

Proposal for a Regulation on the production and marketing of plant reproductive material (PRM)

DG Health and Food Safety
Plant Health Unit

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Structure of the Regulation

- Chapter I: General provisions (objective, scope, definitions...): Art. 1-4
- Chapter II: Requirements for production & marketing of PRM: Art. 5-25
 - Derogations: Art. 26-38
 - Imports: Art. 39-40
- Chapter III: Professional operators: Art. 41-43
- Chapter IV: Variety registration: Art. 44-74
- Chapter V: Procedural provisions: Art. 75-76
- Chapter VI: Reporting, penalties, amendments: Art. 77-81
- Chapter VII: Final provisions (repeals and entry into force): Art. 82-83
- 8 Annexes



Main features (1)

- Single Regulation replacing 10 PRM marketing Directives. (66/401, 66/402, 68/193, 2002/53, 2002/54, 2002/55, 2002/56, 2002/57, 2008/72, 2008/90)
- Two main pillars maintained: Variety registration and PRM certification.
- Strengthened sustainability requirements for the acceptance of varieties of agricultural crops and vine and extension to fruit plants and vegetables.
- Adjusted rules for testing of varieties suitable for organic production to facilitate organic production.



Main features (2)

- Contribution to agro-biodiversity and conservation and sustainable use of plant genetic resources by lighter rules for:
 - conservation varieties
 - conservation networks
 - heterogeneous material
 - exchange of seed in kind between farmers and
 - marketing to final users (amateur gardeners).
- Introduction of innovative production processes, digital tools, and clarification of rules on bio-molecular techniques.
- Within the scope of the Official Controls Regulation.



Exclusions from scope Article 2(4)

- Propagating material of ornamental plants regulated by Directive 98/56/EC;
- Forest reproductive material regulated by new separate proposal on FRM;
- PRM produced for export to third countries;
- PRM sold or transferred in any way, whether free of charge or not, between final users for their own private use and outside their commercial activities;
- PRM used solely for official testing, breeding, inspections, exhibitions or scientific purposes.



Only identity and quality aspects - no more RNQPs under PRM (Articles 4 - 8)

- The proposal only covers identity and quality aspects
- Rules on pests will be exclusively covered by Regulation (EU) 2016/2031 (see Article 4)
- Requirement that PRM is of a registered variety (Article 5) and category (Art. 6)
- Basic requirements for pre-basic, basic and certified seed and material are set out in Article 7 and Annex II
- Basic requirements for standard seed and material are set out in Article 8, and Annex III



Implementing act for certification and other production/marketing requirements (Articles 7(4), 8(5), 9)

- During the transitional period of 3 years, after the entry into force and before the date of application of this Regulation, the Commission will adopt the necessary implementing act specifying the technical requirements for all categories per species: e.g. germination, purity, moisture, distances.
- That implementing act will replace the Annexes of the marketing Directives and other implementing acts currently applicable (e.g. Implementing Directive 2014/98/EU for fruit plants).
- It will mostly replace the existing requirements, but without RNQPs references any more.



Certification under official supervision (Articles 10 – 12)

- Professional operators may be authorised by the competent authorities to carry out some or all parts of the certification process under official supervision ('mix and match').
- The authorisation shall be granted pursuant to certain requirements and also withdrawn if those requirements are no longer fulfilled.
- The competent authorities shall also organise training and examinations of the personnel carrying out field inspections, sampling and testing.
- They shall, at least once per year, conduct audits to ensure that the professional operator fulfils the requirements for its authorisation.



Labels and lots (Articles 15 – 18)

- PRM will be marketed in lots
- Lots of pre-basic, basic or certified material/seed will bear an official label
- Lots of standard material/seed will bear an operator's label (no more 'supplier's label')
- Digital label
- Specific labels for PRM subject to derogations of Art. 26 – 38
- Additional labelling for NGT (Cat 1 and 2) and GMO
- Specific rules for the content, form, size and colour of labels for each category to be adopted by a Commission implementing act (within the transitional period before the application of this Regulation)



New derogation: Conservation varieties (Articles 26 and 53)

- Conservation varieties are varieties traditionally grown or locally newly bred under specific local conditions, and adapted to those conditions, and characterised by a high level of genetic and phenotypical diversity between individual reproductive units.
- PRM of a conservation variety may be produced and marketed as standard seed or material, if it complies with the requirements for standard seed/material.
- It shall be accompanied by an operator's label with the indication 'Conservation variety'.
- A professional operator who uses this derogation shall annually notify to the competent authority this activity.
- Conservation varieties shall be registered on the basis of an officially recognised description and with an indication of their initial regions of origin and included in the variety register.



New derogation: Heterogeneous material (Article 27 and Annex VI)

- Heterogeneous material is defined as: (a) a plant grouping within a single botanical taxon of the lowest known rank which presents common phenotypic characteristics; (b) is characterised by a high level of genetic and phenotypic diversity between individual reproductive units; (c) is not a variety;
- PRM of heterogeneous material may be produced and marketed within the Union without belonging to a variety.
- The heterogeneous material shall be notified to and registered by the competent authority prior to its production.
- Requirements are set out in Annex V, based on the requirements of Commission Delegated Regulation (EU) 2021/1189 on PRM of organic heterogeneous material.



New derogation: PRM for final users (Article 28)

PRM may be marketed to final users, if it complies with all of the following requirements:

- to bear an operator's label with the denomination of the variety and the indication 'PRM for final users – not officially certified';
- in case not belonging to a registered variety, to have a description made publicly available;
- to be practically free from quality pests and fulfil basic quality requirements; and
- to be marketed in small packages.



New derogation: PRM marketed to and between gene banks, organisations and networks (Article 29)

- PRM may be marketed to, or between, gene banks, organisations and networks with an objective to conserve plant genetic resources, whereby any of the activities are carried out for non-profit purposes.
- It can be marketed as well from those gene banks, organisations and networks to persons, including final users, who carry out conservation of that PRM, for non-profit purposes.
- PRM shall be listed in a register kept by those organisations with an appropriate description; be conserved by those gene banks, organisations and networks; samples of that PRM shall be made available to the competent authorities upon request; and PRM shall be practically free from quality pests and any defects.



New derogation: seeds exchanged between farmers (Article 30)

Farmers may exchange seeds in kind, if such seeds fulfill all of the following conditions:

- are produced in the respective farmer's own premises;
- are derived from the respective farmer's own harvest;
- are not subject to a service contract conducted by the respective farmer with a professional operator performing seed production;
- they are used for dynamic management of the farmer's own seed for the purpose of contributing to agro-diversity;
- the seeds don't belong to a protected variety, are limited to small quantities, and are practically free from quality pests and defects.



New derogation: Breeder's seed (Article 31)

- A competent authority may authorise operators to market seed of generations preceding the pre-basic category to another operator, for the purpose of breeding new varieties (breeders' seed).
- The competent authority shall determine the duration of the authorisation and quantities per species, when granting that authorisation.
- The PRM shall be accompanied by a label issued by the professional operator, with the indication 'breeder's seed'



Derogations applicable also under marketing Directives (Articles 32 – 38)

Currently applicable derogations have been retained and updated as needed:

- PRM of not yet registered varieties
- Authorisation in cases of temporary difficulties in the supply
- Provisional authorisation in urgency cases for marketing of seeds not certified as complying with applicable quality requirements
- PRM which is not yet finally certified
- More stringent national production requirements
- Emergency measures
- Temporary experiments to seek improved alternatives to provisions of this Regulation



Imports (Articles 39 and 40)

- Imports of PRM will be allowed on the basis of equivalence, as under the current marketing Directives.
- However, the recognition of equivalence will be decided on the basis of implementing acts (instead of EP/Council Decisions as is the situation today for most of the Directives).
- No more provisional equivalence to be granted by Member States.
- OECD Seed Schemes' label to be used for imports and also for further marketing in the EU of imported PRM.



Requirements for registration of varieties (Article 47)

The varieties have either:

- an official description showing DUS and stability, and fulfil the VSCU requirements or
- an officially recognised description, if they are conservation varieties

In both cases, they shall bear a suitable denomination.



Value for Sustainable Cultivation and Use (1) (Article 52)

- The currently applicable VCU is developed to include a broader concept, namely VSCU (Value for Sustainable Cultivation and Use).
- It shall cover all species, not only agricultural crops and vine.
- It shall be considered as satisfactory if, compared to other registered varieties of the same species, its characteristics, taken as a **whole**, offer a clear improvement for the sustainable cultivation and the uses which can be made of the crops, other plants or the products derived therefrom.
- This means that the performance of all characteristics will be assessed as a combined result, covering cultivation and the use of the variety.



Value for Sustainable Cultivation and Use (2) (Article 52)

The characteristics to be assessed as a whole are the following:

- (a) yield, including yield stability and yield under low-input conditions;
- (b) tolerance/resistance to biotic stresses, including plant diseases caused by nematodes, fungi, bacteria, viruses, insects and other pests;
- (c) tolerance/resistance to abiotic stresses, including adaptation to climate change conditions;
- (d) more efficient use of natural resources, such as water and nutrients;
- (e) reduced need for external inputs, such as plant protection products and fertilisers;
- (f) characteristics that enhance the sustainability of storage, processing and distribution;
- (g) quality or nutritional characteristics.

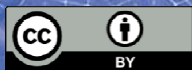


Value for Sustainable Cultivation and Use (3) (Article 52)

- The Commission is empowered to adopt delegated acts establishing:
 - (a) minimum requirements for carrying out the examination;
 - (b) the methodologies for assessing the characteristics;
 - (c) the standards for the evaluation and the reporting of the results of the examination of the value for sustainable cultivation and use.
- For the purposes of registration of organic varieties, the examination of VSCU shall be conducted under organic conditions.



**Thank you for
your attention!**



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