament 2025).

Patents

The European Commission will oversee transparency in licensing practices related to patents of NGO plants, and may provide further guidance or follow-up measures in the future.

Why?

The EU's rules on GMOs were adopted in 2001 (Directive 2001/18/EC). Since then, a variety of NGTs have been developed. A 2021 review of GMO legislation concluded that the current rules did not reflect scientific and technological progress, and prevented the development and marketing of NGT products that could be beneficial to farmers, consumers, and the environment (European Commission 2021).

Timeline

The Regulation must be formally adopted by the Council of the EU (Member States) and the European Parliament. It will be published in 2026 and will apply 2 years after publication.

What are the major implications for exporting countries?

This Regulation will allow non-EU suppliers to place NGT-1 plants and products on the EU market without specific traceability or labelling requirements. Only NGT-1 seeds and other plant reproductive material must be specifically labelled as “NGT-1”.

It will provide legal certainty and confidence to suppliers of all commodities/products that NGT category 1 plants can be grown in the exporting country without risk of damaging exports to the EU.

Background

Discussions centre on the distinction between “conventional” genetic engineering and “new” genomic techniques. In conventional genetic engineering, certain traits related to one organism can be transferred into a second organism by inserting entire genes into the genome of another (third) organism. These genes are not targeted, but inserted randomly into the genome.

By contrast, certain NGTs involve targeting individual parts of the DNA (nucleotides) to obtain certain effects, similarly to natural mutations that occur in living cells. NGTs include:

- mutagenesis: modification of the DNA sequence at precise locations in the genome of an organism

- cisgenesis: insertion in the genome of genetic material already present in the breeder's gene pool.

EFSA (2021) concluded that the mutations induced by NGTs can sometimes be comparable to those that occur in conventional plant breeding. This allows the Regulation to distinguish two categories of plants: those where the effects of NGTs could occur in conventional breeding, and those where they could not.

Resources

EFSA (2021) Overview of EFSA and European national authorities' scientific opinions on the risk assessment of plants developed through New Genomic Techniques. EFSA Journal, 19(4): 6314.

European Commission (2021) Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C-528/16.

European Parliament (2025) New genomic techniques: deal to support the green transition in farming. Press release, 4 December.

Online resources from the European Commission:

- Frequently Asked Questions: Proposal on New Genomic Techniques
- Executive Summary of the Impact Assessment Report
- Impact Assessment Report

Sources

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