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NOTE

Subject: 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
- Analysis of the final compromise text with a view to agreement

I. INTRODUCTION

1. On 5 July 2023, the Commission adopted a legislative proposal for a Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques (NGTs) and their food and feed products¹. The proposal was submitted to the Council on 6 July 2023.
2. Since the adoption of the current EU legislation on genetically modified organisms (GMOs) in 2001, there has been substantial progress in the development of NGTs that enable more targeted, precise and faster changes in the genetic characteristics of plants, as compared to conventional breeding techniques.
3. The proposal aims to enable the EU agri-food sector to contribute to the innovation and sustainability objectives of the European Green Deal and Farm to Fork and Biodiversity strategies, and to enhance the sector's competitiveness, while maintaining a high level of protection of health and of the environment.

¹ 11592/23 + ADD 1

4. The proposal is based on Articles 43, 114 and 168(4)(b) of the Treaty on the Functioning of the European Union (TFEU) (ordinary legislative procedure).
5. Both the European Economic and Social Committee (EESC) and the European Committee of the Regions (CoR) were consulted. The EESC delivered its opinion on 26 October 2023². The CoR delivered its opinion on 17 April 2024³.
6. In the European Parliament, the Committee on Environment, Public Health and Food Safety (ENVI) has the lead responsibility, while the Committee on Agriculture and Rural Development (AGRI) is associated. Ms Jessica Polfjård (EPP, Sweden) has been reappointed as rapporteur. The Parliament adopted its position at first reading on 24 April 2024⁴.
7. On 14 March 2025, the Permanent Representatives Committee agreed on a mandate for the Presidency to enter into negotiations with the European Parliament⁵. On 12 November 2025, it provided the Presidency with flexibilities on key open issues⁶.
8. On 6 May 2025, the first trilogue on the file was held under Polish Presidency and gave a broad mandate for interinstitutional negotiations to start at technical level. The second and third trilogues were held under Danish Presidency and provided political orientation for further work on specific issues at technical level. In total, 27 interinstitutional technical meetings (ITMs) took place. The fourth and final trilogue took place on 3 December 2025.

II. ELEMENTS OF THE FINAL COMPROMISE TEXT

9. Several open issues were discussed during the final trilogue. The main elements of the final compromise are presented below. References to recitals, articles and annexes refer to the final compromise text set out in document 16660/25.
10. On sustainability, the European Parliament insisted on the introduction of sustainability-related criteria for NGT plants to qualify for the NGT-1 category, in addition to the criteria of equivalence to conventional plants. The final compromise excludes plants from the NGT-1

² 14926/23

³ 9226/24

⁴ 10952/24

⁵ 6426/25

⁶ 14579/25

category that bear, as intended trait conveyed by the genetic modification, one of the traits on a negative list (or exclusion list) in a new annex to the Regulation (Article 3(7)(a) and Annex Ia).

11. The Council defended its position that the inclusion of any trait on the negative list must be science-based and duly justified. The final compromise contains two traits in the new annex: ‘tolerance to herbicides’, as set out in the mandates of both co-legislators, and ‘production of a known insecticidal substance’, as such plants may have adverse effects on beneficial insects, e.g. pollinators.
12. The co-legislators also agreed to add a focus on the sustainability impacts of NGT plants to the overall monitoring programme on the impacts of the NGT Regulation (Article 30b).
13. A new article on controls by Member States was added to provide reassurance regarding the effective enforcement of the provisions of the NGT Regulation, without introducing new obligations to Member States beyond the control obligations from existing legislation (Article 30c).
14. In light of the above, the Parliament accepted to withdraw its amendments to introduce plant-specific monitoring plans for NGT-1 plants and a provision on withdrawal of NGT-1 status, but asked for the clarification of the existing safeguards to protect human and animal health and the environment in a recital (Recital 22).
15. On patents, the Parliament withdrew its amendments on a full ban on the patenting of NGT plants and a corresponding amendment of the Biotech Directive⁷, in return for a number of safeguards to address concerns it had and which were also partially shared by the Council.
16. To support transparency on patents on plant biological material, breeders’ access to such material and legal certainty for breeders and farmers, the final compromise provides for a Code of Conduct with certain commitments by patent owners and licensing platforms. While the Code is voluntary in nature, the Commission shall exert oversight in drawing up the Code, monitor its functioning and, if appropriate, take further action including legislative measures (Article 29a).

⁷ Directive 98/44/EC on the legal protection of biotechnological inventions.

17. The final compromise text also contains provisions on a declaration on the willingness of patent holders to license on fair and reasonable terms, to be submitted with the verification request for NGT-1 status and made public in the NGT-1 database. This element has been preserved from the Council mandate and further strengthened as part of the negotiations (Articles 6(3b), 7(2b) and 9(1)(fb)).
18. Further elements from the Council mandate that were retained in the final compromise text are the Commission's guidance for the purpose of assisting operators, in particular breeders and farmers, on matters relating to plant intellectual property (Article 29(2a)), the NGT plant patent expert group and the Commission's assessment on the impact of the patenting of NGT plants, traits and techniques as well as related licensing and transparency practices (Article 30a).
19. In response to other safeguards requested by the Parliament, the final compromise text contains clarifications in recitals. They pertain to plants with traits occurring in nature or obtained through essentially biological processes (Recital 46c), unintentional patent infringements (Recital 46f) and the importance of legal certainty for plant breeders in all Member States by guaranteeing the breeders' exemption to ensure access to genetic material for further breeding and avoid restriction of experiment ("limited breeders' exemption"⁸; Recital 46b).
20. On organics, the final compromise text clarifies that the adventitious or technically unavoidable presence of NGT-1 plants or products in organic production shall not constitute non-compliance with the Organics Regulation⁹ (Article 5(2)). Furthermore, the Commission will assess the impact of the application of the NGT Regulation on the organic sector, as part of the overall monitoring programme on the impacts of the NGT Regulation (Article 30(4)). These two elements were introduced in addition to the provision on the ban of NGT-1 plants and products in organic production from the Commission proposal (Article 5(2)) and the recital on appropriate measures in areas with specific geographical conditions, such as certain

⁸ A limited breeders' exemption in this context allows breeders to freely use plant material with patented traits to develop and breed new varieties. If the breeder wants to commercialise a new variety, the consent of the patent holder is required.

⁹ Regulation (EU) 2018/848 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007.

Mediterranean island Member States and insular regions, from the Council mandate (Recital 23a).

21. On traceability and labelling of NGT-1 plants and products, co-existence measures for NGT-2 plants and opt-out from cultivation of NGT-2 plants, the Council defended its position. Labelling in the NGT-1 category is limited to plant reproductive material (Article 10) as set out in the Commission proposal. Co-existence measures for NGT-2 plants remain optional for Member States (deletion of Article 24, existing GMO rules continue to apply to NGT-2 plants). Member States retain the possibility to opt out from cultivation of NGT-2 plants on their territory (deletion of Article 25, existing GMO rules continue to apply to NGT-2 plants).
22. On the criteria of equivalence to conventional plants, the co-legislators had reached a compromise already at the second trilogue, which retains the key elements of both the Parliament mandate and the Council mandate, without being overly restrictive (Annex I).

III. CONCLUSION

23. The Presidency considers that the final compromise reached with the European Parliament is overall balanced and fully respects the mandate it received from delegations.
24. The Permanent Representatives Committee is invited to examine and approve the final compromise text as set out in document 16660/25 with a view to reaching an agreement at early second reading with the European Parliament.
25. This approval would be conditional upon the receipt of a letter from the Chair of the European Parliament's ENVI Committee confirming that the European Parliament can accept the text as set out in document 16660/25 and that, should the Council adopt this text as its first-reading position, the European Parliament would not adopt any amendments to it in its second reading.