

# Plants obtained by certain new genomic techniques and their food and feed

2023/0226(COD) - 07/02/2024 - Text adopted by Parliament, partial vote at 1st reading/single reading

The European Parliament adopted by 307 votes to 263, with 41 abstentions, **amendments** on the 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.

The matter was referred back to the committee responsible for inter-institutional negotiations.

## *Subject matter*

This proposed regulation, in accordance with the **precautionary principle**, lays down specific rules for the deliberate release into the environment for any other purpose than placing on the market of plants obtained by certain new genomic techniques ('NGT plants') and for the placing on the market of food and feed containing, consisting of or produced from such plants, and of products, other than food or feed, containing or consisting of such plants, ensuring a high level of protection of human and animal health and the environment.

## *Release*

An NTG plant may only be deliberately released into the environment for purposes other than placing on the market, and an NTG product may only be placed on the market if:

- the plant is a category 1 NTG plant that has been the subject of a decision declaring this status;
- the plant is a category 2 NGT plant, and has been granted consent or has been authorised.

## *Ban on all patents filed for NGT plants*

Members included a new article stating that NGT plants, plant material, parts thereof, genetic information and the process features they contain should **not be patentable**. They also request a report by June 2025 on the impact of patents on breeders' and farmers' access to varied plant reproductive material as well as a legislative proposal to update EU rules on intellectual property rights accordingly.

## *NGT 1 plants*

A NGT plant is considered **equivalent to conventional plants** if certain conditions are met. Members, therefore, amend the rules concerning the size and number of modifications needed for a NGT plant to be considered equivalent to conventional plants. The Commission should establish and maintain a **database** listing the decisions declaring the category 1 NGT plant status.

Members called for the database to be publicly available, and in an online format.

Seven years after the entry into force of this Regulation, the Commission should present a report on the evolution of the consumers' and **producers' perception**, accompanied, where appropriate, by a legislative proposal.

## *Labelling*

According to Members, category 1 NGT plants should bear a label indicating the words ‘**New Genomic Techniques**’. In the case of plant reproductive material, it should be followed by the identification number of the NGT plant(s) it has been derived from.

Appropriate document-based traceability for NGTs should be provided by the transmission and holding of information that products contain or consist of NGT plants and product, and the unique codes for those NGTs, at each stage of their placing on the market.

### ***Verification procedure of category 1 NGT plant status***

To obtain the declaration of category 1 NGT plant status, before undertaking a deliberate release of a NGT plant for any other purpose than placing on the market, the person intending to undertake the deliberate release should submit a request to verify whether the criteria set out in Annex I at least one of the traits referred to in Annex III, Part 1, and the exclusion criteria in Annex III, Part 2, are met.

That request should contain information on:

- a description of the trait or traits and characteristics which have been introduced or modified, including information on the technique or techniques used to obtain the trait or the traits and including disclosure of the sequence of genetic modification;
- any patent or pending application for a patent that covers the whole or part of Cat.1 NGT plant.

The other Member States and the Commission may make **reasoned objections** to the verification report, as regards the fulfilment of the criteria set out in Annex I, within 20 days from the date of receipt of that report. In the absence of any reasoned scientific objections from a Member State or the Commission, within this deadline, the national competent authority that prepared the verification report should adopt a decision declaring whether the NGT plant is a category 1 NGT plant. The national competent authority should transmit the decision within **10 working days** to the requester, the other Member States and the Commission.

In cases where a reasoned objection is made by another Member State or by the Commission, the competent authority that prepared the verification report should make the **reasoned objections publicly** available without undue delay.

If the monitoring results show that there is a risk to health or the environment, or if new scientific data supports this hypothesis, the competent authority may **withdraw its decision** declaring whether the NGT plant is a category 1 NGT plant.

### ***Organic production***

Category 2 NGT plants will be banned in organic production. However, it is necessary to clarify the status of category 1 NGT plants for the purposes of organic production.

Currently, the compatibility of the use of new genomic techniques with the principles of organic production requires further consideration. The use of category 1 NGT plants should therefore be **prohibited in organic production**, until such further consideration takes place.

The amended text stipulated that the adventitious or technically unavoidable presence of category 1 NGT plants, reproductive material or parts thereof in organic production, or in non-organic products authorised in organic production in accordance with Regulation (EU) 2018/848, should not constitute non-compliance with that Regulation.

## *NGT 2 plants*

For NGT 2 plants, Members agreed to maintain most of the requirements of the GMO legislation, which is among the strictest in the world, including the authorisation procedure.

In view of the precautionary principle, a monitoring plan for environmental effects should always be required when consent is first given. It should only be possible to waive the requirement for monitoring upon the renewal of consent, provided that it has been demonstrated that the category 2 NGT plant does not pose risks that need monitoring, such as indirect, delayed or unforeseen effects on human health or on the environment.