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From: Presidency
To: Delegations

Subject: AOB item for the meeting of the "Agriculture and Fisheries" Council of 9 and 10 December 2024:
Regulation on plants obtained by certain new genomic techniques and their food and feed products: state of play
– *Information from the Presidency*

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.

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 2024².
6. 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 2023³. The CoR delivered its opinion on 17 April 2024⁴.

State of play of work within the Council and its preparatory bodies

7. The Commission presented the proposal and its impact assessment⁵ at a meeting of the Working Party on Genetic Resources and Innovation in Agriculture (hereinafter 'the Working Party') on 10 July 2023, which was followed by a presentation at the meeting of the **Agriculture and Fisheries Council** on 25 July 2023.
8. The examination of the proposal began under the Spanish Presidency, which presented a compromise text to the **Agriculture and Fisheries Council** in December 2023, with a view to reaching agreement on a General Approach⁶. The Spanish Presidency, while regretting the absence of sufficient support to reach a General Approach at that stage, noted the broad support on its suggestions regarding areas with specific geographical conditions.

2 10952/24
3 14926/23
4 9226/24
5 11592/23 ADD 4
6 16443/23

9. Building on the progress made during the Spanish Presidency, the Belgian Presidency continued the examination of the proposal. On 7 February 2024, the Permanent Representatives Committee was invited to reach agreement on the text prepared by the Belgian Presidency (the “February Compromise Text”)⁷. That text introduced additional changes with a view to addressing concerns only on the impact of patenting practices. While a number of delegations supported the text, a qualified majority in favour could not be reached at that stage. Thereafter, the text was further examined by the Working Party, with sustained focus on the impact of patenting practices.
10. The Hungarian Presidency continued the examination of the proposal. Between July and December 2024, the Working Party held two meetings in person (19 July and 19 November). The Hungarian Presidency focused its efforts on issues⁸ for which it considered that there had been insufficient time for detailed discussions, and presented a non-paper to this end. The Presidency non-paper identified nine topics for further discussion. It summarised the main issues that had emerged in the previous discussions on each topic and tried to find possible avenues to overcome the concerns expressed by delegations. Seventeen delegations provided written comments to the Presidency non-paper, highlighting as appropriate the possible solutions on specific issues which could be acceptable for them. The written submissions were summarised by the Presidency at the Working Party meeting on 19 November.
11. The Presidency also invited representatives from the European Food Safety Authority (EFSA) and two EU-funded research projects to attend a meeting of the Working Party. The purpose was to present to delegations EFSA’s scientific opinion on the analysis by the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) of Annex I to the proposal, and the goals, objectives and results to date of the two projects, respectively.

⁷ 16714/23

⁸ 11820/24

Main issues discussed

12. The issues raised in the Hungarian Presidency's non-paper as well as comments provided by delegations triggered discussions in several areas. Out of these, the Presidency wishes to highlight the following ones.

— Criteria of equivalence of NGT plants to conventional plants

According to the rationale for the equivalence criteria in Annex I of the proposal, the analysis of type, size and number of mutations is considered as sufficient for assessing equivalence of an NGT plant to a conventional plant. ANSES published an analysis⁹, which focuses on the need to clarify the definitions and scope in the proposal, the scientific basis for the equivalence criteria and the need to take potential risks from category 1 NGT plants into account. Following a mandate from the European Parliament, EFSA delivered a scientific opinion¹⁰ on the analysis by ANSES. The Presidency invited a representative from EFSA to present to the Working Party its scientific opinion. While EFSA agreed with ANSES that some definitions require clarifications, EFSA confirmed the scientific basis of the equivalence criteria. EFSA also reiterated the absence of additional hazards and risks of NGTs compared to conventional breeding techniques, referring to its earlier scientific opinions. In their interventions, delegations indicated that their views were close to either the ANSES analysis or the EFSA opinion.

⁹ <https://www.anses.fr/fr/system/files/BIOT2023AUTO0189EN.pdf>

¹⁰ <https://doi.org/10.2903/j.efsa.2024.8894>

— Detection and identification of NGT plants and products

Reliable detection and identification methods for NGT plants and products are challenging to develop, in particular for category 1 NGT plants and products, as by definition the same genetic modification could also occur naturally or be obtained by conventional breeding. This practical issue was one of the factors that led the Council to adopt Decision (EU) 2019/1904¹¹. The Presidency invited representatives from the EU-funded research projects “DARWIN – Transition to safe & sustainable food systems through new & innovative detection methods & digital solutions for plant-based products derived from new genomic techniques, under a co-creation approach” and “DETECTIVE – Detection of NGT products to promote innovation in Europe”, in order to have a clearer picture of the current developments in research and innovation in the field of detection and identification of NGT plants and products.

While both projects work towards the development and validation of detection methods for NGT plants and products in different use scenarios, concrete results are as yet limited because the projects started only in 2024. In the ensuing discussion with the project representatives, several delegations showed interest not only in the technological developments and their possible outcomes but also the socio-economic work packages of both projects, as well as the collaboration between the two projects. Delegations agreed that it would be useful to continue to monitor the progress of the two projects.

¹¹ Council Decision (EU) 2019/1904 of 8 November 2019. The decision was based on Article 241 TFEU and requested the Commission to submit a study on the status of NGTs under EU law, and a proposal, if appropriate in the light of the study.

— Empowerment of the Commission for adopting delegated acts

In accordance with Article 5(3) of the proposal, as amended in the February Compromise Text, the Commission would be empowered to amend the equivalence criteria in Annex I¹² via delegated acts. The exercise of this empowerment would be subject to a number of conditions. Based on relevant comments from several delegations, the Presidency requested a written legal opinion prepared by the Council Legal Service on the said empowerment. The Council Legal Service responded to that request with a contribution¹³, which confirmed, further developed and complemented the advice provided in oral interventions of the representative of the Council Legal Service at earlier meetings of the Working Party. The Council Legal Service came to the conclusion that it is possible to grant the Commission the power to amend Annex I by means of delegated acts within the limits set out in the February Compromise Text, as the co-legislator has defined the essential elements of the act and strictly limited the empowerment given to the Commission. It would however be advisable to make the essential elements of the policy decision being made by the co-legislator clearer in the preamble to the regulation.

¹² Annex I to the proposal sets out the criteria according to which it could be determined that an NGT plant is equivalent to a conventional plant (the “equivalence criteria”) and hence would fall within Category 1.

¹³ 15691/24

— Other issues

The Working Party also discussed other issues raised in the Hungarian Presidency's non-paper, such as the risk assessment for category 1 NGT plants and products, the scope of the regulation – whether wild plant species should be covered or not–, labelling of category 1 NGT food and feed products, the question of sustainability of NGT plants, export to third countries, the verification procedure, and the compliance of the draft regulation with the Cartagena Protocol on Biosafety. Several delegations welcomed the possibility to discuss those issues further. They deemed that previous presidencies had not given sufficient room to debate those matters and reflect their concerns in the successive Presidency texts. On the other hand, several other delegations considered that those issues had been discussed in detail at previous Working Party meetings and that they had accepted compromises up to the limit of what is acceptable to them. Those delegations referred to the February Compromise Text as a solid basis for further discussions. Overall, delegations' interventions on many points displayed the polarised pattern that had emerged in preceding discussions on the proposal.

Conclusion

13. The Council is invited to take note of the state of play of the examination of the proposal.