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MEETING DOCUMENT

From:	General Secretariat of the Council
To:	Delegations
Subject:	Meeting of the Working Party on Genetic Resources and Innovation in Agriculture (Seeds, Propagating and Planting Materials; PRM) on 1 and 2 December 2025 - Meeting document on agenda item 1

In view of the meeting of the Working Party on Genetic Resources and Innovation in Agriculture (Seeds, Propagating and Planting Materials; PRM) on 1 and 2 December 2025, delegations will find in the annex the Presidency's revised drafting suggestions on the recitals of the proposal on the production and marketing of plant reproductive material in the Union.

The latest changes take into account the contributions received from delegations during the written consultation and are marked with yellow.

Presidency revised drafting suggestion on the recitals taking into account the contributions received during the written consultation

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, and (EU) 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)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 43(2) thereof,

Having regard to the proposal from the European Commission¹,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee²,

Having regard to the opinion of the Committee of the Regions³.

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) Rules for the production and marketing of plant reproductive material ('PRM') of agricultural crops, **potato**, vegetables, vine and fruit plants have been established at Union level since the

¹ **COM/2023/414 final**

² ~~Not published yet.~~ **OJ C, C/2024/1583, 5.3.2024**

³ **OJ C, C/2024/3674, 26.6.2024**

1960s. The production and marketing of PRM on the Union territory is regulated by Council Directives 66/401/EEC⁽⁴⁾; 66/402/EEC⁽⁵⁾; 68/193/EEC⁽⁶⁾; 2002/53/EC⁽⁷⁾; 2002/54/EC⁽⁸⁾; 2002/55/EC⁽⁹⁾; 2002/56/EC⁽¹⁰⁾; 2002/57/EC⁽¹¹⁾; 2008/72/EC⁽¹²⁾ and 2008/90/EC⁽¹³⁾ (the ‘PRM marketing Directives’). These legal acts have formed the legal framework for the production and marketing of PRM and therefore have been of major importance for the creation of the internal market of PRM in the Union.

- (2) The impact assessments carried out by the Commission in 2013 and 2023 confirmed that those Directives have had a significant impact on the free movement, availability and high quality of PRM on the Union market and have thus facilitated the trade of PRM within the Union.
- (3) However, the rules on production and marketing of PRM need to be adapted to the scientific and technical developments in the areas of agricultural and horticultural, **fruit-growing and vine-growing** production **techniques** and plant breeding. Moreover, the legislation needs to be updated on the basis of changes in international standards and experience gained by the application of the PRM Directives. Those rules need to be clarified in order to facilitate a more harmonised implementation. Therefore, the PRM marketing Directives should be replaced by a single Regulation on the production and marketing of PRM within the Union.
- (4) PRM constitutes the starting material for plant production in the Union. Therefore, it is critical for the production of raw material for food and feed purposes and for the efficient use of plant

⁴ Council Directive 66/401/EEC of 14 June 1966 on the marketing of fodder plant seed (OJ 125, 11.7.1966, p. 2298).

⁵ Council Directive 66/402/EEC of 14 June 1966 on the marketing of cereal seed (OJ 125, 11.7.1966, p. 2309).

⁶ Council Directive 68/193/EEC of 9 April 1968 on the marketing of material for the vegetative propagation of the vine (OJ L 93, 17.4.1968, p. 15).

⁷ Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species (OJ L 193, 20.7.2002, p. 1).

⁸ Council Directive 2002/54/EC of 13 June 2002 on the marketing of beet seed (OJ L 193, 20.7.2002, p. 12).

⁹ Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed (OJ L 193, 20.7.2002, p. 33).

¹⁰ Council Directive 2002/56/EC of 13 June 2002 on the marketing of seed potatoes (OJ L 193, 20.7.2002, p. 60).

¹¹ Council Directive 2002/57/EC of 13 June 2002 on the marketing of seed of oil and fibre plants (OJ L 193, 20.7.2002, p. 74).

¹² Council Directive 2008/72/EC of 15 July 2008 on the marketing of vegetable propagating and planting material, other than seed (OJ L 205, 1.8.2008, p. 28).

¹³ Council Directive 2008/90/EC of 29 September 2008 on the marketing of fruit plant propagating material and fruit plants intended for fruit production (OJ L 267, 8.10.2008, p. 8).

genetic resources. It contributes to environmental protection and the quality of the food chain and food supply in the Union as a whole. In this regard, the availability, **high** quality and diversity of PRM appears to be of **outmost** importance to achieve the transition to sustainable food systems called for in the Farm to Fork Strategy¹⁴, agriculture, horticulture, environmental protection, climate change mitigation and adaptation, food and feed security, and the economy in general.

- (5) In order to achieve this transition to sustainable food systems, the Union legislation should therefore take account of the need to ensure the adaptability of the PRM production to the changing agricultural, **horticultural** and environmental conditions, to face the challenges of climate change, to protect **and** restore **and promote** biodiversity, **to ensure food security** and to meet increasing farmers' and consumers' expectations related to quality and sustainability of PRM.
- (6) The scope of this Regulation should only cover the PRM of certain genera and species of increased economic and social importance. That importance should be assessed depending on whether **the PRM or the crop of** such genera and species represent a significant area of production and value in the Union, on their role for the security of food and feed production in the Union, and on whether they are marketed in at least two Member States. That area of production and value may concern several technical aspects. Depending on the circumstances, it may be calculated on the basis of factors such as the total size of productive land in several different areas of the Union, the marketing value of PRM in relation to specific sectors, or the demands for those species by farmers, final users and industry.
- (7) Those genera and species should be listed and classified by their intended use, namely **as for** agricultural **plants** crops, vegetables **plants**, fruit **plants, potato or and** vine **purposes**. That classification is necessary to ensure a proportionate approach, as some species are only important for certain uses.
- ~~(8) Furthermore, some varieties may have certain characteristics that, when cultivated under certain conditions, could have undesirable agronomic effects that would undermine the objective of the Regulation to contribute to the sustainability of agricultural production. This objective can only be achieved if such varieties are subject to appropriate cultivation~~

¹⁴ Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system (COM(2020) 381 final).

~~conditions under which those undesirable agronomic effects are avoided. Those conditions should apply to the cultivation of those varieties for the production of food, feed or industrial materials and not only when intended for the production and marketing of PRM. Therefore, this Regulation should cover the conditions under which those varieties are cultivated, also for the production of food, feed or other products.~~

- (9) PRM should be defined in a comprehensive manner, including all plants **or parts of plants** capable of, and intended for, producing entire plants **or the production of fruits, vegetables or other crops**. This Regulation should, therefore, cover seeds, as well as all other forms of plants at any growth stage, capable of and intended for producing entire plants. **It should also cover rootstocks and other parts of plants of genera or species or their hybrids, which are not covered by this Regulation, if the material of genera or species covered by this Regulation or their hybrids is grafted or is to be grafted onto them.**
- (10) This Regulation should not cover forest reproductive material due to its particular characteristics, and very different concepts and applicable terminology. For this reason, forest reproductive material is subject to a separate legal act, and namely Regulation (EU) .../... of the European Parliament and of the Council¹⁵ +.
- (11) This Regulation should not cover **PRM of genera and species intended for propagating material of ornamental plants, purposes with the exception of PRM intended for turf grass purposes** because after consultations with Member States and stakeholders it has been concluded that Council Directive 98/56/EC (¹⁶) still adequately covers the needs of that sector. **However, seed intended for turf grass purposes are within scope of this Regulation.**
- (12) This Regulation should cover neither PRM **intended for** exported to third countries, nor PRM used solely for ~~official testing~~, **inspection, sampling or testing, officially or under official supervision**, breeding, ~~inspections~~, exhibitions or scientific purposes. This is because such categories of PRM do not require particular harmonised identity or quality standards and do not compromise the identity and quality of other PRM marketed in the Union.
- (13) This Regulation should not cover PRM ~~sold or transferred in any other way~~, whether free of charge or not, between **non-professional users** ~~any persons~~ for their own private use and

¹⁵ Regulation (EU) .../... of the European Parliament and of the Council (OJ...., p....).

+ OJ: Please insert in the text the number of the Regulation contained in document (... (COD)) and insert the number, date, title and OJ reference of that Regulation in the footnote.

¹⁶ Council Directive 98/56/EC of 20 July 1998 on the marketing of propagating material of ornamental plants (OJ L 226, 13.8.1998, p. 16).

outside their ~~trade~~ **professional activities**. It would be disproportionate to set out rules for such use of PRM, as this kind of transfer is usually limited to very small amounts, has no commercial purposes and is restricted to private activities.

(13a) This Regulation should not cover PRM sold or transferred in any other way, not aimed at its commercial exploitation but subject to service contracts for the purposes of processing including cleaning, disinfection, treatment, packaging, as well as transport, or storage, provided that the provider of services does not acquire title to that PRM. Such PRM remains under the responsibility of the title holder of that PRM who guarantees the identity or quality standards that PRM.

(13b) This Regulation should not cover PRM supplied to providers of services for the production of certain agricultural raw materials intended for industrial purposes, or PRM produced for that purpose under certain conditions. In this closed loop system the risk of the quality of the PRM is carried by the industrial manufacturer.

(13c) This Regulation should not cover PRM used by gene banks for the conservation of plant genetic resources ~~nor organic heterogenous material produced in accordance with Regulation (EU) 2018/848.~~

(13d) This Regulation should not cover organic heterogenous material as it is already regulated in Regulation (EU) 2018/848.

(13e) PRM produced and marketed in accordance with this Regulation should comply with the relevant requirements in Regulation (EU) 2016/2031 on plant health. The specific requirements on RNQP's were previously regulated in both the marketing directives and Regulation (EU) 2016/2031, however those requirements are now fully covered by that regulation to avoid undisireable overlap.

(14) In order to **enable users to make informed decisions** ~~allow for informed choices by the users~~, PRM should be produced and marketed only if it belongs to varieties registered in a national a variety register.

(15) However, it is appropriate to exempt, where necessary, rootstocks **for fruit plants and vine not belonging to a variety** from the requirement to belong to a variety, as although of a significant value, they ~~frequently do~~ **may** not fall under the definition of a variety. **In addition PRM can be produced and marketed without belonging to a variety in other specific cases.**

- (16) In order to ensure the identity, quality and transparency and to enable informed choices by the users, PRM should as a general rule be produced or marketed under predefined categories. Those categories should reflect different generation stages and quality levels, and, on the basis of the internationally established terminology, be named ‘pre-basic’, ‘basic’, ‘certified’ and ‘standard’ seed, and ‘pre-basic’, ‘basic’, ‘certified’ and ‘standard’ material, in the case of PRM other than seeds, and. **However, PRM can be produced and marketed without belonging to a category in specific cases.**

(28 16a) The PRM marketing Directives and international practice and standards require that PRM belonging to certain species, vine rootstocks and selected clones are only produced and marketed as pre-basic, basic or certified seed and material, due to their importance for food and feed security and industrial processing, and for the protection of the interests of the farmers using them. For this reason, certain PRM of certain species should only be produced and marketed in the pre-basic, basic or certified categories, if the costs for their production and marketing are proportionate to the purpose of ensuring quality PRM for the farmers, food and feed security, or are proportionate to the purpose of ensuring high value of industrial processing. Those costs should also be proportionate to the achievement of the highest standards concerning the identity and quality of the PRM, in line with the requirements for pre-basic, basic and certified PRM. A list of those species of PRM which may only be produced and marketed in the pre-basic, basic or certified categories should thus be established and amended as necessary.

- (17) PRM of each of those categories should be produced and marketed in accordance with the applicable international standards, in order to ensure the highest possible level of its identification and quality, and to be in line with the latest technical and scientific developments. Those standards should include, as applicable, the Schemes for the Varietal Certification or the Control of Seed Moving in International Trade ⁽¹⁷⁾ (‘OECD Seed Schemes’), the seed potato standards of the United Nations Economic Commission for Europe (UNECE), **the rules on selected clones and polyclonal material of the International Organisation of Vine and Wine** and the rules on seed sampling and testing of the International Seed Testing Association (ISTA).
- (18) ~~In accordance with those standards,~~ **e**Compliance of PRM with the requirements for the categories pre-basic, basic or certified should be confirmed by inspections, sampling, testing

¹⁷ Decision Revising the OECD Schemes for the Varietal Certification or the Control of Seed Moving in International Trade [[OECD/LEGAL/0308](#)] (‘OECD Seed Schemes’).

and official control plot testing carried out by the competent authorities ('official certification') or certification as applicable by the professional operator under official supervision and should be attested by an official label.

(18a) It should be possible to specify, by means of implementing acts, more stringent production and marketing requirements that are to be applicable in certain parts of the Union territory, if so required by the agro-climatic conditions, risk of spreading of noxious weeds, for example wild oat, or other special conditions and needs of certain areas. Some Member States have applied stricter requirements to prevent wild oats. In accordance with decisions adopted by the Commission, those requirements have also been applied to seed marketed within the Union and to imported seed. In order to avoid disruption to the long-established production methods in those Member States, it should be possible to maintain those stricter requirements, where appropriate.

(18b) Compliance of PRM with the requirements for the standard category should be confirmed by the professional operator and its compliance with those requirements should be attested by an operator's label.

~~(19) Specific rules should be established for the production and marketing of clones, selected clones, multiclonal mixtures and polyclonal PRM, d Due to their increased importance and use in the PRM sector and . In order to ensure transparency, informed choices for their users and effective official controls, the selected clones and polyclonal material should be registered in a special public register national register established by the competent authorities and specific rules for the production and marketing should be established. Rules for the maintenance of the clones should also be established to ensure their preservation and identification. (Moved to 47a)~~

(31 19a) Control plot tests should be carried out by the competent authority to verify the varietal identity and varietal purity of individual seed lots, except for lots of seed of vine and fruit species and vine. Specific rules should be set out concerning those tests on pre-basic, basic, certified and standard seed, on the basis of the applicable international standards and the experience gained by the application of the PRM marketing Directives.

(20) Professional operators ~~should~~ may be authorised by the competent authority to perform certain certification activities under official supervision of PRM belonging to certain species and categories including printing and affixing ~~and print~~ the official label. Rules should be

set out for the respective official supervision by the competent authority and the withdrawal of that authorisation or its modification. Those rules are necessary to ensure that the entire certification system functions effectively.

(20a) However, certain professional operators may not have the resources to carry out certification activities under official supervision, and therefore it should be provided that any certification steps may also be carried out by the competent authorities upon request of professional operators.

- (21) In order to ensure the **maximum possible** purity and homogeneity of PRM, PRM should be kept in separate lots, and separate from other material different to PRM, such as grain for food or feed.
- (22) In view of the large diversity of PRM, professional operators should **be able to** market the PRM lots in the form of individual plants, packages, bundles or containers, or in bulk.
- (23) Rules should be adopted for the labelling of PRM to ensure the appropriate identification of that **seed or** material per category through the attestation of compliance with the respective requirements concerning pre-basic, basic, certified and standard seed and material.
- (24) In the case of pre-basic, basic and certified seed and material, an official label should be issued by the competent authority, while for standard seed or material an operator's label should be issued. This is necessary to make a distinction between PRM subject to certification (official certification or certification under official supervision) and PRM produced under the responsibility of the professional operator. Issuing of a specific label aims at facilitating informed choices by the professional operators and consumers who may wish to select PRM of different standards. **It This** would also facilitate the work of the competent authorities in **carrying out** ~~designing their~~ official controls **in accordance to verify compliance** with the respective requirements of each category.

~~(25) The official label should be printed and affixed by authorised professional operators and under the official supervision of the competent authorities. However, and since certain professional operators may not have the resources to carry out all the certification activities and print official labels, it should be provided that any certification steps may also be carried out by the competent authorities upon request of professional operators. (Moved to 20a)~~

(26) Rules should be set out concerning the contents and form **characteristics** of the official label and operator's label, to ensure a uniform application of the respective production and marketing requirements for each category and the identification of those labels.

~~(30 26a) — Requirements should be established concerning the re-packaging, re-sealing and re-labelling of pre-basic, basic and certified PRM, in order to guarantee that the identity and the quality of the respective PRM will not be subject to change during those operations. (Moved to 27a)~~

(27) Each official label and operator's label should contain a serial number, so as to guarantee the appropriate identification and traceability of the PRM concerned and the effectiveness of the official controls.

~~(30 27a) Requirements should be established concerning the re-packaging, re-sealing and re-labelling of pre-basic, basic and certified PRM, in order to guarantee that the identity and the quality of the respective PRM will not be subject to change during those operations.~~

~~(28) — The PRM marketing Directives and international practice and standards require that seed belonging to certain species are only produced and marketed as pre-basic, basic or certified seeds, due to their importance for food security and industrial processing, and for the protection of the interests of the farmers using them. For this reason, certain seed should only be produced and marketed as pre-basic, basic or certified seed, if the costs for their production and marketing are proportionate to the purpose of ensuring quality seed for the farmers, food and feed security, or are proportionate to the purpose of ensuring high value of industrial processing. Those costs should also be proportionate to the achievement of the highest standards concerning the identity and quality of the seed, in line with the requirements for pre-basic, basic and certified seed. A list of those species of seed which may only be produced and marketed as pre-basic, basic or certified seed should thus be established.~~

(29) Seeds **are is** frequently marketed in varietal mixtures of same species or species mixtures. However ~~s~~ Seeds of genera or species, covered by this Regulation, should be allowed to be produced and marketed in mixtures only with seeds of the genera or species covered by this Regulation. **This is necessary to ensure that the respective production and marketing standards are respected.** However, Member States should have the possibility to allow the production and marketing of a mixture of seeds covered by this Regulation, with seeds not belonging to genera or species covered by this Regulation, **without prejudice to Regulation (EU)**

No 1143/2014 on the prevention and management of the introduction and spread of invasive alien species.

- (29a) If **such mixtures are produced** for the purposes of conservation of genetic resources and preservation of the natural environment, **the species and genera covered by this Regulation shall not be registered in a national variety register, due to the use of wild types for this purpose. These mixtures they should be marketed only in their region of origin of the component species.** This is **is** because those species are the ones most appropriate for the purpose of that preservation. **Rules should be set out concerning those mixtures to ensure their identity and quality.**
- (30) ~~Requirements should be established concerning the re-packaging and re-labelling of pre-basic, basic and certified seed, in order to guarantee that the identity and the quality of the respective PRM will not be subject to change during those operations.~~
- (31) ~~Control plot tests should be conducted to verify the varietal identity and purity of individual seed lots. Specific rules should be set out concerning those tests on pre-basic, basic, certified and standard seed, on the basis of the applicable international standards and the experience gained by the application of the PRM marketing Directives.~~
- (32) Certain types of varieties **do not fulfil the established requirements concerning distinctness, uniformity and stability. However, they** are important for the conservation and sustainable use of plant genetic resources **which are crucial for crop genetic diversity and essential for adaptation to environmental changes.** They ~~are~~ **can be conservation varieties which are** traditionally grown **varieties of all crop types** or new **they can be** locally produced varieties **of fruit plants or vegetable plants** under specific local conditions and adapted to those **local agro-climatic conditions and farming systems.** They ~~are~~ **can be** characterised, in particular, by reduced uniformity due to a high **certain** level of genetic and phenotypical diversity between individual reproductive units. **Those varieties are referred to as ‘conservation varieties’ or ‘local varieties’.** The production and marketing of those varieties contribute to the objectives of the International Treaty on Plant Genetic Resources for Food and Agriculture to promote the conservation and sustainable use of plant genetic resources for food and agriculture ⁽¹⁸⁾. As a party to the Treaty the Union has committed to support those objectives.

¹⁸ Council Decision 2004/869/EC of 24 February 2004 concerning the conclusion, on behalf of the European Community, of the International Treaty on Plant Genetic Resources for Food and Agriculture (OJ L 378, 23.12.2004, p. 1).

- (33) In view of those special characteristics of the conservation varieties **and local varieties**, and by way of derogation from the established requirements for production and marketing, the production and marketing of PRM belonging to them should be allowed under less stringent requirements. That objective is in line with the principles of the European Green Deal, and in particular, with the principle of protection of the biodiversity. It is thus appropriate to allow for that **material PRM** to comply with the requirements for **the** standard **material category** for the species concerned. That PRM belonging to conservation varieties **or local varieties** should therefore be labelled with the indication ‘**Conservation varieties**’ **or ‘local varieties’**. Those varieties should also be registered, **following an adapted procedure taking into account their special characteristics**, to enable their control by the competent authorities and guarantee the informed choices for their users and the effectiveness of official controls.
- (34) Experience from the application of the marketing Directives has shown that ~~final~~ **non-professional** users of PRM (amateur gardeners and others) are often interested in using more diverse PRM that responds to different needs, without necessarily having the same quality demands as the professional operators. It is therefore appropriate to allow, by way of derogation from certain rules, that PRM **of fruit and vegetable plant species** may be marketed to ~~final~~ **non-professional** users without having to comply with **the all** requirements for variety registration and without having to comply with **the all** certification requirements or with **the all** requirements for **the** standard **material category**. That derogation is necessary to ensure a wider **scope of variety varieties** for consumer offer, while **meeting certain minimum** ~~respecting the general~~ quality requirements. Moreover, for reasons of transparency and better control, rules should be set out for the packaging and labelling of PRM intended for ~~final~~ **non-professional** users only. For the same reason, professional operators using this derogation for **producing and** marketing to ~~final~~ **non-professional** users **should, in case of PRM belonging to an unregistered variety, have a description of the variety made on the basis of private documentation. Furthermore, and they** should **annually** notify that activity to the competent authorities **and inform them, upon request, of the quantities produced and marketed**.
- (35) Many ~~gene banks~~, **non-profit** organisations and networks operate in the Union with an objective to conserve plant genetic resources. In order to facilitate their activity, it is appropriate to allow that PRM **intended for the conservation of plant genetic resources** which is **produced and** marketed **by those organisations and networks** ~~to them, or among them,~~ **to natural or legal persons who carry out conservation of PRM and to farmers or non-professional users** derogates from the established production and marketing

requirements, and that instead it complies with less stringent rules. **Rules should be set out concerning the labeling of such PRM. Organisations and networks using this derogation should notify their activity to the competent authorities and inform them, upon request, of the quantities produced and marketed.**

(36) ~~Farmers habitually exchange in kind small quantities of seeds in order to carry out dynamic management of their own seed.~~ It is ~~thus~~ appropriate **to introduce the possibility for farmers to exchange seed in kind** ~~that as~~ a derogation from the established requirements ~~is provided~~ for the exchanges of small quantities of seeds between farmers **at local level**. Such derogation could ~~should~~ apply **to small quantities and at local level and only** if these ~~that~~ seeds ~~does~~ not belong to a variety for which plant variety rights have been granted in accordance with Council Regulation (EU) 2100/94⁽¹⁹⁾ **or with the national rules on plant variety rights of the Member States of production**. Member States should be ~~allowed~~ **required** to define those small quantities for specific species per year **and per farmer**, in order to ensure that there is no misuse of such derogation impacting the marketing of seeds. **It is not the intention to deviate from the general understanding of the concept of exchange in kind. In general seed exchanged in kind therefore means an exchanged of seeds for goods or services without monetary transactions.**

~~(36a) Fruit plant species and vine are characterised by a slow breeding process due to the growth cycle of those species. For that reason, professional operators experience a significant time delay to enter the market compared to other species. To counteract this delay, it should be possible for PRM of fruit and vine varieties that are not yet registered to be marketed during the process of registration. The varieties should be marketed as standard seed and material as there is no variety description available yet.~~

(36b) The marketing of PRM of a generation prior to generations of pre-basic seed or material from the professional operator responsible for the maintenance to the professional operator carrying out the production of pre-basic, basic, or certified seed or material for the purpose of multiplication of that PRM should be allowed, by derogation from the general requirements that only PRM belonging to a category (pre-basic, basic, certified or standard) may be marketed. In the event of such marketing, the accompanying label must clearly denote the PRM as being designated for this purpose.

¹⁹ Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights (OJ L 227, 1.9.1994, p. 1).

(36c) According to the PRM marketing Directives, derogations from the established requirements are allowed for the marketing of PRM of varieties under registration. Those derogations have been useful and necessary for the professional operators and the competent authorities. Furthermore, farmers are facing increasingly difficult changing weather conditions and new plant health risks. The rapid introduction of new, improved climate smart plant varieties that are adapted to these challenges is important to mitigate these risks for farmers. To speed up the uptake by farmers of those new varieties, in some certain cases and with restrictions, limited marketing of such PRM is should be allowed. For agricultural and potato varieties, fruit and vine varieties and for vegetable varieties, there should be specific requirements based on their characteristics and market dynamics.

(36d) According to the PRM marketing Directives, derogations are established for seed of certain genera and species that does not belong to a registered variety can to be marketed as commercial seed that does not meet the requirements of varietal aspects. This is due to since certain species of agricultural plants, specifically fodder species, serve serving multifaceted roles that extend beyond traditional food and feed production. Those species are instrumental in ecological functions such as attracting pollinators, facilitating nitrogen fixation, and providing ground cover. For those purposes, distinctness, uniformity and stability and the compliance with requirements for value for sustainable cultivation and use are may not be necessary while high quality of this PRM should be guaranteed. Therefore, derogation from registration requirements should be allowed. The designation 'commercial seed' should be retained from the PRM marketing Directives. Species that are added to the scope of this Regulation at a later stage and for which few varieties are developed should also benefit from this derogation in order to allow time for varieties to be developed. Furthermore, commercial seed may be necessary to ensure that seed of new species added to this Regulation can be marketed before registered varieties are available. The possibility to market commercial seed might also be of relevance in case of emergency situations when seed of registered varieties is not available.

(37) According to the PRM marketing Directives, derogations from the established requirements are allowed for the marketing of PRM belonging to not yet registered varieties; of varieties that have not yet been fully tested; of for seed not complying with the applicable requirements to be made rapidly available on the market; of seed not yet finally certified; of PRM to be temporarily authorised to address temporary difficulties in the supply; and of

PRM for the conduct of temporary experiments to seek improved alternatives to certain provisions of the applicable legislation concerning the requirements for the PRM to belong to a registered variety and to fulfil certain identity and quality requirements. Those derogations have been useful and necessary for the professional operators and the competent authorities, without creating problems for the internal market of PRM. Therefore, they should be maintained. Conditions should be set out concerning those derogations, to ensure that they are not misused and that they do not affect adversely the internal market of PRM.

(37a) Member States should be allowed, under certain conditions, to establish more stringent requirements for production and marketing within their own territory. It is important that these more stringent requirements do not impose restrictions on the internal market of the Union.

(37b) In cases where the production of a species covered by this Regulation has no significance in a Member State and where the cultivation is limited due to agro-climatic conditions, Member States should be allowed to derogate from the production requirements of this Regulation if the certification and control activities would pose a disproportionate administrative burden on the Member State. This derogation should not be allowed for if there is a risk that it would cause a disruption to the internal market of the Union.

~~(38) The use of PRM that does not belong to a variety pursuant to this Regulation, but rather belongs to a plant grouping within a single botanical taxon, with a high level of genetic and phenotypic diversity between individual reproductive units ('heterogeneous material'), could have benefits especially in organic production and low input agriculture, through improving resilience and increasing the within species genetic diversity of cultivated plants. Therefore, PRM of heterogeneous material should be allowed to be produced and marketed without having to comply with the requirements for variety registration and the other production and marketing requirements of this Regulation. Specific requirements for the production and marketing of that material should be set out.~~

~~(38a) To facilitate the advancement of agricultural diversity and innovation within the Union, varieties that are developed need to be assessed concerning their commercial viability, cultivation potential, and use for and within the Union. For this reason, derogations from the established requirements are allowed. Marketing of these unregistered varieties is conditionally authorized, strictly in quantities deemed minimal yet sufficient for conducting comprehensive tests and the tests are also authorised in time duration. Each lot must be~~

accompanied by appropriate labelling, clearly indicating its intended use for testing purposes only. This approach ensures that there is no misuse of such derogation impacting the marketing of seeds.

~~(38b) The marketing of PRM from the maintainer or seed house to the multiplier is essential for initiating the production of pre-basic, basic, certified or standard seed or material. In order to allow this marketing, derogations from the established requirements should be allowed. The marketing should only be made possible to the multiplier and the accompanying label must clearly denote the PRM as being designated for this purpose.~~

~~(38c) Certain species of agricultural crops, specifically fodder species, serve multifaceted roles that extend beyond traditional food and feed production. Those species are instrumental in ecological functions such as attracting pollinators, facilitating nitrogen fixation, providing ground cover, among others. For those purposes DUS and VSCU compliance are not necessary while high quality of this PRM should be guaranteed. Therefore, derogation from registration requirements should be allowed. The designation 'commercial seed' should be retained from the PRM marketing directives. Species that are added to the scope of this Regulation at a later stage and for which few varieties are developed can also benefit from this derogation in order to allow time for varieties to be developed.~~

(39) Union production and marketing of PRM needs to comply with the highest possible standards. Therefore, the import of PRM from third countries should only be allowed if an assessment of their applicable identity and quality standards and certification system establishes that such PRM fulfils requirements equivalent to those applicable to PRM produced and marketed in the Union. Such assessment should be based on a thorough examination of the information provided by the third country and its relevant legislation. It should also be based on the satisfactory outcome of an audit carried out by the Commission in the respective third country **asking for equivalence for the first time, or in other cases** where that audit is considered necessary by the Commission.

(39a) Currently vegetable seed that is produced in third countries and that was not assessed as equivalent to Union produced vegetable seed enters the Union for processing ~~in order to comply with the requirements of standard seed~~. After that processing, the seed is **can be** remarketed outside of the Union. **If the seed is going to be** ~~or~~ marketed within the Union **it should comply with the requirements for as standard seed**. That practice should **continue remain possible** as the processing can be checked as equivalent by the competent authority.

- (40) Rules should be set out concerning labelling and information to be provided for the imported PRM for the purposes of its proper identification, traceability, and informed choices by its users and for enabling official controls.
- (41) In order to ensure transparency and more effective controls on the production and marketing of PRM, professional operators **active in the area of production and marketing of PRM** should be **subject to specific obligations to ensure their accountability, more effective official controls and proper application of this Regulation if the operator carries out activities relating to production and marketing of PRM. This includes** registered registration, record keeping and notification of production. It is appropriate that they register **the registration of operators** should be in the registers **already** established by Member States pursuant to Regulation (EU) 2016/2031 of the European Parliament and of the Council ⁽²⁰⁾, in order to reduce the administrative burden for those professional operators. This is also proportionate because the vast majority of professional operators producing and marketing PRM are already registered in the professional operators' registers of that Regulation.

(41a) An application for registration should be submitted by the professional operator to the competent authority. The application should contain all information relevant for the activities carried out by the operator. This information shall be regularly updated when subject to changes. The register should contain relevant elements from the application, the official registration number of the operator and an indication of the activities the operator are carrying out under official supervision.

- ~~(42) Specific obligations should be introduced for professional operators active in the area of the production and marketing of PRM, to ensure their accountability, more effective official controls and proper application of this Regulation.~~

(42a) To minimise as much as possible the administrative burden of professional operators exclusively marketing to non-professional users, organisations and networks marketing PRM for the conservation of plant genetic resources or farmers who exchange seed in kind, certain exceptions to the obligations of professional operators should be

²⁰ Regulation (EU) 2016/2031 of the European Parliament and of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC (OJ L 317, 23.11.2016, p. 4).

introduced, taking into account the proportionality of the obligation concerned in relation to the burden of the operator and the importance of that obligation in relation to the scope of the Regulation.

- (43) Experience has shown that **it is essential to control** the reliability and quality of the marketed PRM **to verify that the PRM on the market complies** ~~can be jeopardised where it is impossible to trace material not complying~~ with the applicable standards. It is therefore necessary to establish a comprehensive traceability system allowing withdrawals from the market or the submission of information to users of PRM or competent authorities. For that reason, the keeping of information and records on transfers from and to professional users should be mandatory for the professional operators. However, such record keeping is not appropriate for marketing in retail.
- (44) It is important to ensure that, as a general rule, all PRM of the genera and species within the scope of this Regulation are subject to the registration of the variety to which that PRM belongs, the description of the variety and the corresponding rules.
- (45) **All Member States shall establish** ~~Varieties should be registered in a national variety register,~~ **containing at least all registered varieties and varieties for which an application for registration have has been submitted,** to ensure informed choices by their users and more effective official controls.
- (46) The national variety register should include two types of varieties: varieties registered on the basis of an official description, if they fulfil the requirements of distinctness, uniformity and stability ('DUS'), and varieties registered on the basis of an officially recognised description in the case of conservation **or local** varieties. The existence of those two different descriptions is necessary to separate the ~~se~~ two **categories types** of varieties, whereby the first one is based on ~~DUS testing results~~ **technical examinations**, while the other one is based on **practical experience and information** ~~historical data~~ concerning the use **or breeding** of the variety ~~and practical experience~~. In addition, such approach can offer the necessary information about the characteristics of the varieties and their identity.
- (47) The registered varieties should be further notified by the competent authorities via ~~the EU Plant Variety~~ **an electronic P**portal to the Union variety register, to ensure an overview of all varieties allowed for marketing in the Union.
- (19 47a) ~~Specific rules should be established for the production and marketing of clones, selected clones, multiclonal mixtures and polyclonal PRM, d~~ **Due to their expected increased**

importance and use in the PRM sector **and**. In order to ensure transparency, informed choices for their users and effective official controls, the **selected clones and polyclonal material** should be registered in a special public register **national register list** established by the competent authorities **and specific rules for the production and marketing should be established**. Rules for the maintenance of the clones should also be established to ensure their **preservation and identification**.

- (48) Herbicide tolerant varieties are varieties that have been bred to be intentionally tolerant to herbicides, in order to be cultivated in combination of **with** the use of those herbicides. If such cultivation is not done under appropriate conditions, it may lead to development of weeds resistant to those herbicides, spread of such resistance genes in the environment or to the need to increase **of the** quantities of herbicides applied. As this Regulation aims to contribute to the sustainability of agricultural production, the competent authorities of Member States responsible for the registration of varieties **and the Member States where the varieties are to be cultivated may** **should** be able to subject the cultivation of those varieties in their territory to cultivation conditions appropriate for avoiding those undesirable effects. Moreover, where varieties have particular characteristics, other than tolerance to herbicides, that could have undesirable agronomic effects, they should also be subject to cultivation conditions, in order to address those agronomic effects. Those conditions should apply to the cultivation of those varieties for any purpose, including food, feed and other products, and not only for purposes of production and marketing of PRM. This is necessary to achieve the objectives of this Regulation to contribute to sustainable agricultural production beyond the stage of production and marketing of PRM.
- (49) In order to contribute to the sustainability of agricultural production and serve economic, environmental and broader societal needs, **the value of a variety for sustainable cultivation and use of** new varieties of all genera or **species of vine, potato and of agricultural plants, except for varieties used exclusively for turf grass purposes, should be assessed in a technical examination (VSCU). New varieties** should show an improvement compared to the other varieties of the same genera or species registered in the same national variety register, concerning certain aspects **on cultivation and use**. Among those **The** aspects **to be assessed are their may be** yield, including yield stability and yield under low input conditions; tolerance/resistance to biotic stresses, including plant diseases caused by nematodes, fungi, bacteria, viruses, insects and other pests; tolerance/resistance to abiotic stresses, including adaptation to climate change conditions; more efficient use of natural resources, such as water and nutrients; reduced need for external inputs, such as plant protection products and

fertilisers; characteristics that enhance the sustainability of storage, processing and distribution; ~~and~~ quality or nutritional characteristics; **and the ability to be cultivated in association with other species or varieties** (~~“value for sustainable cultivation and use”~~). For the purpose of deciding on the variety registration and in order to provide sufficient flexibility to register varieties with the most desirable characteristics, those aspects should be considered for a given variety as a whole.

- (50) As organic varieties suitable for organic production as defined in Article 3 of Regulation (EU) 2018/848 are characterised by a high level of genetic and phenotypical diversity between individual reproductive units, it **is might be** appropriate that their registration is subject to adjusted **requirements of** DUS, and in particular as regards the requirements concerning uniformity. Furthermore, in order for ~~that~~ **such these** varieties to be **better more effectively** adapted to the specific needs of organic production, their examination of the value for sustainable cultivation and use **should can** be conducted under organic conditions.
- (51) For reasons of efficiency and reduction of the administrative burden, varieties that have been granted a plant variety right pursuant to Article 62 of Regulation (EC) No 2100/94, or pursuant to the legislation of a Member State, should be deemed to be distinct, uniform and stable and to have a suitable denomination for the purposes of this Regulation, **where the DUS testing examination was carried out by an suitable examination office that has been found suitable by the CPVO.**
- (51a) The registered variety shall have a suitable denomination to ensure the unique identification of the variety. That denomination should not cause confusion as to the identification of the variety or be misleading or cause offence in any way. In case of conservation varieties synonyms may be used as this is common practice for this type of variety. The synonyms should be indicated in the national variety register.**
- (52) The procedure of variety registration should be precisely defined, in order to ensure legal certainty for the applicants and the competent authorities, and a level playing field for all applicants. For this reason, rules should be set out concerning the submission, content, formal examination and date of submission of the applications, technical examinations, ~~audit of the competent authority’s premises and organisation~~ **examination offices carrying out technical examinations**, ~~additional rules on technical examination, confidentiality, provisional examination report and provisional official description, examination report and final official description,~~ **examination of conservation and local varieties**, examination of the

denomination of a variety and decision on the registration of a variety in the national variety register.

~~(53) For reasons of efficiency and in order to reduce administrative burden for competent authorities and applicants, the competent authorities should register in their national variety registers all varieties officially accepted or registered, before the entry into force of this Regulation, in the catalogues, lists or registers established by their respective Member States pursuant to Directives 68/193/EEC, 2002/53/EC, 2002/55/EC, 2008/62/EC, 2008/90/EC and 2009/145/EC and 68/193/EEC. As those varieties are already marketed in the Union and used by farmers and other professional operators, they should not be subject to a new registration procedure.~~ *(Moved to 56b)*

~~(53a) For the same reason, varieties listed in a national variety register that were not registered pursuant to Directives 68/193/EEC, 2002/53/EC, 2002/55/EC, 2008/62/EC, 2008/90/EC and 2009/145/EC, but will be registered pursuant to this Regulation should be registered without applying the new registration procedure.~~ *(Moved to 56c)*

(54) Rules should be set out concerning the technical examination of varieties, in order to conclude whether they are distinct, uniform and stable. Due to the importance of that examination for the variety breeding sector and the fact that it leads to the production of an official description, that technical examination should be carried out only by suitable examination offices that have been found suitable by the CPVO the competent authority. In addition, rules concerning technical examination of the value for sustainable cultivation and use for certain genera or species should be set out. That examination should be carried out by the competent authority. Already existing examination reports on distinctness, uniformity and stability, and on value for sustainable cultivation and use may under certain conditions be taken into account by the competent authorities.

(55) However, there should be the possibility to carry out the technical examination for the satisfactory value for sustainable cultivation and use of a variety on the premises of the applicant and under the official supervision of the competent authority. This is necessary in order to ease the administrative burden, ensure the availability of testing facilities and reduce costs for the competent authorities. However, it should be possible for the competent authority should be in charge of the testing arrangements. Moreover, to collaborate with professional operators natural or legal persons for the purpose of the technical examination. involved in the breeding of new varieties, and on the basis of their co-operation with the competent authorities, Those persons should have be proven qualified to carry out

such examinations as they possessing the respective **relevant** expertise, knowledge and appropriate resources.

(56) In order to ensure the credibility and high quality of the examinations on distinctness, uniformity and stability, the **examination offices carrying out the examination should be found suitable** premises of the competent authorities where they take place should be audited by the Community Plant Variety Office (‘CPVO’) **in accordance with the CPVO entrustment requirements. If no examination office in the Union has been found suitable, it should be possible to use suitable examination offices in a third country that have been entrusted by the CPVO.** The premises of the applicants where the examination for the satisfactory value for sustainable cultivation and use takes place under official supervision, should be audited by the respective competent authorities, to ensure compliance with the applicable requirements.

(56a) For reasons of legal certainty, a final decision on the registration of the variety should be adopted by the competent authority. Before that, the examination of the variety should be concluded and an examination report and an official description, or in the case of conservation or local varieties an officially recognised description, should be issued. In addition, a decision on the denomination of the variety should be adopted after consulting the CPVO.

(53 56b) For reasons of efficiency and in order to reduce administrative burden for the competent authorities and applicants, the competent authorities should register in their national variety registers all varieties officially accepted or registered, before the entry into force of this Regulation, in the catalogues, lists or registers established by their respective Member States pursuant to Directives **68/193/EEC, 2002/53/EC, 2002/55/EC, **2008/62/EC**, 2008/90/EC **and 2009/145/EC** and 68/193/EEC. As those varieties are already marketed in the Union and used by farmers and other professional operators, they should not be subject to a new registration procedure.**

(53a 56c) For the same reason, varieties listed in an official national variety register that were not registered pursuant to Directives **68/193/EEC, 2002/53/EC, 2002/55/EC, **2008/62/EC**, 2008/90/EC and **2009/145/EC**, but will be registered pursuant to this Regulation should be registered without applying the new registration procedure.**

- (57) The period of ~~the~~ registration of a variety should be 10 years, so as to encourage innovation in the breeding sector, and the removal from the market of old varieties and their replacement by new ones. However, that period should be 30 years for **conservation and local varieties, due to the longterm purpose of conservation but in order to still ensure relevance, as well as for** varieties of genera or species of fruit plants and vine, due to the longer time required for the completion of the productive cycle of those genera or species.
- (58) ~~Upon a request of a~~ **Any interested natural or legal person, with a legitimate interest should have the possibility to apply for renewal of** the period of registration of a variety ~~should be subject to renewal~~, in order to allow for the continuation of marketing of certain varieties if a need is established and they still fulfil applicable requirements. **Rules should also be set out established on the termination of the registration, for example if including cases where no application for renewal has been submitted or if where the conditions for registration are no longer fulfilled.**
- (59) Rules should be set out concerning variety maintenance in accordance with accepted practices. This is necessary to ensure the varietal identity during the period of its registration, which can only be ensured if the maintenance of the respective variety is carried out by the applicant, or other **natural or legal** persons **in the Union or in a third country having the necessary equivalence** ~~notified by the applicant to the competent authority~~, pursuant to certain requirements and subject to official controls by the competent authorities.
- (60) Rules should be set out concerning the content of the national variety registers and the Union variety register, and the keeping of **seed** samples **or living plants** of the registered varieties ('~~official sample~~' or 'standard sample') which is a living description of the variety. This is important to ensure accessibility to the necessary information on the variety, its identification during the period of its registration and the availability of standard samples for control plot testing in the context of PRM certification.
- (60a) Member States should be required to submit to the Commission on a regular basis specified information including in particular the on, inter alia, quantities of produced PRM and number of professional operators. That information is important for being able to evaluate evaluating the effects of this Regulation and to identify needs for amendments in the future amendments needed to better achieve the it's purpose.**
- (60b) Member States should be able empowered to impose, as appropriate, corrective actions or penalties, as appropriate, on professional operators in cases of non-compliance with,**

or infringements of, the rules of this Regulation. The aim objective of those corrective actions or penalties measures is to make ensure compliance of that the PRM concerned will comply with the applicable requirements of this Regulation and to avoid that professional operators do not acquire economic advantage due to from fraudulent practices or from the circumvention of the rules.

(60c) It should be possible for Member States to collect fees for their acts performed in relation to this Regulation. Those fees should be set in order to cover the costs of the competent authority for performing the activity. The amount of those fees should be calculated in accordance with the rules on fees in Regulation (EU) 2017/625.

- (61) The PRM marketing Directives should be repealed, as this Regulation replaces them. As a consequence, Regulation (EU) 2016/2031 should be amended to remove references to those Directives and to ensure that Regulated Non-Quarantine Pests ('RNQPs') are exclusively regulated by that Regulation and that all types of PRM are covered.
- (62) Regulation (EU) 2017/625 of the European Parliament and of the Council²¹ should be amended to include in its scope the production and marketing of PRM in line with this Regulation. This is important in order to guarantee a uniform approach as regards official controls for the entire plant production and food chain, since Regulation (EU) 2017/625 also applies to the scope of Regulation (EU) 2016/2031, and Regulation (EU) 2018/848 of the European Parliament and of the Council²².
- (63) In this respect, the Commission should be empowered to adopt specific rules on official controls and on actions taken by the competent authorities in relation to PRM, in particular for laying down rules for the performance of official controls on PRM for verifying

²¹ Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

²² Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007 (OJ L 150, 14.6.2018, p. 1).

compliance with Union rules, for the import into, and marketing within, the Union of PRM, and on the activities of operators during the production of PRM.

(63a) However, Regulation (EU) 2017/625 should not apply in its entirety to activities relating to variety registration in this Regulation. Furthermore, derogations should be made in this Regulation from specific Articles of Regulation (EU) 2017/625. This includes in particular those provisions of Regulation (EU) 2017/625 that impose new administrative burdens on the competent authorities that would be disproportionate to achieving the objectives of this Regulation.

~~(64) Regulation (EU) 2018/848 should be amended to align the definitions of ‘plant reproductive material’ and ‘heterogeneous material’ with the definitions provided for by this Regulation. Moreover, the empowerment for the Commission to adopt specific provisions for the marketing of PRM of organic heterogeneous material should be excluded from Regulation (EU) 2018/848, as all rules concerning the production and marketing of PRM should be set out in this Regulation for reasons of legal clarity.~~

(65) In order to adapt the list of genera and species of PRM, ~~subject to~~ **within** the scope of this Regulation, to the developments related to the significance of **at least two criteria among the** area and **the** value of production, **the** food **and** feed security and **the** number of Member States ~~where it is cultivated~~ **of cultivation**, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of amending that list.

(65a) In order to adapt the list of genera and species of PRM that can only be produced and marketed as pre-basic, basic or certified seed or material within the scope of this Regulation where there is a need for higher quality guarantees and **where the costs of the relevant certification activities are proportionate, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of amending that list.**

(66) In order to adapt the rules on the production and marketing of PRM to the technical and scientific developments and the applicable international standards, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of amending the requirements of this Regulation concerning the production and marketing of pre-basic, basic, certified and standard **seed and** material ~~and seeds~~.

(66a) In order to confirm the compliance of professional operators with the conditions to carry out certain activities regarding certification under official supervision, the power to

adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of specific actions to be taken by the competent authorities.

(66b) In order to have a harmonised approach, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the data and technical arrangements necessary for the issuance of the official label for pre-basic, basic and certified PRM and of the operator's label for standard PRM.

(66c) In order to ensure harmonised rules on the production and marketing of preservation mixtures, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of further requirements for such mixtures concerning the designation of the region of origin, the use of certain species, the authorization of professional operators, the production by direct collection or by multiplication, the activities carried out by the competent authority and the conditions for production and marketing of seed intended for mixtures.

~~(67) In order to adapt the rules on the production and marketing of PRM of heterogeneous material to the technical and scientific developments, and take into account the experience gained from the application of the rules of this Regulation, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of amending the requirements concerning the production and marketing of heterogeneous material.~~

(67a) In order to adapt the list of genera and species of PRM that can be produced and marketed as commercial seed to the relevant breeding and economic developments, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of amending that list.

(67b) In order to address situations where a registration of certain categories of professional operators would constitute a disproportionate administrative burden on them, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of extending the list of professional operators who are not required to be registered.

(68) In order to adapt the content of variety registers to the technical developments and follow up to the experience gained from variety registration, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of amending the requirements concerning that content.

(68a) In order to adapt the technical requirements for the registration of selected clones and polyclonal material to the scientific and technical developments and to the applicable international standards, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of amending those requirements.

~~(69) In order to adapt the cultivation of varieties to the development of technical and scientific knowledge, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of adopting conditions of cultivation of varieties that are herbicide-tolerant or have other characteristics that could lead to undesirable agronomic effects. Those conditions should include measures in the field, such as crop rotation; monitoring measures; the notification of those measures by Member States to the Commission and the other Member States; reporting by professional operators to the competent authorities concerning the application of those measures; and the indications of those conditions in the national variety registers.~~

~~(70) In order to adapt testing and requirements for the sustainable value of cultivation and use requirements to the potential technical and scientific developments, and the possible development of international standards, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of supplementing this Regulation with certain elements. Those consist of the necessary methodologies for the growing trials to be carried out with a view to assessing, and adopting further requirements for, sustainable value of cultivation and use for certain genera or species.~~

(73 70a) In order to adapt the provisions of this Regulation concerning the examination for sustainable cultivation and use to the technical or scientific developments, and to any new Union policies or rules on sustainable agriculture, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of supplementing this Regulation by establishing the minimum requirements for assessing the characteristics examined and the evaluation and the reporting of the results of this examination.

~~(71) In order to adapt the **set out specific criteria concerning the suitability of** rules on **a** variety denomination to the technical and scientific developments, and follow-up on the experience gained from the application of those rules, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of supplementing this Regulation by setting out specific criteria concerning the suitability of variety denominations **the relation to trademarks, the relation to geographical indications or designation of origin for**~~

agricultural products, the written consent of holders of prior rights to remove impediments to the suitability of a denomination, the use of codes, the definition of closely related species and the determination of misleading, offensive or confusing denominations.

- ~~(72) In order to adapt the provisions of this Regulation concerning technical examinations of varieties to the technical and scientific developments and the practical needs of competent authorities and professional operators, and follow up on the experience gained from the application of the respective rules, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of supplementing this Regulation by setting out the rules concerning the audit of the premises of professional operators to carry out technical examinations for the satisfactory value for sustainable cultivation and use.~~
- ~~(73) In order to adapt the provisions of this Regulation concerning the examination for sustainable cultivation and use to the technical or scientific developments, and to any new Union policies or rules on sustainable agriculture, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of supplementing this Regulation by establishing the minimum requirements for carrying out this examination, establishing the methodologies for assessing the characteristics examined, establishing the standards for the evaluation and the reporting of the results of this examination and amending the characteristics examined.~~
- (74) It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making²³. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.
- (75) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in

²³ OJ L 123, 12.5.2016, p. 1, ELI: http://data.europa.eu/eli/agree_interinstit/2016/512/oj..

accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council²⁴.

(75a) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred to the Commission with respect to specifying the production and marketing requirements laid down in this Regulation for certain genera, species or categories of pre-basic, basic, certified and standard PRM, and, where appropriate, for certain grades, classes, generations or other sub-divisions of the category concerned.

(75b) In order to ensure uniform conditions for the implementation of this Regulation, and to take account of the development of scientific and technical knowledge and international standards, implementing powers should be conferred to the Commission with respect to setting out rules concerning the control plot tests of pre-basic, basic, certified and standard seed lots per genus, species or category.

(76) In order to ensure uniform conditions for the implementation of this Regulation, and to improve the performance of professional operators and the identity and quality of PRM produced and marketed by them, implementing powers should be conferred to the Commission with respect to specifying the requirements for the ~~audits~~ **evaluations**, **trainings**, examinations, inspections, sampling and testing, with regard to particular genera or species, for the official supervision of the professional operators by the competent authorities.

(77) In order to ensure uniform conditions for the implementation of this Regulation concerning handling and marketing **labelling** of PRM **lots**, ~~and adapt the respective rules to the experience gained from the application of the provisions of this Regulation,~~ implementing powers should be conferred to the Commission for adopting specific requirements for all or certain species of PRM, concerning **the maximum size of lots, their identification, testing of lots**, the merging or splitting of lots in relation to the origin of PRM lots, ~~their identification,~~ **recording** on ~~that~~ **those** operations and labelling following the merging or splitting of PRM lots **in accordance with applicable international standards**.

²⁴ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers, ELI: OJ L 55, 28.2.2011, p. 13, ELI: <http://data.europa.eu/eli/reg/2011/182/oj>.

- (78) In order to ensure uniform conditions for the implementation of this Regulation **concerning PRM in packages, bundles or containers**, ~~follow up on the practical experience gained by the application of its provisions, and improve the integrity of the marketed PRM,~~ implementing powers should be conferred to the Commission for adopting specific requirements concerning the sealing, ~~fastening,~~ size and form of packages, bundles and containers of specific species of PRM, **as well as conditions for the marketing of seed and seed potatoes in bulk without sealing or packaging**.
- (79) In order to ensure uniform conditions for the implementation of this Regulation, and in particular concerning the legibility, recognisability and security of labels, implementing powers should be conferred to the Commission for adopting specific provisions concerning the official labels, labels used for certain derogations and, labels used for some specific types of PRM, and **setting** out the content, size, colour, ~~and~~ form **and, in the case of imported PRM, language** of those labels for the respective categories or types of PRM.
- (80) In order to ensure uniform conditions for the implementation of this Regulation **concerning mixtures of seed**, and **to** follow up on any **technical and scientific developments and** practical experience gained by the application of the respective rules, implementing powers should be conferred to the Commission for adopting specific provisions concerning ~~mixtures of seeds~~ **mixing equipment and procedure, sealing, packaging and labelling, content, size, colour and form of the label, applicable use and denomination of mixtures**.
- (80a) In order to ensure uniform conditions for the implementation of this Regulation concerning specific requirements on packaging and sealing of preservation mixtures, implementing powers should be conferred to the Commission for adopting those requirements.**
- (81) In order to ensure uniform conditions for the implementation of this Regulation with respect to retail marketing of PRM **of fruit and vegetable plant species**, and make the marketing of PRM as practical and suitable for each species as possible, implementing powers should be conferred to the Commission for adopting rules concerning the size, form, sealing and handling requirements of **individual plants and** the small packages for seeds ~~and the packages and bundles for other PRM marketed to final~~ **non-professional** users.
- (82) In order to ensure uniform conditions for the implementation of this Regulation **in relation** ~~and to addressing~~ **urgent temporary** supply difficulties of PRM, implementing powers should be conferred to the Commission for authorising, ~~in the case of temporary difficulties in the~~

supply of PRM, for a maximum period of 4-year **18 months**, the marketing of **PRM seed or material** of the categories ~~of~~ pre-basic, basic ~~or~~, certified ~~or standard seed or material~~ ~~or~~ seed subject to less stringent requirements, or to derogate from the requirement to belong to a variety, and with respect to repealing and amending that authorisation.

(83) In order to ensure uniform conditions for the implementation of this Regulation, and ensure some flexibility ~~to~~ **for** Member States to adopt **more stringent** national measures, ~~adapted to their agro-climatic conditions and~~ **including** higher quality standards, implementing powers should be conferred to the Commission for authorising the Member States to **adopt**, with regards to production and marketing of PRM, more stringent **such requirements for the production ~~or~~ and marketing requirements of PRM, provided that those measures correspond to market demands, specific production conditions or agro-climatic conditions of that Member State**, in all or part of the territory of the Member State concerned, and with respect to repealing or amending such measures adopted pursuant to the PRM marketing Directives. **Those more stringent measures shall not impose, or result in, any prohibitions or restrictions on the movement of products originating from, or destined to, other Member States.**

(83a) In order to ensure uniform conditions for the implementation of this Regulation, and ensure some flexibility for Member States concerning species whose cultivation on their territory is insignificant, and where the certification and control of the production of that species would create a disproportionate administrative burden, implementing powers should be conferred to the Commission for temporarily allowing PRM belonging to such species to be produced and marketed in that Member State without being subject to the production and marketing rules under this Regulation.

(84) In order to ensure uniform conditions for the implementation of this Regulation, and ensure a swift response to sudden risks, implementing powers should be conferred to the Commission for taking emergency measures, where **there are detailed reasons based on new or additional scientific knowledge for considering that** the production or marketing of PRM is likely to constitute a serious risk to human, animal or plant health, the environment or cultivation of other species, and such risk **has not been assessed pursuant to any other Union rules and** cannot be contained satisfactorily by measures taken by the Member State concerned, and with respect to repealing or amending any such measure taken by a Member State. **Implementing powers shall be conferred to the Commission to adopt immediately**

applicable implementing acts to, in duly justified cases of urgency, address a serious risk to human health.

- (85) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred to the Commission for deciding on the organisation of temporary experiments to seek improved alternatives to the scope and certain provisions of this Regulation.
- (86) In order to ensure uniform conditions for the implementation of this Regulation with regard to the import of PRM, and ensure compliance of the third country requirements with the **equivalent** Union requirements, implementing powers should be conferred to the Commission with respect to recognising whether PRM of specific genera, species or categories produced in a third country, or particular areas of a third country, fulfils requirements equivalent to those applicable to PRM produced and marketed in the Union, in order to be imported.
- (87) In order to ensure uniform conditions for the implementation of this Regulation and to ensure appropriate maintenance of the registered varieties in third countries too, implementing powers should be conferred to the Commission with respect to recognising that the controls on variety maintenance carried out in the third country afford the same guarantees as those set out in the Union.
- (88) In order to ensure uniform conditions for the implementation of this Regulation, ~~and to adapt its provisions to the evolving applicable~~ **taking into account the protocols established by the CPVO, the applicable guidelines** of the International Union for the Protection of new Varieties of Plants (UPOV) or **other relevant national** protocols ~~established by the CPVO, and the relevant technical and scientific developments~~, implementing powers should be conferred to the Commission for adopting specific requirements concerning distinctness, uniformity and stability per genera or species of varieties, **including requirements for organic varieties suitable for organic production, and the characteristics and information that the officially recognised description of the variety is to cover in case of conservation varieties or local varieties.**
- (88a) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred to the Commission for specifying the elements of suitability of variety denominations laid down in this Regulation, taking into account any applicable international standards, as well as the relevant guidelines on variety denominations developed by the CPVO.**

(88b) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred to the Commission for specifying the way in which competent authorities may collaborate with natural or legal persons for the purpose of the technical examination of distinctness, uniformity and stability and of the value for sustainable cultivation and use.

(89) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred to the Commission for adopting specific rules as regards the size **and replacement** of the standard sample of registered varieties ~~used for the official post controls of PRM, the rules for the renewal of those samples and the provision of those samples to other Member States~~ **competent authorities**.

(89a) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred to the Commission for specifying the technical formats for Member States' reporting on the functioning of the PRM production and marketing system.

(90) Since the objective of this Regulation, namely to ensure a harmonised approach with regard to the production and marketing of PRM, ~~cannot~~ **may not** be sufficiently achieved by the Member States but ~~can~~ **might** rather, by reason of its effects, complexity and international character, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not exceed what is necessary in order to achieve that objective. In this view, and as necessary, it introduces derogations or specific requirements for certain types of PRM and professional operators.

(91) This Regulation should apply from ~~3~~ **5** years after its entry into force, in order to allow the competent authorities and the professional operators to adapt to its provisions and also to provide the necessary time for the adoption of the respective delegated and implementing acts. ~~The rules concerning the satisfactory value for sustainable cultivation and use of varieties of vegetables and fruit plants should however apply from 5 years after its entry into force. That additional time period is needed for the competent authorities and professional operators to make the necessary preparations and carry out the first tests in the fields complying with those new rules.~~