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From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
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To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	SWD(2023) 415 final
Subject:	<p>COMMISSION STAFF WORKING DOCUMENT EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT REPORT <i>Accompanying the documents</i></p> <p>Proposal for a Regulation of the European 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 (Regulation on plant reproductive material)</p> <p>and</p> <p>Proposal for a Regulation of the European Parliament and of the Council on the production and marketing of forest reproductive material in the Union, amending Regulations (EU) 2016/2031 and 2017/625 of the European Parliament and of the Council, and repealing Council Directive 1999/105/EC (Regulation on forest reproductive material)</p>

Delegations will find attached document SWD(2023) 415 final.

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COMMISSION STAFF WORKING DOCUMENT
EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT REPORT

Accompanying the documents

**Proposal for a Regulation of the European 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
(Regulation on plant reproductive material)**

and

**Proposal for a Regulation of the European Parliament and of the Council
on the production and marketing of forest reproductive material in the Union,
amending Regulations (EU) 2016/2031 and 2017/625 of the European Parliament and of
the Council, and repealing Council Directive 1999/105/EC (Regulation on forest
reproductive material)**

{ COM(2023) 414 final } - { SEC(2023) 414 final } - { SWD(2023) 410 final } -
{ SWD(2023) 414 final } - { COM(2023) 415 final }

1. Need for action

What is the problem and why is it a problem at EU level?

The EU legislation on the marketing of plant and forest reproductive material (PRM/FRM) has been in place since 1966. Subsequent amendments have led to a complex legal framework, not fully aligned to closely related policies (plant health, official controls and organic production). Implementation and therefore conditions for operators differ between Member States, as aspects of the legislation leave room for interpretation. National practices have been adopted where the legislation has not followed in a timely manner new developments in science and technology (innovative production processes, bio-molecular techniques, digital solutions).

Due to the initial focus of the legislation on productivity, there are limited means to address the sustainability, climate change adaptation and biodiversity challenges. The assessment of new varieties for characteristics that can contribute to sustainable production is limited. Market access rules are restrictive for organic and conservation varieties and activities that can contribute to the genetic diversity of cultivated crops and cover specific local needs (e.g. short supply chains). The FRM legislation defines FRM in relation to its importance for forestry purposes in all or part of the Union, but it remains vague about the forestry purposes covered by the scope of the legislation. Increasing difficulties in the supply of FRM because of changing climatic conditions are not addressed and rules on the information to be provided to users of FRM are unclear, with the risk that inappropriate FRM is used in afforestation and reforestation.

What should be achieved?

The initiative should ensure, for all types of users, PRM/FRM of high quality and diversity of choice and should ensure a level playing field for operators across the EU. It should contribute to the stability of yield of agricultural production and productivity of forest ecosystems under current and future projected climatic conditions. The initiative should harmonise the official controls, improve coherence with the plant health legislation and enable the uptake of new scientific and technical developments. Finally, it should facilitate the registration of organic varieties and support the conservation and sustainable use of plant and forest genetic resources.

What is the added value of action at EU level (subsidiarity)?

The unrestricted marketing of PRM/FRM throughout the EU is imperative to address transboundary issues such as the need for sustainable production to ensure food security and sustainable forest management and restoration of forest ecosystems. The current geopolitical situation and energy crisis have elevated the importance of this. Access to market of PRM/FRM relies on examinations and inspections by the national competent authorities. Common EU rules ensure the quality of PRM/FRM and the open and fair competition on the single market. Without them, 27 systems instead of one would be in place, thus hindering the movement, distorting competition and increasing the financial burden for operators and authorities.

2. Solutions

What are the various options to achieve the objectives? Is there a preferred option or not?

Three options were assessed, from one of highest flexibility (option 1) to one of highest harmonisation to minimise differences in the implementation of the legislation (option 3), with option 2 balancing the need for flexibility with a higher degree of harmonisation to overcome the problems stemming from differences in interpretation.

Horizontal elements for all options: 1) Simplification of administrative procedures and a more flexible decision-making process 2) Streamlined rules for organic and conservation varieties 3) Harmonisation with the plant health legislation.

Option 1 - Highest flexibility: Option 1 lays down minimum requirements for PRM/FRM official controls, but without linking it to the Official Controls Regulation. Guidelines on the use of innovative production processes, bio-molecular techniques and digital solutions are adopted. The existing assessment of new varieties of agricultural plant species for characteristics contributing to sustainable production are strengthened. A voluntary assessment is introduced for vegetables and fruit plants. The activities of seed conservation networks, marketing to amateur gardeners and exchange in kind of seed between farmers are exempted from the legislation's scope to stimulate the increase in genetic diversity of PRM. The FRM legislation only covers production for "forestry purposes" to ensure the availability of high-quality FRM for afforestation/reforestation. Sustainability requirements are extended to the lower FRM categories. Guidelines on contingency planning for major FRM shortages in case of extreme weather and disasters are introduced.

Option 2 - Balancing flexibility and harmonisation (preferred option): Option 2 brings the official controls on PRM/FRM under the scope of the Official Controls Regulation, but with simplified import controls at appropriate places within the EU to ensure a more targeted and efficient enforcement of existing rules. Basic principles for the use of innovative production processes, bio-molecular techniques and digital solutions are included in the legislation. The assessment of new varieties for characteristics contributing to sustainable production becomes a requirement for all crops groups, but with flexibility for Member States to implement according to their own agro-ecological conditions. The activities of seed conservation networks, marketing to amateur gardeners and exchange in kind of seed between farmers are subject to lighter rules to stimulate the increase in genetic diversity of PRM but also guarantee a minimum quality. The FRM legislation covers production for "forestry" and "non-forestry" purposes to increase FRM quality beyond afforestation/reforestation uses. Sustainability requirements are extended to the lower FRM categories. General legal requirements for contingency planning for major FRM shortages in case of extreme weather and disasters are introduced.

Option 3 - Highest harmonisation: Option 3 brings the official controls on PRM/FRM under the scope of the Official Controls Regulation, with stricter import controls at border control posts requiring special import documentation to strengthen and fully harmonise enforcement. Detailed and binding rules for the use of innovative production processes, bio-molecular techniques and digital solutions are included in the legislation. The assessment of new varieties for characteristics contributing to sustainable production becomes a requirement for all crops, with detailed and harmonised requirements and methodologies for all Member States. The activities of seed conservation networks, marketing to amateur gardeners and exchange in kind of seed between farmers are subject to the general requirements of the PRM

legislation to achieve homogenous rules for all market segments. The FRM legislation covers production for “forestry” and “non-forestry” purposes to increase FRM quality beyond afforestation/reforestation uses. Sustainability requirements are extended to the lower FRM categories and are subject to harmonised rules. Common rules for contingency planning to prepare for major FRM shortages in case of extreme weather and disasters are introduced.

What are the different stakeholders’ views? Who supports which option?

There is overall support for maintaining the current regulatory system for PRM/FRM and its two basic pillars of registration of varieties/basic material and PRM/FRM certification (system to ensure the identity, quality and health of PRM/FRM). There is also broad support for derogations, deemed necessary for meeting the objectives relevant to the conservation and sustainable use of plant genetic resources and organic production. Views in relation to the extent of the derogations vary. Citizens and civil society organisation seek a total exception of activities relevant to the conservation and sustainable use of plant genetic resources from the scope of the legislation. Most industry stakeholders and national competent authorities agree with derogations but ask that quality and health are ensured, while a minority considers that any derogations should be limited. There is support for an increased focus on sustainability but subject to maintaining flexibility to address the different conditions across the EU. However, stakeholders and national competent authorities are concerned about the resulting costs in relation to the introduction of sustainability assessments for fruit plants and vegetables. Civil society organisations stress the contribution of conservation activities and organic production to the sustainability objectives. There is overall agreement that: harmonisation of official controls is necessary, but it should not lead to increased administrative burdens; the use of bio-molecular techniques and digital solutions will have benefits, but should be optional; and the FRM legislation must remain separate from the PRM legislation. Stakeholders expressed diverging views regarding the purposes that are covered by the scope of the current FRM legislation. Option 2 responds best to the different stakeholders’ views.

3. Impacts of the preferred option

What are the benefits of the preferred option?

The preferred option will bring efficiency gains for operators and national competent authorities through extended possibilities for operators to undertake activities under official supervision, harmonisation with the plant health legislation, the introduction of risk-based official controls and the possibility to use bio-molecular techniques and digital solutions in the registration and certification systems. Mandatory strengthened sustainability requirements combined with flexibility to adapt to local agro-ecological conditions will contribute to more sustainable agri-food production and food security, as varieties more suitable for the changing agro-climatic conditions will have a more stable yield. Varieties with disease resistance / tolerance will have a positive environmental impact as they may reduce the need for plant protection products. FRM with improved sustainability characteristics can contribute to adaptation and mitigation of the already visible impact of climate change on forests, therefore delivering important environmental benefits. Preparedness for major shortages of FRM in case of extreme weather and disasters will be improved and the risk of planting of low-quality FRM will be reduced. Finally, benefits are expected for the conservation and sustainable use of plant and forest genetic resources through specific derogations coupled with tools for traceability and quality assurance.

What are the costs of the preferred option?

The preferred option presents considerable economic costs for operators and national competent authorities due to the need for additional investments to conduct additional sustainability assessments. These are however proportional to the objectives and will in the mid-term be compensated by the benefits to be realised in terms of sustainability of the agri-food production and the forestry sectors. Other measures do not result in new obligations for operators but provide them with new options or lighter conditions for accessing the market.

What are the impacts on small and medium-sized enterprises (SMEs)?

SMEs are expected to benefit as all other enterprises from the systemic improvements and resulting efficiency gains. While no specific breakdown is available, SMEs present a great diversity of crops covered (highly specialised in a few crops or a broader portfolio) and geographical coverage (national, EU or international markets). They may be active in one or several stages of the seed industry: plant breeding, seed production, seed conditioning and seed marketing. Depending on their specific activities and degree of innovation some SMEs might not be able to take up new possibilities to be introduced (e.g. use of digital technologies and bio-molecular techniques) or these possibilities might not be relevant to their activities. SMEs with a small number of new varieties per year could be negatively affected in the short term by the increased sustainability requirements, with the need to re-orient investments to varieties with improved sustainability characteristics. Finally, it would be mostly SMEs that would benefit from the measures for organic and conservation varieties, as mostly SMEs are involved in such activities.

Will there be significant impacts on national budgets and administrations?

National competent authorities will most likely have to increase their capacity in order to enforce the increased requirements for sustainability assessments. Adjustment of existing practices and rearrangement of resources in relation to official controls and plant health requirements will also be required, depending however on the current allocation of competencies.

Will there be other significant impacts?

There will be no other significant impacts.

Proportionality

The initiative does not go beyond what is necessary to achieve the objectives of the revision. It does so in a way that is conducive to national action, which would otherwise not be sufficient to achieve those objectives in a satisfactory way.

4. Follow up

When will the policy be reviewed?

An appropriate review period would be 10 years after entry into application. This is consistent with the average time needed for the breeding of a new variety as well as with the time needed to obtain meaningful data through annual monitoring.