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**COMMUNICATION FROM THE COMMISSION
TO THE EUROPEAN PARLIAMENT**

pursuant to Article 294(6) of the Treaty on the Functioning of the European Union

concerning the

**position of the Council on 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**

(Text with EEA relevance)

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1. BACKGROUND

Date of transmission of the proposal to the European Parliament and to the Council (document COM(2023) 411 final – 2023/0226 COD):	6 July 2023
Date of the opinion of the European Economic and Social Committee:	26 October 2023
Date of the opinion of the European Committee of the Regions:	17 April 2024
Date of the position of the European Parliament, first reading:	24 April 2024
Date of transmission of the amended proposal:	N/A
Date of adoption of the position of the Council:	21 April 2026

2. OBJECTIVE OF THE PROPOSAL FROM THE COMMISSION

The Commission proposal aims at enabling the development and placing on the market of plants and products obtained by certain new genomic techniques (NGTs) contributing to an innovative, resilient, sustainable and competitive agri-food sector, while maintaining a high level of protection of human and animal health and of the environment.

3. COMMENTS ON THE POSITION OF THE COUNCIL

The position of the Council as adopted at first reading fully reflects the political agreement reached between the European Parliament and the Council on 3 December 2025. The Commission supports this agreement. The main points of this agreement are the following:

- NGT plants have to fulfil two conditions to obtain category 1 NGT plant status: 1) the **criteria of equivalence** of NGT plants to conventional plants (Annex I to the Commission proposal), 2) the NGT plant must **not include certain traits** among the traits conveyed by the genetic modification ('herbicide tolerance' and 'production of a substance with known insecticidal action') set out in Annex II. If an NGT plant does not fulfil those conditions, it will be treated as category 2. The criteria of

equivalence have been amended on several points, while maintaining the essence and scientific robustness of the Commission proposal. The exclusion of certain traits was not in the Commission proposal, but is acceptable as the number of traits on the list is limited and sufficient justification has been provided for the exclusion of such traits.

- The category 1 status verification process includes a requirement for the requester to accompany the request with **scientific evidence substantiating the relation between the introduced genetic modifications and the intended trait**.
- A recital was added to clarify that the emergency measures in the legislation on food, feed and other products also apply to category 1 NGT plants in case the latter are likely to constitute a serious risk to human health, animal health or the environment. This amendment, and the one above, are in line with the logic of the Commission proposal.
- In the context of the Commission's evaluation of the application of the Regulation, the Commission is required to present a report that is to include producers' and consumers' perception of the ban of NGT plants in **organic production**, and to assess the burden on organic operators resulting from the Regulation. A new provision clarifies that the adventitious or technically unavoidable presence of category 1 NGT plants and their products in organic production should not constitute non-compliance with Regulation (EU) 2018/848 on organic production. Those amendments are intended to facilitate the coexistence between organic, conventional and NGT production chains, in line with the Commission proposal.
- Member States are entitled to request **the exclusion of their territory from the cultivation** of category NGT 2 plants and to take voluntary **co-existence measures**. This is compatible with the logic of the Commission proposal, as it aligns the rules for category NGT 2 plants with the existing legislation on GMOs.
- To strengthen sustainability, an article is added to specify the sustainability elements of the **monitoring programme** and the consideration of its outcome in the implementation reports and evaluation provided for in the Regulation, so as to allow the Commission to assess the need for further sustainability measures. Furthermore, a new article provides for **controls** by Member States of compliance with the Regulation. Those modifications strengthen the monitoring provisions of the Commission proposal.
- The empowerment for the Commission to adopt **delegated acts** (instead of implementing acts) on the technical requirements to demonstrate that a plant is a NGT plant and for the preparation of verification requests for NGT 1 plants is acceptable.
- Several provisions related to **patents** were added. These concern:
 - a voluntary **code of conduct** to enhance patent transparency, ensure fair licensing and enhance legal certainty for breeders and farmers, with the Commission overseeing its establishment, monitoring it, evaluating its operation and taking follow-up actions (including of a legislative nature) if necessary;
 - declarations in the context of the verification procedure to determine that a NGT plant is category 1: the requester must **declare patents** relevant for the plant (that the requester or others hold) and keep the information updated, to the best of their knowledge; the requester may also submit a **declaration of the**

patent holder of whether they intend to license NGT plants under fair and reasonable conditions within the Union. If the requester is the patent holder, they must submit such a declaration and a further declaration indicating if they are or intend to become a member of a licensing platform;

- the Commission is required to publish **guidance** to assist operators on intellectual property matters relevant for NGT plants as well as on financial resources and programmes to support related research and development;
- the Commission is required to conduct **an assessment** on the impact of the patenting of NGT plants and examine measures to follow up (if appropriate, submitting a legislative proposal). It must conduct a second assessment if no follow-up measures are taken after the first study;
- the Commission is to set up **an expert group** on the effect of patents on NGT plants, which would assist the Commission in surveying and exchanging information on issues such as access to genetic resources, transparency on patents and innovation in the field of NGT plants. An expert from the Community Plant Variety Office should participate in the expert group;
- **recitals** recall that patents on plants obtained by technical methods do not extend to plants that have been produced by essentially biological processes; explain the rules applicable in the context of possible unintentional infringements of patents by farmers due to cross-pollination; recall the Commission's evaluation of Council Regulation (EC) No 2100/94 on Community plant variety rights; and encourage all Member States to adopt a limited breeders' exemption.

While patent issues are not the subject-matter of the Commission proposal, those modifications address concerns about the potential impacts of patents in the area of plant breeding without amending the substance of Union patent law and are acceptable to the Commission.

4. CONCLUSION

The Commission supports the results of the inter-institutional negotiations and can therefore accept the Council's position at first reading.

5. STATEMENT FROM THE COMMISSION

The Commission has made a unilateral statement set out in the Appendix.

APPENDIX

Statement from the Commission

The European Commission reiterates its full commitment to protecting the functioning of the internal market and the plant breeding sector, in particular small and medium-sized enterprises (SMEs).

To this end, in accordance with the provisions of the compromise agreement, the Commission recalls the following measures included in the text to be adopted by the Council as its position at first reading:

1. The Commission will closely monitor the impact of the NGT regulation on SMEs in the European seed sector, with the objective to avoid that the development of NGT plants, and in particular their patenting, leads to negative impacts on the plant breeding market, such as the exclusion of SMEs.
2. The Commission will oversee the drawing up of a code of conduct which will be ready as soon as possible and no later than 6 months before entry into application of the regulation.
3. The Commission will assess the functioning of licensing platforms and their use by the seed sector, to ensure transparency on patents and facilitated access to licences for SMEs under fair and reasonable conditions.
4. The Commission will ensure that SMEs have access to support and guidance on patent matters relating to plants, in order to balance the relations between different players in the plant breeding market.
5. The Commission will fulfil all its reporting obligations, which include a report on the implementation of the regulation every 5 years (Article 32(1)), an assessment of the impact of the regulation (Article 32(3)), an assessment of the impact of NGT plant patenting practices (Article 31(4)), and a report on the functioning of the code of conduct every 5 years (Article 30(7)).
6. As part of its assessment under Article 31(4), the Commission will consider the appropriateness of updating or supplementing its interpretative notice 2016/C 411/03 on certain articles of Directive 98/44/EC on the legal protection of biotechnological inventions. In particular, the Commission will assess whether it would be appropriate and legally feasible to further precise and clarify the patentability criteria for inventions relating to plant genetic information, the concept of essentially biological processes and the conditions for compulsory cross-licensing set out in Article 12 of that Directive, without prejudice to the legal framework provided for in the Directive and in full compliance with the international commitments of the EU.
7. In the event that the system is not functioning smoothly, in particular as regards SMEs, the Commission will consider, where appropriate, the establishment of mandatory conditions or safeguards as part of the review clause provided for in Article 31(10), in full compliance with the international commitments of the EU.