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NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee (Part 1) / Council
No. Cion doc.:	11503/23
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. INTRODUCTION

1. On 5 July 2023 the 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. They are part of the Commission food and biodiversity package, a set of legislative proposals also covering soil health, new genomic techniques and the partial revision of the Waste Framework Directive. They were submitted to the Council on 6 July 2023.

2. At present, the legislation comprises a Directive on the common catalogue of varieties of agricultural plant species and 11 marketing Directives covering seeds, plant reproductive material and forest reproductive material. Some of the directives date back to the 1960s. This fragmentation of rules causes diverging implementation practices in Member States and results in a high administrative burden for competent authorities and operators. Moreover, the current legislation lacks coherence with other legislation on plant health, official controls and GMOs, is outdated from a scientific point of view, needs innovation to promote improved varieties and to adapt to the new climate challenges in order to fulfil the objectives of the Green Deal, in particular the Farm to Fork and Biodiversity strategies.
3. The PRM proposal¹ introduces a new legislative approach as it replaces ten marketing Directives with a single regulation. In particular, it aims to:
 - simplify the legal framework through clarified and harmonised rules,
 - facilitate the 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 changing agricultural and environmental conditions,
 - ensure food security, the conservation of plant genetic resources and the protection of biodiversity, and
 - improve the coherence with the official controls and plant health legislation.

¹ 11502-23 + ADD 1

The new Regulation cover seeds 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 other non-marketing purposes.

4. In the European Parliament, the Committee on Agriculture and Rural Development has the lead responsibility and Mr Herbert Dorfmann (EPP, Italy) has been appointed rapporteur. His draft report was published on 10 November 2023. The Committee on the Environment, Public Health and Food Safety will provide an opinion.

II. STATE OF PLAY OF WORK WITHIN THE COUNCIL PREPARATORY BODIES

1. The Commission presented the proposal and its impact assessment² 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 in the AGRIFISH Council on 25 July 2023.
2. The examination and detailed discussions of the articles of the proposal continued between September and December 2023. During the Spanish Presidency a total of three Working Party meetings have focused on the examination and discussion of Articles 1-22 of the proposal.

MAIN ISSUES AND PROGRESS ACHIEVED

3. A large number of technical comments have been made by delegations both orally and in writing on the entire text of the proposal. As indicated above, the Spanish Presidency has worked on a revised text for Articles 1-22 and has tried to accommodate most of these comments, aiming to develop and clarify the content of these Articles.

² 11694/23

a) **General comments**

Delegations generally support the main objectives of the proposal aimed at clarifying the current legislation on the production and marketing of plant reproductive material, increasing consistency and enabling the introduction of new scientific and technical developments. They also welcome the fact that the two pillars of the current system (variety registration and certification) are maintained.

The general comments provided by delegations identify several areas where the provisions need to be fleshed out and clarified:

– **Administrative burden**

Many delegations believe that, based on the content of the proposal, the administrative burden for operators and competent authorities would increase in certain areas and become disproportionate.

The proposal does indeed contain additional reporting and auditing requirements for the competent authorities and a high number of authorisations or registration obligations for professional operators that considerably increase bureaucracy. The introduction of supervision and control requirements for areas not yet regulated, such as authorisation for re-packaging and re-labelling or authorisation for the production of particular types of material, also adds to the administrative burden.

– **Legal instrument/empowerment of the Commission**

The proposal merges a large number of current directives into one single Regulation. Some delegations are of the opinion that its provisions are often vague and that it contains a large number of delegated and implementing acts, which risk generating legal uncertainty, greater fragmentation and incoherence with current national rules. Those delegations are of the opinion that a balance between greater harmonisation and flexibility for national requirements will need to be sought.

– **Application**

The Regulation will apply three years after entering into force. However, this timeline seems to be too short for some delegations given that the Regulation contains a large number of provisions for implementing acts. Those delegations claim that Member States will need more time as they will have to adopt additional national legal acts.

– **Inclusion in the Regulation on official controls**

The advantages and disadvantages of inserting the PRM legislation into the scope of Regulation (EU) 2017/625 (OCR) requires further analysis. Delegations fear that the disadvantages might outweigh the benefits as this will increase the administrative and financial burden on competent authorities given new auditing and reporting obligations.

– **Exemptions**

Some delegations expressed concerns about the exemptions from registration granted to the heterogenous material used for conventional farming, exemptions to the seed exchange between farmers and to the PRM marketed for final users.

– **VSCU/DUS**

Many delegations question the obligations of VSCU (value for sustainable cultivation and use) assessment for fruit and vegetable species. The costs of performing VSCU tests on varieties of fruit and vegetable species and the complex organisation of such tests might be untenable for medium and small breeding companies. In addition, there are doubts about the recognition of all the DUS (distinctness, uniformity and stability) and VCU tests performed by other Member States due to different climatic conditions and the current quality control system.

b) Comments on Articles 1-22

Delegations have made the following remarks in particular:

– **Subject matter (Article 1)**

It is not clear whether this Regulation should include provisions on the control of cultivation conditions or use of PRM other than for the production of food, feed and other products.

– **Scope (Article 2)**

There is need for clarification of the requirements for the inclusion of new species under the scope of this Regulation. Also, some countries requested the inclusion of a clause to exclude from the scope of this Regulation certain PRM not aimed at the commercial exploitation of a variety, the so-called ‘closed loop’ clause.

– **Definitions (Article 3)**

Some definitions need to be reformulated to clarify certain aspects, in particular the definition of: ‘final users’, ‘conservation variety’, ‘officially recognised description’, ‘quality pest’, ‘marketing’, ‘off-type’ and ‘hybrid variety’); others need to be aligned with those in the plant health legislation (for example ‘professional operator’ and ‘seeds’) or with the OECD seed schemes. Finally, many delegations asked for the deletion of ‘multiclonal mixtures’.

Definitions will be revisited a second time in light of a complete first examination of the articles they relate to.

– **General requirements for production and marketing (Articles 5-10)**

PRM of species included in Annex 1 can be produced and marketed only if the species is registered in a national or European variety register and only if it belongs to the following categories (pre-basic, basic, certified and standard). The exclusion of commercial seeds is still under discussion. Derogations from registration apply to heterogenous material, PRM marketed to final users or between conservation networks and seed exchange between farmers.

Selected clones, and polyclonal PRM may also be included in specific registries, and produced and marketed under specific rules. Some delegations pointed out that such provisions should not apply to clones or multiclonal mixtures.

A professional operator may be authorised by the competent authority to certify PRM for pre-basic, basic and certified material or seeds under official supervision. In this regard, some delegations requested that the possibility to reject authorisations for certain sensitive activities be retained. In addition, they indicated that they can only support the certification of PRM under official supervision if the detailed rules on controls remain a national competence. Some delegations have also asked to align these provisions with the OCR Regulation.

– **Labelling (Articles 15-20)**

Rules for the labelling of PRM are established in order to ensure its correct identification. Delegations have requested clarification of some aspects in particular regarding compliance with the obligations for plant passports contained in the plant health legislation, and regarding specific requirements for different kinds of PRM with compulsory labelling.

– **Mixtures of seeds (Articles 21 and 22)**

A number of delegations asked for the possibility to make mixtures of seeds also with species included in Annex I part B, and with other species that are not covered by this Regulation, since this is currently possible with the applicable legislation.

4. The Presidency plans to continue these discussions in the coming weeks and will work on a Presidency text. The Presidency will hold a further informal video conference of the members of the Working Party on 19 and 20 December 2023 with a view to presenting Presidency redrafting suggestions³ for the articles that have been examined so far with the aim to develop and clarify their content.
 5. On the basis of the progress made under the Spanish Presidency, the incoming Belgian Presidency plans to continue the work on this file at technical level.
 6. In the light of the above, the Council is invited to take note of the progress made on the examination of the proposal and to exchange views.
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³ 16295/23 (to be published shortly).