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NOTE

From:	Presidency
To:	Permanent Representatives Committee/Council
No. prev. doc.:	15979/24
Subject:	Proposal for a Regulation of the Parliament and of the Council on the production and marketing of plant reproductive material in the Union, amending Regulations (EU) 2016/2031, 2017/625 and 2018/848 of the European Parliament and of the Council, and repealing Council Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 2002/53/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90/EC (Regulation on plant reproductive material) - Progress report

I. <u>INTRODUCTION</u>

 On 5 July 2023, the European Commission adopted two closely related legislative proposals to revise and update the rules on the production and marketing of plant reproductive material (PRM) and forest reproductive material (FRM) in the EU. The proposals were submitted to the Council on 6 July 2023.

- 2. Currently, the applicable legislation in this area consists of a Directive on the common catalogue of varieties of agricultural plant species and 11 marketing directives covering seeds and other plant reproductive material, propagating material of ornamental plants and forest reproductive material. Some of the directives date back to the 1960s. According to the European Commission, this fragmentation in the rules results in differing implementation in Member States and a high administrative burden for the competent authorities and operators. Moreover, the current legislation is not consistent with other legislation on plant health and official controls, is outdated from a scientific and technical point of view and needs to be modified to promote new improved varieties and to adapt to the climate challenges.
- The PRM proposal¹ introduces a new legislative approach, replacing the 10 PRM marketing directives with a single regulation. In particular, it aims to:
 - simplify the legal framework through clarified and harmonised rules,
 - facilitate technical progress in order to foster digital and novel technologies, such as the use of bio-molecular techniques,
 - reduce the administrative burden,
 - ensure the availability of high-quality PRM adapted to the changing agricultural and environmental conditions,
 - ensure food security, the conservation of plant genetic resources and the protection of biodiversity, and
 - improve consistency with the official controls and plant health legislation.

The proposal covers seed, as well as all other forms of material intended for the vegetative propagation of entire plants. It does not cover forest reproductive material, ornamental plants, PRM exported to third countries or PRM intended for non-commercial purposes.

¹ 11502/23 + ADD 1

- 4. The proposal is based on Article 43(2) of the Treaty on the Functioning of the European Union (TFEU) (ordinary legislative procedure).
- In the European Parliament, the Committee on Agriculture and Rural Development has lead responsibility and Mr Herbert Dorfmann (EPP, Italy) has been re-appointed as rapporteur for the current term. Parliament adopted its position at first reading on 24 April 2024².
- Both the European Economic and Social Committee (EESC) and the European Committee of the Regions (COR) were consulted. The EESC adopted its opinion on 13 December 2023³. The COR adopted its opinion on 17 April 2024⁴.

II. <u>STATE OF PLAY OF WORK WITHIN THE COUNCIL AND ITS PREPARATORY</u> <u>BODIES</u>

- 7. The European Commission presented the proposal and its impact assessment⁵ at an informal videoconference of the members of the Working Party on Genetic Resources and Innovation in Agriculture (hereinafter 'the Working Party') on 6 July 2023, which was followed by a presentation to the Agriculture and Fisheries Council on 25 July 2023.
- The examination of the proposal began under the Spanish Presidency, which drafted a Presidency revised text on Articles 1 to 22⁶, and presented a progress report to the Council in December 2023⁷.
- 9. The Belgian Presidency continued the examination of the proposal and drafted a Presidency revised text on Articles 1 to 43 and 81, as well as on Annexes I to VI⁸. It informed the Council of the state of play of the discussions in June 2024⁹.

² <u>Texts adopted - Production and marketing of plant reproductive material - 24 April 2024</u>

³ 5402/24

⁴ 9226/24

⁵ 11694/23 (the examination of the impact assessment was carried out on the basis of the checklist)

⁶ 16295/23

^{7 16040/23}

⁸ 11303/24

⁹ 11142/24

- Building on the progress made during the previous Presidencies, the Hungarian Presidency continued the technical examination of the proposal focusing on the provisions concerning variety registration.
- Between July and December 2024, the Working Party held three in-person meetings (11 July, 3-4 September and 27-28 November). In addition, one meeting of the members of the Working Party was held by informal videoconference (15-16 October).

III. MAIN ISSUES AND PROGRESS ACHIEVED

A large number of technical comments were made by delegations, both orally at the Working Party meetings and in writing during subsequent written consultations. On the basis of the comments provided by delegations, the Presidency identified several areas where the provisions needed to be further developed or clarified. Among these, the Presidency would like to highlight the following.

- General comments

- Delegations generally welcomed the continuation of the current variety registration system, but at the same time expressed concerns about the practical feasibility of the proposed requirements. During the discussions, the importance of taking into account national specificities was emphasised, and concerns were expressed about the increasing administrative burden on operators and competent authorities. Most delegations agreed that the rules on variety registration should be clear and enforceable in practice.
- Some delegations questioned the high number of empowerments for the adoption of delegated and implementing acts, which risk generating legal uncertainty, greater fragmentation and inconsistency with national rules, while others recognised the need for flexibility to allow for updating in line with scientific and technical developments.
- Furthermore, most delegations highlighted the need for the rules on seed and other plant productive material to be more clearly separated in the proposal and suggested simplifying it by restructuring the text.

- Variety registers (Articles 44-46 and Annex VII)

The proposal introduces a general rule that PRM can only be produced and marketed if they are registered in national variety registers, which are established, published and updated by the Member States. These national variety registers will be linked to a Union variety register, managed by the European Commission.

- An extensive discussion on this topic took place at the meeting of the Working Party in July, where several delegations made suggestions regarding the content of the national and Union variety registers and asked for clarification on their interoperability with the EU Plant Variety Portal.
- Delegations also drew attention to issues related to the registration of heterogeneous materials, selected clones, conservation varieties and components of hybrid varieties, as well as fruit plants with no intrinsic value. They considered that heterogeneous materials should appear on a separate list to avoid confusion with registered varieties.
- Annex VII, which refers to the contents of the national and Union variety registers, was also subject to detailed discussions and was redrafted by the Presidency on the basis of the comments from delegations.

- Requirements for registration in national variety registers (Article 47)

As explained above, the proposal introduces a rule that PRM must belong to registered varieties. It also defines the procedure and conditions for registration, including requirements concerning the value for sustainable cultivation and use (VSCU) and the distinctness, uniformity and stability (DUS) examinations.

As most delegations did not support the VSCU examination of fruit and vegetable species at this stage (more details below), the Presidency proposed to separate the DUS and VSCU examinations, to remove the obligation for the VSCU examination in relation to these species.

- Value for sustainable cultivation and use (Article 52)

As a new element in the proposal, the VSCU examination will have to be carried out not only on agricultural crops but also on vegetable and fruit species, to ensure a broader and more sustainable approach for the entire PRM sector and the agri-food chain. The new varieties must, as a whole, offer an improvement over the other varieties of the same genera or species in order to be eligible for registration.

During the discussions, many delegations supported the VSCU examination for agricultural crops, but at the same time expressed concerns about the practical feasibility of its implementation. Most of them, however, questioned the requirement to subject vegetable and fruit species to mandatory VSCU examination, considering that this would prolong the variety registration process and would possibly also increase administrative and financial burdens for small and medium-sized enterprises and for competent authorities, due to the high costs of such tests and their complex organisation.

The concerns highlighted by delegations, particularly for fruit varieties, included the fact that the time needed for variety testing would increase considerably. In the case of vegetables, it would be difficult to implement the VSCU examination due to the short life span of these varieties and the technological diversity of their cultivation. Among the possible undesirable consequences, the decrease in variety notifications, breeding activities and genetic diversity were highlighted. Delegations also pointed out that no uniform testing methodology for sustainability characteristics currently exists, so a comparison of results would not be possible.

In order to find a compromise on this important issue, the Presidency proposed a transitional period for the mandatory application of the VSCU examination for fruit and vegetable species.

Registration of conservation varieties (Article 53)

- According to the proposal, PRM belonging to conservation varieties must have an officially recognised description. These varieties, if they meet certain conditions, will also have to be registered in a national variety register. This would allow their control by the competent authorities and ensure that their users are properly informed. An important request from delegations was to be able to use, in addition to the names of conservation varieties, their synonymous names, as these are based on Community heritage and are currently in use. During the discussions, it also became clear that in order to clarify the issues related to this article, the definition of "conservation variety" needed to be reworded.
- Delegations were particularly concerned about the requirements for maintaining conservation varieties. The Presidency therefore proposed that, in order to preserve their genetic characteristics, conservation varieties should be only maintained in the region of origin and not in the rest of the Union.

- Technical examination of the variety (Articles 59-63)

- According to the proposal, a technical examination of varieties should be carried out in order to determine whether they are distinct, uniform and stable. Given the importance of this examination for the breeding sector and the fact that it will result in an official description, this technical examination should only be carried out by the competent authority. As far as the VSCU examination is concerned, it could be also carried out at the applicant's premises under the official supervision of the competent authority, in line with Article 61.
- Delegations highlighted that the sections on the different technical examinations (DUS, VSCU) are not clearly separated in the proposal. Based on delegations' comments, the Presidency proposed to separate Article 59 into two parts: one containing provisions on the DUS, and another on the VSCU examination. It was further clarified that Member States can cooperate and also establish shared facilities to carry out examinations.
- Furthermore, delegations wanted to clarify when and how these examinations and audits would be carried out. They requested that the European Commission have no role in auditing the authorities responsible for the DUS examination, since this task falls to the Community Plant Variety Office. While the Presidency addressed the comments in the revised text, further discussions appear to be necessary.

- Variety maintenance (Article 72) and Samples of registered variety (Article 74)

Varieties registered in a national variety register should be maintained by the applicant, or by any other person notified by the applicant to the competent authority. Maintenance ensures preservation of the stability of the variety, which is why the task of the maintainer is very important. According to the proposal, the competent authorities should check the maintenance of varieties. Based on the comments from delegaions, an amendment was made to Article 72 to clarify what constitutes the maintenance of varieties in the context of PRM.

Delegations did not support the idea that the competent authorities should authorise another person to carry out maintenance of the variety, as this would impose an additional burden on the competent authorities. Based on the comments from delegations, the Presidency proposed that the new maintainer be notified as an acceptable alternative maintainer if they submitted a standard sample approved by the competent authority. In this context and for the purposes of seed certification, it became clear that there was also a need to define the concept of "standard sample".

During the discussions, several other aspects were also raised, such as the maintenance of varieties in third countries and potential problems with the preservation of fruit and vine samples. These topics require further consultation. Similarly, it remains to be clarified who has access to the samples of registered varieties and who is responsible for storing these samples.

- Restructuring of the proposal

At the meeting of the Working Party in September, the majority of delegations expressed their wish to modify the structure of the proposal in order to improve its readability and practical implementation. The Presidency therefore presented two options on a possible new structure of the proposal at the meeting of the Working Party in November.

IV. <u>CONCLUSION</u>

12. The Hungarian Presidency has prepared a revised text on Articles 44 to 74 and 83, as well as on Annex VII, and has also amended Article 3 of the proposal¹⁰. In addition, the Presidency has proposed two options for a possible new structure of the proposal.

The Hungarian Presidency thus considers that the progress made under its Presidency term represents a good basis to carry on the examination of the file at technical level.

 In light of the above, the Council is invited to take note of the progress made on examining the proposal.

¹⁰ 15979/24