New genomic techniques: information needed for verification and authorisation

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Two opportunities to comment on future EU rules setting information requirements for the verification and authorisation of plants and products produced with new genomic techniques

Public consultations on:

Plants obtained by new genomic techniques: information requirements and verification of **category 1** status

Plants obtained by new genomic techniques: applications for **category 2** plants and their products

Update

From 17 July 2028, plants and products developed through new genomic techniques (NGTs) may be sold in the European Union (EU) (Regulation 2026/1388). The new rules establish two categories of NGT plants/products:

- Category 1 NGT plants and products are considered to be equivalent to plants produced by conventional breeding. As they are not considered to be genetically modified organisms (GMOs), they do not have to comply with the general GMO rules. They do not have to be risk assessed, but must be verified before being sold in the EU.
- Category 2 NGT plants and products are not equivalent to those produced by conventional breeding. They must undergo risk assessment and authorisation under the existing GMO rules.

The EU will adopt further rules that include the information that operators will need to submit to allow the EU to verify Category 1 NGT plants and products, and to authorise Category 2 ones.

To help develop these information requirements, the European Commission has launched two consultations to gather technical and practical information from stakeholders.

Impacted products

NGT plants and products

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What is changing?

New EU rules on the marketing of crops produced using certain NGTs that change genetic material in plants – without inserting genes from other plants – will apply from 17 July 2028 (see New EU rules on plant genomic techniques). 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 and therefore do not have to comply with EU rules on GMOs. 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 EU GMO rules, including risk assessment and authorisation; however, as NGTs have specific characteristics, special rules apply.

The EU will publish a Regulation on the information that operators will need to submit to allow the EU to verify Category 1 NGT plants and products, and to authorise Category 2 ones. This information will include:

- For Category 1 NGT plants and products – the information needed to demonstrate that a plant or product has Category 1 status, information on patents (published or applications), and the willingness of the patent holder to license their patents.
- For Category 2 NGT plants and products –
  - the methodology and information needed to carry out relevant food and feed safety, and environmental risk assessments
  - the requirements for preparing and submitting notifications and applications for NGT plants and products, and the conditions in which post-market environmental monitoring is not required
  - performance requirements for analytical methods.

Why?

The new NGT rules aim to incentivise and facilitate the development and marketing of safe plants and products obtained using NGTs by lowering market access costs, providing legal clarity, and simplifying rules, with the overall objective of benefiting farmers, consumers, and the environment.

The EU will set harmonised requirements and procedures to ensure a consistent verification process for **Category 1** NGT plants, as verifications will initially be carried out by individual EU Member States.

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Since the risk assessment required for **Category 2** NGT plants provides flexibility according to the characteristics of the product, clear information requirements will help EU Member States to assess applications consistently and reduce the risk of delays in authorisation.

Timeline

Provisions regulating the sale of NGT plants and products on the EU market will apply from **17 July 2028**.

What are the major implications for exporting countries?

These consultations offer an opportunity for operators to highlight the challenges they anticipate, and the measures that could help non-EU operators to participate effectively in the development and marketing of safe plants and products obtained by NGTs.

Recommended Actions

The consultations via the European Commission's Have Your Say platform closed on 28 September 2026. Feedback can be viewed on the platform:

- Plants obtained by new genomic techniques: information requirements and verification of category 1 status
- Plants obtained by new genomic techniques: applications for category 2 plants and their products

Background

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).

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 are inserted randomly into the genome.

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By contrast, certain NGTs involve targeting individual parts of the DNA (nucleotides) to obtain certain effects, similar to natural mutations that occur in living cells. New genomic techniques 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.

Resources

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. Commission Staff Working Document, 29 April.

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

Regulation (EC) No 1829/2003 on genetically modified food and feed

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

Public consultations on:

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