New EU rules on plant genomic techniques

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EU publishes new rules on plant genomic techniques

Regulation (EU) 2026/1388 of the European Parliament and of the Council of 17 June 2026 on plants obtained by certain new genomic techniques and their products, and amending Regulation (EU) 2017/625

Update

The European Union (EU) has published new rules on the marketing of crops produced using certain new genomic techniques (NGTs) that change genetic material in plants. The new rules classify NGTs in two categories as follows.

- Category 1 NGT plants – that could occur naturally or by conventional breeding – will not be considered as genetically modified organisms (GMOs) and therefore do not have to comply with EU GMO rules. They will have to undergo a verification procedure prior to being put on the EU market, but 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.

What is changing?

Scope

Regulation 2026/1388 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 establishes 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. Annex I of Regulation 2026/1388sets criteria for determining whether NGT plants are equivalent to conventional plants. These products 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).

An exception is NGT products that are considered to be equivalent but have certain environmentally damaging traits: tolerance to herbicides, or production of a known insecticidal substance (Art. 13(a) and Annex II). These products fall under category 2, and thus will be subject to authorisation, traceability, and monitoring.

Category 1 NGT plants/products on the EU market 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, and that it does not have the prohibited herbicide tolerance or insecticidal traits. This procedure does not involve risk assessment or risk management. The European Commission will establish and maintain a public database that lists decisions on the status of NGT-1 plants.

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 and their different risk profiles.

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.

Organic production

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

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

Provisions regulating the sale of NGT plants and products on the EU market will apply from **17 July 2028**. Until then, these products remain subject to the existing EU legislation on GMOs.

What are the major implications for exporting countries?

This Regulation allows 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 provides legal certainty and confidence for suppliers that NGT-1 plants can be grown in the exporting country without risk of damaging exports to the EU.

Background

The Regulation distinguishes 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

Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms

Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms

Sources

Regulation (EU) 2026/1388 on plants obtained by certain new genomic techniques and their products

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