Council of the European Union

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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 *- Preparation for the trilogue*

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 products[1]. 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.

[1] 11592/23 + ADD 1

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.

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. 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 Polfjärd (EPP, Sweden) has been reappointed as rapporteur. The Parliament adopted its position at first reading on 24 April 2024[2].

6. On 14 March 2025, the Permanent Representatives Committee agreed on a mandate for the Presidency to enter into negotiations with the European Parliament[3].

7. 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 2023[4]. The CoR delivered its opinion on 17 April 2024[5].

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[2] 10952/24
[3] 6426/25
[4] 14926/23
[5] 9226/24

II. STATE OF PLAY

8. The co-legislators started interinstitutional negotiations with an opening trilogue on 6 May 2025.

9. Following a series of meetings at technical level, a second trilogue took place on 14 October 2025. That trilogue discussed possible ways forward on two key topics on which provisional endorsement could not yet be reached between co-legislators:

   a) the introduction of sustainability requirements for category 1 NGT plants. This is a demand of the European Parliament. The Presidency expressed its willingness to consider compromises that could address the Parliament's request, on the condition that the Parliament shows flexibility on other topics;

   b) provisions on intellectual property rights, in particular patents and their impact on breeders and farmers. The Parliament expressed its willingness to give up its demands for a ban of patents on NGT plants and an amendment of the Biotech Directive[6], on the condition that a number of safeguards are addressed and that the Council shows flexibility on the topic of sustainability requirements.

10. The trilogue of 14 October 2025 tasked the technical level to explore both the options for sustainability requirements and the safeguards for patents, with a view to the next trilogue.

11. On 15 October 2025, the Presidency debriefed Coreper on the outcome of the trilogue. The Presidency informed the Counsellors/Attachés of additional details on the outcome of the trilogue on 16 October 2025, and of the state of play of interinstitutional negotiations at technical level on 29 October 2025, on the basis of a Presidency non-paper[7].

12. In preparation of the next trilogue on 13 November 2025, the Presidency seeks the flexibility of delegations on the two key topics mentioned above, as set out in the following paragraphs.

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6 Directive 98/44/EC on the legal protection of biotechnological inventions.
7 WK 14307/2025 INIT

III. FLEXIBILITY ON SUSTAINABILITY REQUIREMENTS

13. In the Commission's proposal, sustainability criteria are included as regulatory incentives for category 2 NGT plants, based on a list of positive criteria in Annex III, Part 1 and a list of negative criteria in Annex III, Part 2. The Council in its mandate excluded tolerance to herbicides as an intended trait from the NGT-1 category. The European Parliament in its mandate indicated that plants can only be verified as category 1 NGT plants if they meet at least one of the positive criteria in Annex III, Part 1 and none of the negative criteria in Annex III, Part 2.

14. The trilogue on 14 October 2025 concluded that three options for a possible compromise should be explored at technical level. The fulfilment of the criteria to establish equivalence to conventional plants in Annex I to the Regulation remains a condition for NGT-1 status in each of these options:

    a) "Positive list": NGT-1 status should be conditional on compliance with (at least one) sustainability criteria as set out on a broad, dynamic and non-exhaustive positive list of traits;

    b) "Negative list": NGT-1 status should be conditional on not having any of the exclusion criteria as set out on a negative list of traits;

    c) "Incentives": NGT-1 status should not be conditional on compliance with sustainability criteria, but these (positive) criteria/traits will be used as a trigger for incentives, such as comparatively shorter timelines in the verification procedure ("fast-track"), and highlighting of plants in the NGT-1 database.

15. Given the views expressed by Member States and the European Parliament, it is the assessment of the Presidency that the second option, a "negative list", is the only option capable of constituting the basis for a compromise.

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16. The point of departure for the Presidency is to include herbicide tolerance in line with the spirit of the Council mandate. The Presidency would in principle not be opposed to adding more items to the negative list, but these would have to be limited and duly justified.

17. The Presidency is seeking the flexibility of delegations on the possibility of adding a negative list as a condition for NGT-1 status as described above.

IV. FLEXIBILITY ON PATENTS

18. The issue of patents was not addressed in the Commission's proposal. The European Parliament in its mandate introduced a full ban on the patenting of NGT plants and an amendment of the Biotech Directive to this effect. The Council in its mandate reached a balanced compromise consisting of elements on transparency, guidance and monitoring.

19. The trilogue on 14 October 2025 concluded that it should be explored at technical level how to address a number of safeguards put forward by the Parliament, with a view to reaching a compromise.

20. The Presidency considers that certain requested safeguards are addressed by existing legislation and practices, or by provisions in the Council's mandate:

    a) The Parliament requested a safeguard to protect farmers' rights to save and replant seeds covered by a patent ("farmers' privilege"). This is addressed in the Biotech Directive[8] with a reference to the Plant Variety Rights Regulation[9], and with the same extent and conditions of the farmers' privilege in both acts.

[8] See Article 11(1).
[9] Regulation (EC) No 2100/94 on Community plant variety rights; see Article 14.

b) The Parliament requested a safeguard that patents should not be granted for genetic sequences or characteristics that occur in nature or that can be achieved through conventional breeding methods without technical invention. This is addressed through the practice of the European Patent Office to either refuse such patent applications, or to ensure with a "disclaimer" that the protected subject-matter does not extend to plants obtained by essentially biological processes.

c) The Parliament requested a safeguard for more legal certainty as to which traits are protected by a patent. This is addressed in the Council's mandate, through the requirement of an obligatory submission of a statement on the presence or absence of patents or patent applications ("patent information"), as well as through an obligation for the Commission to publish guidelines for the purpose of assisting operators, in particular breeders, in navigating the plant intellectual property landscape.

d) The Parliament requested a safeguard to prevent market concentration and ensure fair competition, particularly for SMEs. This is addressed in the Council's mandate, through the requirement to establish a patent expert group to survey and exchange information as regards the effect of patent law and the implementation practice on access to modified genetic resources, transparency of the patent landscape and innovation in the field of NGT plants. The reports from the expert group shall be taken into account in the Commission study on the impacts of patents and if appropriate, may lead to the presentation of legislative proposals.

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21. The Presidency considers that certain other requested safeguards require the introduction of additional text in the NGT Regulation in order to reach a compromise with the Parliament:

a) The Parliament requested a safeguard for a licensing system to be available under fair, reasonable and non-discriminatory conditions. This is taken up in the Council's mandate through the requirement for a voluntary declaration of the willingness to license the protected trait under equitable conditions. However, it could be significantly strengthened by tasking the Commission to exert oversight of existing licensing platforms to ensure that certain expectations are met (licensing conditions, scope, performance, terms of membership etc.), possibly in the form of a "Code of Conduct".

b) The Parliament requested a safeguard for guaranteeing the breeders' exemption to ensure access to genetic material for further breeding and avoid restriction of experiment ("limited breeders' exemption"[10]). This is provided for in the Agreement on a Unified Patent Court (UPCA)[11], which 18 Member States have implemented. Similar provisions exist in national patent law in several Member States. However, the Parliament has requested to extend the application of a limited breeders' exemption to all Member States.

22. The Presidency is seeking the flexibility of delegations on the suggested approach to address the safeguards requested by the European Parliament, as set out in paragraph 21.

V. CONCLUSION

23. In light of the above, delegations are invited to indicate their possible flexibilities on the options and approaches as outlined in paragraphs 17 and 22.

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10 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.

11 See Article 27(c).