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COMMISSION STAFF WORKING DOCUMENT

EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT

Accompanying the document

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

**On the production and making available on the market of plant reproductive material
(plant reproductive material law)**

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1. PROBLEM DEFINITION

Background

The EU commercial seed market now has a value of approx. EUR 6.8 billion, representing more than 20% of the total worldwide market for commercial seed. In 2002/2003, the EU became a net exporter of planting seeds. Currently, the EU PRM sector is highly competitive at global level: it is the largest exporter with an export value of EUR 4.4 billion which is more than 60% of the worldwide export. The sector is highly concentrated (the largest 10 companies represent nearly 67% of the global seed market), but SME and micro-enterprises play a crucial role in the internal market, notably in niche markets such as organic crops.

Plant reproductive material (PRM) is a fundamental input for the productivity, the diversity, and the quality of plants and food. This has been reflected in national legislation since the late 19th century and in European legislation. The current EU legislation for PRM has been developed since the 1960s This framework consists today of 12 basic Council Directives covering variety listing as an authorisation for marketing and specific marketing requirements for different species (fodder plant seed, cereal seed, beet seed, seed of oil and fibre plants and vegetable seed, vine propagating material, seed potatoes, vegetable reproductive material other than seed, fruit plant propagating material, ornamental plants, forest reproductive material).

GMOs are dealt with in a separate legislation (Directive 2001/18/EC, Regulation (EC) No 1829/2003 and Regulation (EC) No 1830/2003) and are not covered by this initiative.

Problem Identification

While the existing PRM EU legislation has been valuable in achieving the initial objectives of guaranteeing free marketing of material and providing healthy and quality PRM and thus contributing to productivity in the agriculture, horticulture or forestry sectors, an increasing number of problems have been emerging:

- The complexity and fragmentation of the legislation, lack of coherence with other policies, no EU rules for cost recovery, the non-harmonised transposition and implementation of the current Directives and the consequent differences in e.g. technical requirements are obstacles to the establishment of a level playing field for all operators. There is also a need to achieve major gains in legal simplification and policy coherence. The review of the PRM legislation is therefore part of a package of four reviews relating to the health of plants, health of animals, marketing of plant reproductive material and official control of food and feed.
- The rigidity of the current legislation in allocating tasks puts a high administrative burden on public authorities and limits the flexibility of business operators (e.g. impossibility to conduct certain tasks).
- The absence of horizontal coordination with other EU policies and strategies is an obstacle to a more efficient implementation of existing EU legislation, policies and strategies (sustainable agriculture and forestry, biodiversity protection, climate change, bio-economy).

These problems are described in more detail in the report in section 2.3.

Considering the Europe 2020 Strategy "Smart, sustainable and inclusive growth" and the need to foster the competitiveness of European business, notably SMEs, furthermore taking into account the Commission's principles of Smart regulation and the evolution of the economic and scientific-technical contexts of the PRM sector, it is not sufficient to make amendments to the legislation and better implement them.

Evaluation, analysis and broad consultations with Member States and stakeholders thus proved the need to update the system. This can be done by combining measures along three axes (as follows) and which resulted in policy options to be considered:

- (1) Simplification: the legal architecture requires substantive simplification in form of a Regulation so that a harmonised implementation in all Member States and a level playing field for all operators is assured.
- (2) Flexibility and responsibility sharing: operators require more flexibility to carry out work in the context of variety registration and certification and the work of competent authorities needs to focus more on the supervision of the production of PRM in the EU (moving from product inspection to process audits). For this, public services need to be secured financially. The listing of PRM varieties under a unique name in national and the EU registers generally is a requirement for marketing and based on the identity (Distinctness, Uniformity and Stability - DUS) and characteristics (Value for Cultivation and Use - VCU) of the variety. In addition, individual lots of PRM are subject to a

quality control system. These activities could be carried out by competent authorities, by operators under official supervision or (for certain categories of PRM) under the operator's responsibilities. This responsibility sharing and increased flexibility should lead to overall costs savings by a more efficient and timely organisation of the work and will accelerate the access of new innovative varieties to the Internal market.

- (3) Coherence and horizontal linkages: sustainability, biodiversity protection and climate change have to be addressed in addition to productivity and PRM quality.

How would the problem evolve if no action was taken?

The current legislation only allows variety examinations by official authorities. To a certain extent, certification tasks can be carried out by operators under official supervision. However, limitations do not allow certification under supervision for certain species (e.g. potatoes) and categories of PRM. This has an impact on business with limited room to operate, especially when the international context is evolving. If no action was taken, the shortcomings of the system will grow and become an increasingly larger burden for both official authorities and business with consequences for competitiveness, adaptation to market demands as well as export capacities vis-à-vis to non EU competitors.

The provisions could become more problematic given the consequences of growing pressures on national budgets. Furthermore, discrepancies with regard to PRM technical requirements are not supportive to the establishment of a level playing field on the internal market for business. The complexity and fragmentation of the legislation will perpetuate existing uncertainties in its implementation. As regards new issues such as biodiversity, climate change, bio-economy, the current legislation will continue to address them as marginal topics.

No synergies with the Plant Health Law concerning the plant health checks that are part of the PRM certification process or integration of general principles concerning official controls embedded in Regulation (EC) No. 882/2004 would be obtained.

2. ANALYSIS OF SUBSIDIARITY

The PRM legislative framework is based on Article 43 of the Treaty on the Functioning of the European Union (Common Agricultural Policy) whose objectives are to: increase agricultural productivity, ensure a fair standard of living for the agricultural community, stabilise markets, assure availability of supplies at reasonable prices for consumers. The Lisbon Treaty qualifies Agriculture as shared competence. In addition, the rules on the internal market (TFEU 114) and the preservation of the environment (TFEU 191) complete the legal base for EU action.

The introduction in the 60s of the EU legislation on the PRM marketing has contributed to the creation of an internal market for PRM. As confirmed by many stakeholders, these EU rules have had a positive impact on **free movement, availability and quality** of PRM and facilitated trade within the EU. Pre-market authorisations of PRM are performed by national authorities valid for all Member

states, which ensure open competition on the Single market while safeguarding subsidiary elements for Member States taking into consideration their national needs (e.g. VCU are based on agro-ecological evaluation). If there was no action at EU level, 27 systems instead of one would be in place. This would put obstacles to the movement of PRM on the internal market and increase the financial burden associated with the necessary controls on health and quality of PRM.

International standards have been established for PRM quality (OECD, UNECE) and health (IPPC, WTO/SPS agreement) which justify an EU action for establishing a level playing field and a harmonised implementation. With a view to ensuring proportionality of measures, notably reducing administrative burden for stakeholders, the system must take into consideration the freedom and economic viability of stakeholders as well as SME and micro-entities. Measures on conservation or amateur varieties help to ensure access of growers, including amateur gardeners, to wide range of PRM and play a role in maintaining resilient systems in agriculture production and genetic diversity at the field level. Smart growth is fostered by allowing simplified market access for specific varieties.

3. POLICY OBJECTIVES

3.1. Overall objectives

- To assure the health and high quality of PRM;
- To provide a single regulatory framework supportive to innovation and competitiveness;
- To support sustainable production, biodiversity, adaptation to climate change and to contribute to food security and poverty alleviation.

3.2. Specific objectives

- To ensure a level playing field through simplified, harmonised rules;
- To reduce unnecessary costs and administrative burden and increase flexibility;
- To align PRM legislation with other recent Union strategies;
- To foster market access for innovation in plant breeding.

3.3. Operational objectives

- To provide one PRM Law with flexible and proportionate procedures;
- To promote an harmonised implementation of legislation by audits and training;
- To foster innovation by increasing timeliness and information provided in the EU register;

- To enhance market transparency and traceability through the registration of operators.

4. **POLICY OPTIONS**

The problem definition identified the following main axes along which the system has to change in order to be fit for the changing economic, environmental, social, scientific circumstances: (i) Simplification of the basic legal acts (from 12 Directives to one Regulation), (ii) Cost recovery and improvement of the effectiveness and efficiency of the system, (iii) Horizontal coordination with recent, already adopted EU policies. Various ways – increased flexibility, deregulation or centralisation – are explored for improving the efficiency of the system, while maintaining the assurances for high quality PRM, competitiveness and addressing new challenges such as biodiversity. Based on these 3 axes, 5 policy options have been identified in a first stage, where legal simplification and cost recovery are constant for all options. In the various options, issues concerning SMEs and micro-enterprises have been addressed throughout, especially in order to ensure access for these enterprises to public services for the execution of certain tasks they cannot perform themselves and to support and further develop their flexibility to gain improved access to the PRM market.

The baseline and the five options are outlined here:

- Option 0 – baseline: no change in the current situation (12 Directives and no rule with regard to cost recovery).
- Option 1 – Cost recovery: The option does not include any changes to technical provisions of the current legislation or to the allocation of responsibilities between operators and competent authorities. The only change consists in a full recovery from the stakeholders of costs incurred by the competent authorities in all the Member States, which is already the case in most of them.
- Option 2 – Co-system: A degree of flexibility is introduced for operators. Variety registration continues to be obligatory for a list of crops covered by EU legislation (DUS, VCU), but the technical examination can be carried out by the operator under official supervision. The certification requirements for lots of PRM remain unchanged, but it can be carried out by the operator under supervision of the competent authority in all cases. The current specific provisions continue to apply for conservation/amateur varieties.
- Option 3 – Deregulation: More flexibility is put into place by deregulation. As part of the variety registration, DUS-tests continue to be compulsory, while VCU for agricultural crops is no longer a legal requirement. There is no official certification. Instead, all lots of PRM are marketed only on the basis of a suppliers' label, with minimum criteria. The current specific provisions continue to apply for conservation/amateur varieties.
- Option 4 – Enhanced flexibility system: A dual system is established giving operators substantial flexibility by choosing between two systems, namely one

for officially tested varieties (DUS, VCU with sustainability criteria) and one for non-officially tested varieties with a description supplied by the applicant to the authority. Certification of PRM is limited to officially tested varieties. The marketing of, for example, conservation or certain "niche market" varieties is liberalised as there is no obligatory technical examination of varieties and no obligatory certification of PRM, so that they can be marketed as non-tested varieties.

- Option 5 – Centralisation: The Community Plant Variety Office (CPVO) will be given the mandate to coordinate and decide on variety registration, covering both technical examination (DUS and VCU) as well as variety denomination. The certification requirements for lots of PRM remain unchanged, but certification can be carried out under official supervision. “Reference Certification Centres” with the task to develop best practices, to carry out comparative tests and trials and studies in support of policy development and to disseminate knowledge of PRM certification, will be established. The current specific provisions continue to apply for conservation/amateur varieties.

5. ASSESSMENT OF IMPACTS

The current cost of implementing the variety registration provisions amounts to approximately EUR 55-60 Mio per year in the EU. DUS and VCU account for 45% and 55% of the cost, respectively. The expenditure on certification of PRM is in the range of EUR 73-79 Mio. A majority of Member States does already today fully or partly recover costs, while a minority does not. At least 60% of these costs are recovered by competent authorities across all Member States. The combined yearly costs of registration and certification correspond to approximately 3% (out of which at least 60% are already borne by operators) of the market value of agricultural seed crops. The impacts on SMEs and micro-enterprises have been followed throughout.

Option 1 only addresses cost recovery. This option will establish a level playing field for operators, decrease costs for Member states' competent authorities and secure their functioning in the future. This option will not have an impact on competitiveness and provide no support for innovation and the achievement of environmental or sustainability aims. Competent authorities continue to guarantee the availability of public services to perform technical examinations and inspections. SMEs and micro-enterprises, which do not have the resources to carry out these tasks themselves, will be the main beneficiaries of this guarantee. The cost recovery principle will not affect SMEs and micro-enterprises to a significant extent because this principle is already realised in a majority of Member States and offers benefits to these enterprises as it ensures the continuation of access to official services needed for marketing.

Option 2 will also provide a more level playing field for competitors on the Internal Market as costs are fully recovered in all Member States. Administrative burden is decreased as many tasks (certification, testing for registration) can be carried out by operators under official supervision. This will significantly increase the flexibility of operators to bring new varieties to the market. Some jobs are likely to move from the public sector to the private sector. The aim is to provide flexibility for all operators to

carry out some tasks directly if they wish to do so, but the continued existence of public services is also guaranteed, so that SMEs and micro-enterprises can have technical examinations and inspections carried out by competent authorities. This option also has no clear support for the achievement of environmental or sustainability aims.

Option 3 entails a risk to the health and quality of PRM because obligatory certification is abolished. Competent authorities and operators will be able to realize large cost savings, but abolishing certification means that EU equivalence requirements for seed import from third countries will also have to be abolished. It is also likely that economic activities such as seed multiplication will be relocated to a greater extent to non-EU countries. SMEs will be disadvantaged as VCU is abolished, which serves as unbiased information for users independent of market power of the seller. Abolishing VCU also entails threats to environmental aims as there are no means to steer plant breeding towards these aims.

Option 4 offers additional cost savings to competent authorities and operators, like option 3, while at the same time providing some more assurances for the characterisation of PRM (VCU for officially tested varieties). However, risks due to non-obligatory certification and variety registration will remain. A diversity of operators, especially SME and micro-entities active in niche markets, is bound to benefit from the increased freedom to act. This option also offers good opportunities to support sustainable agriculture and agro-biodiversity as the registration of conservation/amateur varieties is administratively simplified and should bolster market access in this area.

Option 5 offers strong assurances for the quality and health of PRM by centralisation of variety registration in the EU, while a level playing field for operators is established. An efficient and transparent system is established with harmonised technical requirements. The speed of market access of new, improved varieties will be increased – this could lead to job growth in the long-term. The possibility is offered to all operators to make a single application at the CPVO in order to receive plant variety registration and/or plant variety protection; this will simplify especially the work of SMEs. However, the option lacks clear means to steer plant breeding towards the aims of sustainability and the protection of agro-biodiversity; it is more geared towards the needs of conventional plant breeding.

6. COMPARISON OF OPTIONS

The summary table below provides an overall comparison of options in terms of achieving the objectives of the review compared to current situation.

		Option 1	Option 2	Option 3	Option 4	Option 5	Preferred Option
Overall objectives	To assure the health and high quality of PRM	0	0	--	--	0	0
	To provide a single and harmonised regulatory framework which is supportive for innovation and the competitiveness of the European PRM industry	+	+	+	++	++	++
	To support sustainable production, biodiversity protection, adaptation to climate change and to contribute to food security and poverty alleviation	0	0	-	++	0	++
Specific objectives	To ensure a level playing field across the EU through simplified, clarified and harmonised basic rules on fundamental principles presented in an improved legal form	+	+	+	+	++	++
	To reduce unnecessary costs and administrative burden and for public authorities and increase flexibility for operators without compromising the general policy objectives	+	++	+	++	++	++
	To foster innovation in plant breeding, especially in SMEs, in order to improve PRM users' choice and access to a wide diversity of plant varieties adapted to conditions in Europe	0	+	0	++	++	++
	To align PRM legislation with other recent Union strategies (agriculture, biodiversity, food security, climate change, bio-based economy)	0	0	-	+	0	+
Operational objectives	To provide a simplified legal framework for marketing of PRM – “PRM Law” - with the establishment of simplified, more flexible and proportionate procedures	0	++	++	++	++	++
	To promote a more harmonised implementation of legislation throughout the EU by audits and training	0	0	0	0	++	++
	To foster innovation by increasing the timeliness and level of information provided in the EU Register	0	0	0	0	++	++
	To enhance market transparency and improve traceability through the registration of operators	0	++	++	+	++	++

Legend: 0: no change with the baseline option +: minor positive effect ++: significant positive effect -: minor negative effect --: significant negative effect

Preferred option

As none of the five options provided an optimal balance between efficiency of the system, the quality assurance of the PRM, the maintenance of competitiveness and halt of loss of biodiversity, a preferred option, combining positive elements of the 5 initial options while maintaining as much choice and flexibility as possible for operators, was designed and selected. This preferred option takes up elements from options 2, 4 and 5. This combination aims at striking a balance between flexibility for operators and biodiversity (options 2 and 4) and the necessary rigor in health and quality requirements (option 2 and 5) for the fair functioning of the market and for maintaining the quality and health of the products. It includes the two horizontal principles of simplification of the PRM legal architecture and cost recovery.

The General principles are: Cost recovery for services carried out by competent authorities. Exemptions are possible depending on the degree of public interest in the respective PRM marketing or in line with the exemptions envisaged by the revision of Regulation 882/2004. Operators can carry out, under official supervision by the competent authority, a wide range of activities in the area of registration and certification. All operators have to be registered in order to guarantee PRM traceability. Specific and strict obligations concerning registration and certification shall apply to a specific list of species important for the EU market. General minimum requirements shall apply to all other PRM (non-listed species) on the market and cover labelling obligations and provision of 'fitness for use'.

The role of the CPVO will be extended to centralising all information on varieties of PRM registered at national or European level. CPVO will harmonise technical requirements and audit the national examination offices which in turn allow private-sector testing stations to carry out technical examinations. CPVO shall take an increased role in the arrangements for making information available on varieties authorised for marketing in the internal market (online database) and verify denominations for all applications. As an alternative to national registration, centralised registration for varieties not requiring VCU-evaluation (e.g. vegetables) by CPVO shall be offered.

The registration of non officially tested varieties, with an officially recognised description, at national and European level shall be an option that is given to conservation and amateur varieties for reasons of public good. Existing restrictions for the marketing of conservation varieties shall be relaxed.

While VCU shall be maintained and shall be decided on a species-by species basis, its criteria shall principally reflect public goods and become a “VCU for sustainability and health”. VCU shall be harmonised as much as possible across agro-ecological regions and continuously improved as much as possible to take care of any evolution of public and private needs and legislative requirements.

Mandatory certification of lots of certain crops shall be maintained. The list of species that have to be covered by this obligation shall be determined on a crop-by crop basis to allow for future changes in, for example, health risks or economical importance. The examination under official supervision shall be widened to all species and all categories (i.e. basic and pre-basic crops).

The needs of micro enterprises and SMEs will be specifically taken into account: The equal access to the internal market for varieties developed by those companies will be guaranteed by maintaining registration rules (upholding of VCU) not based on the market power of the seller. In addition, with the possibility of having a variety description provided by the operator (officially recognised description) increasing opportunities will be created for specific markets (e.g. conservation varieties) which are of particular interest for SMEs and micro-enterprises. Official inspection services shall always be made available by competent authorities to conduct work that SMEs or micro-enterprises can not conduct themselves.

The preferred option thus achieves the five main objectives in the following way:

- (1) simplification through the replacement of 12 Directives with one Regulation;
- (2) reducing administrative burden by introducing cost recovery and the transfer of tasks to operators;
- (3) fostering innovation through allowing more operational flexibility to operators;
- (4) supporting sustainability, biodiversity and adaption to climate change by "sustainable VCU" and a reduced burden for conservation varieties;
- (5) securing transparency and traceability by the registration of all operators and minimum requirements for non-listed species.

7. MONITORING AND EVALUATION

To assess the success of the measures introduced, several indicators are suggested:

- (1) Harmonisation of legislation and implementation in the Member States
 - Number of requests for clarifications and complaints received.
 - Results of FVO or CPVO audits on implementation of the legislation in Member States.
 - Number of notification received from Member States on national measures.
 - Functional register of operators.
- (2) Reduction of administrative burden and costs and introduce flexibility
 - Variety registration
 - Application: number, time needed, cost recovery.
 - PRM companies applying, with a focus on SMEs: number, type, evolution.
 - Number of varieties registered with an ‘officially recognised description’.

- Number of direct application for variety registration to CPVO.
 - PRM quality control
 - Percentage of certification under official supervision compared to official certification in Member States.
 - Cost of PRM quality control.
- (3) Setting up proportionate rules and alignment with other EU policy and strategies
- Number, quantity of conservation and amateur varieties registered and marketed.
 - Number of species concerned by this rules.
 - Harmonised criteria for variety registration (e.g. sustainable VCU).