

INCEPTION IMPACT ASSESSMENT

Inception Impact Assessments aim to inform citizens and stakeholders about the Commission's plans in order to allow them to provide feedback on the intended initiative and to participate effectively in future consultation activities. Citizens and stakeholders are in particular invited to provide views on the Commission's understanding of the problem and possible solutions and to make available any relevant information that they may have, including on possible impacts of the different options.

TITLE OF THE INITIATIVE	<i>Revision of the plant and forest reproductive material legislation</i>
LEAD DG (RESPONSIBLE UNIT)	DG SANTE.G1 – Plant Health
LIKELY TYPE OF INITIATIVE	<i>Legislative</i>
INDICATIVE PLANNING	<i>Q4 2022</i>
ADDITIONAL INFORMATION	<i>Future of EU rules on plant and forest reproductive material</i>

A. Context, Problem definition and Subsidiarity Check

Context

Plant reproductive material (PRM) are plants and all parts of plants capable of, and intended for, producing entire plants for any purpose such as food, industrial uses, forestry or decoration (ornament). It may include seeds, young plants, tubers or plant cuttings. PRM constitutes the very beginning of the agri-food production chain to ensure the availability of diverse, healthy and high-quality food. The EU legislation on PRM is based on two pillars: certification of PRM to be marketed and registration of the varieties of that PRM. A plant variety represents a group of plants with a common set of characteristics (e.g. a plant species can include from a few to hundreds of different plant varieties). In order to be placed on the EU market, new plant varieties have to be tested to show that they are distinct from other varieties, uniform and stable. Moreover, the PRM legislation ensures the identity, quality and health of the marketed PRM for the user. The breeding of new plant varieties contributes to the diversity of PRM that will in turn contribute to the diversity of food available on the market. For example, breeding can result in plant varieties producing strawberries in early spring, or in late summer. Likewise, plant varieties can respond to consumer preferences e.g. big versus small strawberries. More importantly, new plant varieties and plant breeding play an indispensable role in creating plants capable to face the current challenges such as extreme weather events (e.g. withstand heavy winds due to a deeper rooting system), extended drought periods and new plant pests. Furthermore, plant varieties may contribute to a more sustainable farming system by decreasing the use of plant protection products.

Forest reproductive material (FRM), is a particular type of PRM, namely forest seeds and plants, which constitute the starting point for the creation of new forests and the reforestation of existing forests. Global warming has a negative and increasing impact on Europe's forests by shifting biogeographical regions northwards and uphill. FRM that used to be optimal for a given region may no longer be fit for that region because of the changing climatic conditions. The FRM legislation helps to identify FRM and specifies the requirements, such as origin, health and resistance, wood quality, outstanding characters, to be met by trees that will be used for the production of the different types of FRM. The legislation on FRM has been developed as a very particular part of the PRM legislation, with its own basic concepts and approaches that significantly differ from the other PRM sectors. Therefore, and when so needed, special reference to FRM will be made.

The current legislation on the production and marketing of seed and other PRM is composed of 11 Directives, specific for each type of crop (e.g. cereals, fodder plant, oil and fibre plants, beet, seed potatoes, vegetables, ornamentals, fruit plants, vine, FRM) and one Directive establishing the common catalogues of varieties of agricultural species. The aim of these marketing Directives is to lay down requirements for the production and marketing of the different types of PRM and the necessary certification/inspection methods for issuing labels and certificates for the final packages of PRM, so that the users have the necessary information and guarantees.

In 2013, the Commission started a review process of the legislation, adopting a proposal for a Regulation on the production and marketing of plant reproductive material including FRM ('2013 PRM proposal'). In 2015 the proposal was subsequently withdrawn after rejection by the European Parliament in 2014. In May 2021, the

Commission presented a study on possible options to update the existing legislation on the production and marketing of plant reproductive material, which had been requested by the Council¹. The study concluded that the Commission should continue preparatory work to review the existing legislation

Problem the initiative aims to tackle

The current legislation has proven its success in guaranteeing the identity, performance, quality and health of all PRM. Moreover, it has contributed to fostering an internationally competitive PRM industry. Therefore, the core principles of the existing legislation remain valuable for commercial PRM production but there is room for improvement.

Firstly, the content of the 12 Directives is not aligned which causes a lack of coherence, such as different definitions for the term 'marketing' or 'operator'. It leads to inconsistencies in their interpretation for users and competent authorities. This has led to an uneven implementation and application, which creates a non-level playing field and different (market) conditions for operators in the Member States, and thus hinders the smooth operation of the internal market (problem 1). Secondly, the legislation further includes a set of complex and rigid procedures, which result in a high administrative burden in particular for competent authorities and operators. The different and detailed technical requirements included in the 12 Directives create a cumbersome decision-making process for adapting the legislation in case of scientific developments (problem 2).

Problem 1: Divergent implementation practices and non-level playing field

The non-aligned or missing definitions in the Directives have caused different approaches for addressing the same issues, such as adding new species to the scope of the Directives. In some Directives, the procedure for adding or deleting species covered requires an act adopted by the Commission, while in others it requires an act to be adopted by European Parliament and Council. Some Directives do not have specific instruments for protecting conservation varieties² (i.e. the Directives for fruit and vine), while such instruments exist for agricultural and vegetable Directives. The approach for authorising non-EU-countries to export PRM to the EU is also inconsistent across the Directives, which in certain cases requires an approval by the European Parliament and the Council, while in others simply a Commission implementing act.

The definitions of 'marketing' and 'operator' are ambiguous in certain Directives or missing in others, and leave it open if the activities of seed conservation networks³ are covered by the PRM legislation or not, and -if so- to what extent. Furthermore, amateur gardeners have different uses and motivations compared to professional users and this raises the question if PRM marketed to amateur gardeners should be subject to the same rules as PRM marketed to professional users.

Heavy procedures for testing and certification create burdens for operators as some of the certification activities can only be carried out officially. This approach is not aligned with more recent developments in the policy governing official controls and other official activities carried out by Competent Authorities, which recognise the role of activities carried out by operators under official supervision in reducing administrative burdens and ensure an efficient use of public resources.

Member States have used the possibility offered by the legislation to deviate or exempt from the applicable rules in different ways, which causes problems for products marketed in different Member States.

There is no harmonised and risk-based framework for official controls, which limits the ability for Competent Authorities to enforce risk-based measures to ensure the identity, health and quality of PRM. This results in differences of control and enforcement across Member States.

Problem 2: Legislation prevents innovation and use of new technologies and adaptation to policy developments

The creation of synergies with the Green Deal and its related strategies (Farm to Fork Strategy, the Biodiversity Strategy, the EU Adaptation Strategy on adapting to, and mitigating, the impact of climate change, the new EU Forest Strategy on healthy and resilient forests and the European Digital Strategy), is often hindered because complex and rigid procedures and requirements in the current PRM legislation do not pursue always the same objectives as these strategies. Following the withdrawal of the 2013 PRM proposal, the PRM legislation, which

¹ Commission Staff Working Document SWD(2021)90 Study on the Union's options to update the existing legislation on the production and marketing of plant reproductive material

² Conservation varieties are landraces and varieties of agricultural and vegetable species traditionally grown in certain regions.

³ 'Seed conservation networks' are operators exchanging and marketing PRM in limited amounts with the main non-profit purpose of conserving plant and forest genetic resources.

dates back to the 1960s, is in any case not aligned with more recently adopted legislation and the aforementioned strategies.

The lack of clear rules on testing for Value of Cultivation & Use (VCU) and the absence of sustainability criteria (e.g. reduced use of plant protection products and adaptation to changing climatic conditions) in the EU legislation have caused considerable differences between Member States in relation to the sustainability characteristics of new varieties. This in turn has impeded an adequate response to the demand for more sustainable agri-food production.

Currently, the availability of organic seed and of organic varieties suitable for organic cultivation is insufficient. It is important to set appropriate conditions for their development to foster the goal of the Farm to Fork Strategy of reaching 25% of agricultural land under organic farming by 2030. As organic varieties have to be characterised by a high level of genetic and phenotypical diversity between individual reproductive units, the current VCU tests and testing protocols for the distinctness, uniformity and stability (DUS) of varieties are not yet adapted to the needs of organic varieties suitable for organic cultivation. Due to the lack of organic varieties suitable for organic cultivation and a derogation in the organic legislation allowing the use of untreated non-organic PRM, this PRM is still used to varying extents in different Member States for organic production.

The legislation hinders the introduction of new/adapted rules on innovative production processes, which creates barriers for the market access of PRM products obtained through scientific and technical progress. Moreover, the current rules limit or do not place enough emphasis on the use of scientific and technical developments, such as certain biomolecular techniques.

Member States can choose to either apply or not lighter conditions for the registration of amateur and conservation varieties. When the requirements and costs for registering conservation and amateur varieties are identical to those of new varieties, there may be little incentive for seed conservation networks and other operators active in this domain to register conservation and amateur varieties⁴, negatively affecting the diversity of seeds and PRM that contribute to biodiversity and resulting in lack of alignment with recent Commission Strategies. In addition, the current legislation restricts increasing consumer demands for these traditional and local varieties due to production limits imposed by the existing legislation.

Basis for EU intervention (legal basis and subsidiarity check)

The PRM legislative framework is based on **Article 43** of the Treaty on the Functioning of the European Union (TFEU) implementing the Common Agricultural Policy (CAP). The Lisbon Treaty qualifies agriculture as shared competence between the EU and its Member States. All fields of agricultural activity as well as ancillary activities upstream and downstream have been regulated to a very large extent at EU level. **Article 114** provides the legal basis for the establishment and functioning of the internal market and the approximation of provisions laid down by the law, regulation or administrative actions. **Article 191** states as the objectives of EU environment policy the preservation of the environment, the prudent and rational use of natural resources as well as promoting measures at international level to deal with environmental problems.

The introduction of the EU Directives on the marketing of PRM starting in the 1960s has been a major contributor to the creation of an internal market. The evaluation carried out in 2007 – 2008 confirmed that the EU rules on marketing of PRM have had a generally positive impact on free movement, availability and quality of PRM on the EU market and have thus facilitated trade within the EU, despite the still prevalent problems. If there had been no action at EU level, 27 systems instead of one would be in place today. This would put even more serious obstacles to the movement of PRM on the internal market and increase the financial burden associated with the necessary controls on the health and quality of PRM. Therefore, a common EU framework should be retained, and where possible strengthened, as it is considered to be the most appropriate approach.

B. Objectives and Policy options

⁴ Amateur varieties are varieties with no intrinsic value for commercial production but developed for growing under particular conditions (i.e. they are mostly used by amateur gardeners).

The general objectives are to remove any obstacle or barrier in the internal market in order to ensure a level playing field for the marketing of PRM. For all types of users and consumers, a wide diversity of choice of PRM should be ensured. The revision also supports innovation and competitiveness of the EU PRM industry. Finally, it should contribute to the objectives of the Green Deal and its related Farm to Fork, Biodiversity, EU Climate Adaptation, European Digital and New EU Forest Strategies. In particular, it should support adaptation to, and mitigation of, the impact of climate change, and contribute to food security, sustainable production and biodiversity protection.

The specific objectives are to:

- Increase coherence of the legislation through simplified and harmonised basic rules on fundamental principles (e.g. scope of application, definitions of ‘marketing’ and ‘operator’);
- Eliminate fragmentation of requirements that results in adjustment of costs for operators;
- Increase the efficiency/effectiveness of the PRM sector through the establishment of simplified, more flexible and proportionate procedures;
- Clarify rules for seed conservation networks and PRM marketed to amateur gardeners;
- Establish appropriate conditions for the development of organic varieties suitable for the organic production;
- Empower Competent Authorities to allocate control resources through a harmonised and risk-based framework for official controls;
- Support the conservation and sustainable use of plant and forest genetic resources to promote the development of diverse farming systems, defend biodiversity, adapt to, and mitigate, the impact of climate change and contribute to food security;
- Introduce lighter requirements for conservation varieties for all PRM sectors and, where appropriate, for amateur varieties;
- Support innovation and the development of digital technologies and bio-molecular techniques in the PRM sector.

To address the identified problems, and achieve the above objectives, several policy options will be considered in the impact assessment. Those options will be developed on the basis of the following options.

Policy choices

Baseline: Do nothing.

No changes to the current legislation; focus on implementing the legislation in a way, which takes into account, to the extent possible, the objectives of the Green Deal and the Farm to Fork Strategy.

Option 1: Alignment of definitions and structure of the legislation

This option would keep all 12 marketing Directives. It would include alignment and simplification of the structure of the legislation and decision-making procedures and introduce flexibility for operators. It would also introduce measures in support of sustainability. It would focus on the needs of the professional sector. It would establish a lighter registration system for PRM marketed by seed conservation networks and PRM marketed to amateur gardeners but PRM would still need to comply with the requirements of the marketing legislation as regards identity, health and quality of the material. Exchange of PRM between farmers would remain in the scope of the PRM other than FRM legislation, meaning that it would be considered as ‘marketing’.

The amendments would concern:

- Aligning the structure, definitions and decision-making procedures between the Directives;
- Adding definitions on terms such as operator/marketing where missing and/or streamline definitions across Directives;
- Establishing and aligning instruments for protecting conservation varieties in all Directives and, where appropriate, for amateur varieties;
- Removing duplications in inspections, inconsistent rules applicable to the same material and ensuring coherence with the plant health, GMO and organic legislation;
- Relying on tertiary legislation to set requirements and to adapt these requirements to technical and scientific developments;
- Increasing the number of tasks that operators may carry out under supervision of the competent authorities such as the tests carried out for registration and certification;

- Including guidance on how to record the characteristics determining the identity of FRM in relevant documentation;
- Supporting the Green Deal objectives through measures addressing climate change mitigation and adaptation, the conservation and sustainable use of plant and forest genetic resources and the protection of biodiversity;
- Supporting the Farm to Fork Strategy by facilitating the marketing of varieties adapted to the needs of organic agriculture through e.g. adapted DUS and VCU tests and contributing to reaching the organic objective of the Farm to Fork Strategy;
- Amending existing official control rules and adding new rules, catering for the specific needs of the respective sector.

Option 2: Alignment of definitions and structure of the legislation while matching needs of professional sector, seed conservation networks and users

This option would include the general amendments as described under option 1 and additionally would exempt seed conservation networks and marketing to amateur gardeners from the scope of application of the legislation. Exempting the marketing of limited amounts of PRM, in particular by seed conservation networks for non-profit purposes, would incentivise PRM diversity, and boost and promote the marketing of more local and traditional products. It would be analysed if, and how, reducing the overall number of Directives is advantageous and/or constitutes a legal simplification. The FRM legislation would still be kept as a separate legal instrument because the production and certification process of FRM, as well as its basic concepts, are distinct from the one of the other sectors.

The further amendments would concern:

- Scope of application of the PRM other than FRM legislation: clarifying exemptions and in particular create a specific EU framework for the exchange in kind between farmers of PRM and services restricting this activity e.g. to farmers belonging to an association/network; limiting the scope of application of the PRM other than FRM legislation to the professional sector, excluding seed conservation networks and amateur gardeners from the scope of the legislation. No EU rules or national rules should regulate seed conservation networks and the amateur market. Those sectors could be self-regulated;
- Introducing modern and flexible processes adapted to new technologies to enhance the efficiency of the certification/inspection and variety registration systems, and label security, traceability and integrity of PRM;
- Introducing mandatory sustainability criteria into variety testing;
- Including or excluding the PRM legislation in the scope of the Official Controls Regulation;
- Keeping the scope of the FRM legislation or extending the scope to certain clearly defined non-forestry purposes (agroforestry and biodiversity purposes, biomass and energy generation).

Option 3: Full harmonisation of the legislation

This option would create a full harmonisation by proposing one single policy instrument with specific chapters for the different crop groups. The policy instrument on FRM would still be kept separate. The professional sector, seed conservation networks and marketing to amateur gardeners would be covered by the scope of the legislation. Exchange of PRM between farmers would remain in the scope of the PRM other than FRM legislation, meaning that it would be considered as ‘marketing’. This option would focus on PRM quality and high guarantees for users and would improve conditions for its free circulation within the internal market. Derogations and exemptions from the requirements of the legislation would be kept to a strict minimum, by restricting the possibility for Member States to establish less or more stringent national requirements for marketing in comparison to the respective EU requirements. PRM would be included in the scope of the Official Controls Regulation.

In addition to the measures proposed under the bullet points under option 1, the amendments would concern:

- Scope/applicability of the PRM other than FRM legislation to the marketing of varieties of PRM to professional and non-professional end users;
- Applicability of the FRM legislation exclusively to FRM marketed for forestry purposes;
- Including PRM into the scope of the Official Controls Regulation.

C. Preliminary Assessment of Expected Impacts

<p>Likely economic impacts</p> <p>Offering more flexibility to operators would increase the responsiveness and adaptability of companies in bringing PRM to the market. It would continue contributing to food and nutritional security for EU citizens and ensure the availability of sufficient and diverse FRM for afforestation and reforestation. This would have an overall positive economic impact on operators and consumers. The sector's international competitiveness would also be improved. The possibility to carry out variety testing and field inspections and to produce PRM under official supervision would increase the efficiency of the sector and, in addition, would decrease administrative burdens and costs for Competent Authorities. Many SMEs and smaller companies with limited human resources, however, would continue to depend on the expertise and human resources of the Competent Authorities for variety registration and certification and this may limit the savings made by Competent Authorities. Lighter and less costly registration requirements for certain variety types (e.g. conservation varieties) would create more equal conditions for operators across the EU Member States and improve income of small companies producing for niche markets, reducing also costs for other operators. More responsiveness of the legislation to new technical developments in the PRM sector by simplifying procedures to adapt the legislation would support innovation and research, and therefore also competitiveness, in an already research-intensive sector, with positive economic impacts on all types of operators in the sector. A more harmonised implementation of the Directives through, for example, clearer definitions of exemptions to the scope of application and a harmonised and risk-based framework for controls, would help achieve more even conditions and create similar opportunities for producers in different Member States.</p>
<p>Likely social impacts</p> <p>The PRM sector, in particular the breeding industry and FRM sector are highly innovative involving a highly skilled workforce and state of the art facilities. A strong, sustainable and internationally competitive breeding industry and FRM sector would support the creation and maintenance of skilled employment in rural and remote areas. European cultural heritage finds its expression also in landscape and agricultural diversity, and diversity of forests. Facilitated procedures for the registration of conservation and amateur varieties and FRM naturally adapted to local and regional conditions would contribute to the protection and continued viability of this heritage.</p>
<p>Likely environmental impacts</p> <p>Supporting PRM, which contributes to species diversity, genetic diversity within tree species (FRM) and within-field genetic diversity (mixtures of varieties, heterogeneous material, organic varieties) would help lowering the environmental impact of agriculture and forestry. Genetic diversity of a crop in the field could ensure a greater likelihood that, for example, not all plants in the field will be lost in extreme weather events (e.g. better resistance to drought of individual plants) or when the plants are attacked by damaging plant pests. Likewise, genetic diversity within a single tree species is of utmost importance to avoid that entire forests can be wiped out by, for example, bark beetle infestations. Lighter rules for the registration of conservation varieties and creating conditions for amateur gardeners to have a wide choice of old and new varieties, would establish conditions for the conservation of genetic diversity in fields and in gardens, which will therefore remain available for future breeding efforts.</p> <p>In the testing of new varieties during the registration process, sustainability criteria would address resistance to threats from plant pests and from adverse weather conditions. Introducing mandatory sustainability criteria into variety testing would support the development of more climate-proof varieties, which are e.g. resilient in the face of extreme weather events and/or are tolerant or resistant to plant pests. This would contribute to enhancing food security. Establishing a specific system for the registration of organic varieties would support the growth of organic agriculture and help avoiding the use of plant protection products and other external inputs, thereby supporting two core aims of the Farm to Fork Strategy. It is the combination of actions and characteristics at species and variety level that would support adaptation in land ecosystem management and allow adapting to, and mitigating, the impact of climate change.</p> <p>Improved FRM legislation combined with sustainable forest management would result in healthy and resilient forests that would contribute to adaptation to, and mitigation of, the impact of climate change, and would better protect biodiversity.</p>
<p>Likely impacts on fundamental rights</p> <p>None</p>
<p>Likely impacts on simplification and/or administrative burden</p> <p>Legal simplification would improve the coherence of the legislation and lead to a better implementation, with less burdens for operators active in more than one Member State or in more than one sector.</p> <p>Increased flexibility would be achieved by widening the possibility for operators to carry out tasks (inspection/certification, elements of variety testing, FRM production) under the supervision of the Competent Authorities. Companies could more efficiently plan their operations in line with their needs and capacities and could make effective use of in-house expertise. Reducing the complexity of procedures and cumbersome</p>

decision-making processes, increased flexibility and uptake of new technologies (digitalisation, bio-molecular techniques) would reduce administrative burdens for Competent Authorities and increase efficiency of the system, in particular for SMEs developing innovative breeding and PRM production methods.

A harmonised and modern system for risk-based official controls, supported by the deployment of digital technologies and training, would lead to efficiency gains. Especially the introduction of risk-based controls would allow operators, who have a proven track record of reliable production, to make efficiency gains, while Competent Authorities can focus control efforts where they are most needed.

D. Evidence Base, Data collection and Better Regulation Instruments

Impact assessment

An impact assessment will be carried out to support the preparation of this initiative.

Evidence base and data collection

The impact assessment will be based on the following documents:

- The [evaluation](#) carried out in 2007-8;
- The [impact assessment](#) of 2013;
- The [PRM study](#) requested by the Council;
- The [contractor's report](#) supporting the study.

An additional study will be commissioned to support the impact assessment process during the second half of 2021. Findings from the PRM study and the aforementioned additional study will be used to source evidence to assess the impacts of the proposed options, developed on the basis of the options presented above (as well as to further refine such options). In particular, those studies will provide data on expected economic, social, environmental and administrative impacts.

Consultation of citizens and stakeholders

Interested parties will be consulted through a mix of open and targeted consultations. Consultations will be carried out to engage all relevant stakeholders and seek their opinion on the main policy approaches and how they would be affected by them.

The consultation activities will involve all the main stakeholder groups, including Member States' Competent Authorities, PRM industry representatives, farmers' organisations and other interested partners, such as international organisations active in this domain and civil society representatives. An SME test will be carried out.

From November 2021 to February 2022, a public consultation is scheduled to take place via an online questionnaire. This consultation will be available in all official EU languages and will be accessible via the Commission's central [public consultations page](#) ('Have Your Say').

Will an Implementation plan be established?

An implementation plan could be established based on the impact assessment performed. Where necessary, guidance documents could be developed.