

Proposal on new genomic techniques

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European Parliament adopts negotiating position on 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

Update

The European Commission proposes to regulate the marketing of crops produced using certain new techniques that change genetic material in plants (new genomic techniques, NGTs). The Commission proposes that NGT plants that could occur naturally or by conventional breeding will not be considered as genetically modified organisms (GMOs), so will not need to be risk-assessed and authorised. Other NGT plants, where changes to the plant could not occur naturally or through conventional breeding, will require risk assessment and authorisation under GMO legislation.

The [European Parliament \(2024\)](#) has now agreed its negotiating position, and broadly supports the Commission's proposal. However, the Parliament proposes additional labelling rules for NGT plants that could complicate supply of these products. The Council of the EU (Member States) must also reach a common position before negotiating with the European Parliament on a final text. However, at a meeting of Member States on 7 February 2024, no agreement could be reached, due largely to discussions about whether non-GMO NGT plants may be patented, and the potential impacts of NGTs on organic production ([Euractiv 2024](#)).

What is changing?

Scope

The proposed Regulation applies to plants produced using certain NGTs that do not insert genes from other plants (these are known as "NGT plants"). The relevant techniques are targeted mutagenesis and cisgenesis (see Background section for more detail). The rules apply to food, feed and products containing NGT plants, but not to microorganisms, fungi or animals.

Two categories of NGT plants

The proposal creates two categories of plants and related products from NGTs.

Category 1 NGT plants/products

These are considered 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. **They do not require specific labelling or traceability.**

Products of category 1 NGT plants can only be placed for the first time on the EU market following a verification procedure that checks the status of the plant/product, including its equivalence to conventionally bred plants, and does not involve risk assessment and risk management. [Annex I](#) of the proposed Regulation sets out a list of criteria that determine whether NGT plants can be considered equivalent. The Commission will establish a public database that lists decisions on the status of category 1 NGT plants.

Category 2 NGT plants/products

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

*European Parliament position: Traceability and labelling should be required for **all** NGT plants (including category 1 NGT plants indistinguishable from conventional plants).*

Organic production

GMO crops or products may not be produced in organic production. The Commission proposes that category 1 NGT plants should also be prohibited in organic production, although they do not fall under GMO legislation.

European Parliament position: To prevent economic damage to organic production, the presence of category 1 NGT plants, where “adventitious or technically unavoidable”, should not prevent crops from being considered as organic.

Patents

The European Commission proposal did not include rules related to legal protection of NGT plants.

European Parliament position: Category 1 NGT plants/products (those indistinguishable from conventional plants) may not benefit from patent protection. This would be a derogation (exception) from Directive [98/44/EC](#) which provides legal protection to biotechnology inventions.

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 Council of the EU (Member States) must agree a common position before starting negotiations with the European Parliament. Continued disagreement in the Council raises doubts about negotiations being completed before the European Parliament elections in June 2024.

What are the major implications for exporting countries?

If the Commission's original proposal is adopted, this Regulation will allow non-EU suppliers of products from NGT category 1 plants to place products on the EU market without specific traceability or labelling requirements.

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.

However, there are concerns about the European Parliament's proposal for traceability and labelling of NGT category 1, which could create confusion for consumers since these plants are considered to be equivalent to conventional plants ([COCERAL et al. 2024](#), [PFP 2024](#)).

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 proposal to distinguish two categories of plants: those where the effects of NGTs could occur in conventional breeding, and those where they could not.

There is considerable debate within Europe about whether all NGTs should be subject to the same legislation as conventional GMO techniques. The Commission's proposal has been welcomed by some farm and food industry groups that see NGTs as offering innovative solutions to current farming challenges ([CEJA 2023](#), [Copa-Cogeca 2023](#) [direct download], [FoodDrinkEurope 2023](#)). Organic producers (who are not permitted to produce using GMOs) are concerned that, without stricter traceability and labelling, it may not be possible to segregate NGT and organic plants, and that consumers will not know whether they are eating GMOs ([IFOAM 2023](#)). Environmental groups have expressed concerns that not assessing some NGT plants could compromise consumer safety, and they challenge claims that NGT plants could contribute to sustainable agriculture ([Greenpeace 2023](#), [PAN Europe 2023](#)).

Resources

CEJA (2023) [NGTs proposal: A good step towards enriching farmers' sustainability toolbox](#). Council of Young Farmers Press Release, 5 July.

COCERAL, FEDIOL, and FEFAC (2024) [Vote in Parliament on New Genomic Techniques](#). Press Release, 9 February.

Copa-Cogeca (2023) [Copa and Cogeca welcome European Commission's proposal on NGT-plants and plant and forest reproductive materials](#) [direct download].

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.

Euractiv (2024) [European Parliament adopts its position on gene-edited plants](#). News, 7 February.

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 (2024) [Amendments adopted by the European Parliament on 7 February 2024 on the proposal for a regulation on plants obtained by certain new genomic techniques](#).

European Union (2023) 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 – [Information from the Presidency on the state of play](#).

FoodDrinkEurope (2023a) [EU paves way for new genomic techniques](#).

FoodDrinkEurope (2023b) [FoodDrinkEurope Position: New Genomic Techniques](#).

Greenpeace (2023) [GMO deregulation disregards safety and consumer rights](#). Press Release, 5 July.

IFOAM (2023) [NGT proposal a step backward for biosafety, freedom of choice and consumers' information](#). IFOAM Organics Europe, 5 July.

PAN Europe (2023) [By deregulating new GMOs, the European Commission goes against the will of its own citizens](#). Press Release, 5 July.

PFP (2024) [The European Parliament Adopts Position on New Genomic Techniques](#). Primary Food Processors, 9 February.

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

[Proposal](#) for a Regulation on plants obtained by certain new genomic techniques and their food and feed

[Annexes](#) to the Proposal

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