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LEGISLATIVE ACTS AND OTHER INSTRUMENTS

Subject:	Position of the Council at first reading with a view to the adoption of a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the production and marketing of plant reproductive material in the Union, amending Regulations (EU) 2016/2031 and (EU) 2017/625 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 and Council Decisions 2003/17/EC and 2005/834/EC (PRM Regulation)

REGULATION (EU) …/…
OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of …

on the production and marketing of plant reproductive material in the Union, amending Regulations (EU) 2016/2031 and (EU) 2017/625 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 and Council Decisions 2003/17/EC and 2005/834/EC
(PRM Regulation)

(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 Commission,

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

Having regard to the opinion of the European Economic and Social Committee[1],

Having regard to the opinion of the Committee of the Regions[2],

Acting in accordance with the ordinary legislative procedure[3],

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1 OJ C, C/2024/1583, 5.3.2024, ELI: http://data.europa.eu/eli/C/2024/1583/oj.
2 OJ C, C/2024/3674, 26.6.2024, ELI: http://data.europa.eu/eli/C/2024/3674/oj.
3 Position of the European Parliament of 24 April 2024 (OJ C, C/2025/3767, 17.9.2025, ELI: http://data.europa.eu/eli/C/2025/3767/oj), position of the Council at first reading of … (not yet published in the Official Journal). Position of the European Parliament of … (not yet published in the Official Journal).

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 1960s. The production and marketing of PRM in 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'). Those Directives 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 in PRM in the Union.

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4 Council Directive 66/401/EEC of 14 June 1966 on the marketing of fodder plant seed (OJ 125, 11.7.1966, p. 2298, ELI: http://data.europa.eu/eli/dir/1966/401/oj).

5 Council Directive 66/402/EEC of 14 June 1966 on the marketing of cereal seed (OJ 125, 11.7.1966, p. 2309, ELI: http://data.europa.eu/eli/dir/1966/402/oj).

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, ELI: http://data.europa.eu/eli/dir/1968/193/oj).

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, ELI: http://data.europa.eu/eli/dir/2002/53/oj).

8 Council Directive 2002/54/EC of 13 June 2002 on the marketing of beet seed (OJ L 193, 20.7.2002, p. 12, ELI: http://data.europa.eu/eli/dir/2002/54/oj).

9 Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed (OJ L 193, 20.7.2002, p. 33, ELI: http://data.europa.eu/eli/dir/2002/55/oj).

10 Council Directive 2002/56/EC of 13 June 2002 on the marketing of seed potatoes (OJ L 193, 20.7.2002, p. 60, ELI: http://data.europa.eu/eli/dir/2002/56/oj).

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, ELI: http://data.europa.eu/eli/dir/2002/57/oj).

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, ELI: http://data.europa.eu/eli/dir/2008/72/oj).

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, ELI: http://data.europa.eu/eli/dir/2008/90/oj).

(2) The impact assessments carried out by the Commission in 2013 and 2023 confirmed that those Directives have had a significant positive impact on the free movement, availability and 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 developments in scientific and technical knowledge in the areas of agricultural, horticultural, fruit and vine production and plant breeding. Moreover, the legislative framework needs to be updated on the basis of changes in international standards and experience gained through the application of the PRM marketing 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 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 utmost importance for achieving the transition to sustainable food systems called for in the communication of the Commission of 20 May 2020 entitled 'A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system', and for 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 and environmental conditions, to face the challenges of climate change, to protect, restore and promote the genetic diversity of cultivated crops, to ensure food security, to stimulate innovation, and to meet farmers' and consumers' increasing expectations related to quality and sustainability of PRM.

(6) The scope of this Regulation should cover only the PRM of certain genera and species of high economic and social importance. That importance should be determined by assessing whether the PRM or the crop of such genera and species represent a significant area of production and value in the Union, whether they are of substantial importance for the security of food and feed production in the Union, and whether the PRM of such genera and species is marketed in at least two Member States. That area of production and value could concern several technical aspects. Depending on the circumstances, it could 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 genera and species by farmers, non-professional users and industry.

(7) Those genera and species should be listed and classified by their intended use, namely whether they are intended for agricultural, vegetable, fruit, potato or vine production. That classification is necessary to ensure a proportionate approach, as some species are only important for certain uses.

(8) PRM should be defined in a comprehensive manner that includes all plants or parts of plants capable of, and intended for, producing entire plants, or producing fruits, vegetables or other crops. This Regulation should, therefore, cover seed, 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 which are not covered by this Regulation or their hybrids if the material of genera or species covered by this Regulation or their hybrids is grafted or is to be grafted onto them.

(9) This Regulation should not cover forest reproductive material due to its particular characteristics, and very different concepts and applicable terminology. For that reason, forest reproductive material is subject to a separate legal act, namely Regulation (EU) 2026/1392 of the European Parliament and of the Council[14].

(10) This Regulation should not cover PRM intended for ornamental purposes because, following consultations with Member States and stakeholders, it has been concluded that Council Directive 98/56/EC[15] still adequately covers the needs of that sector. However, seed intended for turf grass purposes, even if it is intended for ornamental purposes only, should be covered by this Regulation because of its important marketing value and because of the already established practice of the sector to subject its varieties to testing requirements and to certify their PRM.

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14 Regulation (EU) 2026/1392 of the European Parliament and of the Council of 20 May 2026 on the production and marketing of forest reproductive material, amending Regulations (EU) 2016/2031 and (EU) 2017/625 of the European Parliament and of the Council and repealing Council Directive 1999/105/EC (FRM Regulation) (OJ L, 2026/1392, 26.6.2026, ELI: http://data.europa.eu/eli/reg/2026/1392/oj).

15 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, ELI: http://data.europa.eu/eli/dir/1998/56/oj).

(11) This Regulation should cover neither PRM intended for export to third countries, nor PRM used solely for inspection, sampling or testing, officially or under official supervision, for breeding and selection, for exhibitions or for research or other 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.

(12) This Regulation should not cover PRM transferred in any way, whether free of charge or not, between non-professional users. 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.

(13) This Regulation should not cover PRM subject to service contracts for the purposes of processing, including cleaning, disinfection, treatment and packaging, or of transport or storage, provided that the PRM remains the property of the producer. This is because such PRM remains under the responsibility of the owner of that PRM, who guarantees the identity or quality standards of that PRM.

(14) This Regulation should not cover PRM that is transferred to or from gene banks for the conservation of plant genetic resources in order to facilitate the achievement of that objective. This is because that PRM is not so widely produced or marketed as to justify applying particular identity and quality requirements to it.

(15) This Regulation should not cover organic heterogenous material, as it is already regulated under Regulation (EU) 2018/848 of the European Parliament and of the Council[16].

(16) PRM produced and marketed in accordance with this Regulation should comply with the relevant requirements in Regulation (EU) 2016/2031 of the European Parliament and of the Council[17]. The specific requirements on Union regulated non-quarantine pests were previously regulated in both the PRM marketing Directives and Regulation (EU) 2016/2031. However, those requirements are now fully covered by that Regulation and, to avoid undesirable overlaps, they should not be regulated in this Regulation.

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16 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, ELI: http://data.europa.eu/eli/reg/2018/848/oj).

17 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, ELI: http://data.europa.eu/eli/reg/2016/2031/oj).

(17) Guadeloupe, French Guiana, Martinique, Mayotte, Réunion and Saint-Martin are listed in Article 355(1) of the Treaty on the Functioning of the European Union (TFEU) as subject to the provisions of that Treaty. It is, however, desirable that those territories carry out the marketing of PRM with their neighbouring third countries, rather than with the rest of the Union, due to their particular geographical location and agricultural, ecological and climatic conditions. For the purposes of this Regulation, therefore, references to third countries should be read as including those territories.

(18) In order to enable users to make informed decisions, PRM should be produced and marketed only if it belongs to varieties registered in a national variety register.

(19) However, it is appropriate to exempt, where applicable, rootstocks of fruit plants and vines from the requirement to belong to a variety, as, although of a significant value, they may not fall under the definition of a variety. That exception should also apply to other cases where it is not necessary or possible for the PRM concerned to fulfil varietal identity requirements.

(20) In order to ensure the identity and quality of PRM, as well as transparency that enables users to make informed choices, 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 seed. However, PRM should be allowed to be produced and marketed without belonging to a category where it is not necessary or possible for that PRM to belong to any of those categories.

(21) The PRM marketing Directives and international practice and standards require that PRM belonging to certain species, vine rootstocks and PRM of selected clones be 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, PRM belonging to certain species, vine rootstocks and PRM of selected clones 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 accordance with the requirements for pre-basic, basic and certified PRM. A list of those species should thus be established and, in the future, amended as necessary.

(22) PRM of each of those categories should be produced and marketed in accordance with the applicable international standard, in order to ensure the highest possible level of its identification and quality and to be in line with the latest developments in scientific and technical knowledge. Those standards should include the OECD Schemes for the Varietal Certification or the Control of Seed Moving in International Trade ('OECD Seed Schemes'), the seed potato standards of the United Nations Economic Commission for Europe (UNECE), and the rules on selected clones and polyclonal material of the International Organisation of Vine and Wine.

(23) Specific rules for the production and marketing of pre-basic, basic and certified seed and material should be established and they should reflect those international standards.

(24) Compliance of PRM with the requirements for the pre-basic, basic or certified categories should be confirmed by inspections, sampling and testing, including, where appropriate, control plot testing, carried out by the competent authorities ('official certification') or, where applicable, by the professional operator under official supervision ('certification under official supervision') and should be attested to by an official label.

(25) It should be possible to set out, 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.

(26) 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 to by an operator's label.

(27) Rules for the in vitro production of PRM of clones and its marketing should also be established, because they constitute an increasingly used practice of the sector.

(28) Control plot tests should be carried out by the competent authority to verify the varietal identity and varietal purity of individual seed lots, with the exception of lots of seed of fruit plants and vines. 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 through the application of the PRM marketing Directives.

(29) Professional operators should have the possibility to 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 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.

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

(31) In order to ensure the 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.

(32) In view of the large diversity of PRM, professional operators should market PRM in lots that contain individual plants, packages, bundles or containers, or, in certain cases, as seed in bulk. A lot should be homogeneous in its content and should have its own lot reference number, to ensure its traceability. Uniform rules should be set out for the packaging, bundling and sealing of PRM.

(33) Rules should be adopted for the labelling of PRM to ensure the appropriate identification of that seed or material per category and other types of PRM through the attestation of compliance with the respective requirements.

(34) 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, or PRM not belonging to any category, 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. This would also facilitate the work of the competent authorities in carrying out official controls to verify compliance with the respective requirements for each category.

(35) Rules should be set out concerning the content and characteristics of the official label and operator's label to ensure a uniform application of production and marketing requirements for each category and other types of PRM and for the identification of those labels.

(36) Each official label should contain its own serial number so as to guarantee the appropriate identification and traceability of the PRM concerned and the effectiveness of the official controls.

(37) Requirements should be established concerning the re-packaging, re-sealing and re-labelling of PRM in order to guarantee that the identity and the quality of the PRM is not subject to change during those operations and that its traceability is ensured through the lot reference number.

(38) Seed is frequently marketed in varietal mixtures of same species or species mixtures. Seed of genera or species covered by this Regulation should be allowed to be produced and marketed in mixtures only with seed of other genera or species covered by this Regulation. However, the production and marketing of a mixture of seed covered by this Regulation with seed not belonging to genera or species covered by this Regulation should be allowed, without prejudice to Regulation (EU) No 1143/2014 of the European Parliament and of the Council[18].

[18] Regulation (EU) No 1143/2014 of the European Parliament and of the Council of 22 October 2014 on the prevention and management of the introduction and spread of invasive alien species (OJ L 317, 4.11.2014, p. 35, ELI: http://data.europa.eu/eli/reg/2014/1143/oj).

(39) For the purposes of the conservation of plant genetic resources and the restoration of the natural environment, in particular of natural or semi-natural habitats, it is desirable to use mixtures of seed not belonging to a variety but to wild types of genera and species covered by this Regulation, as well as of genera and species not covered by this Regulation ('preservation mixtures'), as those wild types are the most appropriate for those purposes. Those mixtures should be marketed only in the region of origin of the component seed in order to ensure that only wild types best adapted to that region are used. To ensure that mixtures marketed as preservation mixtures fulfil these requirements, specific rules should be set out to ensure their quality and traceability, and they should only be produced and marketed by professional operators who are authorised for that purpose by the competent authority.

(40) Certain types of varieties 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 can be traditionally grown varieties (‘conservation varieties’) or they can be varieties adapted to local agro-climatic conditions and farming systems, recently bred as a result of dynamic conservation activities or other breeding and selection methods applied under natural or farmer-managed conditions (‘locally adapted varieties’). They can be characterised, in particular, by reduced uniformity due to a certain level of genetic and phenotypical diversity between individual reproductive units. The production and marketing of PRM of those varieties contribute to the objectives of the International Treaty on Plant Genetic Resources for Food and Agriculture[19] to promote the conservation and sustainable use of plant genetic resources for food and agriculture. As a party to that Treaty, the Union has committed to support those objectives.

[19] OJ L 378, 23.12.2004, p. 3, ELI: http://data.europa.eu/eli/agree_internation/2004/869/oj.

(41) In view of those special characteristics of the conservation varieties and locally adapted varieties, and by way of derogation from the established production and marketing requirements, the production and marketing of PRM belonging to them should be allowed under less stringent requirements. This is in line with the principles of the European Green Deal, and in particular with the principle of protection of biodiversity. It is thus appropriate to allow for that PRM to comply with the requirements for the standard category for the species concerned. The PRM belonging to conservation varieties or locally adapted varieties should be labelled with the words ‘conservation variety’ or ‘locally adapted variety’. 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 possibility for their users to make informed choices and the effectiveness of official controls.

(42) Experience from the application of the PRM marketing Directives has shown that non-professional users of PRM, such as amateur gardeners, 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 provide for a derogation from certain rules in order to allow that PRM to be marketed to non-professional users without having to comply with all the requirements for variety registration. That derogation is necessary to ensure a wider scope of varieties is offered to consumers while meeting certain minimum quality requirements. Such minimum requirements are important to address the expectations of many non-professional users for a certain level of quality for their private use.

(43) However, that derogation should not apply to PRM belonging to the species *Cannabis sativa* L., *Papaver somniferum* L. and *Solanum tuberosum* L. and to PRM used for turf grass purposes, due to its particular commercial value or significance for public interest or safety. For that reason, the requirements of this Regulation concerning the quality, identity and professional operators of the respective PRM should continue applying to ensure the most effective possible checks by the competent authorities and the protection of consumer interests.

(44) Moreover, for reasons of transparency and better control, rules should be set out for the packaging and labelling of PRM intended for non-professional users only. For the same reason, professional operators using this derogation for production and marketing to non-professional users should, in the case of PRM belonging to an unregistered variety, have a description of the variety made on the basis of private documentation. Furthermore, they should annually notify that activity to the competent authorities and inform them, upon request, of the quantities produced and marketed.

(45) Many non-profit organisations and networks operate in the Union with the objective of conserving plant genetic resources. In order to facilitate their activity, it is appropriate to allow PRM intended for the conservation of plant genetic resources, which is produced by those organisations and networks and their members or which is marketed without profit by those organisations and networks and their members to any natural or legal persons, including farmers or non-professional users, and vice versa, to derogate from the established production and marketing requirements and to comply with less stringent rules instead. Rules should be set out concerning the labelling of such PRM. Organisations and networks using this derogation should notify their activity to the competent authorities and keep a register with the relevant information of the PRM produced and marketed by or to them. This is necessary in order to ensure effective checks by the competent authorities and the possibility for the users of that PRM to make informed choices.

(46) It is appropriate to introduce the possibility for farmers to exchange PRM in kind as a derogation from the established requirements. Such derogation should apply to small quantities and at local level and only if that PRM does not belong to a variety in respect of which plant variety rights have been granted in accordance with Council Regulation (EC) No 2100/94[20] or with the national rules on plant variety rights of the Member States of production. Member States should be 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 PRM. The intention is not to deviate from the general understanding of the concept of exchange in kind as an exchange of PRM for goods or services without monetary transactions, nor is it to derogate from applicable requirements under Regulation (EU) 2016/2031. For reasons of public interest and safety, such exchange should not be permitted for PRM of the species *Cannabis sativa* L., *Papaver somniferum* L. and *Solanum tuberosum* L. and the genera *Citrus* L. and *Vitis* L..

(47) The marketing of PRM of a generation prior to pre-basic seed or material from the professional operator responsible for the maintenance to the professional operator carrying out the production of pre-basic seed or material for the purposes of multiplication of that PRM should be allowed, by way of derogation from the general requirement 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 should clearly denote the PRM as being designated for that purpose.

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[20] Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights (OJ L 227, 1.9.1994, p. 1, ELI: http://data.europa.eu/eli/reg/1994/2100/oj).

(48) According to the PRM marketing Directives, derogations from the established requirements are allowed for the marketing of PRM belonging to varieties in respect of which a decision on variety registration is pending (‘varieties under registration’). Those derogations have been useful and necessary for the professional operators and the competent authorities. Furthermore, farmers are facing increasingly changing weather conditions and new plant health risks. The rapid introduction of new, improved plant varieties that are adapted to these challenges is important to mitigate the risks for farmers. To speed up the uptake by farmers of those new varieties, in certain cases and with restrictions, limited marketing of such PRM 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.

(49) According to the PRM marketing Directives, derogations are established for seed of certain genera and species to be marketed as seed that does not meet the requirements of varietal aspects but is only subject to quality requirements (‘commercial seed’). This is due to certain species of agricultural plants, specifically fodder species, 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 compliance with requirements for value for sustainable cultivation and use might not be necessary but the high quality of such seed should be guaranteed. It is therefore desirable that those derogations from registration requirements should also be allowed under this Regulation. The designation ‘commercial seed’ should be retained from the PRM marketing Directives. Species 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 might be necessary to ensure that seed of new species added to this Regulation can be marketed before registered varieties are available.

(50) According to the PRM marketing Directives, derogations from the established requirements are allowed for seed not complying with the applicable requirements that needs to be made rapidly available on the market, for seed not yet finally certified, for PRM that needs to be temporarily authorised to address temporary difficulties in the supply, and for PRM intended 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 in 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 in PRM.

(51) In order to have the possibility to address specific conditions in their territories, Member States should be allowed to establish more stringent requirements for production and marketing of PRM within their own territory, without imposing more stringent requirements on the internal market of the Union.

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

(53) PRM produced and marketed in the Union needs to comply with the highest possible standards. Therefore, the import of PRM from third countries should only be allowed if an assessment of its 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 law. It should also be based on the satisfactory outcome of an audit carried out by the Commission of that third country before granting it equivalence for the first time. An audit should also be carried out where the Commission considers it necessary before granting equivalence to a third country for additional species.

(54) PRM imported from third countries whose identity and quality requirements and certification systems have been recognised as equivalent pursuant to the PRM marketing Directives has proven to be compliant with Union quality and identity rules. For this reason, the requirements and systems of those third countries for the genera or species concerned should also be recognised pursuant to this Regulation as equivalent to the ones of the Union.

(55) It is an established practice that vegetable seed produced in third countries is imported into the Union directly after harvesting (‘seed as grown’) in order for it to be processed in the Union so that it complies with the requirements for standard seed before being marketed within the Union. As that practice ensures the identity and quality of the vegetable seed marketed in the Union without requiring it to be subject to recognition of equivalence, it should also remain possible under this Regulation.

(56) Rules should be set out concerning labelling and information to be provided for the imported PRM for the purposes of its proper identification and traceability, and for enabling informed choices by its users and official controls.

(57) In order to ensure transparency of the production and marketing of PRM, professional operators should be subject to specific obligations to ensure their accountability, more effective official controls and proper application of this Regulation if they carry out activities relating to production and marketing of PRM. This includes registration, record keeping and notification of production. It is appropriate that the registration of professional operators should be in the register already established by Member States pursuant to Regulation (EU) 2016/2031 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 under that Regulation.

(58) In this respect, and in order to ensure a uniform and effective registration system for all professional operators concerned, rules should be established concerning the submission of applications by the professional operators, content of the register and updating the relevant information.

(59) To minimise as much as possible the administrative burden of professional operators exclusively producing and marketing PRM of conservation varieties and locally adapted varieties, professional operators exclusively marketing PRM directly to non-professional users, organisations and networks marketing PRM for the conservation of plant genetic resources or farmers who exchange PRM in kind, certain exceptions to the obligations of professional operators should be introduced.

(60) In order to address risks to human, animal or plant health, the environment or the cultivation of other genera and species, Member States should be allowed to adopt proportionate and time-limited interim emergency measures until the Commission adopts corresponding measures at Union level.

(61) Experience has shown that it is essential to control the quality of the marketed PRM to verify that the PRM on the market complies with the applicable requirements. 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.

(62) 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 related rules.

(63) All Member States should establish a national variety register containing at least all registered varieties, varieties for which an application for registration has been submitted, and varieties that are no longer registered in order to enable their users to make informed choices and ensure more effective official controls.

(64) 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, and varieties registered on the basis of an officially recognised description in the case of conservation varieties or locally adapted varieties. The existence of those two different descriptions is necessary to separate these two types of varieties. The first one should be based on technical examinations, while the other should be based on practical experience gained and information obtained through the use or breeding of the variety. Such an approach can offer the necessary information about the characteristics of the varieties and their identity.

(65) The competent authorities should further notify the registered varieties to the Union variety register to ensure an overview of all varieties allowed for marketing in the Union. The Union variety register should be accessible via an electronic portal, currently known as the EU Plant Variety Portal. In order to ensure that the users are more comprehensively informed, that portal should include information from other relevant databases.

(66) Due to their expected increased importance and use for certain species, and in order to ensure transparency and effective official controls and in order to enable their users to make informed choices, selected clones and polyclonal material should be registered in a national list established by the competent authorities and transmitted to the Commission for its publication in the electronic portal.

(67) Herbicide-tolerant varieties are varieties that have been bred to be intentionally tolerant to herbicides, in order to be cultivated in combination with the use of those herbicides. If such cultivation is not done under appropriate conditions, it could lead to development of weeds resistant to those herbicides, to the spread of such resistance genes in the environment or to the need to increase 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 should be able to subject the cultivation of those varieties in their territory to cultivation conditions appropriate for avoiding those undesirable effects.

(68) In order to contribute to the sustainability of agricultural production and serve economic, environmental and broader societal needs, the value for sustainable cultivation and use of new varieties of genera or species of vine, potato and agricultural plants, with the exception of varieties used exclusively for turf grass purposes, should be assessed in a technical examination. 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. The aspects to be assessed should be yield, including yield stability and yield under low input conditions; tolerance or resistance to biotic stresses, including plant diseases caused by nematodes, fungi, bacteria, viruses, insects and other pests; tolerance or resistance to abiotic stresses, including adaptation to climatic conditions; efficiency in the 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 harvesting, storage, processing, distribution and use; quality or nutritional characteristics; and the ability to be cultivated in association with other species or varieties. 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.

(69) Furthermore, in order for the organic varieties suitable for organic production as defined in Article 3, point (19), of Regulation (EU) 2018/848 to be more effectively adapted to the specific needs of organic production, their examination of the value for sustainable cultivation and use should be conducted under organic conditions.

(70) 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 national law of a Member State, should be considered to be distinct, uniform and stable and to have a suitable denomination for the purposes of this Regulation where the examination of distinctness, uniformity and stability was carried out by an examination office that has been authorised by the Commission on the basis of an opinion of the Community Plant Variety Office (CPVO).

(71) Each registered variety should have a suitable unique denomination to ensure the 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 the case of conservation varieties, it should be possible to use synonyms as this is common practice for this type of varieties. Those synonyms should be indicated in the national variety register.

(72) 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, examination offices carrying out technical examinations, confidentiality, examination report and official description, examination of conservation varieties and locally adapted varieties, examination of the denomination of a variety and decision on the registration of a variety in the national variety register.

(73) 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 plant breeding sector and the fact that it leads to the production of an official description, that examination should be carried out by the competent authority. Competent authorities should have the possibility, under certain conditions, to take into account existing examination reports on distinctness, uniformity and stability, and on value for sustainable cultivation and use.

(74) However, in order to ease the administrative burden, ensure the availability of testing facilities and reduce costs for the competent authorities, it should be possible for the competent authority to collaborate with natural or legal persons for the purposes of the technical examination.

(75) 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 should be issued. In addition, a decision on the denomination of the variety should be adopted after consulting the CPVO, in order to make the best possible use of the resources and expertise of the CPVO and to ensure consistency with the application of Regulation (EC) No 2100/94 in this area.

(76) 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 Member States pursuant to Directives 68/193/EEC, 2002/53/EC, 2002/55/EC and 2008/90/EC and Commission Directives 2008/62/EC[21] and 2009/145/EC[22]. As PRM of those varieties is already marketed in the Union and used by farmers and other professional operators, those varieties should not be subject to a new registration procedure.

(77) For the same reason, varieties belonging to species that were not covered by Directives 68/193/EEC, 2002/53/EC, 2002/55/EC, 2008/62/EC, 2008/90/EC and 2009/145/EC but are covered by this Regulation should be registered in accordance with this Regulation without applying the new registration procedure if those varieties were listed in an official national variety register in accordance with national rules.

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21 Commission Directive 2008/62/EC of 20 June 2008 providing for certain derogations for acceptance of agricultural landraces and varieties which are naturally adapted to the local and regional conditions and threatened by genetic erosion and for marketing of seed and seed potatoes of those landraces and varieties (OJ L 162, 21.6.2008, p. 13, ELI: http://data.europa.eu/eli/dir/2008/62/oj).

22 Commission Directive 2009/145/EC of 26 November 2009 providing for certain derogations, for acceptance of vegetable landraces and varieties which have been traditionally grown in particular localities and regions and are threatened by genetic erosion and of vegetable varieties with no intrinsic value for commercial crop production but developed for growing under particular conditions and for marketing of seed of those landraces and varieties (OJ L 312, 27.11.2009, p. 44, ELI: http://data.europa.eu/eli/dir/2009/145/oj).

(78) The period of 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 varieties and locally adapted varieties, due to the long term purpose of conservation but in order to still ensure relevance, as well as for varieties of genera or species of fruit plants and vines, due to the longer time required for the completion of the productive cycle of those genera or species.

(79) Any natural or legal person with a legitimate interest should have the possibility to apply for renewal of the period of registration of a variety so that the marketing of PRM of certain varieties can continue if a need is established and if they still fulfil applicable requirements. Rules should also be established on the termination of the registration, including cases where no application for renewal has been submitted, where the termination of the registration was requested by the applicant ('surrender') or where the conditions for registration are no longer fulfilled.

(80) 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 that has been granted equivalence, pursuant to certain requirements and subject to official controls by the competent authorities.

(81) 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 (‘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.

(82) Member States should be required to submit to the Commission on a regular basis specified information including in particular the quantities of produced PRM and number of professional operators. That information is important for the evaluation of the effects of this Regulation and to identify future amendments needed to better achieve its objectives.

(83) Member States should be empowered to impose corrective actions or penalties, as appropriate, on professional operators in cases of non-compliance with, or infringements of, the rules of this Regulation. The objective of those measures is to ensure compliance of the PRM concerned with the applicable requirements of this Regulation and to avoid that professional operators acquire economic advantage from fraudulent practices or from the circumvention of the rules.

(84) It should be possible for Member States to collect fees for their actions 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.

(85) By five years after the date of application of this Regulation, the Commission should submit to the European Parliament and to the Council a report on the application of the provisions of this Regulation concerning PRM marketed to non-professional users and PRM exchanged in kind between farmers. This is desirable in order to examine whether, and if so the extent to which, the use of the derogations has led to situations where PRM intended for non-professional users or PRM exchanged in kind between farmers has been sold to professional users. This would also be desirable in order to examine the possible prevalence of infringements of plant variety rights.

(86) In order to adapt the list of genera and species of PRM that fall 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 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.

(87) 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.

(88) In order to adapt the rules on the production and marketing of PRM to developments in scientific and technical knowledge 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 certain requirements of this Regulation concerning the production and marketing of pre-basic, basic, certified and standard seed and material.

(89) In order to ensure a harmonised approach to control plot testing of pre-basic, basic, certified and standard lots of seed per genus, species or category, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the criteria that are used to conduct risk analyses, the sampling and testing procedure and the evaluation of test results.

(90) 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.

(91) 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 and any other type of PRM.

(92) 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 authorisation 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 preservation mixtures.

(93) 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.

(94) In order to ensure a harmonised approach to temporary experiments to test potential improvements to this Regulation, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of establishing those experiments, the genera or species concerned by those experiments, the conditions of the experiments per genus or species, the duration of the experiments, and the obligations of Member States participating in those experiments.

(95) 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.

(96) In order to adapt the content of variety registers to developments in technical knowledge 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.

(97) In order to adapt the technical requirements for the registration of selected clones and polyclonal material to developments in scientific and technical knowledge 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.

(98) In order to adapt the provisions of this Regulation concerning the examination of the value for sustainable cultivation and use to developments in scientific and technical knowledge, 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 establishing the minimum requirements for the assessment of the characteristics examined and the evaluation and the reporting of the results of this examination.

(99) In order to set out specific criteria concerning variety denominations in view of their suitability, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of 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.

(100) 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-Making[23]. 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.

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

(101) 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 accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[24].

(102) In order to ensure uniform conditions for the implementation of this Regulation, and to take account of developments in scientific and technical knowledge and in applicable international standards, implementing powers should be conferred on the Commission with respect to laying down rules concerning the control plot testing of pre-basic, basic, certified and standard lots of seed per genus, species or category.

(103) 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 on the Commission with respect to specifying the requirements for the evaluations, training, examinations, inspections, sampling and testing, with regard to particular genera or species, for the official supervision of the professional operators by the competent authorities.

[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 (OJ L 55, 28.2.2011, p. 13, ELI: http://data.europa.eu/eli/reg/2011/182/oj).

(104) In order to ensure uniform conditions for the implementation of this Regulation concerning handling and labelling of PRM lots, implementing powers should be conferred on the Commission for laying down specific requirements for all or certain species of PRM, concerning the maximum size of lots, their identification, the size of the samples and the testing of lots, the merging or splitting of lots in relation to the origin of PRM lots, the recording of those operations and the labelling following the merging or splitting of PRM lots in accordance with applicable international standards.

(105) In order to ensure uniform conditions for the implementation of this Regulation concerning PRM in packages, bundles or containers and as individual plants, implementing powers should be conferred on the Commission for laying down specific requirements concerning the sealing, size and form of packages, bundles and containers of specific species of PRM, as well as conditions for the marketing of seed in bulk without sealing or packaging and the records to be kept.

(106) 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 on the Commission for adopting specific provisions concerning the official labels, operator's labels, labels used for certain derogations and, labels used for some specific types of PRM and laying down the content, size, colour, format and, in the case of imported PRM, the language of those labels, for the respective categories or types of PRM.

(107) In order to ensure uniform conditions for the implementation of this Regulation concerning mixtures of seed, and to follow up on any developments in scientific and technical knowledge and practical experience gained through the application of the respective rules, implementing powers should be conferred on the Commission for adopting specific provisions concerning mixing equipment and procedure, sealing, packaging and labelling, content, size, colour and format of the label, applicable use and denomination of mixtures.

(108) In order to ensure uniform conditions for the implementation of this Regulation concerning specific requirements as regards the packaging and sealing of preservation mixtures, implementing powers should be conferred on the Commission for laying down those requirements.

(109) In order to ensure uniform conditions for the implementation of this Regulation with respect to retail marketing of PRM of fruit and vegetable plants, and make the marketing of PRM as practical and suitable for each species as possible, implementing powers should be conferred on the Commission for adopting rules concerning the size, form, sealing and handling of individual plants and small packages for PRM marketed to non-professional users.

(110) In order to ensure uniform conditions for the implementation of this Regulation concerning the derogation allowing to produce and market PRM belonging to varieties under registration for the purpose of carrying out tests or trials or of making new varieties available on the market without delay, implementing powers should be conferred on the Commission for specifying, where appropriate, the limited quantities of PRM to which that derogation is to apply.

(111) In order to ensure uniform conditions for the implementation of this Regulation in relation to addressing temporary supply difficulties of PRM, implementing powers should be conferred on the Commission for authorising, for a maximum period of 12 months, the marketing of seed or material of the categories pre-basic, basic, certified or standard 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.

(112) In order to ensure uniform conditions for the implementation of this Regulation, and ensure some flexibility for Member States to adopt more stringent national measures, including higher quality standards, implementing powers should be conferred on the Commission for authorising the Member States to adopt such requirements for the production and marketing of PRM, provided that those measures correspond to market demands, specific production conditions or agro-climatic conditions of that Member State. Those more stringent measures should not impose, or result in, any prohibitions or restrictions on the movement of products originating from, or destined to, other Member States.

(113) In order to ensure uniform conditions for the implementation of this Regulation, and ensure some flexibility for Member States concerning species whose cultivation in 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 on 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.

(114) 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 on 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 constitutes a serious risk to human, animal or plant health, the environment or the cultivation of other genera and 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. Implementing powers should be conferred on the Commission to adopt immediately applicable implementing acts, on duly justified imperative grounds of urgency, to address a serious risk to human health.

(115) 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 Union requirements, implementing powers should be conferred on 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. The Commission should perform an audit for any first request of equivalence from a third country. The equivalence of PRM originating from third countries has been recognised through varying procedures in accordance with the PRM marketing Directives, and by acts adopted on the basis of Article 43(2) TFEU, namely Council Decisions 2003/17/EC[25] and 2005/834/EC[26]. In order to ensure legal clarity for the transition to the new legal framework, those equivalence decisions should be repealed, and the equivalence recognitions of such decisions and implementing regulations should be brought under one implementing act. To ensure continuity and uniform conditions in the recognition of equivalence of PRM imported from the third countries concerned as from the date of application of this Regulation, the Commission should include in an implementing act, without audits, countries for which equivalence has been recognised in accordance with those acts.

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25 Council Decision 2003/17/EC of 16 December 2002 on the equivalence of field inspections carried out in third countries on seed-producing crops and on the equivalence of seed produced in third countries (OJ L 8, 14.1.2003, p. 10, ELI: http://data.europa.eu/eli/dec/2003/17(1)/oj).

26 Council Decision 2005/834/EC of 8 November 2005 on the equivalence of checks on practices for the maintenance of varieties carried out in certain third countries and amending Decision 2003/17/EC (OJ L 312, 29.11.2005, p. 51, ELI: http://data.europa.eu/eli/dec/2005/834/oj).

(116) In order to ensure uniform conditions for the implementation of this Regulation and also to ensure consistency in the way the Union recognises the requirements of third countries as equivalent, implementing powers should be conferred on the Commission with respect to specifying the data and information to be provided by third countries for that purpose.

(117) 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 on the Commission with respect to recognising that the checks on variety maintenance carried out in a third country afford the same guarantees as those applicable in the Union.

(118) In order to ensure uniform conditions for the implementation of this Regulation, 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, implementing powers should be conferred on the Commission for laying down specific requirements concerning distinctness, uniformity and stability per genus or species of varieties, including adjusted uniformity 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 the case of conservation varieties or locally adapted varieties.

(119) In order to ensure uniform conditions for the implementation of this Regulation and to ensure the credibility and high quality of the examinations on distinctness, uniformity and stability, implementing powers should be conferred on the Commission for authorising the examination offices to carry out the technical examination of a variety for the respective genera or species. In order to ensure the credibility and high quality of those examinations, that authorisation should be adopted on the basis of an opinion of the CPVO on the suitability of the examination office to carry out such examinations.

(120) Similarly, and in order to enhance the possibility for the Union to register varieties, if no examination office in the Union has been authorised for the respective genera or species, it should be possible to use examination offices in a third country. For this reason, and in order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission for authorising examination offices in third countries. In order to ensure the credibility and high quality of those examinations, that authorisation should be adopted on the basis of an opinion of the CPVO on the suitability of the examination office to carry out such examinations.

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

(122) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission for adopting specific rules specifying the size of the standard sample of registered varieties and laying down the rules for its replacement and for making it available to other competent authorities.

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

(124) In order to avoid the disruption of production and marketing of PRM because of the transition from the PRM marketing Directives to the new rules, special measures should be adopted. Thus, PRM produced or marketed before the application of this Regulation should continue to be made available on the market to allow the use of existing stocks and avoid waste. In addition, varieties that were registered according to the PRM marketing Directives should be registered in accordance with this Regulation without applying the new registration procedure. Furthermore, varieties of genera or species covered by this Regulation which were not covered by the PRM marketing Directives and were registered in a national variety register pursuant to national rules before the date of application of this Regulation should be registered in the relevant national variety registers without applying the rules set out in this Regulation. To ensure legal certainty, such a registration should be made by the date of application of this Regulation. For the same reasons, under specific conditions, professional operators should be registered without the submission of an application for registration, if they are registered in accordance with the PRM marketing Directives.

(125) The PRM marketing Directives should be repealed, as this Regulation replaces them. As a consequence, Regulation (EU) 2016/2031 should be amended to delete references to those Directives and to ensure that Union regulated non-quarantine pests are exclusively regulated by that Regulation and that all types of PRM are covered.

(126) Regulation (EU) 2017/625 of the European Parliament and of the Council[27] 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 and other official activities for the entire plant production and food chain since Regulation (EU) 2017/625 also applies to the scope of Regulations (EU) 2016/2031 and (EU) 2018/848.

(127) In this respect, the Commission should be empowered to lay down rules for the performance of official controls on PRM for verifying compliance with Union rules for the import into, and marketing within, the Union of PRM, and on the activities of professional operators during the production of PRM, as well as rules for action taken by the competent authorities following the performance of those official controls.

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[27] 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, ELI: http://data.europa.eu/eli/reg/2017/625/oj).

(128) 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 that Regulation. 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.

(129) In accordance with the Interinstitutional Agreement on Better Law-Making, the European Parliament and the Council consider that, in order to ensure that sufficient experience has been gathered on the application of this Regulation before any extension of the value for sustainable cultivation and use requirements to additional genera or species is considered, any report assessing such an extension should only be presented 10 years after the date of application of this Regulation. This Regulation is without prejudice to the right of initiative of the Commission under Article 17(2) of the Treaty on European Union (TEU).

(130) Since the objective of this Regulation, namely to ensure a harmonised approach with regard to the production and marketing of PRM, cannot be sufficiently achieved by the Member States but can 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 TEU. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective. In view of this, and as necessary, it introduces derogations or specific requirements for certain types of PRM and professional operators.

(131) This Regulation should apply from 48 months after its entry into force, in order to allow the competent authorities and the professional operators to adapt to its provisions and to provide the necessary time for the adoption of the relevant delegated and implementing acts,

HAVE ADOPTED THIS REGULATION:

Chapter I
General provisions

Article 1

Subject matter

This Regulation lays down rules concerning the production of plant reproductive material ('PRM') with a view to marketing and the marketing of PRM in the Union, and in particular requirements for the production of PRM in the field and on other sites, categories of PRM, identity and quality requirements, certification, labelling, packaging, imports, professional operators, and the registration of varieties.

Article 2

Scope and objectives

1. This Regulation applies to PRM belonging to the genera and species listed in Annex I, in respect of the uses indicated in that Annex, as well as to their hybrids.

   It also applies to rootstocks and other parts of plants of genera or species other than those listed in Annex I or their hybrids if material of genera or species listed in Annex I or their hybrids is grafted or is to be grafted onto them.

2. The requirements of this Regulation concerning the production of PRM shall apply only to production with a view to marketing PRM in the Union.

3. The objectives of this Regulation are the following:

(a) to ensure the quality and diversity of PRM, and the availability of such PRM to all users, including to professional operators and farmers;

(b) to ensure fair conditions for competition between professional operators across the Union, and to ensure the functioning of the internal market in PRM;

(c) to support innovation in and the competitiveness of the PRM sector in the Union;

(d) to contribute to conservation, including dynamic conservation, and the sustainable use of plant genetic resources and agro-biodiversity;

(e) to contribute to sustainable agricultural production that is adapted to current and future projected climatic and other environmental conditions;

(f) to contribute to food and feed security and sovereignty.

4. The Commission is empowered to adopt delegated acts in accordance with Article 79 amending Annex I to adapt it to the developments in scientific and technical knowledge and to changes in the economic data concerning production and marketing of genera and species by adding or deleting genera and species for one or more uses.

The delegated acts referred to in the first subparagraph may add a genus or species for one or more uses to the list in Annex I if it fulfils at least two of the following criteria with regard to their intended uses:

(a) it represents a significant area of the production of PRM or of the relevant crop and a significant value of marketed PRM or of the relevant crop in the Union;

(b) it is of substantial importance for security of food and feed production in the Union, compared to other genera and species not listed in that Annex; and

(c) the PRM of that genus or species is marketed in at least two Member States.

The delegated acts referred to in the first subparagraph may delete a genus or a species for one or more uses from the list in Annex I if it no longer fulfils at least two of the criteria set out in the second subparagraph.

The delegated acts adopted pursuant to this paragraph shall specify the criteria used to determine that the area of production or the market value is significant or that the importance for security of food and feed production is substantial in relation to the genera and species and the uses concerned.

5. This Regulation does not apply to:

(a) PRM of genera and species listed in Annex I intended for ornamental purposes in accordance with Directive 98/56/EC, with the exception of seed intended for turf grass use;

(b) forest reproductive material subject to Regulation (EU) 2026/1392;

(c) PRM solely intended for export to third countries, provided that it is identified as such;

(d) PRM sold or transferred in any way, free of charge or not, between non-professional users;

(e) PRM used solely for inspection, sampling or testing carried out officially or under official supervision, for breeding and selection, for exhibitions or for research or other scientific purposes, provided that it is identified as such;

(f) PRM subject to service contracts for the purposes of processing, including cleaning, disinfection, treatment and packaging, or of transport or storage, provided that the provider of those services does not acquire title to that PRM and that the traceability of that PRM is ensured;

(g) PRM transferred to or from gene banks for the conservation of plant genetic resources;

(h) organic heterogenous material produced in accordance with Regulation (EU) 2018/848.

6. For the purposes of this Regulation, references to third countries shall be considered to be references to third countries and to the territories that are referred to in Article 355(1) TFEU, with the exception of Madeira, the Azores and the Canary Islands.

For the purposes of this Regulation, references to the Union territory shall be considered to be references to the Union territory without the territories that are referred to in Article 355(1) TFEU, with the exception of Madeira, the Azores and the Canary Islands.

Article 3

Definitions

For the purposes of this Regulation, the following definitions apply:

(1) ‘plant reproductive material’ or ‘PRM’ means plants for planting, as defined in Article 2, point (4), of Regulation (EU) 2016/2031, including seed, capable of, and intended for:

(a) the production of entire plants or parts of plants; or

(b) the production of fruits, vegetables or other crops;

(2) ‘seed’ means seed in the botanical sense;

(3) ‘marketing’ means the following actions conducted by a professional operator:

(a) sale, holding with a view to sale, transfer for free, or offering for sale, including online, or any other transfer or distribution within the Union; or

(b) import into the Union;

(4) ‘professional operator’ means any natural or legal person, other than a competent authority, governed by public or private law, involved professionally in, and legally responsible for, one or more of the following activities in the Union concerning PRM:

(a) production with a view to marketing;

(b) marketing;

(c) the maintenance of varieties;

(d) field inspection, sampling, laboratory testing, storage, processing, packaging, sealing or labelling;

(5) ‘non-professional user’ means any natural or legal person acquiring, transferring and using PRM for purposes which are outside that person’s professional activities;

(6) ‘competent authority’ means the central or regional authority of a Member State, or, where applicable, the corresponding authority of a third country, responsible for the organisation of official controls, registration, certification and other official activities concerning the production and marketing of PRM, or any other authority to which those responsibilities have been conferred in accordance with Union law;

(7) ‘category’ of PRM means a group or an individual unit of PRM that qualifies as pre-basic, basic, certified or standard seed or material and is identifiable on the basis of its compliance with specific identity and quality requirements;

(8) ‘pre-basic seed’ means seed that belongs to generations preceding the generation of the basic seed, is intended for the production of further generations of pre-basic, basic or certified seed, and has been found, by means of official certification or certification under official supervision, to satisfy the respective conditions laid down in Annex II;

(9) ‘basic seed’ means seed that has been produced from pre-basic seed or preceding generations of basic seed, is intended for the production of further generations of basic seed or certified seed, and has been found, by means of official certification or certification under official supervision, to satisfy the respective conditions laid down in Annex II;

(10) ‘certified seed’ means seed that has been produced from pre-basic, basic or preceding generations of certified seed, is intended for the production of further generations of certified seed or for cultivation, and has been found, by means of official certification or certification under official supervision, to satisfy the respective conditions laid down in Annex II;

(11) ‘standard seed’ means seed other than pre-basic, basic or certified seed that satisfies the respective conditions laid down in Annex III;

(12) ‘pre-basic material’ means PRM other than seed that belongs to generations preceding the generation of basic material, is intended for the production of further generations of pre-basic, basic or certified material, and has been found, by means of official certification or certification under official supervision, to satisfy the respective conditions laid down in Annex II;

(13) ‘basic material’ means PRM other than seed that has been produced from pre-basic material or preceding generations of basic material, is intended for the production of further generations of basic material or certified material, and has been found, by means of official certification or certification under official supervision, to satisfy the respective conditions laid down in Annex II;

(14) ‘certified material’ means PRM other than seed that has been produced from pre-basic, basic or preceding generations of certified material or seed, is intended for the production of further generations of certified material or for cultivation, and has been found, by means of official certification or certification under official supervision, to satisfy the respective conditions laid down in Annex II;

(15) ‘standard material’ means PRM other than seed or pre-basic, basic or certified material that satisfies the respective conditions laid down in Annex III;

(16) ‘seed potatoes’ means tubers, including minitubers, and micropropagative material of cultivated tuber-forming *Solanum tuberosum* L. used for planting;

(17) ‘true potato seed’ means seed of *Solanum tuberosum* L.;

(18) ‘mother plant’ means an identified plant intended for the production of PRM;

(19) ‘clone’ means an individual plant progeny derived originally from another single plant by vegetative propagation, that remains genetically identical to that plant;

(20) ‘selected clone’ means a clone that is the vegetative progeny of a single plant, is true to the description of a certain variety and was chosen for its phenotypic characteristics and its phytosanitary status;

(21) ‘polyclonal material’ means a group of two or more individual plant progenies, other than mixtures of selected clones, derived from different genotypes of the same variety, selected as a group, of which the individual members have intra-varietal diversity when compared to one another;

(22) ‘official certification’ means an official attestation by the competent authority of the compliance of pre-basic, basic or certified seed or material with the applicable requirements of this Regulation where all relevant inspections, sampling and testing, including, where appropriate, control plot testing, have been carried out by that authority;

(23) ‘certification under official supervision’ means an attestation by an authorised professional operator that pre-basic, basic or certified seed or material complies with the applicable requirements of this Regulation where at least one of the relevant inspections, sampling, testing or label printing and affixing has been carried out by that professional operator under the official supervision of the competent authority;

(24) ‘variety’ means a variety as defined in Article 5(2) of Regulation (EC) No 2100/94;

(25) ‘official description’ means a description of a variety that has been established by a competent authority on the basis of an examination of that variety’s distinctness, uniformity and stability, that includes the relevant characteristics of that variety and that makes the identification of that variety possible;

(26) ‘officially recognised description’ means a written description of a conservation variety or locally adapted variety that is recognised by a competent authority;

(27) ‘variety maintenance’ means the actions taken to ensure varietal purity and varietal identity and in particular to ensure that the variety remains unchanged in the expression of its relevant characteristics after repeated propagation or, in the case of a particular cycle of propagation, at the end of each such cycle;

(28) ‘standard sample’ means a sample of PRM of a variety that is representative of that variety and is used by the competent authority as a reference when checking the varietal identity, varietal purity and variety maintenance for the purposes of this Regulation;

(29) ‘off-types’ means plants that are obviously different from the variety to which they are supposed to belong pursuant to this Regulation in the expression of any relevant characteristic, taking into consideration the particular features of its propagation;

(30) ‘quality pests’ means pests that:

(a) are not Union quarantine pests, protected zone quarantine pests, Union regulated non-quarantine pests within the meaning of Regulation (EU) 2016/2031 or pests subject to the measures adopted pursuant to Article 30(1) of that Regulation;

(b) occur during PRM production or post-harvest; and

(c) by their presence, have an unacceptable adverse impact on the quality of the PRM, and an unacceptable economic impact as regards the use of that PRM in the Union;

(31) ‘practically free from quality pests’ means that the extent to which quality pests are present on PRM is sufficiently low to ensure acceptable quality and usefulness of that PRM;

(32) ‘lot’ means a defined quantity of PRM identifiable on the basis of its homogeneity of composition;

(33) ‘conservation variety’ means a variety that:

(a) is traditionally grown in a certain region of the Union (‘region of origin’);

(b) is adapted to the local agro-climatic conditions and farming systems of that region; and

(c) can be characterised by reduced uniformity due to a certain level of genetic or phenotypical diversity between individual reproductive units;

(34) ‘locally adapted variety’ means a variety that:

(a) has recently been bred in a certain region of the Union (‘region of origin’) as a result of dynamic conservation activities or other breeding and selection methods applied under natural or farmer-managed conditions;

(b) is adapted to the local agro-climatic conditions and farming systems of that region; and

(c) in the case of varieties other than vegetatively propagated varieties, is characterised by reduced uniformity due to a certain level of genetic or phenotypical diversity between individual reproductive units;

(35) ‘farmer’ means any natural or legal person who professionally exercises an activity in the area of plant production, including agriculture and horticulture;

(36) ‘seed as grown’ means unprocessed seed of vegetable plants, as referred to in Annex I, produced in a third country and imported into the Union for processing and marketing in accordance with this Regulation;

(37) ‘gene bank’ means an organisation with the aim of conserving plant genetic resources for the continued public availability of those resources for the purposes of research, breeding and selection, education, training and direct use, and recognised as such by the relevant competent authority;

(38) ‘genetically modified organism’ means a genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC of the European Parliament and of the Council[28], with the exception of organisms obtained through the techniques of genetic modification listed in Annex I B to that Directive;

[28] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1, ELI: http://data.europa.eu/eli/dir/2001/18/oj).

(39) ‘NGT plant’ means an NGT plant as defined in Article 3, point (9), of Regulation (EU) 2026/1388 of the European Parliament and of the Council[29].

Article 4

Compliance with Regulation (EU) 2016/2031

This Regulation shall apply without prejudice to Regulation (EU) 2016/2031.

Any PRM produced and marketed in accordance with this Regulation shall comply with the rules laid down, or provided for, in the relevant provisions of Regulation (EU) 2016/2031 concerning Union quarantine pests, protected zone quarantine pests and Union regulated non-quarantine pests, and with the measures adopted pursuant to Article 30(1) of that Regulation.

[29] Regulation (EU) 2026/1388 of the European Parliament and of the Council of 17 June 2026 on plants obtained by certain new genomic techniques and their products, and amending Regulation (EU) 2017/625 (OJ L, 2026/1388, 26.6.2026, ELI: http://data.europa.eu/eli/reg/2026/1388/oj).

Chapter II

Requirements concerning varieties, categories of PRM, labelling, authorisations, handling, imports and derogations

SECTION 1

GENERAL REQUIREMENTS FOR THE PRODUCTION AND MARKETING OF PRM

Article 5

PRM belonging to a registered variety

1. Only PRM belonging to a variety registered in a national variety register referred to in Article 49 may be produced and marketed within the Union.

2. By way of derogation from paragraph 1, PRM may be produced and marketed within the Union regardless of whether it belongs to a variety registered in accordance with Article 49 in the following cases:

   (a) it is a rootstock for fruit plants and vines which does not belong to any variety and is produced and marketed with a reference to the genus or species to which it belongs, that reference being contained, in the case of marketing, in appropriate labelling;

(b) it is intended for non-professional users in accordance with Article 24;

(c) it is produced or marketed by organisations and networks for the conservation of plant genetic resources in accordance with Article 25;

(d) it is exchanged in kind between farmers in accordance with Article 26;

(e) it is a parental component of a hybrid variety intended for the production of final hybrid varieties;

(f) it belongs to a variety which is subject to an application for registration in accordance with Article 28;

(g) there are temporary difficulties in the supply of PRM as referred to in Article 30.

3. By way of derogation from paragraph 1, the following types of PRM may only be produced and marketed if they do not belong to a registered variety:

(a) preservation mixtures in accordance with Article 22;

(b) commercial seed in accordance with Article 29.

Article 6

PRM belonging to certain categories

1. Only PRM belonging to one of the following categories may be produced and marketed within the Union:

   (a) pre-basic seed or material;

   (b) basic seed or material;

   (c) certified seed or material;

   (d) standard seed or material.

   Where a reference is made in this Regulation to lower or higher categories concerning identity and quality of PRM, that determination shall be based on the ranking of the order of points (a) to (d), with point (a) having the highest ranking and point (d) the lowest ranking.

2. By way of derogation from paragraph 1, PRM may be produced and marketed regardless of whether it belongs to a category listed in points (a) to (d) of that paragraph in the following cases:

   (a) it is a preservation mixture produced in accordance with Article 22;

   (b) it is intended for non-professional users in accordance with Article 24;

(c) it is produced or marketed by organisations and networks for the conservation of plant genetic resources in accordance with Article 25;

(d) it is exchanged in kind between farmers in accordance with Article 26;

(e) it belongs to a generation prior to pre-basic seed or material in accordance with Article 27;

(f) it is commercial seed in accordance with Article 29.

Article 7

PRM to be produced and marketed only as pre-basic, basic or certified seed or material

1. PRM belonging to the genera or species, and for the intended uses, indicated in column 2 of Annex I shall be produced and marketed only as pre-basic, basic or certified seed or material.

2. PRM of selected clones shall be produced and marketed only as pre-basic, basic or certified material of fruit plants and vines.

3. Vine rootstocks shall be produced and marketed only as pre-basic, basic or certified material.

4. The Commission is empowered to adopt delegated acts in accordance with Article 79 in order to amend column 2 of Annex I.

Those delegated acts shall add a genus or a species for one or more uses to column 2 of Annex I if both of the following conditions are fulfilled:

(a) there is a need for higher guarantees for the quality of PRM belonging to that genus or species; and

(b) the costs of the certification activities necessary to produce and market PRM belonging to that genus or species as pre-basic, basic and certified seed or material are proportionate.

The delegated acts referred to in the first subparagraph shall delete a genus or a species for one or more uses from column 2 of Annex I if its inclusion is no longer proportionate.

5. The assessment of the proportionality condition referred to in paragraph 4, second subparagraph, point (b), and third subparagraph, shall be based on an overall assessment of the following elements, in combination with one another:

(a) the importance of the genus or species concerned for ensuring Union food and feed security, or for ensuring high value of industrial processing;

(b) the volume of the production of that genus or species in the Union;

(c) the demand for that genus or species by the professional operators and operators of the food and feed industry;

(d) the costs of the production of pre-basic, basic and certified seed or material compared to the cost of production of standard seed or material or other types of PRM of the same genus or species; and

(e) the economic, phytosanitary or environmental benefits deriving from the production and marketing of pre-basic, basic and certified seed or material applying the highest standards concerning identity and quality for such PRM, compared to the situation for standard seed or material or other types of PRM of the same genus or species.

SECTION 2

REQUIREMENTS FOR THE PRODUCTION AND MARKETING OF PRE-BASIC, BASIC, CERTIFIED AND STANDARD SEED AND MATERIAL

Article 8

Requirements for the production and marketing of pre-basic, basic and certified seed and material

1. Pre-basic, basic and certified seed shall only be produced and marketed within the Union if:

(a) it is practically free from quality pests;

(b) it is marketed after official certification or certification under official supervision has been carried out; and

(c) it is produced and marketed in accordance with the requirements set out in Parts A or B of Annex II and its compliance with those requirements is attested to by the official label referred to in Article 17(1).

2. Pre-basic, basic and certified material shall only be produced and marketed within the Union if:

(a) it is practically free from quality pests;

(b) it is marketed after official certification or certification under official supervision has been carried out; and

(c) it is produced and marketed in accordance with the requirements set out in Parts C, D or E of Annex II and its compliance with those requirements is attested to by the official label referred to in Article 17(1).

3. The Commission is empowered to adopt delegated acts in accordance with Article 79 amending Annex II in order to adapt it to developments in scientific and technical knowledge and in applicable international standards by laying down requirements for one or more of the following activities:

(a) sowing and planting, and field cultivation for the production of pre-basic, basic and certified seed;

(b) the harvesting and post-harvesting of pre-basic, basic and certified seed;

(c) the marketing of pre-basic, basic and certified seed;

(d) sowing and planting, and field cultivation for the production of pre-basic, basic and certified material;

(e) the harvesting and post-harvesting of pre-basic, basic and certified material;

(f) the marketing of pre-basic, basic and certified material;

(g) the production of pre-basic, basic and certified material of selected clones and polyclonal material;

(h) the marketing of pre-basic, basic and certified material of selected clones and polyclonal material;

(i) the production of pre-basic, basic and certified material produced by in vitro propagation;

(j) the marketing of pre-basic, basic and certified material produced by in vitro propagation.

4. The Commission shall adopt implementing acts laying down the production and marketing requirements referred to in Annex II for certain genera, species or categories of PRM and, where appropriate, for certain grades, classes, generations or other sub-divisions of the category concerned, including for mother plants. Those requirements may apply to all or certain genera or species and shall concern one or more of the following:

(a) specific rules for one or more of the intended uses of the genera, species or the types of the PRM concerned;

(b) production methods of PRM, including sexual and asexual reproduction and in vitro propagation;

(c) conditions for sowing or planting;

(d) previous cropping and isolation distances;

(e) field cultivation, including in open field and in a controlled environment;

(f) varietal purity, varietal identity and the levels of presence of other species in the field;

(g) harvesting and post-harvesting;

(h) germination rates, purity, the content of other species, moisture content, vigour and the presence of soil or extraneous matter;

(i) methods of certification of PRM, including requirements on field inspection, sampling and testing, and, where appropriate, the application of biochemical and biomolecular techniques or other technical methods, where applicable on the basis of the relevant international standards, as well as their approval and use, and the listing of approved methods in the Union;

(j) the conditions for rootstocks and other parts of plants of genera or species other than those listed in Annex I or their hybrids if propagating material of the genus or species listed in Annex I or their hybrids is grafted onto them;

(k) conditions for the production of seed from fruit plants, potatoes or vines;

(l) conditions for the production of PRM of fruit plants, PRM of vine or seed potatoes from seed;

(m) conditions for the production and marketing of PRM of selected clones and PRM of polyclonal material.

Those implementing acts may set out more stringent production and marketing requirements to be applied in certain parts of the Union territory if required by agro-climatic conditions, the risk of noxious weeds spreading, or other special conditions and needs of certain areas. Those requirements shall be proportionate in view of the category of PRM concerned.

The initial implementing acts in respect of the requirements listed in the first subparagraph shall be adopted no later than … [48 months from the date of the entry into force of this Regulation]. They may be amended in order to adapt them to developments in scientific and technical knowledge and in applicable international standards.

Those implementing acts shall be adopted in accordance with the examination procedure set out in Article 80(2).

Article 9

Requirements for the production and marketing of standard seed and material

1. Standard seed shall only be produced and marketed within the Union if:

   (a) it is practically free from quality pests;

   (b) it is produced and marketed under the responsibility of the professional operator; and

   (c) it is produced and marketed in accordance with the requirements set out in Parts A or B of Annex III and its compliance with those requirements is attested to by the operator's label referred to in Article 18(1).

2. Standard material shall only be produced and marketed within the Union if:

   (a) it is practically free from quality pests;

(b) it is produced and marketed under the responsibility of the professional operator; and

(c) it is produced and marketed in accordance with the requirements set out in Parts C, D or E of Annex III and its compliance with those requirements is attested to by the operator's label referred to in Article 18(1).

3. The Commission is empowered to adopt delegated acts in accordance with Article 79 amending Annex III in order to adapt it to developments in scientific and technical knowledge and in applicable international standards by laying down requirements for one or more of the following activities:

(a) sowing and planting, and field cultivation for the production of standard seed;

(b) the harvesting and post-harvesting of standard seed;

(c) the marketing of standard seed;

(d) sowing and planting, and field cultivation for the production of standard material;

(e) the harvesting and post-harvesting of standard material;

(f) the marketing of standard material;

(g) the production and marketing of PRM of polyclonal material;

(h) the production of standard material produced by in vitro propagation;

(i) the marketing of standard material produced by in vitro propagation.

4. The Commission shall adopt implementing acts laying down the production and marketing requirements referred to in Annex III for certain genera or species of standard PRM, including for mother plants. Those requirements shall concern one or more of the following, and may apply to all or certain genera or species:

(a) specific rules for one or more of the intended uses of the genera, species or the types of the PRM concerned;

(b) production methods of PRM, including sexual and asexual reproduction and in vitro propagation;

(c) conditions for sowing or planting;

(d) previous cropping and isolation distances;

(e) field cultivation, including in open field and in controlled environment;

(f) varietal purity, varietal identity, and the content of other species in the field;

(g) harvesting and post-harvesting;

(h) germination rates, purity, the content of other species, moisture content, vigour and the presence of soil or extraneous matter;

(i) the application of biochemical and biomolecular techniques or other technical methods, where applicable on the basis of the relevant international standards, as well as their approval and use, and the listing of approved methods in the Union;

(j) the conditions for rootstocks and other parts of plants of genera or species other than those listed in Annex I or their hybrids if propagating material of the genus or species listed in Annex I or their hybrids is grafted onto them;

(k) conditions for the production of seed from fruit plants, potatoes or vine;

(l) conditions for the production of PRM of fruit plants, PRM of vine or seed potatoes from seed;

(m) conditions for the production and marketing of PRM of conservation varieties and locally adapted varieties;

(n) conditions for the production and marketing of PRM of polyclonal material.

Those implementing acts may set out more stringent production and marketing requirements to be applied in certain parts of the Union territory if required by agro-climatic conditions, the risk of noxious weeds spreading, or other special conditions and needs of certain areas. Those requirements shall be proportionate in view of the category of PRM concerned.

The initial implementing acts in respect of the requirements listed in the first subparagraph of this paragraph shall be adopted no later than … [48 months from the date of the entry into force of this Regulation]. They may be amended in order to adapt them to developments in scientific and technical knowledge and in applicable international standards.

Those implementing acts shall be adopted in accordance with the examination procedure set out in Article 80(2).

SECTION 3

SPECIFIC REQUIREMENTS FOR CONTROL PLOT TESTING FOR SEED

Article 10

Control plot testing for pre-basic, basic and certified seed

1. Control plot tests shall be carried out by the competent authority in order to verify that the lots of pre-basic, basic and certified seed with the exception of lots of seed of vine and fruit plants comply with the requirements relating to their varietal identity and varietal purity.

   Those tests shall consist of a visual comparison between a control plot sown with a standard sample and a plot sown with a sample of seed from the lot to be tested. Samples to be tested shall be taken from either:

   (a) lots of pre-basic, basic and certified seed intended for the production of a new generation or category; or

(b) lots of seed of a generation no longer intended for further multiplication.

Samples to be tested shall be taken during the certification or marketing of those lots.

The testing of those samples shall take place at the latest during the growing season following the drawing of the sample.

2. Control plot tests shall be carried out on all lots of pre-basic and basic seed. In the case of certified seed, the proportion of the lots to be tested shall be determined on the basis of a risk analysis concerning the possible non-compliance of that seed with the applicable requirements.

3. The sample from a tested lot of seed referred to in paragraph 1 shall be taken by the competent authority or by a sampler under official supervision and authorised by the competent authority. That sampling may be carried out using an automatic sampling device officially approved by the competent authority. If samples are taken during marketing, they shall be taken by the competent authority.

4. Biochemical and biomolecular techniques or other technical methods recognised in accordance with Article 8(4), point (i), may be used for the control of varietal identity and varietal purity.

5. When the results of the test referred to in paragraph 1 of this Article indicate that the requirements of Article 8 have not been fulfilled, the competent authority shall:

(a) require the withdrawal, or prohibit the further multiplication and marketing, of the seed lot concerned;

(b) require that the seed lot concerned be treated in order to comply with the applicable requirements; or

(c) take other appropriate corrective action.

6. The Commission is empowered to adopt delegated acts in accordance with Article 79 supplementing this Regulation by laying down rules concerning the control plot testing of lots of pre-basic, basic and certified seed per genus or species. Those rules shall be adapted to developments in scientific and technical knowledge and in applicable international standards, and may be established per genus, species or category. They may concern the following elements:

(a) criteria for the conduct of the risk analysis referred to in paragraph 2 of this Article;

(b) the sampling and testing procedure, including appropriate technologies;

(c) the evaluation of the results of the tests.

Article 11

Control plot testing for standard seed

1. Control plot tests shall be carried out by the competent authority in order to verify that the lots of standard seed with the exception of lots of seed of vine and fruit plants comply with the requirements relating to their varietal identity and varietal purity.

   Those tests shall consist of a visual comparison between a control plot sown with a standard sample and a plot sown with a sample of seed from the lot to be tested. Samples to be tested shall be taken during the marketing of the lot.

2. Control plot tests shall be carried out on a proportion of lots of standard seed determined on the basis of a risk analysis concerning the possible non-compliance of that seed with the applicable requirements.

3. The sample to be tested shall be taken by the competent authority. That sampling may be carried out using an automatic sampling device officially approved by the competent authority.

4. Biochemical and biomolecular techniques or other technical methods, recognised in accordance with Article 9(4), point (i), may be used for the control of varietal identity and varietal purity.

5. When the results of the test referred to in paragraph 1 of this Article indicate that the requirements of Article 9 have not been fulfilled, the competent authority shall:

(a) require the withdrawal of the seed lot concerned or prohibit, if feasible, its further multiplication and marketing;

(b) require that the seed lot concerned be treated in order to comply with the applicable requirements; or

(c) take other appropriate corrective action.

6. The Commission is empowered to adopt delegated acts in accordance with Article 79 supplementing this Regulation by laying down rules concerning the control plot testing of lots of standard seed per genus or species. Those rules shall be adapted to developments in scientific and technical knowledge and in applicable international standards, and may be established per genus or species. They may concern the following elements:

(a) criteria for the conduct of the risk analysis referred to in paragraph 2 of this Article;

(b) the sampling and testing procedure, including appropriate technologies;

(c) the evaluation of the results of the tests.

SECTION 4

AUTHORISATION OF PROFESSIONAL OPERATORS AND OFFICIAL SUPERVISION BY THE COMPETENT AUTHORITIES

Article 12

Authorisation of professional operators to carry out certification under official supervision

1. Member States may provide for the possibility for professional operators to carry out certain activities that are required for certification under official supervision.

   In such a case, the competent authority may, upon application, authorise a professional operator to perform all or certain activities required for the certification of PRM, with the exception of control plot testing as referred to in Article 10, and to print an official label as referred to in Article 17(1) and affix it to that PRM.

2. In order to be granted the authorisation referred to in paragraph 1, the professional operator shall comply with all of the following conditions that are relevant for the activities for which the authorisation is to be granted:

   (a) it shall possess the knowledge necessary to enable it to comply with the requirements referred to in Article 8;

   (b) it shall be qualified to carry out the inspections referred to in Annex II, or employ personnel qualified to carry out such inspections;

(c) it shall employ qualified personnel for carrying out the sampling referred to in Annex II, or conclude contracts with other professional operators who employ personnel qualified to carry out such sampling;

(d) it shall employ specialised personnel and possess the necessary equipment to carry out the testing referred to in Annex II, or use laboratories that follow International Seed Testing Association (ISTA) rules or other applicable international standards and that employ personnel qualified to carry out such testing;

(e) it shall have identified, and have the capability to monitor, the critical points of the production process which could influence the quality and identity of the PRM, and keep records of the results of that monitoring;

(f) it shall have in place systems to ensure that the requirements concerning the identification of lots pursuant to Article 15 are fulfilled;

(g) it shall have in place systems to ensure that the traceability requirements set out in Article 47 are fulfilled.

3. Paragraph 2 of this Article shall apply in accordance with the relevant rules set out in the implementing act referred to in Article 8(4), and, in the absence of such rules, in accordance with applicable international standards, and, in the absence of such standards, in accordance with national rules.

4. The Commission is empowered to adopt delegated acts in accordance with Article 79 supplementing this Regulation by laying down the specific actions to be taken by the competent authority in order to confirm that paragraph 2 of this Article has been complied with.

Article 13

Withdrawal or modification of the authorisation of a professional operator

1. Where an authorised professional operator no longer fulfils the requirements set out in Article 12(1), (2) and (3), or where the PRM produced or marketed by that professional operator has been repeatedly found not to be in compliance with this Regulation, the competent authority shall request that professional operator to take corrective action within a specified period.

2. If the professional operator fails to take the corrective action referred to in paragraph 1 within the specified period, the competent authority shall without delay withdraw or modify the authorisation. If it is concluded that the authorisation was granted following fraud, the competent authority shall impose appropriate sanctions on the professional operator.

Article 14

Official supervision by the competent authority

1. For the purposes of certification under official supervision, the competent authority shall conduct regular evaluations to ensure that the professional operator fulfils the requirements set out in Article 12(1), (2) and (3). The frequency of the evaluations shall be determined based on the potential risk that the professional operator is not complying with the relevant requirements of this Regulation. Such evaluations shall be carried out at least once every five years.

2. The competent authority shall organise training and examinations for the personnel of the professional operator carrying out the field inspections, sampling and testing provided for in this Regulation.

3. For the purposes of the certification under official supervision, the competent authority shall carry out official inspections, sampling and testing of a portion of the crops on the site of production and on lots in order to confirm the compliance of PRM with the requirements set out in Article 8.

   That portion shall be determined on the basis of an assessment of the potential risk of the PRM of the professional operator concerned failing to comply with the requirements referred to in the first subparagraph.

4. The Commission may adopt implementing acts laying down the requirements for the evaluations of the professional operator referred to in paragraph 1, the training and examinations for personnel referred to in paragraph 2, and the inspections, sampling and testing of a portion of crops referred to in paragraph 3 with regard to particular genera or species.

Those requirements may concern the following:

(a) the risk criteria referred to in paragraph 1 and the minimum portion of the crops and the lots of PRM to be subject to field inspections, sampling and testing, as referred to in paragraph 3;

(b) the use of quality assurance systems by the professional operator subject to the approval of the competent authority and the possibility for the competent authority to reduce the inspections, sampling and testing referred to in this Article due to the use of those quality assurance systems.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 80(2).

SECTION 5

HANDLING AND LABELLING REQUIREMENTS

Article 15

Lots

1. PRM shall be produced and marketed in lots. It shall be identifiable by a unique lot reference number that ensures its traceability.

2. Lots of PRM may only be merged into a new lot in accordance with Article 20 if they belong to the same variety.

   Where lots consisting of different categories are merged, the new lot shall belong to the category of the component of the lowest category.

3. Lots of PRM may be split into two or more lots in accordance with Article 20.

4. The Commission shall adopt implementing acts laying down specific requirements for all or certain species of PRM concerning the maximum size of lots, their identification, the size of the samples and the testing of lots, the merging or splitting of lots in relation to the origin of the PRM lots, the recording of those operations and the labelling following such merging or splitting. Those requirements shall take into account any applicable international standards.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 80(2).

Article 16

Packages, bundles and containers

1. PRM shall be marketed as individual plants or in packages, bundles or containers bearing a label. Packages, bundles or containers shall be sealed. However, PRM other than seed and seed potatoes may be marketed without sealing where sealing is not feasible.

2. The packages, bundles and containers referred to in paragraph 1 shall be sealed in such a way that they cannot be opened without destroying the sealing or leaving traces demonstrating that the package, bundle or container has been opened. The effectiveness of the sealing shall be ensured either by incorporating the labels provided for in Articles 17 and 18 in the sealing device or by affixing a seal. Packages and containers shall be exempted from this requirement if the seal or the sealing device cannot be reused.

3. Packages, bundles and containers of pre-basic, basic or certified seed and material shall be sealed by the competent authority or by the professional operator under official supervision.

4. By way of derogation from paragraph 1, certified seed may be marketed by a professional operator directly to a farmer in bulk.

It shall be necessary for the professional operator to have been authorised for that purpose by the competent authority. That professional operator shall keep records of such activity and of the lot from which such seed came. Those records shall be made available to the competent authority on request.

Where seed is loaded directly into the farmer's machinery or trailer, the professional operator shall ensure that that seed is traceable by issuing and retaining documents indicating the species and variety, the quantity, the date of transfer, the lot reference number and the means of transport used.

5. The Commission may adopt implementing acts laying down:

(a) specific requirements concerning the sealing, size and form of the packages, bundles and containers for PRM of specific genera and species, including the technical and biological reasons that mean that sealing or packaging is not feasible; and

(b) conditions for the marketing of seed in bulk and the records to be kept.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 80(2).

Article 17

Official label for pre-basic, basic and certified seed and material

1. Pre-basic, basic and certified seed and material shall be identified, and their compliance with this Regulation shall be attested to, by means of an official label issued by the competent authority confirming that the requirements set out in Article 8 have been fulfilled (‘official label’).

2. The official label shall be issued by the competent authority and shall bear a unique serial number provided by the competent authority.

That official label shall be printed by:

(a) the competent authority; or

(b) the professional operator under official supervision, where the professional operator is authorised to carry out such printing in accordance with Article 12.

3. The official label shall be affixed to the outside of the individual plant, bundle, package or container, or printed indelibly on the package or container, by the professional operator under official supervision.

4. Some of the information in the official label may be provided in digital form, in accordance with the delegated act referred to in paragraph 5 once that delegated act becomes applicable.

5. The Commission is empowered to adopt delegated acts in accordance with Article 79 supplementing this Regulation by establishing rules on:

(a) the digital recording and collection of data on the certification activities carried out by professional operators and competent authorities for the purpose of issuing the official labels;

(b) the establishment of a centralised platform that connects the Member States and the Commission and facilitates the processing of, access to, and use of the information referred to in point (a);

(c) the data that can be provided, in digital or physical form as appropriate, for the specific type of PRM; and

(d) the technical arrangements for the issuance of the official label in digital form.

6. By way of derogation from paragraphs 1 to 5 of this Article and provided that the requirements laid down in Article 40 are fulfilled, pre-basic, basic and certified seed and material imported from third countries pursuant to Article 38 may be marketed in the Union with the relevant OECD Seed Schemes label ('OECD label'), or with an official label issued by the competent authority of the third country for seed of species for which there is no OECD Seed Scheme available or for PRM other than seed.

Article 18

Operator's label for standard seed and material

1. Standard seed and material shall be identified by means of an operator's label that attests to their compliance with the production and marketing requirements set out in Article 9 ('operator's label').

2. The operator's label shall be issued, printed and affixed by the professional operator to the outside of the individual plant, bundle, package or container, or printed indelibly on the package or container.

3. Some of the information in the operator's label may be provided in digital form, in accordance with the delegated act referred to in paragraph 4 once that delegated act becomes applicable.

4. The Commission is empowered to adopt delegated acts in accordance with Article 79 supplementing this Regulation by establishing rules on:

(a) the digital recording and collection of data on the activities carried out by professional operators for the purpose of issuing the operator's labels;

(b) the data that can be provided in digital or physical form for the specific type of PRM; and

(c) the technical arrangements for the issuing of operator's labels in digital form.

Article 19

Content and characteristics of the official label and the operator's label

1. The official label and the operator's label shall be written in at least one of the official languages of the institutions of the Union.

2. The official label and the operator's label shall be legible, indelible, made of material strong enough to prevent damage in the course of ordinary use, not modifiable, not reusable, not previously used, and easily visible.

3. Adhesive labels may be used where there is no risk that they can be re-used.

4. In addition to the elements to be set out pursuant to paragraph 6, the official label and the operator's label may include additional information concerning applicable Union rules related to production and marketing requirements other than those set out in this Regulation.

Such information shall be presented in an appropriate space on the label, in a legible way and in letters no larger than those used for the content of the official label or the operator's label pursuant to paragraph 6.

5. The competent authority may allow the professional operators to indicate at the periphery of the official label information additional to that referred to in paragraphs 4 and 6, provided that it is not advertising material. That additional information shall be placed in an area of a size no larger than 20 % of the total area of the official label and shall appear under the heading 'Non-official information'. It shall be presented in letters no larger than those used for the content of the official label pursuant to paragraph 6.

6. The Commission shall adopt implementing acts specifying for the respective categories or types of PRM the content, size, colour and format of the official label and the operator's label, in their respective physical and digital forms.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 80(2).

Article 20

Re-packaging, re-sealing and re-labelling of PRM

1. When entire lots or parts of lots of PRM are merged or split pursuant to Article 15(2) and (3), they shall be re-packaged, re-sealed and re-labelled in accordance with this Article.

   Where necessary, a single entire lot of PRM may also be re-packaged, re-sealed and re-labelled in accordance with this Article.

2. Where entire lots or parts of lots of PRM are merged or split, new official labels or new operator's labels shall be issued to the new lot or lots and new lot reference numbers shall be given to the new lot or lots pursuant to Article 15(2) and (3).

   The new label shall also state the original lot reference number or numbers.

   If a package, bundle or container is resealed, the date of re-sealing shall be stated on the new official label or new operator's label.

3. A professional operator that re-packages, re-seals and re-labels an entire PRM lot or part of it shall take all steps to ensure that, during those operations, the varietal identity and varietal purity of the PRM and the homogeneity of the lot are maintained and that no contamination occurs.

4. The re-packaging, re-sealing and re-labelling of pre-basic, basic and certified seed and material shall be carried out by the competent authority or by the professional operator under the official supervision of the competent authority.

5. In addition to the traceability requirements pursuant to Article 47, professional operators shall keep records of any re-packaging, re-sealing or re-labelling of PRM lots that they carry out for six years thereafter. The information contained in those records shall include:

(a) the reference number of the original lot;

(b) the reference number of the re-packaged or re-labelled lot;

(c) the weight or units of PRM of the original lot;

(d) the weight or units of PRM of the re-packaged or re-labelled lot;

(e) the most recent date of re-sealing of the lot.

Those records shall be made available to the competent authority on request.

6. The original seals and labels shall be removed from the original lot. Where such removal is not possible, it shall be indicated on the original seal or label that it is no longer valid.

Where a professional operator chooses to keep records of the content of labels that were removed, those records may be kept in electronic format on condition that they include the label information necessary to guarantee traceability in this activity.

SECTION 6

SPECIFIC REQUIREMENTS FOR MIXTURES OF SEED

Article 21

Mixtures of seed

1. Seed of two or more genera or species listed in Annex I, as well as of different varieties of those genera or species belonging to any of the categories referred to in Article 6(1) that, prior to mixing, complied with the requirements of Article 8 or 9, as applicable, may be marketed in the Union as a mixture of seed of those genera, species or varieties (‘mixture’).

2. Mixtures may also include, or consist of, commercial seed subject to Article 29.

3. Where the mixture consists of pre-basic, basic and certified seed only, it shall be accompanied by an official label. In all other cases, it shall be accompanied by an operator’s label.

   By way of derogation from the first subparagraph, a mixture that consists of pre-basic, basic and certified seed only may be marketed in small packages accompanied by an operator’s label.

4. Where a mixture contains pre-basic, basic and certified seed, the professional operator shall submit to the competent authority the list of components of that mixture and the ratios between them so that the eligibility of those components to be part of that mixture can be verified.

In any other case, that information shall be submitted at the request of the competent authority.

5. Mixtures may only be produced by professional operators that have been authorised for that purpose by the competent authority. Such authorisation shall only be granted to professional operators that:

(a) have installed suitable mixing equipment and appropriate procedures ensuring that the finished mixture is uniform and the stated ratio between the component varieties in each container can be achieved;

(b) have a person in charge who has direct responsibility for the mixing and packaging operations; and

(c) maintain records of mixtures.

6. The mixing and packaging of the seed referred to in paragraph 1 shall be carried out under the supervision of the competent authority.

7. The mixing of the seed referred to in paragraph 1 shall be carried out in a manner that ensures that there is no risk of seed not intended for inclusion in the mixture being present in it, and that the resulting mixture is as homogeneous as possible.

8. By way of derogation from paragraph 1, mixtures may include seed of genera or species not listed in Annex I. That derogation is without prejudice to Regulation (EU) No 1143/2014 and the requirements laid down in paragraphs 4, 5 and 7.

Those mixtures shall be accompanied by an operator's label with the indication of the recommended use.

9. The Commission may adopt implementing acts laying down, on the basis of developments in scientific and technical knowledge and the experience gained from the application of this Article, the rules concerning:

(a) the mixing equipment and procedure;

(b) sealing, packaging, including maximum size of small packages, and labelling;

(c) the content, size, colour and format of the official label and operator's label for mixtures;

(d) maximum weight of seed in a single container for cases where the mixture contains seed of significantly different sizes;

(e) in the case of mixtures referred to in paragraph 8, possible uses; and

(f) the denomination of mixtures.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 80(2).

Article 22

Preservation mixtures

1. Without prejudice to Regulation (EU) No 1143/2014, Member States may decide to allow the production and marketing, in their territories or parts of their territories, of seed intended for, or used in, a mixture of genera or species listed in Annex I and genera or species not listed in that Annex if the mixture contributes to the conservation of genetic resources or the restoration of the natural environment and is naturally associated with a certain region (‘region of origin’).

Such mixtures shall be referred to as ‘preservation mixtures’.

Articles 7 to 14, 16 and 21 shall not apply to preservation mixtures.

2. Preservation mixtures may only be produced and marketed by professional operators who are authorised for that purpose by the competent authority.

3. Preservation mixtures shall be marketed only in their region of origin and accompanied by an operator's label with the words 'Preservation mixture', and the indication of that region.

4. The Commission is empowered to adopt delegated acts in accordance with Article 79 supplementing this Regulation by laying down requirements concerning:

(a) the designation of the region of origin;

(b) the use of certain species in preservation mixtures;

(c) the authorisation of professional operators;

(d) the production of preservation mixtures by direct collection from a natural place belonging to a defined region of origin;

(e) the production of preservation mixtures by multiplication;

(f) the inspection, sampling, testing and other activities carried out by the competent authority; and

(g) the conditions for the production and marketing of seed intended for preservation mixtures.

Those requirements shall be based on the experience gained from applying Union rules concerning preservation mixtures and on any relevant developments in technical and scientific knowledge. It shall be possible for those requirements to apply exclusively to particular genera or species.

5. The Commission may adopt implementing acts laying down specific requirements concerning the packaging, sealing, and content, size, colour and format of the operator's label for preservation mixtures.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 80(2).

6. Professional operators shall notify the competent authorities, for each production season, of the amount of preservation mixtures that they produced and marketed.

The Member States shall on request notify the Commission and the other Member States of the amount of preservation mixtures produced and marketed in their territory and, where applicable, of the names of competent authorities responsible for plant genetic resources or of organisations recognised for this purpose.

SECTION 7

DEROGATIONS FROM THE REQUIREMENTS OF ARTICLES 5 TO 22

Article 23

PRM belonging to conservation varieties or locally adapted varieties

1. PRM belonging to a conservation variety or a locally adapted variety registered in a national variety register referred to in Article 49 may only be produced and marketed in the Union as standard seed or material if it complies with all the requirements set out in Article 9.

   Articles 7 and 11 shall not apply to such PRM.

2. PRM belonging to a conservation variety or a locally adapted variety shall be maintained only in that variety's region of origin, unless it belongs to a variety that has previously been registered in a national variety register with an official description and the region of origin was not defined.

3. PRM referred to in paragraph 1 shall be accompanied by an operator's label with the words 'Conservation variety' or 'Locally adapted variety', as applicable.

4. A professional operator who produces or markets PRM of a conservation variety or a locally adapted variety shall notify that activity to the competent authority annually and keep records regarding the quantities produced during the last six years with regard to the genera or species and varieties concerned.

Professional operators shall provide data from those records to the competent authority at the competent authority's request and in accordance with its instructions.

Article 24

PRM produced for and marketed to non-professional users

1. PRM intended to be used exclusively by non-professional users, with the exception of PRM belonging to the species *Cannabis sativa* L., *Papaver somniferum* L., *Solanum tuberosum* L. and PRM used for turf grass purposes, may be produced and marketed if:

(a) it bears an operator's label with the denomination of the PRM and the words 'Plant reproductive material for non-professional users';

(b) in the case of PRM not belonging to a variety registered in a national variety register referred to in Article 49:

(i) it uses a denomination that complies with the requirements in Article 60(1) and (2);

(ii) a description of that PRM has been made publicly available on the basis of private documentation kept by the professional operator and that documentation is available to the competent authority upon request;

(c) it is practically free from quality pests and any defects likely to impair its quality as PRM and:

(i) in the case of seed, it has the minimum germination rate applicable for the standard category of the genera or species concerned; and

(ii) in the case of PRM other than seed, it has sufficient vigour and dimensions; and

(d) it is marketed in small quantities as individual plants, or in small packages, bundles or containers.

Articles 7 to 11 and 16 to 20 shall not apply to such PRM.

2. A professional operator who produces and markets PRM intended to be used exclusively by non-professional users pursuant to paragraph 1 shall annually notify that activity to the competent authority and keep records regarding the quantities produced during the last six years with regard to the genera or species concerned.

Professional operators shall provide data from those records to the competent authority, at the competent authority's request and in accordance with its instructions.

3. The Commission may adopt implementing acts laying down rules concerning the size, form, sealing and handling of individual plants and the small packages referred to in paragraph 1, point (d), of this Article and concerning the size, format, colour and content of the operator's label for PRM produced for and marketed to non-professional users.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 80(2).

Article 25

PRM produced or marketed by organisations and networks for the conservation of plant genetic resources

1. PRM intended for the conservation of plant genetic resources may be:

(a) produced by non-profit organisations and networks and natural persons who are their members; or

(b) marketed, without profit, by such non-profit organisations and networks, and natural persons who are their members, to any natural or legal person, and vice versa.

The non-profit organisations and networks referred to in the first subparagraph shall have as their express purpose the conservation of plant genetic resources.

Articles 7 to 22 shall not apply to such PRM.

2. The PRM referred to in paragraph 1 shall:

(a) be accompanied by a label that is distinct from any other label referred to in this Regulation and includes:

(i) the words: ‘Plant reproductive material for the conservation of plant genetic resources’;

(ii) the name of the genera or species concerned;

(iii) the name of the organisation or network concerned;

(iv) any other information considered appropriate by the organisation or network concerned for the marketing of the PRM;

(b) if it does not belong to a variety registered in a national variety register referred to in Article 49, be listed in a register kept by the organisation or network concerned with appropriate information relating to that PRM; and

(c) be practically free from quality pests and any defects likely to impair its quality as PRM.

3. The organisations and networks referred to in paragraph 1 shall notify as soon as possible any activity pursuant to this Article, and any changes thereof, to the competent authority, with an indication of the genera or species concerned.

Article 26

PRM exchanged in kind between farmers

1. Farmers may exchange in kind PRM, with the exception of PRM belonging to the species *Cannabis sativa* L., *Papaver somniferum* L. and *Solanum tuberosum* L. and the genera *Citrus* L. and *Vitis* L., that:

   (a) is produced in the respective farmer's own premises;

   (b) is derived from the respective farmer's own crops; and

   (c) in the case of seed, is not subject to a service contract between the farmer and a professional operator for seed multiplication.

   Articles 7 to 22 shall not apply to such PRM.

2. The PRM referred to in paragraph 1 shall:

   (a) not belong to a variety in respect of which plant variety rights have been granted either in accordance with Regulation (EU) No 2100/94 or with the national rules on plant variety rights of the Member State of production;

   (b) be limited to small quantities, defined by the competent authorities for specific genera or species per year and per farmer;

(c) be exchanged at a local level, defined by the competent authorities concerned, without using commercial intermediaries or public offer of marketing; and

(d) be practically free from quality pests and any defects likely to impact its quality as PRM.

3. Member States shall notify the Commission and the other Member States of their definitions of small quantities in accordance with paragraph 2, point (b), and of any subsequent changes to those definitions.

Article 27

PRM of a generation prior to pre-basic category

1. PRM that belongs to a generation prior to pre-basic seed or material may be produced and marketed for the purposes of its multiplication for the production of pre-basic seed or material if:

(a) it is marketed directly from the breeder of the variety or its maintainer to the professional operator carrying out the production of pre-basic seed or material, and there is no further marketing of that PRM thereafter; and

(b) it is accompanied by an operator's label bearing the denomination of the variety and the words 'Seed prior to pre-basic seed' or 'Material prior to pre-basic material'.

Articles 7 to 22 shall not apply to such PRM.

2. The Commission may adopt implementing acts laying down rules concerning the size, format, colour and content of the operator's label for PRM of a generation prior to the pre-basic category.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 80(2).

Article 28

PRM belonging to varieties under registration

1. A competent authority may authorise professional operators to produce and market pre-basic, basic, certified and standard seed or material belonging to a variety in respect of which a decision on variety registration is pending ('variety under registration'), with the aim of having sufficient stock available for further multiplication once the variety is registered, if:

(a) the PRM belongs to a variety in respect of which the competent authority has confirmed the submission of the application for variety registration in accordance with Article 64;

(b) the PRM fulfils the requirements of Article 8 or 9, as applicable, for the categories of pre-basic, basic, certified and standard seed or material;

(c) the PRM is marketed between the authorised professional operator and the professional operators carrying out the multiplication, and there is no further marketing of that PRM thereafter;

(d) there is no risk that such an authorisation will lead to insufficient identification or quality of the marketed PRM; and

(e) the PRM bears a breeder's reference or a denomination considered suitable pursuant to Article 60.

The authorisation shall automatically expire if the application for variety registration is withdrawn or a decision pursuant to Article 72(1) or (2) is adopted.

Such authorisation shall only be granted by the competent authority of the Member State where the application for registration has been submitted.

Articles 10 and 11 shall not apply to PRM produced and marketed pursuant to this paragraph.

2. A competent authority may authorise professional operators to produce and market standard seed or material of agricultural plants and potatoes belonging to a variety under registration for the purpose of carrying out tests or trials with the aim of gathering information on the cultivation or use of that variety if:

(a) the PRM belongs to a variety in respect of which the competent authority has confirmed the submission of the application for variety registration in accordance with Article 64;

(b) the PRM fulfils the applicable requirements of Article 9 for standard seed or material;

(c) the PRM is only used by professional operators on the premises of specifically designated natural or legal persons;

(d) the PRM is marketed by the authorised professional operators carrying out the tests and trials to the persons referred to in point (c) only, and there is no further marketing of that PRM thereafter;

(e) there is no risk that such an authorisation will lead to insufficient identification or quality of the marketed PRM; and

(f) the PRM bears a breeder's reference or a denomination considered suitable pursuant to Article 60.

The authorisation shall automatically expire if the application for variety registration is withdrawn or a decision pursuant to Article 72(1) or (2) is adopted.

Such authorisation shall only be granted by the competent authority of the Member State where the application for registration has been submitted.

Such authorisation may be granted for limited quantities per genus or species laid down in the implementing acts referred to in paragraph 12, point (a), of this Article and, in the absence of such implementing acts, by the competent authority.

Articles 7 and 11 shall not apply to PRM produced and marketed pursuant to this paragraph.

3. Professional operators may produce and market standard seed or material of fruit plants and vines except vine rootstocks belonging to a variety under registration for the purpose of making new varieties available on the market without delay if:

(a) the PRM belongs to a variety in respect of which the competent authority has confirmed the submission of the application for variety registration in accordance with Article 64;

(b) the PRM fulfils the requirements of Article 9 for standard seed or material;

(c) there is no risk that the marketing will lead to insufficient identification or quality of the marketed PRM; and

(d) the PRM bears a breeder's reference or a denomination considered suitable pursuant to Article 60.

That production and marketing shall cease if the application for registration of the variety is withdrawn or a decision rejecting registration is adopted in accordance with Article 72(2).

If the variety is not registered, the professional operator shall take the necessary actions to withdraw the PRM concerned from the market.

4. A competent authority may authorise professional operators to produce and market standard seed or material of vegetable plants belonging to a variety under registration for the purpose of making new varieties available on the market without delay if:

(a) the PRM belongs to a variety in respect of which the competent authority has confirmed the submission of the application for variety registration in accordance with Article 64;

(b) the PRM fulfils the requirements of Article 9 for standard seed or material;

(c) there is no risk that such an authorisation will lead to insufficient identification or quality of the marketed PRM; and

(d) the PRM bears a breeder's reference or a denomination considered suitable pursuant to Article 60.

The authorisation shall automatically expire if the application for variety registration is withdrawn or a decision pursuant to Article 72(1) or (2) is adopted.

If the variety is not registered, the professional operator shall take the necessary actions to withdraw the PRM from the market.

Such authorisation shall only be granted by the competent authority of the Member State where the application for registration was submitted.

Such authorisation may be granted for limited quantities per genus or species as specified in the implementing acts referred to in paragraph 12, point (a), of this Article and, in the absence of such implementing acts, by the competent authority.

Article 11 shall not apply to PRM produced and marketed pursuant to this paragraph.

5. In order to obtain the authorisation referred to in paragraphs 1, 2 and 4 of this Article, the professional operator shall submit to the competent authority a request containing information about:

(a) the species;

(b) the breeder's reference or, if the competent authority has taken a positive decision pursuant to Article 71, the denomination of the variety;

(c) in the case of an authorisation pursuant to paragraph 1 and 4 of this Article, the sites where production of PRM is to take place;

(d) in the case of an authorisation pursuant to paragraph 2 of this Article, the sites where tests and trials are to take place; and

(e) the envisaged quantities of seed and material to be produced.

6. The Member States whose competent authorities have granted the authorisation referred to in paragraphs 1, 2 and 4 of this Article shall inform the other Member States and the Commission thereof without delay, using the electronic portal referred to in Article 50(3).

7. The verification of compliance with the conditions concerning the varietal identity and varietal purity of the PRM referred to in paragraphs 1 to 4 of this Article shall be based on the description of the variety as supplied by the applicant or, where available, the provisional description of the variety drawn up on the basis of the results of the official examination of distinctness, uniformity and stability of the variety, as provided for in Article 65.

8. Pre-basic, basic and certified seed or material referred to in paragraph 1 shall be accompanied by an official label, and standard seed or material referred to in paragraph 1 shall be accompanied by an operator's label, in both cases with the words: 'Variety under registration – stock for multiplication'.

9. Seed or material referred to in paragraph 2 shall be accompanied by an operator's label with the words: 'Variety under registration – tests and trials'.

10. PRM referred to in paragraphs 3 and 4 shall be accompanied by an operator's label with the words: 'Variety under registration'.

11. A professional operator using this derogation shall keep records regarding the quantities of PRM of the relevant varieties produced during the last six years.

Professional operators shall provide data from those records to the competent authority, at the competent authority's request and in accordance with its instructions.

12. The Commission may adopt implementing acts:

(a) specifying the amounts of limited quantities, as referred to in paragraphs 2 and 4;

(b) laying down rules concerning the size, format, colour and content of the official label and the operator's label, as referred to in paragraph 8.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 80(2).

Article 29

Requirements for the production and marketing of commercial seed

1. Seed of the genera or species included in column 3 of Annex I may be produced and marketed as commercial seed if it complies with the requirements set out in Annex III, with the exception of requirements concerning varietal aspects.

Articles 7 to 11 shall not apply to the production and marketing of commercial seed.

2. Commercial seed shall be practically free from quality pests, and produced and marketed under the responsibility of the professional operator.

3. Seed referred to in paragraph 1 shall be accompanied by an operator's label with the words: 'Commercial seed'.

4. The Commission is empowered to adopt delegated acts in accordance with Article 79, amending Annex I by adding genera or species to, or deleting genera or species from, column 3 of that Annex.

Those delegated acts shall take into account the breeding and economic developments concerning the production and marketing of PRM of the genera or species concerned.

5. The Commission may adopt implementing acts laying down rules concerning the size, format, colour and content of the operator's label for commercial seed.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 80(2).

Article 30

Authorisation in cases of temporary difficulties in supply

1. In order to remove temporary difficulties in the supply of pre-basic, basic, certified or standard seed or material that may occur in the Union due to adverse climatic conditions or other unforeseen circumstances, the Commission may adopt implementing acts authorising one or more Member States, for a maximum period of 12 months, to allow the marketing of the categories of pre-basic, basic, certified or standard seed or material that fulfils one or both of the following conditions:

   (a) it belongs to a variety not included in a national variety register referred to in Article 49;

   (b) it complies with less stringent requirements than those referred to in Article 8(1) and (2) and Article 9(1) and (2).

   Those implementing acts may set out the maximum quantities which can be produced and marketed per genus or species and the territories where that PRM can be produced and marketed.

   Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 80(2).

2. PRM referred to in paragraph 1 of this Article shall be accompanied by an official label or an operator's label that states that the PRM concerned belongs to a non-registered variety or fulfils less stringent requirements than the ones set out in Article 8(1) and (2) and Article 9(1) and (2). Where the less stringent quality requirements concern a reduced germination rate, the official label or an operator's label shall indicate the germination rate of the seed lot concerned.

3. The Commission may adopt implementing acts deleting or amending the terms of the authorisation granted pursuant to paragraph 1 of this Article if it concludes that such authorisation is no longer necessary or proportionate to the objective of removing the temporary difficulties in the supply of the PRM concerned.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 80(2).

4. By way of derogation from the requirement for Commission authorisation referred to in paragraph 1, in the case of pre-basic and basic seed, Member States may decide to allow, for a maximum period of 12 months and for a limited amount of quantities per genus or species necessary in order to ease the supply difficulties in question, the marketing of pre-basic and basic seed with a germination rate not lower than 50 %. The Member State concerned shall immediately notify such decisions to the Commission and the other Member States, mentioning the genus or species and the germination rate allowed.

Such seed may be marketed only between professional operators within the territory of the Member State of production and only for multiplication purposes. The official label shall also bear the words: ‘Seed with a reduced germination rate of [germination rate] % – Restricted to marketing in [name of the Member State]’.

5. By way of derogation from the requirement for Commission authorisation referred to in paragraph 1 of this Article, in the case of certified seed, Member States may decide to allow, for a maximum period of 12 months and for a limited amount of quantities per genus or species necessary in order to ease the supply difficulties in question, the marketing of certified seed that fulfils germination rates reduced by up to 15 percentage points compared to the ones set out pursuant to Article 8(4), point (h). The Member State concerned shall immediately notify such decisions to the Commission and the other Member States mentioning the genus or species and the germination rate allowed.

Such seed may be marketed only within the territory of the Member State of production. The official label shall also bear the words: ‘Seed with a reduced germination rate of [germination rate] % – Restricted to marketing in [name of the Member State]’.

6. The Commission may adopt implementing acts laying down rules concerning the size, format, colour and content of the official label and operator’s label as referred to in paragraphs 1 to 5.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 80(2).

Article 31

Marketing of seed certified on the basis of provisional analyses regarding germination in the case of rapid supply needs

1. For the purpose of making seed rapidly available on the market, competent authorities may, for a maximum period of three months from the drawing of the respective sample, temporarily authorise professional operators to market pre-basic, basic or certified seed if that seed is found to comply with all of the requirements set out in Article 8 other than those concerning germination. For the purposes of such authorisation, the fulfilment of the requirements concerning germination shall be demonstrated on the basis of a provisional analytical report.

2. The authorisation referred to in paragraph 1 of this Article shall be granted on condition that the professional operator:

   (a) has the necessary procedures in place to sufficiently guarantee that the seed marketed complies with all of the requirements of Article 8 other than those concerning germination, and has identified the critical points in those procedures; and

   (b) has procedures in place to ensure the traceability requirements set out in Article 47.

3. The professional operator shall keep the name and address of the first recipients of the seed and the provisional analytical report, as referred to in paragraph 1, and make it available to the competent authority on request.

4. The seed referred to in paragraph 1 shall bear an official label with the words: ‘Germination analysis not concluded’.

Article 32

Marketing of PRM which is not finally certified

1. PRM which has been produced in the Union and for which compliance with the production requirements set out in Article 8(1) and (2) has been confirmed but has not yet been finally certified as pre-basic, basic or certified seed or material pursuant to Article 8 may be marketed with a reference to any of those categories provided that:

   (a) prior to the harvesting, a field inspection has been carried out by the competent authority or by the professional operator under official supervision;

   (b) the PRM is in the process of being certified by the competent authority or by the professional operator under official supervision; and

   (c) the PRM is accompanied by an official label with the words: ‘Seed/material not finally certified’.

2. PRM referred to in paragraph 1 may be marketed only by the professional operator who produced that PRM to the professional operator that is going to have the PRM finally certified. That professional operator may not transfer that PRM to any other person before its final certification.

3. If the competent authority of the territory where the PRM has been harvested ('competent authority of production') and the competent authority of the territory where the PRM is to be certified pursuant to Article 8 ('certifying competent authority') are different, the competent authority of production shall provide the relevant information concerning the production and marketing of that PRM to the certifying competent authority.

4. PRM which has been harvested in a third country but has not yet been certified as pre-basic, basic or certified seed or material pursuant to Article 8 may be marketed in the Union by reference to any of those categories provided that:

(a) a decision on equivalence has been adopted pursuant to Article 39 concerning that third country;

(b) the requirements set out in paragraphs 1 and 2 of this Article have been fulfilled and there is official supervision of the professional operators of the third county concerned by their competent authorities;

(c) arrangements are in place for the competent authorities of the Member State and the competent authorities of the third country concerned to exchange relevant information concerning the marketing of that PRM; and

(d) there is a procedure in place whereby, on request, the competent authorities of the third country concerned will provide all relevant production information to the competent authorities of the Member State of final certification.

For the purposes of this paragraph, the reference to the competent authority of production in paragraph 3 of this Article shall be understood as a reference to the competent authority of the third country concerned and the reference to the requirements set out in Article 8(1) in paragraph 1 of this Article shall be understood as a reference to the equivalent requirements of the third country recognised pursuant to Article 39(1).

5. The Commission may adopt implementing acts laying down rules concerning the size, format, colour and content of the official label referred to in paragraph 1, point (c).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 80(2).

Article 33

More stringent requirements

1. Subject to a prior authorisation by the Commission, Member States may adopt for their entire territory, or part thereof, more stringent requirements for the production and marketing of PRM than those laid down in Article 8 or 9, as applicable, provided that those more stringent requirements correspond to market demand and specific production conditions in, or agro-climatic needs of, that Member State in regard to the PRM concerned.

Those more stringent requirements shall not impose, or result in, any prohibitions or restrictions on the movement of PRM originating from, or destined to, other Member States.

2. The Commission may adopt implementing acts authorising a Member State to impose the more stringent requirements referred to in paragraph 1 in order to ensure uniform conditions for their implementation.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 80(2).

3. In order to obtain the authorisation referred to in paragraph 2, Member States shall submit to the Commission a request setting out:

(a) the draft provisions containing the more stringent requirements proposed; and

(b) a justification that those requirements are necessary and proportionate in view of the objectives to be achieved, taking into account additional costs and benefits.

4. The authorisation referred to in paragraph 2 shall be granted only if:

(a) the implementation of the more stringent requirements proposed is likely to ensure an improvement in the identity and quality of the PRM concerned and is justified by the specific agricultural or climatic conditions of the Member State concerned; and

(b) the more stringent requirements proposed are necessary and proportionate in view of the objective to be achieved.

Article 34

Derogation from the production and marketing rules for certain species

1. PRM belonging to certain genera and species listed in Annex I may, subject to paragraph 2 of this Article, be produced or marketed in accordance with a Member State's national rules rather than those in Articles 5 to 22. The PRM concerned shall only be marketed in the Member State concerned and shall bear a label stating that this is the case.

Member States intending to apply the first subparagraph of this paragraph shall submit to the Commission a request demonstrating, on the basis of consultations with the professional operators concerned, that:

(a) the cultivation of that genus or species in the requesting Member State is insignificant, in terms of economic value and area of cultivation, due to the agro-climatic conditions in that Member State; and

(b) the certification and control of the production of PRM of that genus or species would impose a disproportionate administrative burden on the competent authority of that Member State.

2. The Commission may adopt implementing acts temporarily allowing the production and marketing of PRM as referred to in paragraph 1.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 80(2).

Article 35

PRM for the production of agricultural raw materials intended for industrial purposes

PRM may be produced by a natural or legal person that multiplies that PRM on behalf of the owner of that PRM or that produces from that PRM agricultural raw materials to be used by the owner for industrial purposes, or it may be transferred between the owner of that PRM and such natural or legal person, provided that:

(a) that activity is subject to a service contract between the owner of the PRM and those persons;

(b) that natural or legal person does not acquire title to either that PRM or the product of the harvest;

(c) the traceability of that PRM is ensured; and

(d) the owner of that PRM has provided the competent authority in advance with a copy of the relevant parts of the service contract made with that natural or legal person, including at least the contracting parties, the PRM concerned, the duration of the contract, the location of production, and the conditions to be met by that PRM.

Articles 5 to 22 shall not apply to PRM produced and marketed pursuant to this Article.

Article 36

Emergency measures

1. Where there is new or additional scientific evidence suggesting that the production, marketing or cultivation of PRM, or the use of the final product, constitutes a serious risk to human, animal or plant health, the environment or the cultivation of other genera and 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, the Commission shall adopt without delay, on its own initiative or at the request of a Member State, implementing acts laying down appropriate and proportionate interim emergency measures.

   Such measures shall be limited in time and may include provisions restricting or prohibiting the production and marketing of the PRM concerned.

   Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 80(2).

On duly justified imperative grounds of urgency relating to a serious risk to human health, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 80(3).

2. Where a Member State officially informs the Commission of the need to take emergency measures and the Commission has not acted in accordance with paragraph 1, that Member State may adopt appropriate, proportionate and time-limited interim emergency measures. Those measures may include provisions restricting, prohibiting or laying down appropriate conditions for the production or marketing of PRM within the territory of that Member State, depending on the gravity of the situation. The Member State concerned shall immediately notify the Commission and the other Member States of the measures adopted and the period they cover, stating the grounds for its decision.

3. Within 60 days from the receipt of the notification of the measures adopted pursuant to in paragraph 2 of this Article, the Commission shall put those measures before the Committee referred to in Article 80(1) with a view to adopting an implementing act extending, amending or repealing the national interim emergency measure concerned in accordance with the regulatory procedure referred to in Article 80(2).

Article 37

Temporary experiments to seek improved alternatives to certain provisions of this Regulation

1. By way of derogation from Articles 1 to 78, the Commission is empowered to adopt delegated acts in accordance with Article 79 supplementing this Regulation by establishing temporary experiments to test potential improvements to this Regulation in accordance with paragraph 2 of this Article.

   Such experiments may take the form of scientific or technical trials examining the feasibility and appropriateness of new provisions compared to the ones set out in Articles 1 to 78.

2. The delegated acts referred to in paragraph 1 shall specify one or more of the following elements:

   (a) the genera or species concerned;

   (b) the conditions of the experiments per genus or species;

   (c) the duration of the experiment;

   (d) the monitoring and reporting obligations of the participating Member States.

   Those delegated acts shall reflect the developments in scientific and technical knowledge as regards the production of the PRM concerned and shall be based on any comparative trials carried out by the Member States.

3. The Commission shall review the results of any experiments conducted pursuant to the delegated acts referred to in paragraphs 1 and 2 of this Article and summarise them in a report, indicating, if necessary, the need to amend Articles 1 to 78.

SECTION 8

IMPORTS FROM THIRD COUNTRIES

Article 38

Imports of PRM

1. PRM may only be imported from third countries if it has been recognised pursuant to Article 39(1) that it fulfils requirements equivalent to those applicable to PRM produced and marketed in the Union.

2. PRM belonging to preservation mixtures as referred to in Article 22 and PRM subject to the derogations set out in Articles 23 to 26, 29, 31 and 34 shall not be imported, and no equivalence shall be recognised pursuant to Article 39.

3. By way of derogation from paragraph 1, seed as grown may be imported into the Union for the purpose of being processed and marketed as standard seed without the need to comply with the requirements referred to in that paragraph. Such seed shall comply with the following conditions:

   (a) it shall be accompanied by a label pursuant to Article 40(4) and its identity shall be ensured; and

(b) it shall be marketed only up to the place of processing without further marketing before its processing.

The professional operator shall notify the import of that seed in advance to the competent authority.

The professional operator responsible for the imported seed as grown shall provide, at the request of the competent authority, information on the conditions under which the production or multiplication took place, the place of processing, the varieties to which the seed belongs and the quantities of it that have been imported pursuant to this paragraph.

Article 39

Recognition of equivalence

1. The Commission may adopt implementing acts recognising that PRM of specific genera, species or categories produced in a third country, or a particular region of a third country, fulfils requirements equivalent to those applicable to PRM produced and marketed in the Union, on the basis of all of the following:

(a) a thorough examination of the information and data provided by that third country for the concerned PRM;

(b) an audit of the third country, carried out by the Commission, showing that the system in place ensures that PRM produced in that country, or a particular region of that country, fulfils requirements equivalent to those applicable to PRM produced and marketed in the Union when it is the first request for recognition of equivalence concerning that third country; and

(c) in the case of seed belonging to a species for which an OECD Seed Scheme exists, the fact that the third country concerned participates in the OECD Seed Schemes and additionally implements the methods of ISTA, or, where applicable, implements the rules of the Association of Official Seed Analysts (AOSA) or other international standard-setting bodies and organisations.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 80(2).

2. Where necessary and at the request of the Commission, experts from Member States may assist the Commission in the conduct of the examination and audit referred to in paragraph 1, points (a) and (b).

3. For the purposes of paragraph 1, the Commission shall examine:

(a) the legislation of the third country concerning the production of PRM for the genera or species concerned;

(b) the structure of the competent authorities of the third country concerned, or region thereof, and its control services, the powers of those competent authorities, the guarantees that can be provided with regard to the application and enforcement of the legislation applicable to the sector concerned in the respective third country or region thereof, and, where applicable, the reliability of the official certification procedures;

(c) the performance of adequate official controls by the competent authorities of the third country concerned regarding the identification and quality of the PRM of the genera or species concerned;

(d) the guarantees provided by the third country that:

(i) the requirements applied to the production sites of PRM to be imported to the Union are equivalent to those applicable to the production sites of PRM produced and marketed in the Union; and

(ii) the production sites referred to in point (i) are subject to regular and effective controls by the competent authorities of the third country.

After the conduct of the audit referred to in paragraph 1, point (b), the Commission may carry out further audits to verify compliance with this paragraph by the third country concerned. For that purpose, and at the request of the Commission, Member States may make their experts available to assist the Commission.

4. The implementing acts referred to in paragraph 1 may provide for one or more of the following, as appropriate for the PRM concerned:

(a) conditions relating to inspections in the production site carried out in third countries;

(b) in the case of seed, conditions relating to the issuance in the third country of a certificate provided by ISTA, or, where applicable, AOSA or other international standard-setting bodies and organisations;

(c) conditions relating to PRM subject to the derogation referred to in Article 32;

(d) conditions relating to packaging, sealing and labelling of PRM;

(e) conditions relating to the production, identity and marketing of PRM, in addition to the ones provided for by the third country's legislation, if needed to address particular aspects concerning the identity and quality of that PRM;

(f) requirements to be fulfilled by the professional operators producing and marketing that PRM.

5. The Commission may adopt implementing acts specifying the data and information to be provided for PRM from a third country or region thereof to be recognised as equivalent in accordance with paragraph 1 of this Article.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 80(2).

6. By … [date of application of this Regulation], the Commission shall adopt an implementing act listing the third countries and the respective genera, species and categories for which an equivalence has already been recognised in:

(a) Decision 2003/17/EC; and

(b) the Implementing Regulations adopted pursuant to Article 16 of Directive 2008/72/EC and Article 12(1) of Directive 2008/90/EC.

That implementing act shall be adopted in accordance with the examination procedure referred to in Article 80(2).

PRM from the countries and territories included in that list shall be considered to fulfil requirements equivalent to those applicable to PRM produced and marketed in the Union, without prejudice to future assessments of the Commission in accordance with this Article.

7. The Commission may adopt implementing acts recognising that the checks on variety maintenance carried out in a third country afford the same guarantees as those provided for in Article 76(1), (2) and (5) if varieties registered in a national variety register or in the Union variety register are to be maintained in that third country.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 80(2).

Article 40

Labelling of PRM imported from third countries

1. Pre-basic, basic and certified seed from third countries may only be imported if it bears an OECD label or an official label issued by the competent authority of the third country for genera and species for which there is no OECD Seed Scheme available and, where applicable, is accompanied by a certificate issued by ISTA or AOSA or other international standard-setting bodies and organisations.

2. Pre-basic, basic and certified material from third countries may only be imported if it bears an official label issued by the competent authority of the third country concerned.

3. Standard seed and material from third countries may only be imported if it bears, where applicable, an OECD label issued by a professional operator or an operator's label.

4. Seed as grown may only be imported if it bears an operator's label with the words: 'Seed as grown'.

5. The Commission shall adopt implementing acts laying down the format, colour, language, size and content of the labels referred to in paragraphs 1 to 4.

   Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 80(2).

Article 41

Information provided for PRM imported from third countries

PRM may be imported into the Union only after an electronic notification has been submitted by the professional operator through the information management system for official controls (IMSOC) referred to in Article 131 of Regulation (EU) 2017/625. That notification shall include the place of destination.

Chapter III

Requirements for professional operators

Article 42

Obligations of professional operators

Professional operators shall:

(a) be established in the Union;

(b) be registered in the register referred to in Article 65 of Regulation (EU) 2016/2031, for the purposes of this Regulation;

(c) be available personally, or designate another person to be available personally, to liaise with the competent authorities for facilitating the performance of official controls;

(d) identify and monitor the critical points of the production process or of the marketing which may influence the identity and quality of PRM;

(e) keep records of the monitoring of the critical points referred to in point (d) of this Article and provide them for examination where requested by the competent authorities;

(f) ensure that lots of PRM remain separately identifiable;

(g) keep up-to-date information on the address of the premises and other locations, including those of contracting parties, used for the activities referred to in Article 3, point (4);

(h) ensure that competent authorities have access to the premises and other locations where the activities referred to in Article 3, point (4), take place, including premises and fields of contracting parties, and to the records of the monitoring and all related documents;

(i) take measures, where appropriate, for the maintenance of the identity of the PRM in accordance with the requirements of this Regulation; and

(j) make available to the competent authorities at their request any contracts with contracting parties.

The competent authorities shall process the information made available to them pursuant to point (j) in accordance with Union and national rules on confidentiality, access to information and the protection of personal data.

Article 43

Registration procedure

1. Professional operators to be registered in accordance with Article 42, point (b), shall submit an application for registration to the competent authority.

2. The application for registration referred to in paragraph 1 shall include:

   (a) the name and address in the Member State of registration and contact details of the professional operator;

   (b) a statement concerning the intention of the professional operator to exercise one or more of the activities referred to in Article 3, point (4);

   (c) a statement concerning the intention to carry out activities of certification under official supervision;

   (d) the address of the premises used by the professional operator in the Member State concerned to carry out the activities referred to in Article 3, point (4), for the purposes of the registration; and

   (e) the commodity types, and genera or species of the PRM, concerned by the activities referred to in Article 3, point (4), carried out by the professional operator.

3. Where the competent authority considers that the application for registration referred to in paragraph 1 contains all of the data set out in paragraph 2, it shall, register the professional operator without delay.

4. Registered operators shall submit without delay an update concerning any changes, in relation to the next production season, in the data referred to in paragraph 2.

5. Where the competent authority becomes aware that the professional operator is no longer carrying out the activities referred to in Article 3, point (4), or that the data included in the application submitted by the professional operator in accordance with paragraph 2 of this Article are no longer correct, it shall request that operator to correct those data immediately or within a specified period.

   Where the professional operator does not correct those data within the period set by the competent authority, the competent authority shall amend or revoke the registration of that operator.

6. The competent authorities shall have full access to the register referred to in Article 65(1) of Regulation (EU) 2016/2031 of their Member State.

Article 44

Content of the register

The register of professional operators shall contain the data set out in Article 43(2), points (a), (b), (d) and (e), as well as:

(a) the official registration number;

(b) where applicable, an indication of which of the activities referred to in Article 43(2), point (c), the professional operator is authorised for.

Article 45

Derogations from the obligations of professional operators

1. By way of derogation from Article 42, point (b), professional operators shall not be required to be registered if they exclusively carry out one or more of the following activities:

   (a) the production or marketing of PRM intended to be used exclusively by, and marketed directly to, non-professional users pursuant to Article 24;

   (b) the production or marketing of PRM intended for the conservation of plant genetic resources by organisations and networks pursuant to Article 25;

   (c) the exchange of PRM in kind between farmers pursuant to Article 26.

2. Professional operators whose activities are limited to the production and marketing of PRM of conservation varieties or locally adapted varieties in accordance with Article 23 shall not be subject to the requirement in Article 42, point (e).

3. Professional operators whose activities relating to PRM are limited to marketing directly to non-professional users in accordance with Article 24 without altering the content of the lots, or any packaging or labelling, shall not be subject to the requirements of Article 42, points (d), (e) and (g).

4. Organisations and networks involved in the conservation of plant genetic resources in accordance with Article 25 shall not be subject to the requirements in Article 42, points (d) and (e).

5. Farmers exchanging PRM in kind in accordance with Article 26 shall not be subject to the requirements of Article 42, points (d), (e), (f), (i) and (j).

6. The Commission is empowered to adopt delegated acts in accordance with Article 79 amending paragraph 1 of this Article by adding other types of professional operators to be exempted from the requirement in Article 42, point (b), where a registration would constitute an administrative burden for such professional operators that is disproportionate to the low risk related to their professional activities.

Article 46

Availability of information of official registers

1. The Member State of the competent authority keeping the register referred to in Article 42, point (b), shall make available, upon reasoned request, the information contained therein to the Commission or to other Member States.

2. The competent authority keeping the register shall make available, upon reasoned request, the information referred to in Article 43(2), points (a) and (b), and Article 44, point (b), concerning a particular registered professional operator to any natural or legal person established in the Union for that person's own use.

3. This Article is without prejudice to Union and national rules on confidentiality, access to information and the protection of personal data.

Article 47

Traceability

1. Professional operators shall ensure that PRM is traceable at all stages of production and marketing to or from another professional operator.

2. Professional operators shall keep information or records allowing them to identify:

(a) the professional operators or other natural or legal persons who have supplied them with the PRM concerned;

(b) the professional operators to whom they have supplied PRM and the PRM concerned.

They shall, upon request, make such information available to the competent authorities.

3. Professional operators shall keep records of the PRM and the information of the professional operators and natural or legal persons referred to in paragraph 2 for at least six years after the PRM was supplied to or by them.

4. This Article shall not apply to the activities referred to in Articles 25 and 26.

Article 48

Notification of production

1. At least once a year, professional operators shall notify the competent authority in advance, in accordance with its instructions, of the following:

(a) their intended production of pre-basic, basic and certified seed and material during that year; and

(b) their production of pre-basic, basic and certified seed and material that started in previous years and continues in the year concerned.

That notification shall state the genera or species, varieties or, where appropriate, selected clones or polyclonal material, categories of the PRM concerned and the exact location of production.

2. Professional operators shall keep data regarding the quantities of standard seed and material and commercial seed produced during the last six years with reference to the genera or species concerned. Professional operators shall provide those data to the competent authority at its request and in accordance with its instructions.

Chapter IV
Variety registration

SECTION 1
VARIETY REGISTERS

Article 49

Establishment of national variety registers

1. Each Member State shall establish, publish in electronic format, and keep up-to-date a single national register of varieties (‘national variety register’) containing at least the following:

   (a) all varieties registered pursuant to the procedure set out in Section 3, including the varieties whose registration has been terminated pursuant to Article 75(1);

   (b) varieties for which an application has been submitted pursuant to Article 61 and have not yet been registered pursuant to Article 72, including the varieties whose application has been rejected or withdrawn, as referred to in Annex IV, point (f).

2. Any varieties, including varieties of genera or species not listed in Annex I, which have been registered in accordance with national rules shall be indicated in the national variety register separately.

3. PRM belonging to a variety that is registered in accordance with paragraph 1, point (a), in at least one national variety register may be immediately produced and marketed in the Union, in accordance with this Regulation.

4. Following the establishment of their national variety registers, as well as following any of their updates, Member States shall immediately notify the Commission of any elements of those registers which are subject to this Regulation for the purposes of their inclusion in the Union variety register.

5. Varieties which are intended solely as parental components of hybrid varieties and are not marketed as individual varieties shall not be required to be registered pursuant to this Chapter.

Article 50

Establishment of a Union variety register

1. The Commission shall establish, publish in an electronic format, and keep up-to-date a single register of varieties (‘the Union variety register’).

2. The Union variety register shall include the elements of the national variety registers as notified in accordance with Article 49(4) and shall be immediately updated on the basis of such notifications.

3. The Union variety register shall be accessible by an electronic portal established and managed by the Commission. That portal may enable access to other registers of plant varieties, lists of selected clones and polyclonal material, or other plant databases, including those of forest reproductive material and organic heterogeneous material.

Article 51

Contents of the national and Union variety registers

1. The national variety registers and Union variety register shall contain all the elements set out in Annex IV concerning the varieties referred to in Article 49(1).

2. The Commission is empowered to adopt delegated acts in accordance with Article 79 amending Annex IV in order to take into account developments in scientific and technical knowledge and the need of competent authorities or professional operators to obtain more precise information about the varieties referred to in Article 49(1), where indicated by experience.

Article 52

Establishment of national lists of selected clones and polyclonal material

1. Each Member State shall establish, publish in electronic format, and keep up-to-date a single national list of selected clones and polyclonal material (‘national list of selected clones and polyclonal material’) of varieties of genera and species of fruit plants and vines as listed in Annex I.

Those selected clones and that polyclonal material shall belong to a variety that has been registered pursuant to Article 72 in a national variety register referred to in Article 49.

2. Member States shall notify to the Commission the national list of selected clones and polyclonal material and any updates thereof. The Commission shall publish the up-to-date list on the electronic portal referred to in Article 50(3).

3. Any natural or legal person established in the Union may submit to the competent authority an application for listing of a selected clone or polyclonal material in the national list of selected clones and polyclonal material. That application shall include at least the following:

(a) the genus or species and the variety to which the selected clone or polyclonal material belongs;

(b) the proposed denomination for the selected clone or polyclonal material in accordance with Article 60(4);

(c) the natural or legal person that carried out the selection;

(d) the professional operator that maintains the selected clone or polyclonal material, if different from the natural or legal person referred to in point (c) of this paragraph;

(e) documentation of the methodology that led to the selected clone or polyclonal material;

(f) where applicable, the description of the composition of the polyclonal material;

(g) a description of the effective genetic gains in relation to the overall performance of the relevant variety as regards agronomic or technological characteristics or characteristics related to sustainable cultivation such as disease resistance or tolerance of the selected clone or polyclonal material;

(h) information on whether the selected clone or polyclonal material is already listed in a national list of selected clones and polyclonal material of another Member State.

4. The competent authority shall only include the selected clone or the polyclonal material in the national list of selected clones and polyclonal material if it concludes that the application is complete, the denomination is accepted, and the requirements set out in Annex V are fulfilled.

5. The Commission is empowered to adopt delegated acts in accordance with Article 79 amending Annex V in order to adapt that Annex to developments in scientific and technical knowledge and in applicable international standards.

6. The national list of selected clones and polyclonal material shall at least include all information referred to in paragraph 3.

SECTION 2

REQUIREMENTS FOR REGISTRATION OF VARIETIES

Article 53

Requirements for registration in national variety registers

1. A variety shall be registered in a national variety register in accordance with Section 3 if:

(a) it has:

(i) an official description as referred to in Article 54(1), and, in the case of the genera and species as indicated in column 4 of Annex I, it fulfils the requirements for satisfactory value for sustainable cultivation and use set out in Article 59; or

(ii) in the case of a conservation variety or locally adapted variety, an officially recognised description as referred to in Article 54(2) and an indication of its region of origin;

(b) it bears a denomination considered suitable pursuant to Article 60;

(c) the requirements concerning variety maintenance set out in Article 76 are fulfilled;

(d) where the variety contains, or consists of, genetically modified organisms, that genetically modified organism is authorised for cultivation in the Union in accordance with Article 19 of Directive 2001/18/EC, Articles 7 and 19 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council[30] or Chapter III of Regulation (EU) 2026/1388, and that cultivation is not excluded in the Member State concerned in accordance with Article 26b of Directive 2001/18/EC;

(e) where the variety contains, or consists of, category 1 NGT plants as defined in Article 3, point (13), of Regulation (EU) 2026/1388, that plant has obtained a declaration of category 1 NGT plant status pursuant to Article 6 or 7 of that Regulation or is progeny of such plants; and

(f) where the variety is tolerant to herbicides, it is subject to cultivation conditions to avoid the development of herbicide resistance in weeds due to its use where such conditions are determined by the competent authority for the territory of the Member State concerned.

2. A variety shall not be listed in the national variety register as a conservation variety or locally adapted variety if:

(a) it is listed in the Union variety register with an official description;

[30] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1, ELI: http://data.europa.eu/eli/reg/2003/1829/oj).

(b) the registration in the Union variety register as a variety with an official description was terminated pursuant to Article 75 within the last two years;

(c) it is protected by a Community plant variety right as provided for in Regulation (EC) No 2100/94, or by a plant variety right pursuant to national rules of a Member State; or

(d) an application for registration of a variety pursuant to paragraph 1, point (a)(i), of this Article or an application for Community plant variety rights or national plant variety rights is pending.

Article 54

Official description and officially recognised description of a variety

1. The official description referred to in Article 53(1), point (a)(i), shall show the compliance of the variety with the requirements of distinctness, uniformity and stability set out in Articles 55, 56 and 57.

2. The officially recognised description referred to in Article 53(1), point (a)(ii), shall specify the characteristics that makes the variety qualify as a conservation variety or a locally adapted variety.

The officially recognised description shall be based on knowledge gained from practical experience during cultivation, reproduction and use, or other information, in particular from the plant genetic resource authorities or from organisations recognised for that purpose by Member States.

That officially recognised description shall refer to relevant characteristics of the species included in the protocols established by the Community Plant Variety Office (CPVO) or, in the absence of such protocols, in the guidelines of the International Union for the Protection of new Varieties of Plants (UPOV), in other relevant national protocols, or other relevant sources.

The competent authority may recognise as an officially recognised description an official description that has been previously produced for the registration of a variety.

3. A variety shall not be registered with both an official description and an officially recognised description.

4. The Commission may adopt implementing acts laying down specific requirements for certain genera or species concerning:

(a) the evaluation of the distinctness, uniformity and stability of varieties, per genus or species, in order to produce an official description;

(b) the characteristics and information that the officially recognised description referred to in paragraph 2 is to cover, and, where appropriate, for specific genera or species.

Those requirements shall be based on protocols established by the CPVO or, in the absence of such protocols, the applicable guidelines of UPOV or other relevant national protocols. In the case of organic varieties suitable for organic production, as defined in Article 3, point (19), of Regulation (EU) 2018/848, the requirements concerning uniformity may be adjusted for specific genera or species. In the case of the officially recognised description as referred to in point (b) of the first subparagraph of this paragraph, those requirements may also be based on other relevant sources.

Those requirements shall be adapted to developments in scientific and technical knowledge and in applicable international standards.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 80(2).

Article 55

Distinctness

1. For the purposes of the official description referred to in Article 54(1), a variety shall be considered to be distinct if it is clearly distinguishable, by reference to the expression of the characteristics that results from a particular genotype or combination of genotypes, from any other variety whose existence is a matter of common knowledge on the date of the submission of the application established in accordance with Article 64.

2. The existence of another variety, as referred to in paragraph 1, shall be considered to be a matter of common knowledge in view of the relevant UPOV guidelines, in particular if one or more of the following conditions are met:

   (a) the variety has been registered in a national variety register in the Union or in any third country;

   (b) the variety has been granted a plant variety right in the Union or in any third country;

   (c) an application for registration of the variety has been submitted in accordance with Article 61 of this Regulation and is under examination; or

   (d) an application for granting a plant variety right in respect of that variety has been submitted in accordance with Regulation (EC) No 2100/94 or in accordance with national rules of a Member State and is under examination.

Article 56

Uniformity

For the purposes of the official description referred to in Article 54(1), a variety shall be considered to be uniform if, subject to the variation that may be expected from the particular features of its reproduction, it is sufficiently uniform in the expression of those characteristics which are included in the examination for distinctness, as well as in the expression of any other characteristics used for its official description.

Article 57

Stability

For the purposes of the official description referred to in Article 54(1), a variety shall be considered to be stable if the expression of the characteristics included in the examination for distinctness and of any other characteristics used for the variety description remains unchanged after repeated reproduction or, in the case of a particular cycle of reproduction, at the end of each such cycle.

Article 58

Granted plant variety rights

1. Where a plant variety right pursuant to Article 62 of Regulation (EC) No 2100/94 or pursuant to national rules of a Member State has been granted in respect of a variety, that variety shall be considered to be distinct, uniform and stable for the purposes of the official description referred to in Article 54(1) of this Regulation and to have a suitable denomination as referred to in Article 60 of this Regulation.

2. This Article shall apply only where the official description was produced on the basis of a technical examination carried out by an examination office that has been found suitable pursuant to Article 67.

Article 59

Value for sustainable cultivation and use

1. For the purpose of fulfilling the requirements set out in Article 53(1), point (a)(i), the value of a variety for sustainable cultivation and use shall be considered to be satisfactory if, compared to other varieties of the same species registered in the national variety register of the respective Member State, its characteristics, taken as a whole, offer an improvement for the sustainable cultivation and the uses which can be made of the crops, or the products derived therefrom.

2. The characteristics referred to in paragraph 1 are, as appropriate for the species, regions, agro-ecological conditions and uses concerned, the following:

(a) the yield, including yield stability and yield under low-input conditions;

(b) the tolerance or resistance to biotic stresses, including plant diseases caused by nematodes, fungi, bacteria, viruses, insects and other pests;

(c) the tolerance or resistance to abiotic stresses, including adaptation to climatic conditions;

(d) the efficiency in the use of natural resources, such as water and nutrients;

(e) the reduced need for external inputs, such as plant protection products and fertilisers;

(f) the characteristics that enhance the sustainability of harvesting, including pre- or post-harvest waste reduction, storage, processing, distribution and use;

(g) the quality or nutritional characteristics; and

(h) the ability to be cultivated in association with other species or varieties.

3. The Commission is empowered to adopt delegated acts in accordance with Article 79 supplementing this Regulation by establishing the minimum requirements for:

(a) the assessment of the characteristics listed under paragraph 2 of this Article; and

(b) the evaluation and the reporting of the results of the examination of the value for sustainable cultivation and use.

Those requirements shall be adapted to developments in scientific or technical knowledge and to any new Union policies or rules on sustainable agriculture.

4. Where no relevant minimum requirements have been established pursuant to paragraph 3, Member States may apply national rules on their territories. They shall notify those rules to the Commission and the other Member States.

5. For the purposes of registration of organic varieties suitable for organic production as defined in Article 3, point (19), of Regulation (EU) 2018/848, the examination of the value for sustainable cultivation and use shall be conducted under organic conditions in accordance with that Regulation, and in particular Article 5, points (d), (e), (f) and (g), and Article 12 thereof and Part I of Annex II to that Regulation.

Where competent authorities are not able to carry out such an examination, or the examination of certain characteristics, including disease susceptibility, under organic conditions, testing may be carried out under in-conversion or low-input conditions and only with those treatments with pesticides and those other external inputs that are absolutely necessary for the completion of the examination. Where Member States make use of this subparagraph, they shall report annually to the Commission on the reasons behind not testing under organic conditions and on the implementation of testing under non-organic conditions.

Article 60

Suitability of variety denominations

1. For the purposes of Article 53(1), point (b), the denomination of a variety shall not be considered suitable if:

(a) its use in the Union territory is precluded by the prior right of a third party;

(b) it could commonly cause its users difficulties as regards recognition or reproduction;

(c) it is identical to, or could be confused with, a denomination:

(i) under which another variety of the same or of a closely related species is entered in a national variety register, or has been granted a plant variety right pursuant to Regulation (EC) No 2100/94 or pursuant to national rules of a Member State or of a third country which is a member of UPOV, unless that variety no longer remains in existence and its denomination has acquired no special significance; or

(ii) under which another variety of the same or of a closely related species has been made available on the market in a Member State or in a third country which is a member of UPOV, unless that variety no longer remains in existence and its denomination has acquired no special significance;

(d) it is identical to, or could be confused with, other designations which are commonly used for making available on the market goods or which have to be kept free pursuant to Union law;

(e) it is liable to give offence in one of the Member States or is contrary to public policy; or

(f) it is liable to mislead or to cause confusion concerning the characteristics, the value or the identity of the variety, or the identity of the breeder or the applicant.

2. Without prejudice to paragraph 1, where a variety is already registered in other national variety registers, the denomination shall be considered suitable only if it is identical to the denomination appearing in those registers.

The first subparagraph shall not apply if:

(a) the denomination is likely to mislead, offend or cause confusion concerning the relevant variety in one or more Member States; or

(b) rights of third parties impede the free use of that denomination in connection with the variety in question.

3. In the case of conservation varieties, one or more commonly used synonyms may also be indicated in the national variety register. The denomination of conservation varieties that were registered on the basis of an official description but are no longer registered in a national variety register, shall be retained for the purposes of this Article.

4. The denomination of a selected clone and of polyclonal material shall include the denomination of the variety to which it belongs, followed by a suffix in the form of an alphanumerical code. The requirements set out in paragraphs 1 and 2 apply also to that code.

5. The Commission is empowered to adopt delegated acts in accordance with Article 79 supplementing this Regulation by further specifying the elements referred to in paragraphs 1 and 2 of this Article and by developing the requirements for the suitability of denominations laid down therein, including by laying down specific criteria on the suitability of variety denominations concerning:

(a) their relation to trademarks;

(b) their relation to geographical indications or designations of origin for agricultural products;

(c) the written consents of holders of prior rights to remove impediments to their suitability;

(d) their use in the form of a code;

(e) the definition of closely related species as referred to in paragraph 1, point (c); and

(f) the determination of whether they are misleading, offensive or confusing as referred to in paragraph 1, points (e) and (f).

Those delegated acts shall take into account any applicable international standards, as well as the relevant guidelines on variety denominations developed by the CPVO.

SECTION 3

PROCEDURE FOR REGISTRATION OF VARIETIES IN THE NATIONAL VARIETY REGISTERS

Article 61

Submission of application

Any natural or legal person established in the Union may submit to the competent authority an application for registration of a variety in the national variety register.

Article 62

Contents of the application for registration of a variety

1. The application for registration of a variety in a national variety register shall include at least all applicable elements referred to in Annex IV, accompanied by the necessary documentation, as well as all of the following elements that are relevant for the application, accompanied by the necessary documentation:

   (a) the name and address of the applicant or, where applicable, the names and addresses of the joint applicants, and the credentials of any procedural representative;

(b) the official registration number, as referred to in Article 44, of any applicant that is a professional operator;

(c) a proposed variety denomination;

(d) the description of the main characteristics of the variety and its propagation method included, as applicable, in protocols established by the CPVO, or other relevant guidelines of UPOV, or other national protocols, and information on whether it is adapted only for particular seasons of the year;

(e) where the application concerns conservation varieties or locally adapted varieties, information related to the origin and creation of the relevant officially recognised description;

(f) information on whether the variety has been registered in another national variety register or an application for registration in another national variety register has been submitted;

(g) information on whether the variety has been granted plant variety rights pursuant to Regulation (EC) No 2100/94 or pursuant to national rules of a Member State, or an application for plant variety rights has been submitted;

(h) where the variety contains, or consists of, genetically modified organisms, evidence that the genetically modified organism in question is authorised for cultivation in the Union, in accordance with Article 19 of Directive 2001/18/EC, Articles 7 and 19 of Regulation (EC) No 1829/2003, or Chapter III of Regulation (EU) 2026/1388, and that cultivation is not excluded in the Member State concerned in accordance with Article 26b of Directive 2001/18/EC; and

(i) the intended use of the variety.

Where no variety denomination is proposed pursuant to point (c), it may be proposed by the applicant at a later stage and within a reasonable time.

2. The application for registration of a variety in a national variety register shall be accompanied by a sample. The competent authority shall set a deadline for the submission of that sample and specify its quality and quantity.

Article 63

Formal examination of the application

1. The competent authority shall register and examine each application referred to in Article 61 in order to establish whether it complies with the requirements laid down in Article 62.

2. If the application does not comply with the requirements laid down in Article 62, the competent authority shall give the applicant the opportunity to rectify the application accordingly within a given amount of time. If the application does not comply with those requirements by the expiry of that given amount of time, the competent authority shall reject the application.

Article 64

Date of application for registration

The date of the submission of the application for registration shall be the date on which the application is received by the competent authority.

The competent authority shall inform the applicant of the successful submission of the application, confirming the date of receipt of that application.

Article 65

Technical examination of distinctness, uniformity and stability

1. Where, as a result of the formal examination, the application is found to comply with the requirements referred to in Article 62, an examination office, as referred to in Article 67, shall carry out a technical examination of the variety, with the exception of conservation varieties or locally adapted varieties, in order to verify its compliance with the requirements of distinctness, uniformity and stability laid down in Articles 55, 56 and 57.

2. The Commission may adopt implementing acts specifying the ways in which the examination office can collaborate with other natural or legal persons for the purposes of the technical examination pursuant to this Article.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 80(2).

3. The technical examination shall be carried out by growing the variety, taking into account the intended use and the conditions for cultivation of the variety. On the basis of that technical examination, an examination report and, where applicable, an official description shall be issued.

However, where an examination report on the distinctness, uniformity and stability of the variety or an official description produced by the CPVO, another competent authority or examination office in accordance with Article 67 is already available, the competent authority may take into consideration or accept the results of that report or that official description without growing the variety.

4. The examination office, as referred to in Article 67, may use other means than those referred to in paragraph 3, including biochemical and biomolecular techniques or other technical methods, as compulsory tools, when required to do so in accordance with CPVO protocols, and as supplementary tools, when appropriate for the purposes of the technical examination, the species concerned or the characteristics to be checked.

Article 66

Technical examination of the value for sustainable cultivation and use

1. In the case of varieties of the genera and species indicated in column 4 of Annex I, where, as a result of the formal examination, the application is found to comply with the requirements referred to in Article 62, the competent authority shall carry out a technical examination of the variety, with the exception of conservation varieties or locally adapted varieties, in order to verify whether the variety has value for sustainable cultivation and use in accordance with Article 59.

2. The Commission may adopt implementing acts specifying the way in which the competent authority can collaborate with natural or legal persons for the purposes of the technical examination pursuant to this Article.

   Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 80(2).

3. The technical examination shall be carried out by growing the variety, taking into account the intended use and the conditions for cultivation of the variety. The technical examination shall be concluded with the adoption of an examination report.

   However, where an examination report of the requirements for value for sustainable cultivation and use has been produced by a competent authority of another Member State with similar agro-ecological conditions, the competent authority may take into consideration or accept that report without growing the variety.

4. Member States may collaborate with other Member States with similar agro-ecological conditions. Those Member States may establish shared facilities and resources for carrying out the whole or part of the examination for value for sustainable cultivation and use.

5. The competent authority may use other means than those referred to in paragraph 3, including biochemical and biomolecular techniques or other technical methods, as compulsory tools, when required to do so in accordance with applicable national rules, and as supplementary tools, when appropriate for the purposes of the technical examination, the species concerned or the characteristics to be checked.

Article 67

Examination offices carrying out technical examination for distinctness, uniformity and stability

1. The technical examinations of a variety pursuant to Article 65 shall be carried out by the examination offices which have been authorised by the Commission pursuant to the implementing act referred to in paragraph 2 of this Article for the genera or species concerned.

2. The Commission shall adopt implementing acts authorising the examination offices to carry out the technical examination of a variety pursuant to Article 65 for the genera or species concerned.

That authorisation shall be adopted on the basis of an opinion of the CPVO on the suitability of the examination office to carry out such examinations.

Those implementing acts shall include the examination offices that are entrusted by the CPVO for the respective genera or species, in accordance with Article 55(1) of Regulation (EC) No 2100/94, subject to any further opinion of the CPVO and any other assessment of their suitability for the purposes of this Article, as appropriate.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 80(2) of this Regulation.

3. The CPVO opinion referred to in paragraph 2 of this Article shall be issued on the basis of the relevant entrustment requirements applied pursuant to Article 30(4) and Article 55(1) of Regulation (EC) No 2100/94 for the genera or species concerned.

The suitability of the examination office shall be assessed by the CPVO on the basis of regular audits taking place within specific periods, depending on the genera or species concerned.

4. Where, for certain genera or species, no examination offices in the Union have been found suitable in accordance with paragraph 3, the technical examination referred to in paragraph 1 may be carried out in the examination office of a third country. In such case, paragraph 2, second subparagraph, and paragraph 3 shall apply *mutatis mutandis*.

Article 68

Confidentiality

1. Where, for the purposes of the technical examination provided for in Article 65, an examination of the genealogical components is considered to be necessary, the results of that examination and the description of those components shall be treated as confidential. The confidential treatment of this information is without prejudice to the possibility for competent authorities to exchange information among each other or with the Commission.

2. This Article shall apply without prejudice to Article 8 of Regulation (EU) 2017/625.

Article 69

Examination report and official description

1. Following the technical examination provided for in Article 65 and, where applicable, Article 66, the competent authority shall communicate a draft of the examination report to the applicant and give the applicant an opportunity to provide comments within a reasonable time.

2. After examining the comments of the applicant referred to in paragraph 1, the competent authority shall issue:

   (a) a final examination report and an official description on the distinctness, uniformity and stability of the variety; and

(b) where applicable, a final examination report on the value for sustainable cultivation and use.

3. The competent authority shall, on reasoned request, make available the examination reports and the official description to third parties, subject to Union or national rules on confidentiality and the protection of personal data.

Article 70

Examination of conservation and locally adapted varieties

The competent authority shall examine whether the proposed description of a conservation or locally adapted variety complies with the requirements of Article 54(2).

That examination may include a growing trial.

If that compliance is established, the competent authority shall officially recognise the respective description in accordance with Article 54(2).

Article 71

Examination of the denomination of a variety

1. Prior to the registration of a variety in a national variety register pursuant to Article 72, the competent authority shall take a decision on the variety denomination after consulting the CPVO on the denomination proposed by the applicant. That decision shall determine the suitability of the denomination on the basis of the facts existing at the time of the proposal for that denomination pursuant to Article 62(1).

2. The CPVO shall give to the competent authority a recommendation on the suitability of the variety denomination proposed by the applicant in accordance with Article 60.

3. If the CPVO gives a negative recommendation on the suitability of the variety denomination, or if the competent authority takes a decision rejecting the proposed variety denomination, the competent authority shall give the applicant the opportunity to propose a new denomination within a reasonable time.

4. Where, after the registration of a variety, it is established by the competent authority that at the time of the registration the denomination of the variety was not suitable within the meaning of Article 60, the applicant shall submit an application for a new denomination. The competent authority shall decide on that application following consultation with the CPVO.

   The competent authority may allow the proposed denomination to be used temporarily.

Article 72

Decision on the registration of a variety in the national variety register

1. If, on the basis of the procedure set out in Articles 61 to 71, the competent authority decides that the variety complies with the requirements set out in Article 53(1), it shall register the variety in the national variety register.

2. The competent authority shall adopt a decision rejecting registration in the national variety register if:

   (a) it establishes that the applicable requirements set out in Article 53(1) are not fulfilled;

   (b) the applicant has failed to comply with one or more of the applicable requirements set out in Articles 61 to 71;

   (c) the applicant has failed to pay any fee that has been set pursuant to Article 84.

3. Decisions rejecting the registration of a variety in the national variety register shall state the reasons justifying such rejection.

4. The competent authority shall communicate the decision referred to in paragraphs 1 and 2 to the applicant.

5. The applicant may appeal against the decisions referred to in paragraphs 1 and 2 in accordance with the administrative rules of the Member State concerned.

SECTION 4

PERIOD OF REGISTRATION AND VARIETY MAINTENANCE

Article 73

Period of registration

1. The period of registration of a variety in a national variety register ('period of registration') shall run until 31 December of the 10th calendar year after the date of registration.

   However, for conservation varieties and locally adapted varieties, as well as for varieties of genera and species of fruit plants and vines, as listed in Annex I, the period of registration shall run until 31 December of the 30th calendar year after the date of registration.

2. The period of registration of a variety in a national variety register may be renewed for a further period of 10 years in the case of varieties referred to in paragraph 1, first subparagraph, or of 30 years in the case of varieties referred to in paragraph 1, second subparagraph, of this Article in accordance with the procedure and the conditions laid down in Article 74.

3. Notwithstanding paragraphs 1 and 2, in the case of varieties consisting of, or containing, a genetically modified organism, the initial period of registration and any renewed period of registration shall not exceed the period for which that genetically modified organism is authorised for cultivation pursuant to Directive 2001/18/EC, Regulation (EC) No 1829/2003, or Chapter III of Regulation (EU) 2026/1388.

The period of registration shall not be renewed where cultivation is excluded in the Member State concerned in accordance with Article 26b of Directive 2001/18/EC.

Article 74

Procedure and conditions for renewal of registration

1. Any person with a legitimate interest intending to renew the registration of a variety shall submit an application no earlier than 36 months and no later than 24 months before the expiration of the period of registration.

2. The application shall be submitted to the competent authority accompanied by evidence showing that the conditions set out in paragraph 3 are fulfilled.

3. The renewal of the registration of a variety in a national variety register may only be granted if:

(a) the variety continues to comply with the requirements of Article 53(1), other than the requirements concerning the value for sustainable cultivation and use; and

(b) the requirements concerning variety maintenance in accordance with Article 76 are fulfilled.

4. Paragraph 3 of this Article shall not apply to varieties referred to in Articles 90 and 91 as long as those varieties remain true to their description.

In the case of the varieties referred to in Article 53(1), point (a)(i), the competent authority may conduct a technical examination in accordance with Article 65 to determine whether the variety is uniform and stable.

Article 75

Termination of variety registration

1. The competent authority shall terminate the registration of a variety if:

(a) it concludes, on the basis of any new evidence, that the requirements for registration set out in Article 53(1), other than the requirements concerning value for sustainable cultivation and use, are no longer fulfilled;

(b) it concludes, on the basis of any new evidence, that the requirements for registration set out in Article 53(1) were not fulfilled at the time of registration;

(c) the applicant has failed to pay any fee that has been set pursuant to Article 84;

(d) the variety is no longer maintained pursuant to the requirements in Article 76, or the natural or legal person responsible for the variety maintenance, as referred to in that Article requests to terminate the registration, or that person has ceased to maintain the variety and no other person has become responsible for its maintenance;

(e) it has been found that, at the time of the application, false or fraudulent data had been submitted on the basis of which the registration was decided;

(f) no application for renewal was submitted during the period set out in Article 74(1) and the period of registration has expired; or

(g) the applicant has requested the termination of the registration unless another natural or legal person has requested the continuation of that registration and has taken over the responsibilities of the applicant under this Chapter.

2. At the request of any natural or legal person with a legitimate interest, the competent authority may allow PRM of a variety the registration of which has been terminated in accordance with paragraph 1, point (d), (f) or (g), to be marketed until 30 June of the third year following the date of that termination. Such a decision shall be indicated in the national variety register.

3. Following the termination of its registration, the variety shall remain in the national and the Union variety registers with an indication of its registration status, as referred to in point (f) of Annex IV.

Article 76

Variety maintenance

1. Varieties registered in a national variety register shall be maintained by the applicant or by any other natural or legal person in the Union, or in a third country that is subject to the implementing act referred to in Article 39(7) (‘maintainer’). The name and address of that other natural or legal person shall be recorded by the competent authority. That other natural or legal person may be accepted by the competent authority as a maintainer of that variety if that person is able to demonstrate its capability to carry out the maintenance.

2. Variety maintenance shall take place in accordance with accepted practices concerning the relevant genera, species or particular types of varieties.

3. The maintainer shall keep records concerning the variety maintenance. The competent authority may check the variety maintenance from those records at any time. Those records shall also cover all the relevant stages of production of PRM, including the relevant categories.

4. The maintainer shall provide the competent authority, on request, with a standard sample of the variety concerned. In the case of vegetatively propagated varieties, instead of a standard sample, the maintainer may demonstrate that it has living plants of that variety for the appropriate checks and maintenance.

5. The competent authority shall carry out checks on the manner in which the variety maintenance is carried out and may, for this purpose, take samples of the variety concerned. The frequency of those checks shall be based on the likelihood of non-compliance with paragraphs 1 to 4.

6. Where the competent authority finds that the variety is not maintained in accordance with paragraphs 1 to 4 of this Article, it shall give the maintainer appropriate time to take corrective action or to request another person to carry out that maintenance. If no such action is taken within that time, the competent authority shall terminate the registration of the variety in accordance with Article 75(1), point (d).

7. Where variety maintenance takes place in a Member State other than the Member State in whose national variety register the variety has been registered, the competent authorities of the two Member States concerned shall assist each other in the checks on variety maintenance. If no such assistance is provided by the competent authority of the Member State where the variety maintenance takes place within a reasonable period or if it is concluded that the variety maintenance is not carried out in accordance with this Article, the competent authority of the Member State in whose national variety register the variety has been registered shall request the maintainer to take corrective action. If the corrective action is not taken within a reasonable time, that competent authority shall terminate the registration of the variety in accordance with Article 75(1), point (d).

8. Where variety maintenance takes place in a third country, the competent authority of the Member State in whose national variety register the variety has been registered shall request the third country's authorities' assistance in the checks on variety maintenance if that maintenance has been subject to the recognition of equivalence referred to in Article 39(7). If no such assistance is provided by that third country's authorities within a reasonable period or if it is concluded that the variety maintenance is not carried out in accordance with this Article, the competent authority of the Member State in whose national variety register the variety has been registered shall request the maintainer to take corrective action. If the corrective action is not taken within a reasonable time, that competent authority shall terminate the registration of the variety in accordance with Article 75(1), point (d).

SECTION 5

KEEPING OF DOCUMENTATION AND SAMPLES

Article 77

Documentation on the registered varieties

The competent authority shall keep for each variety registered in the national variety register at least:

(a) the official description or the officially recognised description of the variety; and

(b) the examination reports or the documents supporting the officially recognised description.

Article 78

Standard samples of the registered varieties

1. The competent authority shall keep standard samples of the varieties registered in the national variety registers and make them available to other competent authorities for official purposes.

   In the case of vegetatively propagated varieties, instead of a standard sample, the competent authority or the maintainer may keep living plants of that variety.

2. The Commission may adopt implementing acts specifying the size of standard samples and laying down the rules for their replacement where the quantity of the original standard sample is too limited or no longer adequate due to its use in other examinations and for making them available to other competent authorities.

   Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 80(2).

Chapter V
Procedural provisions

Article 79

Exercise of delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The delegation of power referred to in Article 2(4), Article 7(4), Article 8(3), Article 9(3), Article 10(6), Article 11(6), Article 12(4), Article 17(5), Article 18(4), Article 22(4), Article 29(4), Article 37(1), Article 45(6), Article 51(2), Article 52(5), Article 59(3) and Article 60(5) shall be conferred on the Commission for five years from the date of the entry into force of this Regulation.

   The delegation of power shall be tacitly extended for periods of five years, unless the European Parliament or the Council opposed such extension not later than three months before the end of each period. The Commission shall draw up a report in respect of the delegation of power no later than nine months before the end of the first five-year period.

3. The delegation of power referred to in Article 2(4), Article 7(4), Article 8(3), Article 9(3), Article 10(6), Article 11(6), Article 12(4), Article 17(5), Article 18(4), Article 22(4), Article 29(4), Article 37(1), Article 45(6), Article 51(2), Article 52(5), Article 59(3) and Article 60(5) may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 2(4), Article 7(4), Article 8(3), Article 9(3), Article 10(6), Article 11(6), Article 12(4), Article 17(5), Article 18(4), Article 22(4), Article 29(4), Article 37(1), Article 45(6), Article 51(2), Article 52(5), Article 59(3) or Article 60(5) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 80

Committee procedure

1. The Commission shall be assisted by the Standing Committee on Plants, Animals, Food and Feed established by Article 58(1) of Regulation (EC) No 178/2002 of the European Parliament and of the Council[31]. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

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[31] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1, ELI: http://data.europa.eu/eli/reg/2002/178/oj).

Where the opinion of the committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time limit for delivery of the opinion, the chair of the committee so decides or a simple majority of committee members so request.

3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

Chapter VI

Reporting, penalties, official controls and amendments of Regulations (EU) 2016/2031 and (EU) 2017/625

Article 81

Reporting

1. By … [5 years after the date of application of this Regulation], and every five years thereafter, Member States shall transmit to the Commission a report on the following:

   (a) annual quantities produced of pre-basic, basic, certified and standard seed and material and commercial seed per genus or species;

   (b) annual quantities of produced PRM of conservation varieties and locally adapted varieties per genus or species in accordance with Article 23;

(c) the number of professional operators using the derogations for production and marketing of PRM to non-professional users in accordance with Article 24 and the annual quantities produced by them per genus or species;

(d) the number of organisations and networks using the derogation for production and marketing of PRM for the conservation of plant genetic resources in accordance with Article 25 and the genera or species concerned;

(e) annual quantities of PRM per genus or species authorised in accordance with Article 28(2) and (4);

(f) annual quantities of PRM per genus or species that is allowed to be marketed in accordance with Article 30(5);

(g) the number of professional operators registered in accordance with Article 42, point (b); and

(h) the number and types of violations for which penalties were imposed annually in accordance with Article 83.

2. The Commission shall adopt implementing acts laying down the technical format to be used for reporting pursuant to paragraph 1 of this Article.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 80(2).

Article 82

Non-compliance of PRM with production and marketing requirements

Where checks carried out by the competent authority during the production and marketing of PRM reveal non-compliance with the relevant requirements referred to in this Regulation, the competent authority shall ensure that the professional operator takes the necessary corrective action with regard to that PRM and to its premises and production methods. That action shall have one or more of the following objectives:

(a) the PRM concerned complies with the applicable requirements;

(b) the PRM concerned is withdrawn from the market or is used as material other than PRM; or

(c) where relevant, the PRM concerned is produced or marketed under a lower category in accordance with the requirements applicable for that category.

Article 83

Penalties

1. Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. Member States shall, without delay, notify the Commission of those rules and of those measures and shall notify it of any subsequent amendment affecting them.

2. Member States shall ensure that financial penalties for infringements of this Regulation resulting from fraud are at least equal to either:

   (a) he acquired economic advantage for the professional operator; or

   (b) a certain percentage of the professional operator's turnover.

Article 84

Fees

Member States may collect, in a non-discriminatory manner, fees or charges to cover the costs of actions carried out by them pursuant to this Regulation.

Article 85

Amendments of Regulation (EU) 2016/2031

Article 37 of Regulation (EU) 2016/2031 is amended as follows:

(1) paragraph 2 is replaced by the following:

‘2. The Commission shall adopt implementing acts establishing a list setting out the Union regulated non-quarantine pests and the specific plants for planting, as referred to in Article 36, point (d), where appropriate with reference to the categories, specific cases and other plants for planting referred to, respectively, in paragraphs 7, 7a and 7b of this Article and thresholds referred to in paragraph 8 of this Article.’;

(2) paragraph 4 is replaced by the following:

‘4. The Commission shall adopt implementing acts, where appropriate, setting out measures to prevent the presence of Union regulated non-quarantine pests on the plants for planting concerned, as referred to in Article 36, point (f). Those measures shall, where appropriate, concern the introduction into, and the movement within, the Union of those plants. Those measures shall be adopted in accordance with the principles set out in Section 2 of Annex II.’;

(3) paragraph 7 is replaced by the following:

‘7. Where Article 36, point (e), is only fulfilled by one or more of the categories of plant reproductive material referred to in Article 6(1) of Regulation (EU) …/… of the European Parliament and of the Council[*+], the list referred to in paragraph 2 of this Article shall indicate those categories, stating that the prohibition of introduction and movement provided for in paragraph 1 of this Article only applies to them.

7a. Where Article 36, point (e), is only fulfilled in one or more of the cases referred to in Article 6(2) of Regulation (EU) …/…[*++], the list referred to in paragraph 2 of this Article shall indicate those specific cases, stating that the prohibition of introduction and movement provided for in paragraph 1 of this Article only applies to them.

7b. Where, as a result of the phytosanitary risks related to each of them, Article 36, point (e), is only fulfilled by other plants for planting, the list referred to in paragraph 2 of this Article shall indicate those plants for planting, stating that the prohibition of introduction and movement provided for in paragraph 1 of this Article only applies to them.

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[*] Regulation (EU) …/… of the European Parliament and of the Council of … on the production and marketing of plant reproductive material in the Union, amending Regulations (EU) 2016/2031 and (EU) 2017/625 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 and Council Decisions 2003/17/EC and 2005/834/EC (PRM Regulation) (OJ L, …, ELI: …).’.

[+] OJ: Please insert the number, and in the corresponding footnote the number, date of adoption and publication reference of this Regulation.

[++] OJ: Please insert the number of this Regulation.

Article 86

Amendments of Regulation (EU) 2017/625

Regulation (EU) 2017/625 is amended as follows:

(1) in Article 1(2), the following point is added:

‘(k) production and marketing of plant reproductive material with the exception of Chapter IV (Variety registration) of Regulation (EU) …/… of the European Parliament and of the Council[*+].

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[*] Regulation (EU) …/… of the European Parliament and of the Council of … on the production and marketing of plant reproductive material in the Union, amending Regulations (EU) 2016/2031 and (EU) 2017/625 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 and Council Decisions 2003/17/EC and 2005/834/EC (PRM Regulation) (OJ …, ELI: …).’;

(2) in Article 3, the following point is added:

‘(52) “plant reproductive material” means plant reproductive material as defined in Article 3, point (1), of Regulation (EU) …/…[++]’;

[+] OJ: Please insert the number, and in the corresponding footnote the number, date of adoption and publication reference of this Regulation.

[++] OJ: Please insert the number of this Regulation.

(3) the following article is inserted:

‘*Article 22a*

Specific rules on official controls and action taken by the competent authorities in relation to plant reproductive material

1. Official controls to verify compliance with the rules referred to in Article 1(2), point (k), shall include official controls on plant reproductive material, professional operators and other persons subject to those rules.

2. The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation by laying down rules for the performance of official controls on plant reproductive material in order to verify compliance with Union rules referred to in Article 1(2), point (k), applicable to those goods and for action taken by the competent authorities following the performance of those official controls.

Those delegated acts shall lay down rules on specific requirements for the performance of such official controls on:

(a) the import into, and marketing within, the Union of particular plant reproductive material subject to the rules referred to in Article 1(2), point (k), concerning its identification and quality; and

(b) the activities of professional operators during the production or marketing of particular plant reproductive material subject to the rules referred to in Article 1(2), point (k).

3. The Commission shall adopt implementing acts laying down rules on uniform practical arrangements for the performance of official controls on plant reproductive material in order to verify compliance with Union rules referred to in Article 1(2), point (k), applicable to those goods, and for action taken by the competent authorities following such official controls, on:

(a) uniform minimum frequency of such official controls where a minimum level of official control is necessary to respond to recognised uniform risks of non-compliance with the rules on plant reproductive material of a particular origin or provenance;

(b) uniform frequency of official controls performed by competent authorities on operators authorised to carry out certification under official supervision in accordance with Article 14(1) of Regulation (EU) …/…[+].

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

[+] OJ: Please insert the number of this Regulation.

4. For the purposes of Article 30, the delegation of certain official control tasks, referred to in this Article, to one or more natural persons shall be allowed.';

(4) Article 144 is amended as follows:

(a) paragraphs 2 and 3 are replaced by the following:

'2. The power to adopt delegated acts referred to in Article 18(7), Article 21(8), Article 41, Article 45(4), Article 47(3), Article 48, Article 50(4), Article 51, Article 53(1), Article 62(3), Article 64(2) and (5), Article 77(1) and (2), Article 92(4), Article 99(2), Article 100(6), Article 101(2), Article 126(1), Article 142(1) and (2), Article 149(2), Article 150(3), Article 154(3), Article 155(3) and Article 165(3) shall be conferred on the Commission for a period of five years from 28 April 2017. The power to adopt delegated acts referred to in Article 22a(2) shall be conferred on the Commission for a period of five years from 28 April 2027. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the respective five year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Article 18(7), Article 21(8), Article 41, Article 22a(2), Article 45(4), Article 47(3), Article 48, Article 50(4), Article 51, Article 53(1), Article 62(3), Article 64(2) and (5), Article 77(1) and (2), Article 92(4), Article 99(2), Article 100(6), Article 101(2), Article 126(1), Article 142(1) and (2), Article 149(2), Article 150(3), Article 154(3), Article 155(3) and Article 165(3) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.';

(b) paragraph 6 is replaced by the following:

‘6. A delegated act adopted pursuant to Article 18(7), Article 21(8), Article 22a(2), Article 41, Articles 45(4), Article 47(3), Article 48, Article 50(4), Article 51, Article 53(1), Article 62(3), Article 64(2) or (5), Article 77(1) or (2), Article 92(4), Article 99(2), Article 100(6), Article 101(2), Article 126(1), Article 142(1) or (2), Article 149(2), Article 150(3), Article 154(3), Article 155(3) or Article 165(3) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.’.

Article 87

Derogation from the rules on official controls and other official activities laid down in Regulation (EU) 2017/625

Article 6, Article 37(4), point (e), and Articles 109 to 113 of Regulation (EU) 2017/625 shall not apply to official controls or other official activities within the scope of this Regulation.

The competent authorities shall perform audits of official laboratories as provided in Article 39(1) of Regulation (EU) 2017/625 unless they find those audits redundant since the official laboratory is verified by ISTA on the technical competence of official laboratories to carry out seed testing procedures in accordance with the ISTA International Rules and runs a quality assurance system fulfilling the requirements of the ISTA Standards.

Chapter VII
Final and transitional provisions

Article 88

Repeals

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 and Decisions 2003/17/EC and 2005/834/EC are repealed.

References to the repealed acts shall be construed as references to this Regulation and shall be read in accordance with the correlation tables in Annex VI.

Article 89

PRM produced or marketed before [date of application of this Regulation]

PRM produced or marketed before … [date of application of this Regulation] in accordance with the acts referred to in Article 88 or in accordance with national rules may continue to be marketed until stocks are exhausted, with the appropriate label issued pursuant to those acts or pursuant to national rules.

Article 90

Varieties registered or accepted pursuant to Directives 68/193/EEC, 2002/53/EC, 2002/55/EC, 2008/62/EC, 2008/90/EC and 2009/145/EC

1. The competent authorities shall immediately register in their national variety registers, with an official description or an officially recognised description, as applicable, all varieties officially accepted or registered before … [date of application of this Regulation] in the catalogues, lists or registers established by their Member States pursuant to Article 5 of Directive 68/193/EEC, Article 3 of Directive 2002/53/EC, Article 3(2) of Directive 2002/55/EC and Article 7(4) of Directive 2008/90/EC, without applying the registration procedure set out in Chapter IV, Section 3, of this Regulation.

Varieties accepted in accordance with Article 3 of Directive 2008/62/EC and Article 3(1) of Directive 2009/145/EC before … [date of application of this Regulation] shall be registered immediately in the national variety registers as conservation varieties provided with an officially recognised description without applying the registration procedure set out in Chapter IV, Section 3, of this Regulation.

Varieties accepted in accordance with Article 21 of Directive 2009/145/EC may be registered with the respective officially recognised description as locally adapted varieties at the request of the applicant or the maintainer without applying the registration procedure set out in Chapter IV, Section 3, of this Regulation.

2. The period of registration of the varieties referred to in paragraph 1 of this Article shall, without prejudice to Article 73(1), begin on the date on which they were registered or accepted pursuant to the Directives referred to in paragraph 1 of this Article. For varieties of vine, the period of registration shall begin on … [date of application of this Regulation].

3. Paragraphs 1 and 2 of this Article shall apply to the selected clones accepted pursuant to Article 5 of Directive 68/193/EEC *mutatis mutandis*.

4. Technical examinations of distinctness, uniformity and stability of varieties and their value for sustainable cultivation and use that started prior to the date of application of this Regulation shall be completed in accordance with the relevant Directives referred to in paragraph 1 of this Article. The decision on variety registration shall be taken in accordance with Articles 71 and 72 of this Regulation.

Article 91

Varieties of species registered pursuant to national rules

Varieties of genera or species listed in Annex I that are not covered by the Directives referred to in Article 88 and that are registered in a national variety register pursuant to national rules before … [date of application of this Regulation] shall by that date be registered in the relevant national variety registers without applying the registration procedure set out in Chapter IV, Section 3.

Article 92

Professional operators registered before … [the date of application of this Regulation]

By way of derogation from Article 43(1) and (2), the competent authority shall register the professional operator without requiring the submission of an application for registration if that operator has been registered in accordance with the Directives referred to in Article 88 and if all of the data referred to in Article 43(2) are available to that competent authority. Where relevant, the professional operator concerned shall submit an update of those data within a deadline to be set by the competent authority.

Article 93

More stringent national rules adopted before … [the date of entry into force of this Regulation]

Each Member State shall, by … [one year after the date of application of this Regulation], review any measures it has adopted pursuant to Article 5 of Directive 66/401/EEC, Article 5 of Directive 66/402/EEC, Article 7 of Directive 2002/54/EC, Article 24 of Directive 2002/55/EC, Article 5 of Directive 2002/56/EC and Article 7 of Directive 2002/57/EC, and, where necessary, either repeal those measures or amend them to comply with the production and marketing requirements set out in, or adopted pursuant to, Articles 8 and 9 of this Regulation.

The Member State concerned shall inform the Commission and the other Member States of those actions.

Article 94

Evaluation and reporting by the Commission

1. By … [five years after the date of application of this Regulation], the Commission shall submit to the European Parliament and to the Council a report on the application of Articles 24 and 26.

2. The report shall examine the effect of the derogations contained in Articles 24 and 26 on the market for the supply of PRM to professional users. In particular, the report shall examine whether, and if so the extent to which, the use of the derogations has led to situations where PRM intended for non-professional users or PRM exchanged in kind between farmers has been sold to professional users. That report shall also examine the possible prevalence of infringements of plant variety rights.

3. The report can, as the Commission may see necessary, cover the application of other provisions of this Regulation than Articles 24 and 26.

4. The report shall be based on available information and data, including those submitted by the Member States and professional operators or associations.

5. The report shall be accompanied, if appropriate, by a legislative proposal to amend this Regulation.

Article 95

Review of provisions on satisfactory value for sustainable cultivation and use

1. After … [the date of application of this Regulation plus 10 years], the Commission shall submit to the European Parliament and the Council a report on the application of Article 53(1), point (a), concerning the value for sustainable cultivation and use.

2. The report shall, where relevant, assess the need to modify column 4 of Annex I concerning the genera or species for which varieties are to be registered only if they show satisfactory value for sustainable cultivation and use.

3. Where appropriate, the Commission may, on the basis of that report, present a legislative proposal to amend the Regulation.

Article 96

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from … [48 months from the date of the entry into force of this Regulation].

However, where this Regulation confers delegated and implementing powers upon the Commission, those provisions shall apply from … [the date of entry into force of this Regulation].

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at …,

For the European Parliament	*For the Council*
The President	*The President*

ANNEX I

Genera and species referred to in Articles 2, 7, 29 and 53

1	2	3	4
Genera or species per intended use	Genera or species the PRM of which is to be produced and marketed only as pre-basic, basic or certified seed or material in accordance with Article 7	Genera or species the PRM of which can also be produced and marketed as commercial seed in accordance with Article 29	Genera or species for which VSCU is mandatory in accordance with Article 53 *Not applicable to varieties intended to be used as turf grasses
Agricultural plants			
Agrostis canina L.	X	X	X*
Agrostis capillaris L.	X		X*
Agrostis gigantea Roth	X	X	X*
Agrostis stolonifera L.	X		X*
Alopecurus pratensis L.	X		X*
Arachis hypogaea L.	X	X	X

1	2	3	4
Arrhenatherum elatius (L.) P. Beauv. ex J. Presl & C. Presl	X		X*
Avena nuda L.	X		X
Avena sativa L.	X		X
Avena strigosa Schreb.	X		X
Beta vulgaris L. (partim)	X		X
Biserrula pelecinus L.	X	X	X
Brassica juncea (L.) Czern.	X		X
Brassica napus L. (partim)	X		X
Brassica nigra (L.) W. D. J. Koch	X	X	X
Brassica oleracea L. (partim)	X		X
Brassica rapa L. (partim)	X		X
Bromus catharticus Vahl var. *elatus* (É. Desv.) Planchuelo	X	X	X*
Bromus sitchensis Trin.	X	X	X*
Camelina sativa (L.) Crantz	X	X	X
Cannabis sativa L.	X		X

1	2	3	4
Carthamus tinctorius L.	X		X
Carum carvi L.	X		X
Chenopodium quinoa Willd.	X	X	X
Cicer arietinum L.	X	X	X
Cichorium intybus L. (partim)	X	X	X
Cynodon dactylon (L.) Pers.	X	X	X*
Dactylis glomerata L.	X		X*
Fagopyrum esculentum Moench	X	X	X
Festuca arundinacea Schreb.	X		X*
Festuca filiformis Pourr.	X	X	X*
Festuca ovina L.	X		X*
Festuca pratensis Huds.	X		X*
Festuca rubra L.	X		X*
Festuca trachyphylla (Hack.) Hack.	X	X	X*
Galega orientalis Lam.	X	X	X
Glycine max (L.) Merr. (partim)	X		X

1	2	3	4
Gossypium L.	X		X
Helianthus annuus L.	X		X
Hordeum vulgare L.	X		X
Lathyrus cicera L.	X	X	X
Lathyrus sativus L.	X	X	X
Lens culinaris Medik.	X	X	X
Linum usitatissimum L.	X		X
Lolium multiflorum Lam.	X		X*
Lolium perenne L.	X		X*
Lolium x-hybridum Hausskn.	X		X*
Lotus corniculatus L.	X		X
Lupinus albus L.	X		X
Lupinus angustifolius L.	X		X
Lupinus luteus L.	X		X
Medicago doliata Carmign.	X	X	X
Medicago italica (Mill.) Fiori	X	X	X

1	2	3	4
Medicago littoralis Rohde ex Loisel.	X	X	X
Medicago lupulina L.	X	X	X
Medicago murex Willd.	X	X	X
Medicago polymorpha L.	X	X	X
Medicago rugosa Desr.	X	X	X
Medicago sativa L.	X		X
Medicago scutellata (L.) Mill.	X	X	X
Medicago truncatula Gaertn.	X	X	X
Onobrychis viciifolia Scop.	X	X	X
Ornithopus compressus L.	X	X	X
Ornithopus sativus Brot.	X	X	X
Oryza sativa L.	X		X
Panicum miliaceum L.	X	X	X
Papaver somniferum L.	X		X
Phacelia tanacetifolia Benth.	X		X

1	2	3	4
Phalaris aquatica L.	X	X	X*
Phalaris canariensis L.	X	X	X
Phleum nodosum L.	X	X	X*
Phleum pratense L.	X		X*
Pisum sativum L. (partim)	X		X
Plantago lanceolata L.	X	X	X
Poa annua L.	X	X	X*
Poa nemoralis L.	X	X	X*
Poa palustris L.	X	X	X*
Poa pratensis L.	X		X*
Poa trivialis L.	X		X*
Raphanus sativus L. (partim)	X		X
Secale cereale L.	X		X
Sinapis alba L.	X		X
Sorghum bicolor (L.) Moench	X		X

1	2	3	4
Sulla coronaria (L.) B. H. Choi & H. Ohashi	X	X	X
Trifolium alexandrinum L.	X		X
Trifolium fragiferum L.	X	X	X
Trifolium glanduliferum Boiss.	X	X	X
Trifolium hirtum All.	X	X	X
Trifolium hybridum L.	X		X
Trifolium incarnatum L.	X		X
Trifolium isthmocarpum Brot.	X	X	X
Trifolium michelianum Savi	X	X	X
Trifolium pratense L.	X		X
Trifolium repens L.	X		X
Trifolium resupinatum L.	X		X
Trifolium squarrosum L.	X	X	X
Trifolium subterraneum L.	X	X	X
Trifolium vesiculosum Savi	X	X	X
Trigonella foenum-graecum L.	X	X	X

1	2	3	4
Trisetum flavescens (L.) P. Beauv.	X		X*
Triticum aestivum L. subsp. *aestivum*	X		X
Triticum aestivum L. subsp. *spelta* (L.) Thell.	X		X
Triticum durum Desf.	X		X
Vicia benghalensis L.	X	X	X
Vicia ervilia (L.) Willd.	X	X	X
Vicia faba L. (partim)	X		X
Vicia narbonensis L.	X	X	X
Vicia pannonica Crantz	X	X	X
Vicia sativa L.	X		X
Vicia villosa Roth	X		X
x-Festulolium Asch. & Graebn.	X		X*
x-Triticosecale Wittm. ex A. Camus	X		X
Zea mays L. **(**partim**)**	X		X

1	2	3	4
Potato			
Solanum tuberosum L.	X		X
Vegetable plants			
Allium cepa L.			
Allium fistulosum L.			
Allium porrum L.			
Allium sativum L.			
Allium schoenoprasum L.			
Anthriscus cerefolium (L.) Hoffm.			
Apium graveolens L.			
Asparagus officinalis L.			
Beta vulgaris L. (partim)			
Brassica napus L. (partim)			
Brassica oleracea L. (partim)			
Brassica rapa L. (partim)			
Capsicum annuum L.			

1	2	3	4
Cichorium endivia L.			
Cichorium intybus L. (partim)			
Citrullus lanatus (Thunb.) Matsum. et Nakai			
Cucumis melo L.			
Cucumis sativus L.			
Cucurbita maxima Duchesne			
Cucurbita moschata Duchesne			
Cucurbita pepo L.			
Cynara cardunculus L.			
Daucus carota L.			
Foeniculum vulgare Mill.			
Glycine max (L.) Merr. (partim)			
Lactuca sativa L.			
Petroselinum crispum (Mill.) Nyman ex A. W. Hill			
Phaseolus coccineus L.			
Phaseolus vulgaris L.			

1	2	3	4
Pisum sativum L. **(**partim**)**			
Raphanus sativus L. **(**partim**)**			
Rheum rhabarbarum L.			
Scorzonera hispanica L.			
Solanum lycopersicum L.			
Solanum melongena L.			
Spinacia oleracea L.			
Valerianella locusta (L.) Laterr.			
Vicia faba L. **(**partim**)**			
Zea mays L. **(**partim**)**			
Fruit plants			
Actinidia Lindl.			
Castanea sativa Mill.			
Citrus L.			
Corylus avellana L.			

1	2	3	4
Cydonia oblonga Mill.			
Ficus carica L.			
Fragaria L.			
Juglans regia L.			
Malus Mill.			
Olea europaea L.			
Pistacia L.			
Prunus armeniaca L.			
Prunus avium (L.) L.			
Prunus cerasus L.			
Prunus domestica L.			
Prunus dulcis (Mill.) D.A. Webb			
Prunus persica (L.) Batsch			
Prunus salicina Lindl**.**			

1	2	3	4
Pyrus L.			
Ribes L.			
Rubus L.			
Vaccinium L.			
Vine			
Vitis L.			X

ANNEX II

Requirements for the production and marketing of pre-basic, basic and certified seed and material as referred to in Article 8

PART A

Requirements for the production and marketing of pre-basic, basic and certified seed of agricultural and vegetable plants, and true potato seed

1. Requirements for the production of pre-basic, basic and certified seed of agricultural and vegetable plants, and true potato seed

A. Sowing or planting:

(a) The variety and identity of the seed sown, including, where applicable, mother plants planted, shall be determined by the competent authority or by the professional operator, and shall be recorded to ensure its traceability.

(b) The previous cropping of the field shall not have been incompatible with the production of seed of the species, variety and category of the crop, and the field shall be sufficiently free from plants which could have remained from previous cropping (volunteers).

(c) The seed or mother plants, where applicable, shall be sown or planted in such a way that there is sufficient distance from pollen sources of the same genus or the same species and different varieties, determined by the botanical characteristics, to ensure protection from any undesirable foreign pollination, including cross pollination with other crops.

(d) Where appropriate, the production of seed shall take place separately from the cultivation of seed belonging to the same genera or species intended for the production of food or feed, to ensure that the requirements applicable only to the seed concerned are fulfilled.

(e) Plants derived from in vitro propagation may be used for the production of seed.

B. Field cultivation:

(a) The field crop shall have sufficient varietal identity and varietal purity.

It shall be ensured that plants of other species, other varieties, or off-types are absent from the field. Where this is not possible, due to the characteristics of the species concerned, they shall be present at the lowest possible level.

Where off-types or other plant species are present during the cultivation stage, they shall be removed or appropriate treatment shall be applied.

(b) The plants shall be treated or excluded as a source of PRM where there are positive test results or visual symptoms of pests, in accordance with Regulation (EU) 2016/2031, or defects.

(c) All crops in the field shall be inspected officially or under official supervision at their relevant growth stages, at the relevant frequency and with the relevant methods for the genera or species concerned to verify their compliance with the respective requirements. If it is not possible to remove or separate non-compliant plants during the growing phase, the entire field or part of it shall be rejected for seed production, or, if possible, shall be used for the production of seed belonging to a lower category or generation, unless the undesirable seeds can be mechanically separated at a later stage.

C. Harvesting and post-harvesting:

(a) The seed shall be harvested in a way that ensures its identity, purity and traceability.

(b) A sample of seed shall be taken officially or under official supervision from each lot. The sample size and the sampling intensity, equipment and method shall be appropriate for the species concerned and shall take into account any applicable international standards.

(c) The seed sample shall be subject to official laboratory testing, or laboratory testing under official supervision, to ensure the fulfilment of the quality requirements for the respective species. Laboratory testing shall be carried out in accordance with methods, equipment and growing media appropriate for the species concerned and shall take into account any applicable international standards.

2. Requirements for the marketing of pre-basic, basic and certified seed of agricultural and vegetable plants, and true potato seed

The seed shall, depending on the characteristics of each genus or species and the category concerned, fulfil the following quality requirements:

(a) it shall have a sufficient germination rate that shall be confirmed through retesting after an appropriate period for the respective species;

(b) it shall have no more than a maximum allowed content of seed regarded as capable of germination at a later stage (hard seed);

(c) it shall have a sufficient analytical purity and, where applicable, have no more than a maximum allowed presence of soil or extraneous matter;

(d) it shall have an appropriate moisture content;

(e) it shall have no more than a maximum allowed content of seed of other genera or species;

(f) it shall be practically free from significant defects and damage.

PART B

Requirements for the production and marketing of pre-basic, basic and certified seed of fruit plants and vines

1. Requirements for the production of pre-basic, basic and certified seed of fruit plants and vines

A. Sowing or planting:

(a) The variety and identity of the material, mother plants or seed planted or sown shall be determined by the competent authority or by the professional operator, and shall be recorded to ensure their traceability.

(b) The material, mother plants or seed and, where appropriate, the pollinator plants shall be planted or sown in such a way that there is sufficient distance from other plants of the same genus or the same species and different varieties, determined by the botanical characteristics, to ensure protection from any undesirable foreign pollination, including cross pollination with other crops.

(c) Where appropriate, the production of seed shall take place separately from the cultivation of plants belonging to the same genera or species intended for the production of food or feed, to ensure that the requirements applicable only to the seed concerned are fulfilled.

(d) Plants derived from in vitro propagation may be used for the production of seed.

B. Field cultivation:

(a) Off-types and deformed or damaged mother plants and pollinator plants shall be disposed of at all stages of cultivation in order to ensure that the cultivated plants are true to the identity of the variety, or for plants not belonging to a variety, to ensure that they are true to the identity of the species to which they belong, their sufficient purity and efficient production.

(b) Mother plants and pollinator plants shall be treated or excluded as a source of PRM where there are positive test results or visual symptoms of pests, in accordance with Regulation (EU) 2016/2031, or defects.

(c) Mother plants and pollinator plants shall be excluded as a source of seed where there are significant defects likely to impair the quality of such seed.

(d) Mother plants and pollinator plants shall be cultivated, in all stages of development, in such a way as to enable the production of seed and to permit their identification and verification of compliance with the official description or the officially recognised description of their variety. In the case of mother plants and pollinator plants not belonging to a variety, the verification of compliance shall concern the species to which those mother plants and pollinator plants belong.

(e) Mother plants and pollinator plants shall be inspected officially or under official supervision at their relevant growth stages, at the relevant frequency and with the relevant methods for the genera or species concerned to verify its compliance with the respective requirements.

C. Harvesting and post-harvesting:

(a) The seed shall be harvested in a way that ensures its identity, purity and traceability.

(b) A sample of seed shall be taken officially or under official supervision from each lot. The seed sample to be drawn from a lot shall have the appropriate minimum size for determining the fulfilment of the quality requirements for the respective genera or species. The sample size and the sampling intensity, equipment and method shall be appropriate for the genera or species concerned and shall take into account any applicable international standards.

(c) Testing shall be carried out in accordance with the methods, equipment and growing media appropriate for the genera or species concerned, in order to ensure that the quality requirements have been fulfilled.

2. Requirements for the marketing of pre-basic, basic and certified seed of fruit plants and vines

The seed shall, depending on the characteristics of each genus or species and the category concerned, fulfil the following quality requirements:

(a) it shall have a sufficient germination rate;

(b) it shall be practically free from significant defects and damage;

(c) it shall have sufficient analytical purity and, where applicable, have no more than a maximum allowed presence of soil or extraneous matter;

(d) it shall have an appropriate moisture content;

(e) it shall have no more than a maximum allowed content of seed of other genera or species.

PART C

Requirements for the production and marketing of pre-basic, basic and certified material of agricultural, vegetable and fruit plants and vines, including selected clones and polyclonal material

1. Requirements for the production of pre-basic, basic and certified material of agricultural, vegetable and fruit plants and vines, including selected clones and polyclonal material

A. Sowing or planting:

(a) The variety and identity of the material, mother plants or seed planted or sown shall be determined by the competent authority or by the professional operator, and shall be recorded to ensure their traceability.

(b) The material, mother plants or seed, where applicable, shall be planted or sown in a way that ensures their viability and quality throughout the production process.

(c) Where appropriate, the cultivation of material shall take place separately from the cultivation of material belonging to the same genera or species intended for food or feed purposes.

(d) Plants derived from in vitro propagation may be used for the production of material.

B. Field cultivation:

(a) The field crop shall have sufficient varietal identity and varietal purity.

(b) Off-types and deformed or damaged mother plants and material shall be disposed of at all stages of cultivation.

(c) Mother plants and material shall be treated or excluded as a source of PRM where there are positive test results or visual symptoms of pests, in accordance with Regulation (EU) 2016/2031 or defects.

(d) Mother plants and material shall be cultivated, in all stages of development, in such a way as to enable the production of material and to permit their identification and verification of compliance with the official description or the officially recognised description of their variety, selected clone or polyclonal material. In the case of mother plants and material not belonging to a variety, the verification shall concern the species to which those mother plants and material belong.

(e) Mother plants and material shall be inspected officially or under official supervision at their relevant growth stages, at the relevant frequency and with the relevant methods for the genera or species concerned to verify their compliance with the respective requirements.

C. Harvesting and post-harvesting:

(a) The material shall be harvested in a way that ensures its identity, purity and traceability.

(b) The sample to be drawn officially or under official supervision from a lot shall have the appropriate minimum size for determining the fulfilment of the quality requirements for the respective genera or species. The intensity, equipment and method of sampling shall be appropriate for the genera or species concerned and shall take into account any applicable international standards.

(c) Official testing or testing under official supervision shall be carried out in accordance with the methods, equipment and growing media appropriate for the genera or species concerned and shall take into account any applicable international standards, in order to ensure that the quality requirements have been fulfilled.

2. Requirements for the marketing of pre-basic, basic and certified material of agricultural, vegetable and fruit plants and vines, including selected clones and polyclonal material

The material shall, depending on the characteristics of each genus or species and the category concerned, fulfil the following requirements:

(a) it shall have sufficient vigour and, where applicable, specific grading;

(b) it shall be practically free from significant defects and damage.

The composition of polyclonal material shall be made before the final packaging of that material and shall include identical proportions of material from all genotypes that constitute the polyclonal material.

PART D

Requirements for the production and marketing of pre-basic, basic and certified seed potatoes and other material of potatoes

1. Requirements for the production of pre-basic, basic and certified seed potatoes and other material of potatoes

A. Sowing or planting:

(a) The variety and identity of the material, mother plants or seed planted or sown shall be determined by the competent authority or the professional operator, and shall be recorded to ensure its traceability.

(b) The material, mother plants or seed, where applicable, shall be planted or sown in a way that ensures their viability and quality throughout the production process.

(c) Where appropriate, the production of seed potatoes shall take place separately from the cultivation of potatoes intended for the production of food or feed purposes.

(d) Plants derived from in vitro propagation may be used for the production of seed potatoes or other material of potatoes.

B. Field cultivation:

(a) The field crop shall have sufficient varietal identity and varietal purity.

(b) Off-types and deformed or damaged plants or tubers shall be disposed of at all stages of cultivation.

(c) Mother plants and material shall be treated or excluded as a source of PRM where there are positive test results or visual symptoms of pests, in accordance with Regulation (EU) 2016/2031, or defects.

(d) Mother plants and material shall be cultivated, in all stages of development, in such a way as to enable the production of material and to permit their identification and verification of compliance with the official description or the officially recognised description of their variety.

(e) Mother plants and material shall be inspected officially or under official supervision at their relevant growth stages, at the relevant frequency and with the relevant methods to verify their compliance with the respective requirements.

C. Harvesting and post-harvesting:

(a) The seed potatoes shall be harvested in a way that ensures their identity and traceability.

(b) A sample of tubers shall be taken officially or under official supervision from each lot. The sample size and the sampling intensity, equipment and method shall be appropriate for determining the fulfilment of the quality requirements and shall take into account any applicable international standards. The sample may be also taken from the field.

(c) The tuber samples shall be subjected to official laboratory testing, or laboratory testing under official supervision, and visual inspection to ensure the fulfilment of the quality requirements. Laboratory testing shall be carried out in accordance with methods, equipment and growing media appropriate for potato and shall take into account any applicable international standards.

2. Requirements for the marketing of pre-basic, basic and certified seed potatoes and other material of potatoes

The seed potatoes and other material of potatoes shall, depending on the category concerned, fulfil the following requirements:

(a) it shall have sufficient vigour, defined dimension and specific grading;

(b) it shall be practically free from significant defects and damage.

PART E

Requirements for the production and marketing of pre-basic, basic and certified material produced by in vitro propagation

1. Requirements for the production of pre-basic, basic and certified material produced by in vitro propagation

A. In vitro culture

The variety and identity of the in vitro or in vivo material, as applicable, shall be determined by the competent authority or by the professional operator, and shall be recorded to ensure its traceability.

B. In vitro production

(a) The material that originates from the material referred to under point A shall be produced by in vitro propagation.

(b) The number of successive propagation cycles by in vitro propagation shall be restricted, as appropriate, for the genera or species concerned.

(c) The material shall be cultivated, in all stages of development, in such a way as to permit its identification and verification of compliance with the official description or the officially recognised description of their variety. Where the official description or officially recognised description cannot be used because of the particular growth stage of the plant, biochemical and biomolecular techniques or other technical methods recognised in accordance with Article 8(4), point (i), or a sample of material planted in vivo may be used. In the case of material not belonging to a variety, the verification of compliance shall concern the species to which that material belongs.

(d) The material shall be officially inspected or inspected under official supervision at the relevant frequency and with the relevant methods for the genera or species concerned to verify its compliance with the respective requirements.

(e) The sample to be drawn officially or under official supervision from a lot shall have the appropriate minimum size for determining the fulfilment of the quality requirements for the respective genera or species. The intensity, equipment and method of sampling shall be appropriate for the genera or species concerned and shall take into account any applicable international standards.

(f) Official testing or testing under official supervision shall be carried out in accordance with the methods, equipment and growing media appropriate for the genera or species concerned and shall take into account any applicable international standards.

2. Requirements for the marketing of pre-basic, basic and certified material produced by in vitro propagation

The in vitro material shall, depending on the characteristics of each genus or species and the category concerned, fulfil the following requirements:

(a) it shall belong to the variety and, in the case of material not belonging to a variety, to the species concerned;

(b) it shall have sufficient vigour, defined dimension and, where applicable, specific grading;

(c) it shall be practically free from significant defects and damage.

ANNEX III

Requirements for the production and marketing of standard seed and material as referred to in Article 9

PART A

Requirements for the production and marketing of standard seed of agricultural and vegetable plants, and true potato seed

1. Requirements for the production of standard seed of agricultural and vegetable plants, and true potato seed

A. Sowing or planting:

(a) The variety and identity of the seed sown, including, where applicable, mother plants planted, shall be determined and recorded by the professional operator to ensure its traceability.

(b) The previous cropping of the field shall not have been incompatible with the production of seed of the species and variety of the crop, and the field shall be sufficiently free from plants which could have remained from previous cropping (volunteers).

(c) The seed or mother plants, where applicable, shall be sown or planted in such a way that there is sufficient distance from pollen sources of the same genus or the same species and different varieties, determined by the botanical characteristics, to ensure protection from any undesirable foreign pollination, including cross pollination with other crops.

(d) Where appropriate, the production of seed shall take place separately from the cultivation of seed belonging to the same genera or species intended for the production of food or feed, to ensure that the requirements applicable only to the seed concerned are fulfilled.

(e) Plants derived from in vitro propagation may be used for the production of seed.

B. Field cultivation:

(a) The field crop shall have sufficient varietal identity and varietal purity.

It shall be ensured that plants of other species, other varieties, or off-types are absent from the field. Where this is not possible due to the characteristics of the species concerned, they shall be present at the lowest possible level.

Where off-types or other plant species are present during the cultivation stage, they shall be removed or appropriate treatment shall be applied.

(b) The plants shall be treated or excluded as a source of PRM where there are positive test results or visual symptoms of pests, in accordance with Regulation (EU) 2016/2031 or defects.

(c) All crops in the field shall be checked by the professional operator at their relevant growth stages and at the relevant frequency for the genera or species concerned to verify their compliance with the respective requirements.

C. Harvesting and post-harvesting:

(a) The seed shall be harvested in a way that ensures its identity, purity and traceability.

(b) A sample of seed shall be taken by the professional operator from each lot and tested to ensure the fulfilment of the quality requirements for the respective species. The sample size and the sampling intensity, equipment and method shall be appropriate for the species concerned and shall take into account any applicable international standards.

2. Requirements for the marketing of standard seed of agricultural and vegetable plants, and true potato seed

The seed shall, depending on the characteristics of each genus or species concerned, fulfil the following quality requirements:

(a) it shall have a sufficient germination rate that shall be confirmed through retesting after an appropriate period for the respective species;

(b) it shall have no more than a maximum allowed content of seed regarded as capable of germination at a later stage (hard seed);

(c) it shall have a sufficient analytical purity and, where applicable, have no more than a maximum allowed presence of soil or extraneous matter;

(d) it shall have an appropriate moisture content;

(e) it shall have no more than a maximum allowed content of seed of other genera or species;

(f) it shall be practically free from significant defects and damage.

PART B

Requirements for the production and marketing of standard seed of fruit plants and vines

1. Requirements for the production of standard seed of fruit plants and vines

A. Sowing or planting:

(a) The variety and identity of the material, mother plants or seed grown shall be determined and recorded by the professional operator to ensure their traceability.

(b) The material, mother plants or seed and, where appropriate, the pollinator plants shall be planted or sown in such a way that there is sufficient distance from other plants of the same genus or the same species and different varieties, determined by the botanical characteristics, to ensure protection from any undesirable foreign pollination, including cross pollination with other crops.

(c) Where appropriate, the production of seed shall take place separately from the cultivation of plants belonging to the same genera or species intended for the production of food or feed, to ensure that the requirements applicable only to the seed concerned are fulfilled.

(d) Plants derived from in vitro propagation may be used for the production of seed.

B. Field cultivation:

(a) Off-types and deformed or damaged mother plants and pollinator plants shall be disposed of at all stages of cultivation in order to ensure that the cultivated plants are true to the identity of the variety, or for plants not belonging to a variety, to ensure that they are true to the identity of the species to which they belong, their sufficient purity and efficient production.

(b) Mother plants and pollinator plants shall be treated or excluded as a source of PRM where there are positive test results or visual symptoms of pests, in accordance with Regulation (EU) 2016/2031, or defects.

(c) Mother plants and pollinator plants shall be excluded as a source of seed in the case of significant defects likely to impair the quality of such seed.

(d) Mother plants and pollinator plants shall be cultivated, in all stages of development, in such a way as to enable the production of seed and to permit their identification and verification of compliance with the official description or the officially recognised description of their variety. In the case of mother plants and pollinator plants not belonging to a variety, the verification of compliance shall concern the species to which those mother plants and pollinator plants belong.

(e) Mother plants and pollinator plants shall be checked at their relevant growth stages, at the relevant frequency for the genera or species concerned to verify their compliance with the respective requirements.

C. Harvesting and post-harvesting:

(a) The seed shall be harvested in a way that ensures its identity, purity and traceability.

(b) A sample of seed shall be taken by the professional operator from each lot and tested to ensure the fulfilment of the quality requirements for the respective genera or species. The sample size and the sampling intensity, equipment and method of sampling shall be appropriate for the genera or species concerned and shall take into account any applicable international standards.

2. Requirements for the marketing of standard seed of fruit plants and vines

The seed shall, depending on the characteristics of each genus or species concerned, fulfil the following quality requirements:

(a) it shall have a sufficient germination rate;

(b) it shall be practically free from significant defects and damage;

(c) it shall have a sufficient analytical purity and, where applicable, have no more than a maximum allowed presence of soil or extraneous matter;

(d) it shall have an appropriate moisture content;

(e) it shall have no more than a maximum allowed content of seed of other genera or species.

PART C

Requirements for the production and marketing of standard material of agricultural, vegetable and fruit plants and vines, including polyclonal material

1. Requirements for the production of standard material of agricultural, vegetable and fruit plants and vines, including polyclonal material

A. Sowing or planting:

(a) The variety and identity of the material, mother plants or seed planted or sown shall be determined and shall be recorded by the professional operator to ensure their traceability.

(b) The material, mother plants or seed, where applicable, shall be planted or sown in a way that ensures their viability and quality throughout the production process.

(c) Where appropriate, the cultivation of material shall take place separately from the cultivation of material belonging to the same genera or species intended for food or feed purposes.

(d) Plants derived from in vitro propagation may be used for the production of material.

B. Field cultivation:

(a) The field crop shall have sufficient varietal identity and varietal purity.

(b) Off-types and deformed or damaged mother plants and material shall be disposed of at all stages of cultivation.

(c) Mother plants and material shall be cultivated, in all stages of development, in such a way as to enable the production of material and to permit their identification and verification of compliance with the official description or the officially recognised description of their variety, or polyclonal material. In the case of mother plants and material not belonging to a variety, the verification shall concern the species to which those mother plants and material belong.

(d) Mother plants and material shall be checked at their relevant growth stages and at the relevant frequency for the genera or species concerned to verify their compliance with the respective requirements.

(e) Mother plants shall be treated or excluded as a source of PRM where there are positive test results or visual symptoms of pests, in accordance with Regulation (EU) 2016/2031 or defects.

C. Harvesting and post-harvesting:

The material shall be harvested in a way that ensures its identity, purity and traceability.

2. Requirements for the marketing of standard material of agricultural, vegetable and fruit plants and vines, including polyclonal material

The material shall, depending on the characteristics of each genus or species concerned, fulfil the following requirements:

(a) it shall have sufficient vigour and, where applicable, specific grading;

(b) it shall be practically free from significant defects and damage;

The composition of polyclonal material shall be made before the final packaging of that material and shall include identical proportions of material from all genotypes that constitute the polyclonal material.

PART D

Requirements for the production and marketing of standard seed potatoes and other material of potatoes

1. Requirements for the production of standard seed potatoes and other material of potatoes

A. Sowing or planting:

(a) The variety and identity of the material, mother plants or seed planted or sown shall be determined and recorded by the professional operator to ensure their traceability.

(b) The material, mother plants or seed, where applicable, shall be planted or sown in a way that ensures their viability and quality throughout the production process.

(c) Where appropriate, the production of seed potatoes shall take place separately from the cultivation of potatoes intended for the production of food or feed purposes.

(d) Plants derived from in vitro propagation may be used for the production of seed potatoes or other material of potatoes.

B. Field cultivation:

(a) The field crop shall have sufficient varietal identity and varietal purity.

(b) Off-types and deformed or damaged plants or tubers shall be disposed of at all stages of cultivation.

(c) Mother plants and material shall be treated or excluded as a source of PRM where there are positive test results or visual symptoms of pests, in accordance with Regulation (EU) 2016/2031, or defects.

(d) Mother plants and material shall be cultivated, in all stages of development, in such a way as to enable the production of material and to permit their identification and verification of compliance with the official description or the officially recognised description of their variety.

(e) Mother plants and material shall be checked at their relevant growth stages, at the relevant frequency and with the relevant methods to verify their compliance with the respective requirements.

C. Harvesting and post-harvesting:

(a) The seed potatoes shall be harvested in a way that ensures their identity and traceability.

(b) A sample of tubers shall be taken from each lot. The sample may be also taken from the field.

(c) The tuber samples shall be subjected to testing and visual inspection, to ensure the fulfilment of the quality requirements.

2. Requirements for the marketing of standard seed potatoes and other material of potatoes

The seed potatoes and other material of potatoes shall fulfil both of the following requirements:

(a) they shall have sufficient vigour, defined dimension and specific grading;

(b) they shall be practically free from significant defects and damage.

PART E

Requirements for the production and marketing of standard material produced by in vitro propagation

1. Requirements for the production of standard material produced by in vitro propagation

A. In vitro culture:

The variety and identity of the in vitro or in vivo material, as applicable, shall be determined and shall be recorded by the professional operator to ensure its traceability.

B. In vitro production:

(a) The material that originates from the material referred to under point A shall be produced by in vitro propagation.

(b) The number of successive propagation cycles by in vitro propagation shall be restricted, as appropriate, for the genera or species concerned.

(c) The material shall be cultivated, in all stages of development, in a way that permits its identification and verification of compliance with the official description or the officially recognised description of their variety. Where the official description or officially recognised description cannot be used because of the particular growth stage of the plant, biochemical and biomolecular techniques or other technical methods recognised in accordance with Article 9(4), point (i), or a sample of material planted in vivo may be used. In the case of material not belonging to a variety, the verification of compliance shall concern the species to which that material belongs.

(d) The material shall be checked by the professional operator at the relevant frequency for the genera or species concerned to verify its compliance with the respective requirements.

(e) The sample to be drawn by the professional operator from a lot shall have the appropriate minimum size for determining the fulfilment of the quality requirements for the respective genera or species. The intensity, equipment and method of sampling shall be appropriate for the genera or species concerned and shall take into account any applicable international standards.

(f) Testing shall be carried out in accordance with the methods, equipment and growing media appropriate for the genera or species concerned and shall take into account any applicable international standards.

2. Requirements for the marketing of standard material produced by in vitro propagation

The in vitro material shall, depending on the characteristics of each genus or species concerned, fulfil the following requirements:

(a) it shall belong to the variety and, in the case of material not belonging to a variety, belong to the species concerned;

(b) it shall have sufficient vigour, defined dimension and, where applicable, specific grading;

(c) it shall be practically free from significant defects and damage.

ANNEX IV

Contents of the national and Union variety registers
referred to in Article 51

The national variety registers and the Union variety register shall contain all of the following elements, as applicable:

(a) the scientific name of the genus or species to which the variety belongs;

(b) in the case of national registers only, the common name of the genus or species to which the variety belongs;

(c) the breeder's reference, the denomination of the variety and known synonyms used for that variety;

(d) the name of the applicant and, where applicable, the name of the applicant's representative;

(e) the date of application for registration;

(f) the status of the variety, including an indication whether the variety is registered or its registration is terminated, or whether there is an application pending for its registration, or an application that has been withdrawn by the applicant or rejected by the competent authority;

(g) the date of the registration of the variety and any change of its status according to point (f);

(h) the date of termination of the registration and, where applicable, the date of the end of marketing pursuant to Article 75(2);

(i) a link to the official description of the variety, or the officially recognised description of the variety;

(j) an indication whether it is a conservation or locally adapted variety, and if that is the case, the region of origin;

(k) the name, address and, where applicable, the official registration number of the maintainer as referred to in Article 44, point (a);

(l) in the case of the Union register, the name of the Member States having established the relevant national variety registers;

(m) the unique variety identifier under which the variety has been registered in the national variety registers;

(n) the indication that the variety is an ‘organic variety suitable for organic production’ according to Regulation (EU) 2018/848;

(o) the indication that the variety contains, or consists of, genetically modified organisms;

(p) the indication that the variety is a component variety of another registered variety;

(q) the indication that PRM belonging to the variety is only produced and marketed as rootstocks;

(r) an indication of the reproduction method of the variety, including information on whether it is:

(i) a hybrid;

(ii) a synthetic variety; or

(iii) a vegetatively propagated or seed-propagated variety, in the case of species with both types of propagation;

(s) indication whether the variety contains, or consists of, category 1 NGT plants within the meaning of Article 3, point (13), of Regulation (EU) 2026/1388 and the identification numbers referred to in Article 9(1), point (e), of that Regulation assigned to the category 1 NGT plants it has been derived from;

(t) in the case of varieties tolerant to herbicides, an indication of that fact, and the active substance to which the variety is tolerant;

(u) types, uses and technical characteristics of the variety, including winter or spring type, turf grass uses, or industrial, or food or feed uses.

ANNEX V

Technical requirements for the registration of selected clones and polyclonal material

A. In order to be included in the list referred to in Article 52(1), the selected clone shall fulfil the following requirements:

(a) it shall be selected within the variety to which it belongs, in respect of some special intravarietal phenotypic traits and its phytosanitary status that give the selected clone a better performance, in accordance with internationally accepted methods, and, in the case of vine, on the basis of methods prescribed by the International Organisation of Vine and Wine;

(b) it shall be true to the identity of the variety to which it belongs, and this shall be ensured through the observation of the phenotypic characteristics and, where appropriate, through molecular analysis pursuant to internationally accepted standards;

(c) it shall be maintained in accordance with internationally accepted practices.

B. In order to be included in the list referred to in Article 52(1), the polyclonal material shall fulfil the following requirements:

(a) it shall be selected in a single field trial containing a representative sample of the overall genetic diversity of the variety, in accordance with a statistically valid design based on internationally accepted methods, and, in the case of vine, based on methods prescribed by the International Organisation of Vine and Wine;

(b) in the case of vine, it shall be composed of 7 to 20 distinct genotypes;

(c) each genotype of its polyclonal material shall be true to the identity of the variety to which they belong, and this shall be ensured through the observation of the phenotypic characteristics and, where appropriate, through molecular analysis pursuant to internationally accepted standards;

(d) it shall be maintained in accordance with internationally accepted practices.

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