

Brussels, 8 April 2026
(OR. en)

Interinstitutional File:
2023/0226 (COD)

17037/25
ADD 1

AGRI 736
AGRILEG 210
ENV 1429
PI 233
CODEC 2178

DRAFT STATEMENT OF THE COUNCIL'S REASONS

Subject: Position of the Council at first reading with a view to the adoption of a Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their products, and amending Regulation (EU) 2017/625
– Draft Statement of the Council's reasons

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. 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).

¹ 11592/23 + ADD 1

3. 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.
4. 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.
5. The proposal and the relevant impact assessment were presented at the meeting of the Working Party on Genetic Resources and Innovation in Agriculture (Innovation in Agriculture) on 10 July 2023. The Working Party continued the examination of the proposal in 16 further meetings under the Spanish, Belgian, Hungarian and Polish Presidencies.
6. On 14 March 2025, the Permanent Representatives Committee agreed on a mandate for the Presidency to enter into negotiations with the European Parliament⁵. On that basis, negotiations took place with the European Parliament and the Commission with a view to an early second reading agreement. On 12 November 2025, the Permanent Representatives Committee provided the Presidency with flexibilities on key open issues⁶.
7. Trilogues were held on 6 May, 14 October, 13 November and 3 December 2025 under the Polish and Danish Presidencies. The co-legislators reached an overall provisional agreement in the last trilogue. That agreement was subsequently consolidated into a final compromise text.

2 14926/23
3 9226/24
4 10952/24
5 6426/25
6 14579/25

8. On 19 December 2025, the Permanent Representatives Committee analysed the final compromise text and confirmed the agreement⁷.
9. On 28 January 2026, the European Parliament's ENVI Committee voted in favour of the final compromise text. On 28 January 2026, the Chair of the ENVI Committee addressed a letter to the Chair of the Permanent Representatives Committee⁸ stating that, should the Council transmit to the European Parliament its position as agreed, subject to legal-linguistic revision, he will recommend to the Plenary that the Council's position be accepted without amendments at Parliament's second reading. The text annexed to the letter corresponds to the text supported by the Permanent Representatives Committee on 19 December 2025.

II. OBJECTIVE

10. 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.
11. 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.

⁷ 16659/25, 16660/25

⁸ 6131/26

III. ANALYSIS OF THE COUNCIL'S POSITION AT FIRST READING

12. The Council's position at first reading contains the following main elements, on which an agreement has been found between the co-legislators:
13. The **overall structure** of the Commission proposal is preserved, distinguishing two different categories of NGT plants.
14. Category 1 comprises NGT plants that are equivalent to conventional plants, i.e. the genetic modification introduced through NGTs could also occur naturally or be obtained by conventional breeding. Such plants are subject to a verification procedure, in which a national competent authority or the Commission establishes that they are indeed equivalent to conventional plants. Once confirmed, category 1 NGT plants are exempt from the requirements of the GMO legislation.
15. Category 2 comprises NGT plants with more complex modifications that do not contain foreign DNA. Such plants are subject to a notification procedure or an authorisation procedure, in line with the GMO legislation. In contrast to genetically modified plants containing foreign DNA, category 2 NGT plants benefit from limited derogations from the GMO legislation. Notably, the risk assessment and monitoring requirements are more flexible and can be adapted according to the risk profile of the plants.
16. On the **criteria of equivalence** of category 1 NGT plants to conventional plants, the key elements of both the Parliament mandate and the Council mandate are retained. Those elements include the types of genetic modifications, a limit to the size of certain modifications, as well as limits to the number of genetic modifications in each protein-coding sequence and in each plant. The overall limit in each plant takes account of the number of sets of chromosomes, to reflect the complexity of plant genomes.

17. In addition to the criteria of equivalence to conventional plants, **sustainability**-related criteria for NGT plants to qualify for category 1 are introduced, as a negative list (or exclusion list) of traits in a new annex to the Regulation. Traits on the negative list are considered to have the potential for adverse effects as regards sustainability. If one of the traits borne by the NGT plant and intended to be conveyed by the genetic modification is on that list, the NGT plant is excluded from category 1 and is therefore subject to authorisation, traceability and monitoring requirements as well as other provisions on category 2 NGT plants.
18. Notifiers and applicants for category 2 NGT plants may benefit from certain regulatory incentives such as an accelerated procedure for risk assessment, fee waivers and enhanced pre-submission advice, if one of the traits borne by the NGT plant and intended to be conveyed by the genetic modification has the potential to contribute positively to sustainability.
19. A number of safeguards address concerns on potential adverse impacts of the **patenting** of NGT plants and related licensing and transparency practices, e.g. regarding breeders' access to plant biological material and techniques, and risks of market concentration.
20. The 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 proposing legislative measures.
21. Transparency, access and legal certainty are also enhanced through the submission of information on patents or published patent applications as well as of a declaration on the willingness of patent holders to license on fair and reasonable terms, to be submitted with the verification request for category 1 NGT status and made public in a database.

22. The Commission shall publish guidance for the purpose of assisting operators on matters relating to plant intellectual property, establish an NGT plant patent expert group, and assess the impact of the patenting of NGT plants, traits and techniques as well as related licensing and transparency practices.
23. Category 1 NGT plants are exempt from **labelling** requirements, except for plant reproductive material of category 1 NGT plants. Labelling requirements of the GMO legislation continue to apply to category 2 NGT plants.
24. Neither category 1 nor category 2 NGT plants or products may be used in **organic** production, despite the exemption of category 1 NGT plants and products from the requirements of the GMO legislation. However, the adventitious or technically unavoidable presence of category 1 NGT plants and products in organic production shall not constitute non-compliance with the Organics Regulation⁹.
25. **Co-existence measures** for category 2 NGT plants remain optional for Member States. Furthermore, Member States retain the possibility to **opt out from cultivation** of category 2 NGT plants on their territory. The status quo of existing GMO rules thus continues to apply to category 2 NGT plants in this regard.
26. An article on **controls** by Member States provides reassurance with respect to the effective enforcement of the provisions of the NGT Regulation, without introducing new obligations to Member States beyond the control obligations from existing legislation.

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

27. The overall **monitoring** programme is strengthened as regards the impact of the patenting of NGT plants, traits and techniques, as well as related licensing and transparency practices; the impact of the application of the NGT Regulation on the organic sector; and the sustainability impact of NGT plants.
28. On the vast majority of elements negotiated during trilogues, the co-legislators have been able to find a compromise wording. On occasion, the Council has accepted in its own position elements of the Parliament's first reading position, such as the exclusion from category 1 of 'tolerance to herbicides' as intended trait conveyed by the genetic modification. Conversely, the Council has not been able to accept certain elements of the Parliament's position, such as labelling requirements for category 1 NGT plants and products throughout the food chain. This was however considered acceptable by the co-legislators in view of the overall compromise package negotiated and agreed in the last trilogue, which included concessions from both sides notably in the areas of sustainability-related requirements and of patenting of NGT plants.

IV. CONCLUSIONS

29. The Council's position supports the aim of the Commission proposal and fully reflects the compromise reached in the negotiations between the Council and the European Parliament, with the support of the Commission.
30. The Council therefore believes that its position at first reading is a balanced representation of the outcome of the negotiations and that, once adopted, the Regulation will contribute to facilitating innovation, increasing sustainability, enhancing the competitiveness of the EU agri-food sector, and maintaining a high level of protection of health and of the environment.