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From:	General Secretariat of the Council
To:	Delegations
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Subject:	Proposal for 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, 2017/625 and 2018/848 of the European Parliament and of the Council, and repealing Council Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 2002/53/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90/EC (Regulation on plant reproductive material) *- Mandate for negotiations with the European Parliament*

Delegations will find in the annex the mandate for negotiations with the European Parliament as approved by the Permanent Representatives Committee (Part 1) on 10 December 2025.

The changes compared to the Commission proposal are marked with ***bold and italics*** for added text and ~~strikethrough~~ for deleted text, with the exception of Annex I, where additions to the Latin names of species are marked with **bold and underline**.

ANNEX

Draft

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the production and marketing of plant reproductive material in the Union, amending Regulations (EU) 2016/2031, *and (EU)* 2017/625~~ and 2018/848~~ of the European Parliament and of the Council, and repealing Council Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 2002/53/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90/EC (Regulation on plant reproductive material)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the European Commission,[1]

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

Having regard to the opinion of the European Economic and Social Committee[2],

Having regard to the opinion of the Committee of the Regions[3],

Acting in accordance with the ordinary legislative procedure,

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[1] ***COM/2023/414 final***
[2] ***OJ C, C/2024/1583, 5.3.2024***
[3] ***OJ C, C/2024/3674, 26.6.2024***

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

(2) The impact assessments carried out by the Commission in 2013 and 2023 confirmed that those Directives have had a significant impact on the free movement, availability and high quality of PRM on the Union market and have thus facilitated the trade of PRM within the Union.

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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).

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

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

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

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

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

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

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

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

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

(3) However, the rules on production and marketing of PRM need to be adapted to the scientific and technical developments in the areas of agricultural ~~and~~***,*** horticultural***, fruit and vine*** production ~~techniques~~ and plant breeding. Moreover, the legislation needs to be updated on the basis of changes in international standards and experience gained by the application of the PRM Directives. Those rules need to be clarified in order to facilitate a more harmonised implementation. Therefore, the PRM marketing Directives should be replaced by a single Regulation on the production and marketing of PRM within the Union.

(4) PRM constitutes the starting material for plant production in the Union. Therefore, it is critical for the production of raw material for food and feed purposes and for the efficient use of plant resources. It contributes to environmental protection and the quality of the food chain and food supply in the Union as a whole. In this regard, the availability, ***high*** quality and diversity of PRM appears to be of ~~outmost~~***utmost*** importance to achieve the transition to sustainable food systems called for in the Farm to Fork Strategy[14], agriculture, horticulture, environmental protection, climate change mitigation and adaptation, food and feed security, and the economy in general.

(5) In order to achieve this transition to sustainable food systems, the Union legislation should therefore take account of the need to ensure the adaptability of the PRM production to the changing agricultural~~, horticultural~~ and environmental conditions, to face the challenges of climate change, to protect ~~and~~***,*** restore ***and promote*** biodiversity***, to ensure food security*** and to meet ~~increasing~~ farmers' and consumers' ***increasing*** expectations related to quality and sustainability of PRM.

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

(6) The scope of this Regulation should only cover the PRM of certain genera and species of increased economic and social importance. That importance should be assessed depending on whether ***the PRM or the crop of*** such genera and species represent a significant area of production and value in the Union, on their role for the security of food and feed production in the Union, and on whether they are marketed in at least two Member States. That area of production and value may concern several technical aspects. Depending on the circumstances, it may be calculated on the basis of factors such as the total size of productive land in several different areas of the Union, the marketing value of PRM in relation to specific sectors, or the demands for those species by farmers, final users and industry.

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

~~(8) Furthermore, some varieties may have certain characteristics that, when cultivated under certain conditions, could have undesirable agronomic effects that would undermine the objective of the Regulation to contribute to the sustainability of agricultural production. This objective can only be achieved if such varieties are subject to appropriate cultivation conditions under which those undesirable agronomic effects are avoided. Those conditions should apply to the cultivation of those varieties for the production of food, feed or industrial materials and not only when intended for the production and marketing of PRM. Therefore, this Regulation should cover the conditions under which those varieties are cultivated, also for the production of food, feed or other products.~~

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

(10) This Regulation should not cover forest reproductive material due to its particular characteristics, and very different concepts and applicable terminology. For this reason, forest reproductive material is subject to a separate legal act, and namely Regulation (EU) .../… of the European Parliament and of the Council[15] +.

(11) This Regulation should not cover ~~propagating material of~~***PRM intended for*** ornamental ~~plants,~~***purposes*** because after consultations with Member States and stakeholders it has been concluded that Council Directive 98/56/EC ([16]) still adequately covers the needs of that sector. ***However, seed intended for turf grass purposes are within the scope of this Regulation.***

(12) This Regulation should cover neither PRM ~~exported~~***intended for export*** to third countries, nor PRM used solely for ~~official~~***inspection, sampling or*** testing, ***officially or under official supervision,*** breeding~~, inspections~~, exhibitions or scientific purposes. This is because such categories of PRM do not require particular harmonised identity or quality standards and do not compromise the identity and quality of other PRM marketed in the Union.

(13) This Regulation should not cover PRM ~~sold or~~ transferred in any ~~other~~ way, whether free of charge or not, between ~~any persons~~***non-professional users*** for their own private use and outside their ~~trade~~***professional activities***. It would be disproportionate to set out rules for such use of PRM, as this kind of transfer is usually limited to very small amounts, has no commercial purposes and is restricted to private activities.

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

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[15] Regulation (EU) .../… of the European Parliament and of the Council …. (OJ…., p….). + OJ: Please insert in the text the number of the Regulation contained in document (… (COD)) and insert the number, date, title and OJ reference of that Regulation in the footnote.

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

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

(13c) This Regulation should not cover PRM used by gene banks for the conservation of plant genetic resources.

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

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

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

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

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

(~~28~~***16a***) The PRM marketing Directives and international practice and standards require that ~~seeds~~***PRM*** belonging to certain species***, vine rootstocks and selected clones*** are only produced and marketed as pre-basic, basic or certified ~~seeds~~***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 ~~seeds~~***species, vine rootstocks and selected clones*** should only be produced and marketed ~~as~~***in the*** pre-basic, basic or certified ~~seeds~~***categories***, if the costs for their production and marketing are proportionate to the purpose of ensuring quality ~~seed~~***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 ~~seed~~***PRM***, in line with the requirements for pre-basic, basic and certified ~~seed~~***PRM***. A list of those species of ~~seeds for~~***PRM*** which ~~seed~~ may only be produced and marketed ~~as~~***in the*** pre-basic, basic or certified ~~seeds~~***categories*** should thus be established ***and amended as necessary***.

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

(17a) 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.

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

(18) ~~In accordance with those standards,~~ Compliance of PRM with the requirements for the categories pre-basic, basic or certified should be confirmed by inspections, sampling, testing and official control plot testing carried out by the competent authorities ('official certification') ***or as applicable by the professional operator under official supervision*** and should be attested by an official label.

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

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

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

(20) Professional operators ~~should~~***may*** be authorised by the competent authority to perform ***certain*** certification ***activities*** under official supervision of PRM belonging to certain species and categories ***including printing and affixing***~~and print~~ the official label. Rules should be set out for the respective official supervision by the competent authority and the withdrawal of that authorisation or its modification. Those rules are necessary to ensure that the entire certification system functions effectively.

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

(21) In order to ensure the~~ maximum possible~~ purity and homogeneity of PRM, PRM should be kept in separate lots, and separate from other material different to PRM, such as grain for food or feed.

(22) In view of the large diversity of PRM, professional operators should~~ be able to~~ market the PRM lots in the form of individual plants, packages, bundles or containers, or in bulk. ***Rules should be set out for the packaging, bundling and sealing of PRM.***

(23) 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~~ concerning pre-basic, basic, certified and standard seed and material~~.

(24) In the case of pre-basic, basic and certified seed and material, an official label should be issued by the competent authority, while for standard seed or material an operator's label should be issued. This is necessary to make a distinction between PRM subject to certification (official certification or certification under official supervision) and PRM produced under the responsibility of the professional operator. Issuing of a specific label aims at facilitating informed choices by the professional operators and consumers who may wish to select PRM of different standards. ~~It~~***This*** would also facilitate the work of the competent authorities in ~~designing their~~***carrying out*** official controls ~~in accordance~~***to verify compliance*** with the respective requirements of each category.

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

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

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

(29) ~~Seeds are~~***Seed is*** frequently marketed in varietal mixtures of same species or species mixtures. ~~However seeds~~***Seed*** of genera or species, covered by this Regulation, should be allowed to be produced and marketed in mixtures only with ~~seeds~~***seed*** of the genera or species covered by this Regulation~~. This is necessary to ensure that the respective production and marketing standards are respected~~. However, Member States should have the possibility to allow the production and marketing of a mixture of ~~seeds~~***seed*** covered by this Regulation, with ~~seeds~~***seed*** not belonging to genera or species covered by this Regulation, ~~for the purposes of conservation of genetic resources and preservation~~***without prejudice to Regulation (EU) No 1143/2014 on the prevention and management*** of the ~~natural environment. This is is because those~~***introduction and spread of invasive alien*** species~~ are the ones most appropriate for the purpose of that preservation. Rules should be set out concerning those mixtures to ensure their identity and quality.~~

(29a) If mixtures are produced for the purposes of conservation of genetic resources and preservation of the natural environment, specific rules should be set out to ensure the quality and traceability of those mixtures. These mixtures contain seed from wild types of species and genera covered by this Regulation. This seed should not belong to a variety. These mixtures should be marketed only in the region of origin of the component species. This is because those species are the ones most appropriate for the purpose of that preservation.

(32) Certain types of varieties~~ do not fulfil the established requirements concerning distinctness, uniformity and stability. However, they~~ are important for the conservation and sustainable use of plant genetic resources ***which are crucial for crop genetic diversity and essential for adaptation to environmental changes. They can be conservation varieties which***~~.~~ ~~They~~ are traditionally grown ***varieties of all crop types or they can be local***~~or new locally produced~~ varieties ~~under specific~~***of fruit plants or vegetable plants adapted to*** local ***agro-climatic*** conditions and ~~adapted to those conditions. They are~~***farming systems. They can be*** characterised, in particular, by reduced uniformity due to a ~~high~~***certain*** level of genetic and phenotypical diversity between individual reproductive units~~. Those varieties are referred to as 'conservation varieties'~~. The production and marketing of those varieties contribute to the objectives of the International Treaty on Plant Genetic Resources for Food and Agriculture to promote the conservation and sustainable use of plant genetic resources for food and agriculture ([18]). As a party to the Treaty the Union has committed to support those objectives.

(33) In view of those special characteristics of the conservation ***varieties and local*** varieties, and by way of derogation from the established requirements for production and marketing, the production and marketing of PRM belonging to them should be allowed under less stringent requirements. That objective is in line with the principles of the European Green Deal, and in particular, with the principle of protection of the biodiversity. It is thus appropriate to allow for that ~~material~~***PRM*** to comply with the requirements for ***the*** standard ~~material~~***category*** for the species concerned. That PRM belonging to conservation ***varieties or local*** varieties should therefore be labelled with the indication 'conservation varieties' ***or 'local varieties'***. Those varieties should also be registered***, following an adapted procedure taking into account their special characteristics***, to enable their control by the competent authorities and guarantee the informed choices for their users and the effectiveness of official controls.

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

(34) Experience from the application of the marketing Directives has shown that ~~final~~***non-professional*** users of PRM (amateur gardeners and others) are often interested in using more diverse PRM that responds to different needs, without necessarily having the same quality demands as the professional operators. It is therefore appropriate to allow, by way of derogation from certain rules, that PRM ~~may~~***of fruit and vegetable plant species*** be marketed to ~~final~~***non-professional*** users without having to comply with ~~the~~***all*** requirements for variety registration~~ and without having to comply with the certification requirements or with the requirements for standard material~~. That derogation is necessary to ensure a wider ~~variety~~***scope of varieties*** for consumer offer, while ~~respecting the general~~***meeting certain minimum*** quality requirements. ~~Moreover, for reasons of transparency and better control, rules should be set out for the packaging and labelling of PRM intended for final~~ ***Such minimum requirements are important to address the expectations of many non-professional***users ~~only. For the same reason, professional operators using this derogation for marketing to final users should notify that activity to the competent authorities~~***for a certain level of quality for their private use***.

(34a) 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 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.

(35) Many ~~gene banks,~~***non-profit*** organisations and networks operate in the Union with an objective to conserve plant genetic resources. In order to facilitate their activity, it is appropriate to allow that PRM ***intended for the conservation of plant genetic resources*** which is ***produced and*** marketed ***by those organisations and networks to natural or legal persons who carry out conservation of PRM and to farmers or non-professional users***~~to them, or among them,~~ derogates from the established production and marketing requirements, and that ***it*** instead ~~it~~ complies with less stringent rules. ***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 inform them, upon request, of the quantities produced and marketed.***

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

(36a) 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 purpose of multiplication of that PRM should be allowed, by 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 must clearly denote the PRM as being designated for this purpose.

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

(36b) According to the Directives on marketing of seed and other reproductive material, derogations from the established requirements are allowed for the marketing of PRM of varieties under registration. Those derogations have been useful and necessary for the professional operators and the competent authorities. Furthermore, farmers are facing increasingly 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.

(36c) According to the Directives on marketing of seed and other reproductive material, derogations are established for seed of certain genera and species to be marketed as commercial seed that does not meet the requirements of varietal aspects. 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 the compliance with requirements for value for sustainable cultivation and use may not be necessary while high quality of this PRM should be guaranteed. Therefore, derogation from registration requirements should be allowed. The designation 'commercial seed' should be retained from the PRM marketing Directives. Species that are added to the scope of this Regulation at a later stage and for which few varieties are developed should also benefit from this derogation in order to allow time for varieties to be developed. Furthermore, commercial seed may be necessary to ensure that seed of new species added to this Regulation can be marketed before registered varieties are available. The possibility to market commercial seed might also be of relevance in case of emergency situations when seed of registered varieties is not available.

(37) According to the ~~PRM~~***Directives on*** marketing ~~Directives~~***of seed and other reproductive material***, derogations from the established requirements are allowed for ~~the marketing of PRM belonging to not yet registered varieties; of varieties that have not yet been fully tested; of~~ seed not complying with the applicable requirements to be made rapidly available on the market; ~~of~~ seed not yet finally certified; ~~of~~ PRM to be temporarily authorised to address temporary difficulties in the supply; and ~~of~~ PRM for the conduct of temporary experiments to seek improved alternatives to certain provisions of the applicable legislation concerning the requirements for the PRM to belong to a registered variety and to fulfil certain identity and quality requirements. Those derogations have been useful and necessary for the professional operators and the competent authorities, without creating problems for the internal market of PRM. Therefore, they should be maintained. Conditions should be set out concerning those derogations, to ensure that they are not misused and that they do not affect adversely the internal market of PRM.

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

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

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

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

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

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

(41) In order to ensure transparency and more effective controls on the production and marketing of PRM, professional operators should be ~~registered~~***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 ~~they~~***the registration of professional operators should be in the*** register ~~in the registers~~***already*** established by Member States pursuant to Regulation (EU) 2016/2031 of the European Parliament and of the Council ([20]), in order to reduce the administrative burden for those professional operators. This is also proportionate because the vast majority of professional operators producing and marketing PRM are already registered in the professional operators' registers of that Regulation.

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

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

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

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

(43) Experience has shown that ***it is essential to control*** the ~~reliability and~~ quality of the marketed PRM ~~can be jeopardised where it is impossible to trace material not complying~~***to verify that the PRM on the market complies*** with the applicable ~~standards~~***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. However, such record keeping is not appropriate for marketing in retail.

(44) It is important to ensure that, as a general rule, all PRM of the genera and species within the scope of this Regulation are subject to the registration of the variety to which that PRM belongs, the description of the variety and the corresponding rules.

(45) ~~Varieties should be registered in~~***All Member States shall establish*** a national variety register***, containing at least all registered varieties and varieties for which an application for registration has been submitted***, to ensure informed choices by their users and more effective official controls.

(46) The national variety register should include two types of varieties: varieties registered on the basis of an official description, if they fulfil the requirements of distinctness, uniformity and stability ('DUS'), and varieties registered on the basis of an officially recognised description in the case of conservation ***or local*** varieties. The existence of those two different descriptions is necessary to separate ~~the two categories~~***these two types*** of varieties~~, whereby~~***.*** The first one ~~is~~***should be*** based on ~~DUS testing results~~***technical examinations***, while the other one ~~is~~***should be*** based on ~~historical data concerning the use of the variety and~~ practical experience ***and information concerning the use or breeding of the variety***. In addition, such approach can offer the necessary information about the characteristics of the varieties and their identity.

(47) The registered varieties should be further notified by the competent authorities via ~~the EU Plant Variety~~***an electronic*** portal to the Union variety register, to ensure an overview of all varieties allowed for marketing in the Union.

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

(48) Herbicide tolerant varieties are varieties that have been bred to be intentionally tolerant to herbicides, in order to be cultivated in combination ~~of~~***with*** the use of those herbicides. If such cultivation is not done under appropriate conditions, it may lead to development of weeds resistant to those herbicides, spread of such resistance genes in the environment or to the need to increase ~~of~~***the*** quantities of herbicides applied. As this Regulation aims to contribute to the sustainability of agricultural production, the competent authorities of Member States responsible for the registration of varieties ~~should~~***and the Member States where the varieties are to be cultivated may*** be able to subject the cultivation of those varieties in their territory to cultivation conditions appropriate for avoiding those undesirable effects. ~~Moreover, where varieties have particular characteristics, other than tolerance to herbicides, that could have undesirable agronomic effects, they should also be subject to cultivation conditions, in order to address those agronomic effects. Those conditions should apply to the cultivation of those varieties for any purpose, including food, feed and other products, and not only for purposes of production and marketing of PRM. This is necessary to achieve the objectives of this Regulation to contribute to sustainable agricultural production beyond the stage of production and marketing of PRM.~~

(49) In order to contribute to the sustainability of agricultural production and serve economic, environmental and broader societal needs, ***the value for sustainable cultivation and use (VSCU) of*** new varieties of ~~all~~ genera or species ***of vine, potato and of agricultural plants, except for varieties used exclusively for turf grass purposes, should be assessed in a technical examination. 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***~~. Among those~~ aspects ~~are their~~***to be assessed may be*** yield, including yield stability and yield under low input conditions; tolerance/resistance to biotic stresses, including plant diseases caused by nematodes, fungi, bacteria, viruses, insects and other pests; tolerance/resistance to abiotic stresses, including adaptation to climate change conditions; more efficient use of natural resources, such as water and nutrients; reduced need for external inputs, such as plant protection products and fertilisers; characteristics that enhance the sustainability of storage, processing and distribution; ~~and~~ quality or nutritional characteristics ~~('value for sustainable cultivation and use')~~***; 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.

(50) As organic varieties suitable for organic production as defined in Article 3 of Regulation (EU) 2018/848 are characterised by a high level of genetic and phenotypical diversity between individual reproductive units, it ~~is~~***might be*** appropriate that their registration is subject to adjusted ***requirements of*** DUS, and in particular as regards the requirements concerning uniformity. Furthermore, in order for ~~that such~~***these*** varieties to be ~~better~~***more effectively*** adapted to the specific needs of organic production, their examination of the value for sustainable cultivation and use should be conducted under organic conditions.

(51) For reasons of efficiency and reduction of the administrative burden, varieties that have been granted a plant variety right pursuant to Article 62 of Regulation (EC) No 2100/94, or pursuant to the legislation of a Member State, should be deemed to be distinct, uniform and stable and to have a suitable denomination for the purposes of this Regulation***, where the DUS examination was carried out by an examination office that has been found suitable by the Community Plant Variety Office (CPVO)***.

(51a) The registered variety shall have a suitable denomination to ensure the unique identification of the variety. That denomination should not cause confusion as to the identification of the variety or be misleading or cause offence in any way. In case of conservation varieties synonyms may be used as this is common practice for this type of variety. The synonyms should be indicated in the national variety register.

(52) The procedure of variety registration should be precisely defined, in order to ensure legal certainty for the applicants and the competent authorities, and a level playing field for all applicants. For this reason, rules should be set out concerning the submission, content, formal examination and date of submission of the applications, technical examinations, ~~audit of the competent authority's premises and organisation, additional rules on~~***examination offices carrying out*** technical ~~examination~~***examinations***, confidentiality, ~~provisional~~ examination report and ~~provisional~~ official description, examination ~~report and final official description~~***of conservation and local varieties***, examination of the denomination of a variety and decision on the registration of a variety in the national variety register.

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

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

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

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

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

(56c) For the same reason, varieties of species listed in an official national variety register 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, should be registered in accordance with this Regulation without applying the new registration procedure.

(57) The period of ~~the~~ registration of a variety should be 10 years, so as to encourage innovation in the breeding sector, and the removal from the market of old varieties and their replacement by new ones. However, that period should be 30 years for ***conservation and local varieties, due to the 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 vine, due to the longer time required for the completion of the productive cycle of those genera or species.

(58) ~~Upon a request of any interested~~***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 ~~should be subject to renewal~~, in order to allow for the continuation of marketing of certain varieties if a need is established and they still fulfil applicable requirements. ***Rules should also be established on the termination of the registration, including cases where no application for renewal has been submitted or where the conditions for registration are no longer fulfilled.***

(59) Rules should be set out concerning variety maintenance in accordance with accepted practices. This is necessary to ensure the varietal identity during the period of its registration, which can only be ensured if the maintenance of the respective variety is carried out by the applicant, or other ***natural or legal*** persons ~~notified by the applicant to the competent authority~~***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.

(60) Rules should be set out concerning the content of the national variety registers and the Union variety register, and the keeping of ***seed*** samples ***or living plants*** of the registered varieties (~~'official sample' or~~ 'standard sample') which is a living description of the variety. This is important to ensure accessibility to the necessary information on the variety, its identification during the period of its registration and the availability of standard samples for control plot testing in the context of PRM certification.

(60a) Member States should be required to submit to the Commission on a regular basis specified information including in particular the 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 purpose.

(60b) 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.

(60c) It should be possible for Member States to collect fees for their acts performed in relation to this Regulation. Those fees should be set in order to cover the costs of the competent authority for performing the activity.

(61) The PRM marketing Directives should be repealed, as this Regulation replaces them. As a consequence, Regulation (EU) 2016/2031 should be amended to remove references to those Directives and to ensure that ~~Regulated Non-Quarantine Pests (~~'RNQPs'~~)~~ are exclusively regulated by that Regulation ***and that all types of PRM are covered***.

(62) Regulation (EU) 2017/625 of the European Parliament and of the Council[21] should be amended to include in its scope the production and marketing of PRM in line with this Regulation. This is important in order to guarantee a uniform approach as regards official controls for the entire plant production and food chain, since Regulation (EU) 2017/625 also applies to the scope of Regulation (EU) 2016/2031, and Regulation (EU) 2018/848 of the European Parliament and of the Council[22].

(63) In this respect, the Commission should be empowered to adopt specific rules on official controls and on actions taken by the competent authorities in relation to PRM, in particular for laying down rules for the performance of official controls on PRM for verifying compliance with Union rules, for the import into, and marketing within, the Union of PRM, and on the activities of operators during the production of PRM.

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

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

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

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

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

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

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

(66a) In order to confirm the compliance of professional operators with the conditions to carry out certain activities regarding certification under official supervision, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of specific actions to be taken by the competent authorities.

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

(66c) In order to ensure harmonised rules on the production and marketing of preservation mixtures, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of further requirements for such mixtures concerning the designation of the region of origin, the use of certain species, the 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 mixtures.

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

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

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

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

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

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

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

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

(71) In order to ~~adapt the rules on~~***set out specific criteria concerning the suitability of a*** variety denomination~~ to the technical and scientific developments, and follow up on the experience gained from the application of those rules~~, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of ~~supplementing this Regulation by setting out specific criteria concerning~~***the 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 ~~variety~~***a denomination, the use of codes, the definition of closely related species and the determination of misleading, offensive or confusing*** denominations.

~~(72) In order to adapt the provisions of this Regulation concerning technical examinations of varieties to the technical and scientific developments and the practical needs of competent authorities and professional operators, and follow up on the experience gained from the application of the respective rules, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of supplementing this Regulation by setting out the rules concerning the audit of the premises of professional operators to carry out technical examinations for the satisfactory value for sustainable cultivation and use.~~

(74) It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-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.

(75) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[24].

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

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

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

[24] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers, ***ELI:*** OJ L 55, 28.2.2011, p. 13~~–18~~***, ELI: http://data.europa.eu/eli/reg/2011/182/oj.***

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

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

(78) In order to ensure uniform conditions for the implementation of this Regulation ***concerning PRM in packages, bundles or containers and as individual plants***~~, follow up on the practical experience gained by the application of its provisions, and improve the integrity of the marketed PRM~~, implementing powers should be conferred to the Commission for adopting specific requirements concerning the sealing, ~~fastening,~~ size and form of packages, bundles and containers of specific species of PRM ***, as well as conditions for the marketing of seed in bulk without sealing or packaging***.

(79) In order to ensure uniform conditions for the implementation of this Regulation, and in particular concerning the legibility, recognisability and security of labels, implementing powers should be conferred to the Commission for adopting specific provisions concerning the official labels, ***operator's labels,*** labels used for certain derogations and, labels used for some specific types of PRM~~, and set~~ ***and setting*** out the content, size, colour~~ and form~~***, form and, in the case of imported PRM, language*** of those labels for the respective categories or types of PRM.

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

(80a) In order to ensure uniform conditions for the implementation of this Regulation concerning specific requirements on packaging and sealing of preservation mixtures, implementing powers should be conferred to the Commission for adopting those requirements.

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

(82) In order to ensure uniform conditions for the implementation of this Regulation ~~and to address urgent~~***in relation to addressing temporary*** supply difficulties of PRM, implementing powers should be conferred to the Commission for authorising, ~~in the case of temporary difficulties in the supply of PRM,~~ for a maximum period of ~~1 year~~***18 months***, the marketing of ~~PRM~~***seed or material*** of the categories ~~of~~ pre-basic, basic~~ or~~***,*** certified ~~material or seed~~***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.

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

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

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

(85) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred to the Commission for deciding on the organisation of temporary experiments to seek improved alternatives to the scope and certain provisions of this Regulation.

(86) In order to ensure uniform conditions for the implementation of this Regulation with regard to the import of PRM, and ensure compliance of the third country requirements with the~~ equivalent~~ Union requirements, implementing powers should be conferred to the Commission with respect to recognising whether PRM of specific genera, species or categories produced in a third country, or particular areas of a third country, fulfils requirements equivalent to those applicable to PRM produced and marketed in the Union, in order to be imported.

(87) In order to ensure uniform conditions for the implementation of this Regulation and to ensure appropriate maintenance of the registered varieties in third countries too, implementing powers should be conferred to the Commission with respect to recognising that the controls on variety maintenance carried out in the third country afford the same guarantees as those set out in the Union.

(88) In order to ensure uniform conditions for the implementation of this Regulation, ~~and to adapt its provisions to the evolving~~***taking into account the protocols established by the CPVO, the*** applicable ~~protocols~~***guidelines*** of the International Union for the Protection of new Varieties of Plants (UPOV) or ~~protocols established by the CPVO, and the~~***other*** relevant ~~technical and scientific developments~~***national protocols***, implementing powers should be conferred to the Commission for adopting specific requirements concerning distinctness, uniformity and stability per genera or species of varieties***, including requirements for organic varieties suitable for organic production, and the characteristics and information that the officially recognised description of the variety is to cover in case of conservation varieties or local varieties***.

(88a) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred to the Commission for specifying the elements of suitability of variety denominations laid down in this Regulation, taking into account any applicable international standards, as well as the relevant guidelines on variety denominations developed by the CPVO.

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

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

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

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

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

HAVE ADOPTED THIS REGULATION:

CHAPTER I
GENERAL PROVISIONS

Article 1

Subject matter

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

~~This Regulation also lays down rules concerning the conditions of cultivation of certain varieties that could have undesirable agronomic effects, including the cultivation for purposes beyond the production and marketing of PRM, for the production of food, feed and other products.~~

Article 2

Scope and objectives

1. This Regulation applies ***to PRM belonging*** to the genera and species listed for the respective uses referred to in ~~Parts A to E of~~ Annex I***, as well as to their hybrids***.

   ~~Its requirements concern, respectively, all types of PRM, only seeds, or only material~~ ***It also applies to rootstocks and other parts of plants of genera or species*** other than ~~seeds~~***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***.

   The requirements concerning production of PRM shall apply only to production with a view to its marketing ***in the Union***.

2. The objectives of this Regulation are the following:

   (a) to ensure quality and diversity of choice ~~for~~***of*** PRM, and its availability ~~for professional operators and final~~***to all*** users;

   (b) to ensure ~~a~~ equal conditions for the competition of the professional operators across the Union and the functioning of the internal market in PRM;

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

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

   (e) to contribute to sustainable agricultural production, adapted to current and future projected climatic conditions;

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

3. The Commission is empowered in accordance with Article 75 to adopt delegated acts, ~~amend~~***amending*** Annex I, in order to adapt ~~it~~***that Annex*** to the developments of technical and scientific knowledge, and the economic data concerning production and marketing of genera and species, by adding genera and species to or removing them from ~~the list~~ that Annex ***for one or more uses***.

The delegated ~~act~~***acts*** referred to in the first subparagraph ~~shall~~***may*** add genera or species to the list in Annex I if they fulfil at least two of the following ~~elements~~***criteria with regard to their respective uses***:

(a) represent a significant area of production of PRM ***or the respective crop,*** and a significant value of marketed PRM ***or the respective crop*** in the Union***;***

(b) are 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) ~~are~~***the PRM is*** marketed in at least two Member States.

The delegated ~~act~~***acts*** referred to in the first subparagraph ~~shall~~***may*** remove genera or species from the list in Annex I if they no longer fulfil at least two of the ~~elements~~***criteria*** set out in the second subparagraph.

Those delegated acts shall specify the criteria used to define the extent of the significant area and value or the substantial importance, in relation to the genera and species concerned.

4. This Regulation does not apply to:

(a) ~~propagating material of~~***PRM of species listed in Annex I, intended for*** ornamental ~~plants as defined in Article 2 of~~***purposes in accordance with*** Directive 98/56/EC***, with the exception of seed intended for turf grass use***;

(b) forest reproductive material ~~as defined in Article 3 of~~***(FRM) subject to*** Regulation (EU) .../… of the European Parliament and of the Council[25]+;

(c) PRM ~~produced~~***solely intended*** for export to third countries***, under the condition that it is identified as such***;

[25] Regulation (EU) .../… of the European Parliament and of the Council …. (OJ…., p….).
+ OJ: Please insert in the text the number of the Regulation contained in document (… (COD)) and insert the number, date, title and OJ reference of that Regulation in the footnote.

(d) PRM ~~sold or~~ transferred in any way, whether free of charge or not, between ~~final~~***non-professional*** users for their own private use and outside their ~~commercial~~***professional*** activities;

(e) PRM used solely for ~~official~~***inspection, sampling, or*** testing, ***officially or under official supervision,*** breeding~~, inspections~~, exhibitions or scientific purposes~~.~~***, under the condition that it is identified as such;***

(f) PRM transferred in any way, not aimed at its commercial exploitation but subject to service contracts for the purposes of processing including cleaning, disinfection, treatment, packaging, as well as transport, or storage, provided that the provider of services does not acquire title to that PRM and its traceability is ensured;

(g) PRM supplied under certain conditions to providers of services for the production of certain agricultural raw materials, intended for industrial purposes, or PRM produced for that purpose, provided that:

(i) the provider of services does not acquire title to either that PRM or the product of the harvest;

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

(iii) the supplier of that PRM has provided the competent authority with a copy of the relevant parts of the contract made with the provider of services including the standards and conditions met by the PRM provided;

(h) PRM used by gene banks for the conservation of plant genetic resources;

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

Article 3

Definitions

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

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

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

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

(2) ‘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) maintenance of varieties ***pursuant to Article 72***;

~~(d) provision of services for identity and quality;~~

(e) ~~preservation~~***field inspections, sampling, laboratory testing***, storage~~, drying~~, processing~~, treating~~, packaging, sealing, ***or*** labelling~~, sampling or testing~~;

(3) ‘marketing’ means the following actions ~~conducted by a professional operator~~***in relation to PRM***: sale, holding ***with a view to sale***, transfer for free, or offering for sale ***including online,*** or any other ~~way of transferring~~***transfer*** or distribution within, or import into, the Union***;***

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

(5) ‘clone’ means an individual plant progeny, originally derived from another single plant by vegetative reproduction, remaining genetically identical to that plant;

(6) ‘selected clone’ means a clone~~ that has been selected and chosen for some special intravarietal phenotypic traits and its phytosanitary status that give the selected clone a better performance~~***, which is the vegetative progeny of a single plant***, is true to the description of ~~the~~***a certain*** variety ~~to which it belongs and, in the case of selected clones not belonging to a variety, it is true to the description of the species to which it belongs~~***and chosen for its phenotypic characteristics and its phytosanitary status***;

(7) ‘Polyclonal~~ plant reproductive~~ material’ means a group of several ~~distinct~~ individual plant progenies***, other than mixtures of selected clones,*** derived from different genotypes~~, each of which is true to the description~~ of the ***same*** variety~~ to which it belongs~~***, containing intra-varietal diversity between the individual plants, selected as a group by the performance of polyclonal selection methods based on recommendations of international standards***;

~~(8) ‘multiclonal mixture’ means a mixture of selected clones, all belonging to the same variety or species, as appropriate, whereby each of them has been obtained through independent selection;~~

(9) ‘competent ~~authoritiy~~***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 that responsibility has been conferred in accordance with Union law;

(10) ‘official description’ means a description ***of a variety*** that has been established by a competent authority, ***which*** includes the relevant characteristics of the variety and makes the variety identifiable as a result of the examination on its distinctness, uniformity and stability;

(11) ‘officially recognised description’ means a written description of a conservation variety ***or local variety, in accordance with Article 47(1)(a)(ii) that is***~~, which has been~~ recognised by a competent authority~~, includes the specific characteristics of the variety, and has been obtained by other means than the examination of its distinctness, uniformity and stability~~;

(12) ‘variety maintenance’ means the actions taken for ~~controlling~~***ensuring*** varietal purity and ***varietal*** identity with the aim to ensure that ~~a~~***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***~~in accordance with its description over subsequent cycles of reproduction~~;

(13) ‘~~seeds~~***seed***’ means ~~seeds~~***seed*** in the botanical sense;

(14) ‘pre-basic seed’ means seed that belongs to ~~a generation~~***generations*** preceeding the generation of the basic seed, is intended for the production ~~and certification~~ 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 ~~Part A of~~ Annex II;

(15) ‘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 which has been found by means of official certification, or certification under official supervision, to satisfy the respective conditions laid down in ~~Part A of~~ Annex II;

(16) ‘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 which has been found by means of official certification, or certification under official supervision, to satisfy the respective conditions laid down in ~~Part A of~~ Annex II;

(17) ‘standard seed’ means seed, other than pre-basic, basic or certified seed~~, that is not intended for further multiplication, and~~ ***that*** satisfies the respective conditions laid down in ~~Part A of~~ Annex III;

(17a) ‘mother plant’ means an identified plant intended for the production of PRM;

(17b) ‘pre-basic mother plant’ means a mother plant intended for the production of seed or material of the pre-basic category or lower categories;

(17c) ***'basic mother plant' means a mother plant intended for the production of seed or material of the basic category or lower categories;***

(17d) ***'certified mother plant' means a mother plant intended for the production of seed or material of the certified category or lower categories;***

(17e) ***'standard mother plant' means a mother plant intended for the production of standard material;***

(18) 'pre-basic material' means PRM, other than ~~seeds~~***seed***, that belongs to ~~a generation~~***generations*** preceeding the generation of basic material, is intended for the production ~~and certification~~ 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 ~~Part B of~~ Annex II;

(19) '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 ~~and certification~~ 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 ~~Part B of~~ Annex II;

(20) '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 ~~Part B of~~ Annex II;

(21) 'standard material' means PRM other than seed, and other than pre-basic, basic or certified material, that ~~is not intended for further multiplication, and~~ satisfies the respective conditions laid down in ~~Part B of~~ Annex III;

(22) ‘official certification’ means official attestation by the competent authority of the compliance of pre-basic, basic or certified seed or material with the respective requirements of this Regulation, where all relevant inspections~~ on site~~, sampling and testing***,*** including where appropriate control plot testing***,*** have been carried out by that authority~~, and if it has concluded that the seed or material concerned meets those requirements~~;

(23) ‘certification under official supervision’ means attestation by ~~a specifically~~***an*** authorised professional operator that pre-basic, basic or certified seed or material complies with the ~~applicable~~***respective*** requirements, and where at least one~~ or more~~ of the relevant inspections, sampling, testing or label printing ~~have~~***and affixing has*** been carried out by that professional operator, under the official supervision of the competent authority~~, and if it has concluded that the seed or material concerned meets those requirements~~;

(24) ‘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 by complying with specific identity and quality requirements;

(25) ‘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 ([26]), excluding organisms obtained through the techniques of genetic modification listed in Annex I B to Directive 2001/18/EC;

(25a) ‘NGT plant’ means NGT plant as defined in Article 3(3) of Regulation (EU) (…);

(26) ‘lot’ means a ~~unit~~***defined quantity*** of PRM, identifiable by its ~~homogeneity of composition and origin~~***homogeneous constituents***;

~~(27) ‘heterogeneous material’ means a plant grouping within a single botanical taxon of the lowest known rank which:~~

~~(a) presents common phenotypic characteristics;~~

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[26] ***[1]*** 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, 17.4.2011, p. 1).

~~(b) is characterised by a high level of genetic and phenotypic diversity between individual reproductive units, so that that plant grouping is represented by the material as a whole, and not by a small number of units;~~

~~(c) is not a variety; and~~

~~(d) is not a mixture of varieties;~~

(28) '~~final~~***non-professional*** user' means any ***natural or legal*** person acquiring, transferring and using PRM ***for final use and*** for purposes which are outside that person's professional activities;

(29) 'conservation variety' means a variety that is~~:~~ ***traditionally grown under specific local conditions in a certain region of the Union ('region of origin'), and adapted to those conditions, and may be characterised by reduced uniformity due to a certain level of genetic and phenotypical diversity between individual reproductive units, except in the case of vegetatively propagated varieties;***

~~(a) traditionally grown or locally newly bred under specific local conditions in the Union, and adapted to those conditions; and~~

~~(b) characterised by a high level of genetic and phenotypical diversity between individual reproductive units;~~

(29a) 'local variety' means a variety of fruit plant or vegetable plant species listed in Annex I that is:

(a) newly or recently locally bred in a certain region of the Union ('region of origin');

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

(c) characterised by reduced uniformity due to a certain level of genetic and phenotypic diversity between individual reproductive units, except in the case of vegetatively propagated varieties;

(30) ‘quality pests’ means pests fulfilling all of the following ***criteria***:

(a) they are ~~not~~***neither*** Union quarantine pests, protected zone quarantine pests, ~~or~~***nor*** regulated non-quarantine pests (‘RNQPs’) within the meaning of Regulation (EU) 2016/2031, nor pests subject to the measures adopted pursuant to Article 30(1) of that Regulation;

(b) they occur during PRM production or ~~storage~~***post-harvest***; and

(c) their presence has 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 ~~completely free from pests, or a situation where the presence of~~***that the extent to which*** quality pests ***are present*** on~~ the respective~~ PRM is ~~so low that those pests do not affect adversely the~~***sufficiently low to ensure acceptable*** quality ***and usefulness*** of that PRM;

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

(32a) ‘true potato seed’ means seed of Solanum tuberosum L.;

(33) ‘farmer’ means ~~farmer as defined in Article 3(1) of Regulation (EU) 2021/2115 of the European Parliament and of the Council~~ ~~[27]~~***any natural or legal person who exercises an agricultural activity professionally***;

~~[27] Regulation (EU) 2021/2115 of the European Parliament and of the Council of 2 December 2021 establishing rules on support for strategic plans to be drawn up by Member States under the common agricultural policy (CAP Strategic Plans) and financed by the European Agricultural Guarantee Fund (EAGF) and by the European Agricultural Fund for Rural Development (EAFRD) and repealing Regulations (EU) No 1305/2013 and (EU) No 1307/2013 (OJ L 435, 6.12.2021, p. 1).~~

(34) 'off-type' means~~, in relation with seed or other plants, a seed or other PRM not corresponding to the description of~~ ***a plant that can be clearly distinguished from*** the variety~~ or species~~ to which it is supposed to belong pursuant to this Regulation ***in the expression of any relevant characteristic, taking into consideration the particular features of its propagation;***

~~(35) 'hybrid variety' means a variety produced as a result from the crossbreeding of two or more other varieties.~~

(35a) 'gene bank' means an organisation officially recognised in accordance with national rules, with an objective, set out in the organisation's articles of association or other equivalent document, of conserving plant genetic resources for the continued public availability of those resources for research and breeding;

(35b) 'seed as grown' means unprocessed seed of vegetable species, produced in a third country and imported into the Union for the purpose of being processed and marketed in accordance with this Regulation;

(36) 'standard sample' means a sample of PRM of a variety that represents that variety, and is used by the competent authority as reference to check the varietal identity, varietal purity and maintenance for the purpose of this Regulation.

Article 4

Compliance with Regulation (EU) 2016/2031

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

Any PRM~~ lot~~ produced and marketed in accordance with this Regulation, shall ~~also~~ comply with the rules set out in, or pursuant to, ~~Articles 36, 37, 40, 41, 42, 49, 53 and 54~~***the relevant provisions*** of Regulation (EU) 2016/2031 concerning Union quarantine pests, protected zone quarantine pests and RNQPs, and with the measures adopted pursuant to Article 30(1) of that Regulation.

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

Belonging to a registered variety

1. Only PRM belonging to a variety registered in a national variety register referred to in Article 44 may be produced and marketed within the Union~~, except the following cases:~~**.**

1a. ***By way of derogation from paragraph 1, PRM of the following cases may be produced and marketed within the Union without belonging to a variety registered in accordance with Article 44:***

(a) as rootstocks ***for fruit plants and vine which do not belong to any variety, provided that the material is***~~, if~~ produced and marketed with a reference, contained in an appropriate labelling, to the species to which they belong;

~~(b) as heterogeneous material in accordance with Article 27.~~

(c) as PRM ~~marketed to final~~***intended for non-professional*** users in accordance with Article 28;

(d) as PRM produced and marketed ***by organisations and networks*** for the~~ purposes of~~ conservation of ***plant*** genetic resources in accordance with Article 29;

(e) as seed exchanged in kind between farmers in accordance with Article 30;

~~(f) as breeder's seed, in accordance with Article 31;~~

~~(g) as PRM of not yet registered varieties in accordance with Article 32;~~

(h) in the event of ~~supply~~***temporary*** difficulties ***in the supply*** of PRM in accordance with Article 33;

(ha) as PRM of parent lines of hybrid varieties for the production of final hybrid varieties;

(i) as PRM of a variety which is subject to an application for registration in accordance with the derogation set out in Article 32.

1b. By way of derogation from paragraph 1, PRM produced and marketed in the following cases shall not belong to a registered variety:

(a) as PRM for preservation mixtures in accordance with Article 22;

(b) as commercial seed in accordance with Article 32a.

Article 6

Belonging to certain categories of PRM

1. Only PRM belonging to one of the following categories may be produced and marketed within the Union~~, except in the cases provided for in paragraph 2~~:

(a) pre-basic ***seed or*** material~~ or seed~~;

(b) basic ***seed or*** material~~ or seed~~;

(c) certified ***seed or*** material~~ or seed~~;

(d) standard ***seed or*** material~~ or seed~~.

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) indicating the highest rank and point (d) the lowest one.

2. By way of derogation from paragraph 1, PRM may be produced and marketed without belonging to a category listed in ***points (a) to (d) of that paragraph***~~(a) - (d)~~ in the following cases:

~~(a) marketing of PRM of heterogeneous material in accordance with Article 27;~~

(aa) as preservation mixtures produced in accordance with Article 22;

(b) ~~marketing to a final user~~***as PRM intended for non-professional users*** in accordance ~~to~~***with*** Article 28;

(c) ~~marketing to and between~~***as PRM produced and marketed by organisations, and networks for the*** conservation ~~networks as referred to in~~***of plant genetic resources in accordance with*** Article 29;

(d) as seed exchanged in kind between farmers in accordance with Article 30;

~~(e) breeder's seed as referred to in Article 31.~~

(ea) as PRM of a generation prior to pre-basic category in accordance with Article 30a;

(f) as commercial seed in accordance with Article 32a.

*Article ~~20~~**6a***

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

1. PRM belonging to the genera or species as ~~listed in~~***indicated in column 2 of*** Annex ~~IV~~***I*** may only be produced and marketed as pre-basic, basic or certified ~~seeds~~***seed*** or material.

1a. Selected clones may only be produced and marketed as pre-basic, basic or certified material of fruit plants and vine.

1aa. Vine rootstocks may be produced and marketed only as pre-basic, basic or certified material.

2. The Commission is empowered to adopt ~~a~~ delegated ~~act~~***acts*** in accordance with Article 75 in order to amend ***column 2 of*** Annex ~~IV~~***I***.

The delegated ~~act~~***acts*** referred to in the first subparagraph shall add a genus or a species to ***column 2 of*** Annex ~~IV,~~***I*** if both ***of*** the following conditions are fulfilled:

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

(b) the costs of the certification activities, necessary to produce and market the respective ~~seed~~***PRM*** as pre-basic, basic and certified seed ***or material*** are proportionate:

(i) to the purpose of ensuring food and feed security, or ensuring high value of industrial processing; ~~and~~***or***

(ii) to the economic***, phytosanitary and environmental*** benefits deriving from the highest standards concerning identity and quality of the ~~seed~~***PRM***, resulting from the compliance with the requirements for pre-basic, basic and certified ~~seed~~***PRM*** compared to those for standard ~~seed~~***PRM***.

3. ~~That~~***The assessment of*** proportionality ***referred to in paragraph 2, point (b)*** shall be based on an overall assessment of the following elements in combination: ~~the importance of the respective genus or species for the Union food and feed security; the volume of its production in the Union; its demand by the professional operators and operators of the food/feed industry; the costs of the production of pre-basic, basic and certified seed compared to the cost of production of other seed of the same genus or species; and the economic benefits derived from the production and marketing of pre-basic, basic and certified seed compared to other seed of the same genus or species.~~

(a) the importance of the respective genus or species for the Union food and feed security;

(b) the volume of its production in the Union;

(c) its demand by the professional operators and operators of the food/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 and environmental benefits derived from the production and marketing of pre-basic, basic and certified seed or material compared to those for standard seed or material or other types of PRM of the same genus or species.

The delegated ~~act~~***acts*** referred to in ~~the first subparagraph~~***paragraph 2*** shall remove a genus or a species from ***column 2 of*** Annex ~~IV~~***I***, if one of the conditions set out in the second subparagraph, point (b), points (i) and (ii), is ~~no longer~~***not*** fulfilled.

SECTION 2

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

Article 7

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

1. Pre-basic, basic and certified seed may only be produced and marketed within the Union, if all the following conditions are fulfilled:

   (a) ~~the pre-basic, basic or certified seed~~***it*** is practically free from quality pests;

   (aa) it is marketed following official certification by the competent authorities, or certification by the professional operator under official supervision pursuant to Article 10;

   (b) it is produced and marketed~~:~~ ***in accordance with the requirements set out in Part A and Aa of Annex II, and its compliance with those requirements is attested by the official label referred to in Article 15(1).***

   ~~(i) following official certification by the competent authorities, or certification by the professional operator under official supervision;~~

   ~~(ii) in accordance with the requirements set out in Part A of Annex II, and its compliance with those requirements is attested by the official label referred to in Article 15(1).~~

2. Pre-basic, basic and certified material may only be produced and marketed within the Union, if all the following conditions are fulfilled:

   (a) ~~the pre-basic, basic or certified material~~***it*** is practically free from quality pests;

(aa) it is marketed following official certification by the competent authorities, or certification by the professional operator under official supervision pursuant to Article 10;

(b) it is produced and marketed~~:~~ ***in accordance with the requirements set out in Part B, Ba, or E of Annex II, and its compliance with those requirements is attested by the official label referred to in Article 15(1).***

~~(i) following official certification by the competent authorities, or certification by the professional operator under official supervision;~~

~~(ii) in accordance with the requirements set out in Part B of Annex II, and its compliance with those requirements is attested by the official label referred to in Article 15(1).~~

3. The Commission is empowered to adopt delegated acts in accordance with Article 75, in order to amend Annex II. Those amendments shall adapt ***that Annex*** to the ***scientific and technical*** developments ~~of~~***and applicable*** international ~~technical and scientific~~ standards***, and shall*** ~~and may~~ concern ~~the~~ requirements for ***one or more of*** the following ***elements***:

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

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

(c) marketing of ~~seeds~~***pre-basic, basic and certified seed***;

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

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

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

(g) ***production of*** pre-basic, basic and certified material of ~~clones,~~ selected clones~~,~~ ~~multiclonal mixtures~~ and polyclonal ~~PRM~~***material***;

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

(h) production of pre-basic, basic and certified material produced by ~~in vitro~~***in vitro*** propagation;

(i) marketing of pre-basic, basic and certified material produced by ~~in vitro~~***in vitro*** propagation.

4. The Commission ~~may~~***shall*** adopt implementing acts specifying the production and marketing requirements referred to in ~~Part A and Part B of~~ 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. Those requirements shall concern one or more of the following elements ***for all or certain 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~~***in vitro*** propagation;

(c) conditions for sowing or planting;

(ca) previous cropping and isolation distances;

(d) ***open*** field ***or greenhouse*** cultivation;

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

(e) harvesting and post-harvesting;

(f) germination rates, purity and content of other ~~PRM~~***species***, moisture, vigour, presence of ~~earth~~***soil*** or extraneous matter;

(g) ***methods of*** certification ~~methods~~ of PRM, including the application of bio-molecular or other technical methods, as well as their approval and use, and the listing of approved methods in the Union;

(h) 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;

(i) conditions for the production of ~~seeds~~***seed*** from fruit plants***, potatoes*** or vine;

(j) conditions for the production of fruit plants, vine or seed potatoes from ~~seeds.~~ ***seed;***

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

Those implementing acts shall be adopted in accordance with the examination procedure set out in Article 76(2)~~,~~***. They may be amended*** in order to adapt ***them to scientific and technical***~~to the~~ developments ~~of the relevent~~***and applicable*** international ~~technical and scientific~~ standards. ***Those implementing acts may specify more stringent production and marketing requirements to be applicable in certain parts of the Union territory, if so required by the agro-climatic conditions, risk of spreading of noxious weeds, or other special conditions and needs of certain areas.***

Implementing acts for each of the requirements listed above shall be adopted no later than [60 months from the date of the entry into force of this Regulation].

Article 8

Requirements for the production and marketing of standard seed and material

1. Standard seed may only be produced and marketed within the Union, if all the following conditions are fulfilled:

(a) it is practically free from quality pests;

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

~~(i) under the responsibility of the professional operator;~~

~~(ii)~~***(c)it is produced and marketed*** in accordance with the requirements set out in Part A ***and Aa*** of Annex III, and its compliance with those requirements is attested by the operator's label referred to in Article 16.

2. Standard material may only be produced and marketed within the Union, if all the following conditions are fulfilled:

(a) it is practically free from quality pests;

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

~~(i) under the responsibility of the professional operator;~~

~~(ii)~~***(c)it is produced and marketed*** in accordance with the requirements set out in Part B***, Ba, and E*** of Annex III, and its compliance with those requirements is attested by the operator's label referred to in Article 16.

~~3. Once a year, professional operators shall submit to the competent authority a declaration concerning the quantities per species of standard seed and material they produced.~~

4. The Commission is empowered to adopt delegated acts~~,~~ in accordance with Article 75, in order to amend Annex III~~, to~~***. Those amendments shall*** adapt ~~the requirements referred to in paragraphs 1 and 2~~***that Annex*** to the scientific and technical developments and to the applicable international standards~~. Those amendments~~***, and*** shall concern ***requirements for one or more of*** the following ***elements***:

(a) ~~requirements for sowing and planting, and~~ production ~~in the~~***(sowing, planting and*** field~~,~~ ***cultivation)*** of standard ~~seeds~~***seed***;

(b) ~~requirements for~~ harvesting and post-harvesting of standard ~~seeds~~***seed***;

(c) ~~requirements for~~ marketing of standard ~~seeds~~***seed***;

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

(e) ~~requirements for~~ harvesting and post-harvesting of standard material;

(f) ~~requirements for the~~ marketing of standard material;

(g) ~~requirements for clones, selected clones, multiclonal mixtures and~~***production and marketing of*** polyclonal ~~PRM of standard~~ material;

(h) ~~requirements for the~~ production of standard material produced by ~~in vitro~~***in vitro*** propagation;

(i) ~~requirements for the~~ marketing of standard material produced by ~~in vitro~~***in vitro*** propagation.

5. The Commission ~~may~~***shall*** adopt implementing acts specifying the production and marketing requirements referred to in ~~Part A and Part B of~~ Annex III for certain~~–~~ genera or species of standard ~~seed or material~~***PRM***. Those requirements shall concern one or more of the following elements ***for all or certain 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~~***in vitro*** propagation;

(c) conditions for sowing or planting;

(ca) previous cropping and isolation distances;

(d) ***open*** field ***or greenhouse*** cultivation;

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

(e) harvesting and post-harvesting;

(f) germination rates, purity and content of other ~~PRM~~***species***,~~–~~ moisture, vigour, presence of ~~earth~~***soil*** or extraneous matter;

(g) the application of bio-molecular or other technical methods, as well as their approval and use, and the listing of approved methods in the Union;

(h) 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;

(i) conditions for the production of ~~seeds~~***seed*** from fruit plants***, potatoes*** or vine;

(j) conditions for the production of fruit plants, vine or seed potatoes from ~~seeds.~~ ***seed;***

(k) conditions for the production and marketing of conservation varieties and local varieties;

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

Those implementing acts shall be adopted in accordance with the examination procedure set out in Article 76(2)~~,~~. ***They may be amended*** in order to adapt ***them to scientific and technical***~~to the~~ developments ~~of the relevent~~***and applicable*** international ~~technical and scientific~~ standards. ***Those implementing acts may specify more stringent production and marketing requirements to be applicable in certain parts of the Union territory, if so required by the agro-climatic conditions, risk of spreading of noxious weeds, or other special conditions and needs of certain areas.***

Implementing acts for each of the requirements listed above shall be adopted no later than [60 months from the date of the entry into force of this Regulation].

~~*Article 9*~~

~~**Production, marketing and registration of clones, selected clones, multiclonal mixtures and polyclonal PRM**~~

~~1. In addition to the requirements referred to in Articles 4 to 43, pre-basic, basic, certified and standard material of clones, selected clones, multiclonal mixtures and polyclonal PRM shall be produced and marketed in accordance with paragraphs 2 and 3 and the requirements set out respectively in Annex II, Part C, and Annex III, Part C.~~

~~2. Clones, selected clones, multiclonal mixtures and polyclonal PRM may only be produced and marketed if they are registered by a competent authority in at least one official register for clones established by a Member State.~~

~~That register shall include all elements referred to in the application for the registration of a clone, selected clone, multiclonal mixture and polyclonal PRM, as set out in Annex II, Part B, Part C point 2.~~

~~3. Clones, selected clones, multiclonal mixtures and polyclonal PRM shall be maintained for the purpose of preserving their identity. The persons responsible for maintenance of the clones, selected clones, multiclonal mixtures and polyclonal PRM shall take all measures to be able to make them verifiable by the competent authorities or any other person, on the basis of kept records.~~

SECTION 2A

SPECIFIC REQUIREMENTS FOR CONTROL PLOT TESTS FOR SEED

Article ~~24~~9a

Control plot tests for pre-basic, basic and certified ~~seeds~~ *seed*

1. ~~After the production~~***Control plot tests shall be carried out by the competent authority in order to verify that the lots*** of pre-basic, basic and certified ~~seeds, the competent authorities shall carry out annual field tests, immediately after, or during, the season following the drawing of the samples, additionally to field inspection, in plots where the variety is compared to an officially validated sample~~***seed, except for lots*** of seed of ~~the variety to ascertain that the characteristics of varieties have remained unchanged in the process of production and to verify the~~***vine and fruit species, placed on the market comply with the requirements relating to their*** varietal identity and ***varietal*** purity~~ of individual seed lots~~.

Those tests shall ***consist of a visual comparison between the control plot sown with a standard sample and a plot sown with a sample of the lot under testing. The sample of the lot shall be taken during the certification or marketing of***~~be used for assessing~~:

~~a)~~***(a)*** ~~whether the requirements~~***a lot of pre-basic, basic and certified seed intended*** for the ~~next categories or generations are fulfilled. When, as a result of such tests of the immediately descending category or~~***production of a new*** generation~~, it is established that the varietal identity or purity of the seeds has not been maintained, the competent authority shall not certify seed derived from the lot concerned;~~ ***or category; or***

~~b)~~***(b)*** ~~that such seed complies with the respective identity, quality and other certification requirements. When, as a result of such test, it is established that the requirements of Article 7 have not been fulfilled, the competent authority shall withdraw the lot concerned from the market or ensure that it complies with the applicable requirements.~~***a lot of seed of a generation no longer intended for further multiplication.***

Those tests shall take place no later than during the growing season following the drawing of the sample.

2. ~~The proportion of these~~***Those*** control plot tests ~~for~~***shall be carried out on all lots of*** pre-basic~~,~~ ***and*** basic ~~and~~***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 possible non-compliance of the ~~seeds~~***seed*** with the respective requirements.

3. ~~On the basis of the risk analysis~~***The sample from a tested lot of seed*** referred to in paragraph ~~2, control plot tests~~***1*** shall be ~~carried out through samples~~ taken by the competent authority***, by a sampler under official supervision and authorised by the competent authority, or by using an automatic sampling device officially approved by the competent authority*** ~~from the harvested seed~~. ***If samples are taken during marketing, they shall be taken by the competent authority.***

4. For the purpose of control of varietal identity and varietal purity, biochemical and bio-molecular techniques recognised in accordance with Article 7(4), point (g), may be used.

5. When the results of the test referred to in paragraph 1 indicate that the requirements of Article 7 have not been fulfilled, the competent authority shall:

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

(b) require that the seed lot concerned complies with the applicable requirements; or

(c) take other appropriate corrective actions.

~~4~~***6***. The Commission ~~is empowered to adopt delegated~~***may, by means of implementing*** acts in accordance with ***the examination procedure set out in*** Article ~~75, supplementing this Regulation by setting~~***76(2) set*** out rules ~~for~~***concerning*** the control plot tests of ~~seeds~~***lots of pre-basic, basic and certified seed*** per genera or species. Those rules shall ~~adapt~~***be adapted*** to the development of scientific and technical knowledge and international standards, and may be established per particular genera, species or ~~categories~~***category***. They may concern the following ***elements***:

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

(b) the ***sampling and*** testing procedure;

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

~~5. In the case of control of varietal identity and purity, the use of bio-molecular techniques may be used as a supplementary tool where the results of the conrol plot tests referred to in paragraph 1 are non conclusive~~

*Article ~~25~~**9b***

Control plot tests for standard ~~seeds~~*seed*

1. ~~After the marketing of standard seeds, the competent authorities shall carry out~~ Control plot tests ~~to check whether the seeds~~***shall be carried out by the competent authority in order to verify that the marketed lots of standard seed, except for lots of seed of vine and fruit species,*** comply with the ~~respective~~***requirements relating to their*** varietal identity and varietal purity ~~requirements, and with other requirements, as appropriate~~.

Those tests shall consist of a visual comparison between the control plot sown with a standard sample and a plot sown with a sample of the lot under testing. That sample shall be taken during the marketing of the lot.

2. ~~The proportion of the~~***Those*** control plot tests shall be ***carried out on a proportion of lots of standard seed*** determined on the basis of a risk analysis concerning possible non-compliance of the ***seed with the*** respective ~~seeds with those~~ requirements.

3. ~~Based on the risk analysis of non-compliance with the respective rules, the control plot tests~~***The sample from a tested lot*** referred to in paragraph 1 shall be ~~carried out anually, by using samples~~ taken by the competent authority ~~from homogeneous seed lots. Those tests shall assess identity and varietal purity of the seed concerned, and its germination rate and analitical purity~~***. That sampling may be carried out using an automatic sampling device officially approved by the competent authority***.

4. ~~In the case~~***For the purpose*** of control of varietal identity and ***varietal*** purity, ~~the use of~~***biochemical and*** bio-molecular techniques ***recognised in accordance with Article 8(5), point (g),*** may be ~~use as a supplementary tool where the results of the conrol plot tests referred to in paragraph 1 are non conclusive~~***used***.

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

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

(b) take other appropriate corrective actions.

6. The Commission may, by means of implementing acts in accordance with the examination procedure set out in Article 76(2), set out rules concerning the control plot tests of standard seed lots per genera or species. Those rules shall be adapted to the development of scientific and technical knowledge and international standards, and may be established per particular genera or species. They may concern the following elements:

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

(b) the testing procedure;

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

SECTION 3

AUTHORISATION OF PROFESSIONAL OPERATORS AND OFFICIAL SUPERVISION ~~OF~~*BY* THE COMPETENT AUTHORITIES

Article 10

Authorisation of professional operators to carry out certification under official supervision

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

In such a case, a professional operator may, upon application, be authorised by the competent authority to perform all or certain activities required for ***the*** certification of PRM***, except for control plot testing as referred to in Article 9a,*** under official supervision ~~of~~***by*** the competent authority~~ for pre-basic, basic and certified material or seeds~~, and to ~~issue~~ ***print and affix*** an official label ~~for them~~***on that PRM***.

In order to be granted such ***an*** authorisation and depending on the activities to be authorised for, the professional operator shall ***comply, where so applicable for the authorised activities, with all of the following conditions***:

(a) possess the necessary knowledge for complying with the requirements referred to in Article 7;

(b) be qualified to carry out the inspections referred to in Annex II ***in accordance with international standards*** or employ personnel qualified for such inspections;

(c) employ qualified personnel for carrying out the sampling referred to in Annex II, or conclude contracts with ~~companies~~***other professional operators*** employing qualified personnel for those activities;

(d) employ specialised personnel and ***possess the necessary*** equipment to carry out the testing referred to in Annex II, or use laboratories ***performing according to International Seed Testing Association (ISTA) rules or other international standards where applicable,*** employing qualified personnel for those activities;

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

(f) have in place systems to ensure the fulfilment of the requirements concerning the identification of lots pursuant to Article 13;

(g) have in place systems to ensure the fulfilment of the traceability requirements set out in Article 42.

2. The Commission is empowered to adopt delegated acts in accordance with Article 75, supplementing paragraph 1 as regards ~~one or more of the following elements:~~***specific actions to be taken by the competent authority, in order to confirm the compliance with paragraph 1, points (a) to (g).***

~~(a) procedure for the application submitted by the professional operator;~~

~~(b) specific actions to be taken by the competent authority, in order to confirm the compliance with paragraph 1, points (a) to (g).~~

Article 11

Withdrawal or modification of the authorisation of a professional operator

Where an authorised professional operator no longer fulfils the requirements set out in Article 10(1)***, or if the PRM produced or marketed by that professional operator has been repeatedly found to be in non compliance with the provisions of the Regulation***, the competent authority shall request that operator to take corrective actions within a specified period of time.

The competent authority shall without delay withdraw, or modify as appropriate, the authorisation, if the professional operator does not apply the corrective actions referred to in the first subparagraph within the specified period of time. In case it is concluded that the authorisation had been granted following fraud, the competent authority shall impose the appropriate sanctions to the professional operator.

Article 12

Official supervision by the competent ~~authorities~~*authority*

1. For the purposes of the certification ***activities*** under official supervision, the competent ~~authorities~~***authority*** shall~~, at least once per year,~~ conduct ~~audits~~***regular evaluations*** to ensure that the professional operator fulfils the requirements referred to in Article 10(1). ***The frequency of the evaluations shall be determined by the likelihood that the professional operator does not comply with the relevant requirements of this Regulation.***

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

2. For the purposes of the certification under official supervision, the competent ~~authorities~~***authority*** shall carry out official inspections, sampling and testing on a portion of the crops on the site of production and on lots ~~of the PRM~~ in order to confirm compliance of that ~~material~~***PRM*** with the requirements referred to in Article 7.

   That portion shall be determined on the basis of the assessment of the potential risk of non-compliance of the PRM with those requirements ***by the professional operator concerned***.

3. The Commission may, by means of implementing acts, specify the requirements for the ~~audits, training~~***evaluations, trainings***, examinations, inspections, sampling and testing, as referred to in paragraphs 1 and 2, with regard to particular genera or species.

Those implementing acts may specify ~~one or more of~~ the following elements:

(a) the risk criteria as referred to in paragraph ~~2~~***1*** and minimum portion of the crops and the lots of PRM~~,~~ to be subject to ***field*** inspections, sampling and testing~~,~~ as referred to in paragraph 2;

~~(b) monitoring activities to be carried out by the competent authorities;~~

(c) ***the*** use of ~~particular accreditation schemes~~***quality assurance systems*** by the professional operator ***subject to the approval of the competent authority***, and the possibility for the competent ~~authorities~~***authority*** to reduce the inspections, sampling and testing~~, and monitoring activities~~ referred to in this Article due to the use of those ~~schemes.~~ ***quality assurance systems.***

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).

SECTION 4

HANDLING *AND LABELLING* REQUIREMENTS

Article 13

Lots

1. PRM shall be ***produced and*** marketed ~~in lots. The content of the varieties and species of each lot~~***with reference to a lot. It*** shall be ~~sufficiently homogeneous regarding and~~ identifiable by its ~~users as distinct from other lots of PRM~~***unique lot reference number ensuring traceability***.

2. ~~During processing, packaging, storage, or at delivery,~~ Lots of PRM may be merged into a new lot only if they belong to the same variety ~~and harvest year~~***. If several lots of the same variety are merged into a new lot, a new official label or operator's label shall be issued in accordance with Article 17a***.

Where lots consisting of different ~~certification~~ categories are merged, the new lot shall belong to the category of the component of the lowest category. ***In the case of pre-basic, basic or certified seed or material,*** the merging operation may only be undertaken ~~in a facility and by persons authorised by~~***by the professional operator under the official supervision of*** the competent authority ~~for this specific purpose~~.

3. ~~During processing, packaging, storage, or at delivery,~~ Lots of PRM may be split into two or more lots. ***If a lot is split into two or more lots, a new official label or operator's label, as applicable, shall be issued for each resulting lot in accordance with Article 17a.***

~~4. In cases of merging or splitting of the lots of PRM, as referred to in paragraphs 2 and 3, the professional operator shall keep records concerning the origin of the new lots.~~

5. The Commission ~~may~~***shall***, by means of implementing acts, adopt specific requirements for all or certain species of PRM, concerning the maximum size of lots, their identification ~~and labelling~~***, testing of lots***, the merging or splitting of lots in relation to the origin of the PRM lots, recording of those operations and labelling following the merging or splitting***, in accordance with applicable international standards***. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).

Article 14

Packages, bundles and containers

1. PRM shall be marketed ***as individual plants or in sealed***~~in fastened~~ packages, bundles or containers, bearing a ~~sealing device and marking. In the case of~~***label. However,*** PRM other than ~~seeds, it may also~~***seed and seed potatoes may*** be marketed ~~in the form of individual plants~~***without a sealing device where such a device is not practically feasible***.

2. The packages, bundles and containers referred to in paragraph 1 shall be ~~fastened~~***sealed*** in such a way, that they cannot be opened without destroying that ~~fastening~~***seal*** or leaving traces demonstrating that the package, bundle or container has been opened. The ~~The~~ effectiveness of the ~~fastening~~***sealing*** device shall be ensured, either by incorporating the labels provided for in Articles 15 and 16 in the device or by use of a seal. Packages and containers shall be exempted from this requirement if the ~~fastening~~***sealing*** cannot be reused.

3. In the case of pre-basic, basic or certified ~~PRM~~***seed and material***, those packages, bundles and containers shall be ~~fastened~~***sealed*** by the competent authority~~, or by the professional operator under the official supervision of the competent authority. Those packages and containers shall not be refastened unless this is done by the competent authority~~ or by the professional operator under the official supervision of the competent authority. If a package, bundle or a container is ~~refastened~~***re-sealed***, the date of ~~refastening~~***resealing*** and the details of the responsible competent authority shall be stated on the label referred to in Article 15.

4. ~~Lots~~***PRM may be re-packaged, re-labelled, and re-sealed. In the case*** of pre-basic, basic or certified ~~PRM~~***seed or material, it*** may be ~~repackaged, re-labelled, and re-sealed only under official control or~~***done by the competent authority or the professional operator*** under the official supervision of the competent authority.

5. By way of derogation from paragraph 1, ~~seeds~~***certified seed*** may be marketed from a professional operator directly to a farmer in bulk.

   That professional operator shall be ~~authorized~~***authorised*** for that purpose by the competent authority. It shall ~~inform the competent authority in advance~~***keep records*** of such activity and of the lot from which such seed ~~comes~~***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~~ and the farmer concerned~~ shall ensure traceability of that seed by issuing and retaining documents indicating the species and variety, quantity, the ~~time~~***date*** of transfer and lot ~~identification~~***reference number***.

6. The Commission may, by means of implementing acts, adopt specific requirements concerning sealing~~, fastening~~, size and form of packages, bundles and containers of specific species of PRM, and specify conditions for the marketing of ~~seeds~~***seed*** in bulk ***including technical and biological reasons which do not allow for sealing or packaging***. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).

~~SECTION 5~~

~~LABELLING REQUIREMENTS~~

Article 15

Official label ***for pre-basic, basic and certified PRM***

1. Pre-basic, basic and certified ***seed and*** material~~ and seeds~~ shall be identified, and their compliance with this Regulation shall be attested, through an official label, issued ~~after the conclusion~~ by the competent authority ***confirming*** that the requirements referred to in Article 7 have been fulfilled.

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

   It shall be printed by:

   (a) the competent authority~~, if so requested by the professional operator, or if the professional operator is not authorised to carry out certification under official supervision, by the competent authority in accordance with Article 10~~; or

   (b) the professional operator~~,~~ under the official supervision of the competent authority, ~~where~~***when*** the professional operator is authorised to carry out ~~certification under official supervision~~***such printing*** in accordance with Article 10.

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 the official supervision of the competent authority~~, or by a person acting under the responsibility of the professional operator~~.

~~4. The official label shall benewly issued. Adhesive official labels may be used, if so authorised by the competent authority where there is no risk that they can be re-used.~~

4a. The official label may contain some of the information in digital form.

5. The Commission is empowered to adopt delegated acts in accordance with Article 75, supplementing this Article by establishing ***rules on*** the following~~ rules on~~:

(a) the digital recording ***and collection of data on the certification activities carried out by***~~of all actions taken by the~~ professional operators and~~ the~~ competent authorities in order to issue the official ~~label~~***labels with information in a digital form***;

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

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

(c) the technical arrangements for the issuance of ~~electronic~~***the*** official ~~labels.~~ ***label in digital form.***

~~Following the adoption of such delegated act,~~***Information may only be provided in*** the official label ~~may also be issued in an electronic form ('electronic official label')~~***in digital form once such delegated acts have entered into application***.

6. By way of derogation from paragraphs 1 to 5, pre-basic, basic ~~material and seed basic material and seed~~ and certified ***seed and*** material~~ and seed~~, imported from third countries pursuant to Article 39, ~~shall~~***may*** be marketed in the Union with the respective OECD ***Seed Schemes*** label ***('OECD label')*** that was accompanying them at import***, 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 Schemes available or for PRM other than seed***.

Article 16

Operator's label *for standard PRM*

1. ~~Standard material and~~ Standard seed ***and material*** shall be identified through an operator's label~~. That label shall attest that standard material or standard seed complies~~ ***that attests their compliance*** with the~~ relevant~~ production and marketing requirements~~,~~ referred to in Article 8~~, on the basis of inspections, sampling and testing carried out by the professional operator~~.

2. The operator's label shall be issued, printed and affixed by the professional operator~~, or by a person acting under the responsibility of the professional opeartor, on~~ ***to*** the outside of ~~a~~***the individual plant,*** bundle, package or container***, or printed indelibly on the package or container***.

3. The operator's label may contain some of the information in digital form.

4. The Commission is empowered to adopt delegated acts in accordance with Article 75, supplementing this Article by establishing rules on:

(a) the digital recording and collection of data on the activities carried out by professional operators in order to issue operator's labels with information in a digital form;

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

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

Information may only be provided in the operator's label in digital form once such delegated acts have entered into application.

Article 17

Content *and characteristics* of labels

1. The official label and the operator's label~~,~~ shall be written in at least one of the official ~~Union~~ languages ***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 ordinary use,*** not modifiable if tampered with, ~~printed on one side, not having been used previously~~***not reusable, unused***, and easily visible.

2a. Adhesive labels may be used where there is no risk that it can be re-used.

3. ~~Any space of~~***Where applicable,*** the official label ~~or~~***and*** the operator's label***,*** apart from the elements ~~mentioned in~~***to be adopted pursuant to*** paragraph 4, ~~may be used for~~***shall include in an appropriate space,*** additional information ~~by the competent authority. Such information shall be presented in letters not larger than those used for the content of the official label or the operator's label as referred to in paragraph 4. That additional information shall be strictly factual, it shall not represent advertising material, and shall be~~***concerning any applicable Union rules*** related ~~only to the~~***to*** production and marketing requirements~~ or to labelling requirements for genetically modified organisms or category 1 NGT plants as defined in Article 3(7) of~~***, other than the ones set out in this*** Regulation ~~(EU) …/… (Office of Publications, please insert reference to NGT Regulation ...).~~.

Such information shall be presented in a legible way in letters not larger than those used for the content of the official label or the operator's label as referred to in paragraph 4.

3a. The competent authority may allow the professional operators to indicate at the periphery of the official label information other than the content referred to in paragraphs 3 and 4, and other than advertising material, placed in an area of a size not larger than 20 % of the total area of the official label, bearing the title 'Non official information'. Such information shall be in letters not larger than those used for the content of the official label as referred to in paragraph 4.

4. The Commission shall, by means of implementing acts, specify the content, size, colour and form of the official ~~or~~***label as referred to in Article 15 and the*** operator's label ***as referred to in Article 16***, as applicable***, in physical and digital form***, in relation to the respective categories or types of PRM~~, for:~~**.**

~~(a) the official label referred to in Article 15(1);~~

~~(b) the operator's label referred to in Article 16;~~

~~(c) the label for mixtures referred to in Article 21(1);~~

~~(d) the label for preservation mixtures referred to in Article 22(1);~~

~~(e) the label for repackaged and relabelled seeds referred to in Article 23(5);~~

~~(f) the label for PRM belonging to conservation varieties referred to in Article 26(2);~~

~~(g) the label for PRM marketed to final users referred to in Article 28(1), point (a);~~

~~(h) the label for the PRM marketed by certain gene banks, organisations and networks referred to in Article 29;~~

~~(i) the label for breeder's material referred to in Article 31(2);~~

~~(j) the label for PRM of not yet registered varieties referred to in Article 32(5);~~

~~(k) the label for PRM authorised in cases of temporary difficulties in the supply referred to in Article 33(2); and~~

~~(l) the label for seeds with a provisional authorisation for marketing referred to in Article 34(3);~~

~~(m) the label for seeds which are not finally certified referred to in Article 35(3);~~

~~(n) the label for PRM imported from third countries referred to in Article 40(1) and (2).~~

~~That~~***Those*** implementing ~~act~~***acts*** shall be adopted in accordance with the examination procedure referred to in Article 76(2).

~~5. The competent authority may authorise the professional operator to indicate information other than the content referred to in paragraph 4, and other than advertising material, placed at the periphery of the official label, in an area of a size not larger than 20 % of the total area of the official label, bearing the title 'Non official information'. Such information shall be in letters not larger than those used for the content of the official label as referred to in paragraph 4.~~

*Article ~~23~~**17a***

Re-packaging, *re-sealing* and re-labelling of ~~seed lots~~*PRM*

~~1. Seed lots of pre-basic, basic and certified seed shall be repackaged and relabeled in accordance with this Article, Articles 14 and 15, where this is necessary for splitting or merging of lots.~~

~~2. The re-packaging and re-labelling of a seed lot shall be conducted by:~~

~~(a) the professional operator under the official supervision of the competent authority; or~~

~~(b) a seed sampler, who is authorised and supervised for that purpose by, and reports to, the competent authority.~~

~~In the case of point (b), the professional operator shall be notified in advance by the competent authority so as to organise its co-operation with the seed sampler.~~

3. The professional operator ~~and the seed sampler~~ carrying out re-packaging***, re-sealing*** and re-labelling of ~~seed lots~~***a lot of PRM, or part of it***, shall take all steps to ensure that during ~~the~~***that*** operation~~ of re-packaging~~, the identity~~ and~~***,*** varietal purity ~~of the seed lot~~***and homogeneity*** is maintained, ***and*** no contamination occurs~~, and the resulting seed lot is as homogeneous as possible~~.

In the case of pre-basic, basic and certified seed and material, the re-packaging, re-sealing and re-labelling shall be conducted by the competent authority or the professional operator under the official supervision of the competent authority as referred to in Article 14(4).

4. ***In addition to the traceability requirements pursuant to Article 42,*** the professional operators ~~and the seed sampler~~ shall keep records~~, when~~ ***of*** re-packaging***, re-sealing*** and re-labelling ~~seed lots, for 3~~***performed by them, for 6*** years after the respective ~~re-labelling and re-packaging~~***activity***. The information contained in ~~the~~***those*** records shall include:

(a) the reference number of the original ~~seed~~ lot;

(b) the reference number of the ~~repackaged or relabeled seed lot;~~***re-packaged or re-labeled lot;***

(c) the weight ***or units*** of the original ~~seed~~ lot;

(d) the weight ***or units*** of the re-packaged or ~~relabeled seed lot;~~***re-labeled lot;***

(e) the ***most recent*** date of ~~final disposal~~***re-sealing*** of the lot.

Those records shall be kept in a form allowing ~~to identify and verify~~***identification and verification of*** the authenticity of the original ~~seed lot,~~***lot*** which is subject to re-packaging and re-labelling. They shall be made available to the competent authority on request.

5. The original seals and labels shall be removed from the ~~seed lot~~***original lot where possible, or it shall be indicated on the seal or label that they are no longer valid***. The professional ~~operators or the seed sampler~~***operator*** shall also keep the ***replaced*** label, ~~which was~~***a record of its content or a digital equivalent for each original lot for at least 6 years after the respective re-sealing. If the professional operator chooses to keep a record of the content of the*** replaced~~, of each component seed lot~~ ***label instead of the label itself, that record may be kept in electronic format, provided that it includes the information that is needed to guarantee traceability***.

The new ~~labels~~***label*** shall~~ either~~ state the original~~ seed~~ lot reference number~~ or a new seed lot reference number assigned by the competent authority~~.

~~6. Where the competent authority assigns a new seed lot reference number, it shall either keep a record of the former seed lot reference number or ensure that this former number is included on the new labels.~~

~~7. Repackaging of mixtures of certified seed may only be carried out where the professional operator or the seed sampler has established that the ratio of the different components within a mixture will be maintained during the repackaging process.~~

~~*Article 18*~~

~~**Reference to lots**~~

~~The official label and the operator's label shall be issued for each lot.~~

~~If a lot of the same variety is split into two or more lots, a new official label or operator's label shall be issued for each lot.~~

~~If several lots of the same variety are merged into a new lot, a new official label or operator's label shall be issued for that new lot.~~

SECTION 6

SPECIFIC REQUIREMENTS FOR MIXTURES OF ~~SEEDS, RE-PACKAGING OF SEEDS AND CONTROL PLOT TESTS FOR SEEDS~~*SEED*

Article 21

Mixtures of ~~seeds~~*seed*

1. ~~Mixtures of certified seed or mixtures of standard~~ Seed of various genera or species listed in ~~Part A of~~ Annex I~~ and complying with the requirements of Articles 5 to 8~~, as well as of different varieties of those genera or species, ***belonging to any of the categories referred to in Article 6(1) and complying prior to mixing with the respective requirements of Articles 7 or 8*** may be~~ produced and~~ marketed in the Union~~, if they fullfill the requirements of this Article~~ ***as a mixture of those genera, species or varieties***.

1a. ***Mixtures referred to in paragraph 1 may also include, or consist of, commercial seed subject to Article 32a.***

1b. ~~The seeds included in those~~ Mixtures shall be accompanied by:

(a) an official label, where the mixture consists only of ~~certified seeds~~***categories referred to in Article 6(1), points (a), (b) and (c)***; or

(b) an operator's label, in ~~the case where the mixture consists only of standard seed, or of certified and standard seed~~***all other cases***.

By way of derogation from point (a), a mixture referred to in that point may be marketed in small packages accompanied by an operator's label.

1c. ~~For the purposes of the second subparagraph, point (a)~~***In cases where the mixture contains seed of categories referred to in Article 6(1), points (a), (b) and (c)***, the professional ~~operators~~***operator*** shall submit to the competent authority the list of ~~constituent varieties~~***components*** of the mixture and their ratios, for verification of eligibility of those ~~varieties~~***components to be part of that mixture***.

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

2. Mixtures~~ of seeds referred to in paragraph 1~~ may only be produced by ***a*** professional ~~operators~~***operator***, which ~~are~~***is*** authorised for that purpose by the competent authority. In order to ~~receive~~***be eligible for*** an authorisation for the production of such mixtures, ***the*** professional ~~operators~~***operator*** shall fulfil the following requirements:

(a) having 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) having a person in charge who has direct responsibility for the mixing and packaging operation; and

(c) maintaining ~~a register~~***records*** of seed mixtures~~ and their intended use~~.

3. The mixing and packaging operation of the ~~seeds~~***seed*** referred to in paragraph 1~~, point (a),~~ shall be carried out under the supervision of the competent authority.

3a. The mixing operation shall be carried ***out*** in a manner to ensure that there is no risk of presence of ~~seeds~~***seed*** not intended for inclusion and that the resulting mixture is as homogeneous as possible.

~~The weight of the seed in a single container, which consists of a mixture of both small-seeded species and species of which the seed is larger than the size of wheat, shall not exceed 40 kg.~~

3b. By way of derogation from paragraph 1, mixtures may include seed of genera or species not listed in Annex I without prejudice to Regulation (EU) No 1143/2014 of the European Parliament and of the Council and subject to the requirements as referred to in paragraphs 1c, 2 and 3a.

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

4. The Commission may, by means of implementing acts, specify, on the basis of technical and scientific developments and the experience gained from the application of this Article, ***the*** rules concerning:

(a) the mixing equipment and procedure;

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

(ab) content, size, colour and form of the official label and operator's label;

~~(b) maximum lot sizes for particular species and varieties.~~

(c) in case of mixtures referred to in paragraph 3b, possible applicable use; and

(d) denomination of mixtures.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).

5. This Article shall not apply to preservation mixtures as referred to in Article 22.

Article 22

Preservation mixtures

1. By way of derogation from ~~Article 21(1)~~***Articles 5 to 12, 14 and 21(1b) to (4)***, Member States may ~~authorise~~***decide to allow*** the production and marketing~~ of a mixture of seeds~~***, in their territories, or part of those territories, of seed intended for, or used in mixtures*** of various genera or species listed in ~~Part A of~~ Annex I, as well as~~ of different varieties of those genera or species, together with seeds of genera or species of other Parts of that Annex, or~~ of genera or species not listed in that Annex, ***without prejudice to Regulation (EU) No 1143/2014,*** if such a mixture fulfils~~ all of~~ the following conditions:

(a) it contributes to the conservation of genetic resources, or the restoration of the natural environment; and

(b) it is naturally associated with a particular ~~area ('source area') contributing to the conservation of genetic resources or the restoration of the natural environment;~~***region ('region of origin').***

~~(c) it complies with the requirements of Annex V.~~

Such mixture constitutes a 'preservation mixture'~~ and this shall be mentioned on its label.~~**.**

1a. Preservation mixtures may only be produced and marketed by professional operators who are authorised for that purpose by the competent authority.

1b. Preservation mixtures shall be marketed only in their region of origin and accompanied by an operator's label with the indication 'Preservation mixture', and the indication of that region.

2. The Commission is empowered to adopt~~ a~~ delegated ~~act,~~***acts*** in accordance with Article 75, ~~amending Annex V~~***supplementing this Article with requirements*** concerning~~ the following elements~~:

(-a) the designation of the region of origin;

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

(-c) the authorisation of professional operators;

(a) ~~authorisation requirements for~~***the production of preservation*** mixtures ~~of seeds collected directly~~***by direct collection*** from a natural place belonging to a defined ~~source area, for the conservation and restoration of the natural environment~~***region of origin*** (directly harvested preservation mixtures);

(b) ~~authorisation requirements for crop-grown~~***the production of*** preservation mixtures ***by multiplication***;

~~(c) use and content of certain species;~~

~~(d) requirements on sealing and packaging;~~

~~(e) requirements for the authorisation of the professional operators.~~

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

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

~~Those amendments shall be based on the experience gathered by the implementation of this Article, and any technical and scientific developments and the improvement of the quality and identification of preservation mixtures. They may concern particular genera or species only.~~

2a. ***The Commission may, by means of implementing acts, adopt specific requirements concerning packaging, sealing, content, size, colour and form of the operator's label. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).***

3. Professional operators shall report to the respective competent authorities, for each production season, the amount of preservation mixtures produced and marketed by them.

The Member States shall report on request to the Commission and to the other Member States the amount of preservation mixtures produced and marketed in their territory and, where applicable, 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 ~~25~~*22*

Article 26

PRM belonging to conservation varieties *or local varieties*

1. By way of derogation from ~~Article 20~~***Articles 6a and 9b***, PRM belonging to a conservation ***variety or a local*** variety registered in a national variety register referred to in Article ~~44(1), point (b), may~~***44 may only*** be produced and marketed in the Union as standard seed or material, if it complies with all the requirements ~~concerning standard seed and material for the respective species, as~~ referred to in Article 8.

1a. ***PRM of a conservation variety or a local variety shall be produced only in the respective region of origin unless it belongs to a variety that has previously been registered in a national variety register with an official description.***

2. PRM referred to in paragraph 1 shall be accompanied by an operator's label ***as referred to in Article 16,*** with the indication 'Conservation variety' ***or 'Local variety', as applicable***.

3. A professional operator who uses this derogation shall annually notify ***this activity*** to the competent authority ~~this activity, with regard to the species and quantities concerned~~.

On request of the competent authority, and in accordance with the instructions of that authority, the professional operator shall report the quantities produced and marketed with regard to the genera or species and varieties concerned.

~~*Article 27*~~

~~**PRM of heterogeneous material**~~

~~1.~~ ~~By way of derogation from Article 5, PRM of heterogeneous material may be produced and marketed within the Union without belonging to a variety. The heterogeneous material shall be notified to and register by the competent authority prior to its production and/or marketing, in accordance with the requirements set out in Annex VI.~~

~~2.~~ ~~By way of derogation from Articles 7(1), (3) and Article 8(1), (3), the PRM of heterogeneous material referred to in paragraph 1 shall be produced and marketed in accordance with the requirements set out in Annex VI.~~

~~3.~~ ~~The Commission is empowered to adopt a delegated act in accordance with Article 75, amending Annex VI. Those amendments may concern all, or particular genera or species only, and shall:~~

~~(a)~~ ~~improve the provision of information in notifications, description and identification of heterogeneoys PRM, on the basis of experience gained by the application of the respective rules;~~

~~(b)~~ ~~improve the rules concerning packaging and labelling of heterogeneous PRM, on the basis of the experience gained from the checks carried out by the competent authorities;~~

~~(c)~~ ~~improve the rules on maitenance of heterogenous PRM, on the basis of the emergence of best practices.~~

~~Those amendments shall be adopted in order to adapt to the development of the respective technical and scientific evidence, and the international standards, and to follow up on the experience gained by the application of this Article concerning all or certain genera or species only.~~

~~4. Any professional operator producing and/or intending to market PRM of heterogeneous material shall submit a notification to the competent authority prior to marketing. If no further information is requested by the national competent authority within a time determined by the competent authority, the PRM of heterogeneous material may be marketed.~~

~~5. The professional operator shall ensure the traceability of the PRM of heterogeneous material by keeping information allowing to identify the professional operators which have supplied them with the initial material used for the production (parental material) of heterogeneous material.~~

~~The professional operator shall keep that information for 5 years.~~

~~The professional operator producing PRM of heterogeneous material intended for marketing shall also record and keep the following information:~~

~~(a) the name of the species and denomination used for each notified heterogeneous material;~~

~~(b) the type of technique used for the production of heterogeneous material as referred to in paragraph 1;~~

~~(c) the characterisation of the notified heterogeneous material;~~

~~(d) the breeding location of the PRM of heterogeneous material and production location;~~

~~(e) the surface area for the production of PRM of heterogeneous material and quantity produced.~~

~~The competent authorities shall have access to the information referred to in this paragraph.~~

~~6. Article 54 shall apply accordingly for the suitability of the denomination of heterogeneous material.~~

~~7. Heterogeneous material as notified pursuant to paragraph 1, shall be registered by the competent authorities in a dedicated register (‘heterogeneous material register’).~~

~~The competent authorities shall keep, update and publish that register, and notify immediately its content and updates to the Commission.~~

Article 28

PRM *produced for and* marketed to ~~final~~*non-professional* users

1. By way of derogation from Articles 5 ~~– 12, 14, 15 and 20, PRM~~***to 9b and 14 to 17a, PRM of fruit and vegetable plant species intended to be used exclusively by non-professional users*** may be ***produced, and*** marketed to ~~final~~***non-professional*** users, if it complies with all of the following requirements:

(a) ~~to bear~~***it bears*** an operator's label with the denomination of the PRM and the indication 'Plant reproductive material for ~~final users – not officially certified' or, in the case of seeds, 'Seeds for final users – not officially certified~~***non-professional user***';

(b) in case ***of PRM*** not belonging to a variety registered in a national variety register referred to in Article 44~~, to have a description made publicly available, on the basis of a private documentation, in a commercial catalogue kept by the professional operator. This private documentation shall be made available by the professional operator upon request to the competent authority;~~***:***

(i) use a denomination complying with Article 54(1) and (2);

(ii) it has the indication on the operator's label 'variety not registered pursuant to Regulation (EU) .../…'; and

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

(c) ~~to be~~***it is*** practically free from quality pests and any defects likely to impair its quality as reproductive material, and ~~shall have satisfactory vigour and dimensions in respect of its usefulness as PRM, and, in the case of seeds, shall have satisfactory germination capacity; and~~***:***

(i) ***in the case of seed, has minimum germination as applicable for the lowest possible category of the respective species; and***

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

(d) ~~to be~~***it is*** marketed as individual plants, or~~, in the case of seeds and tubers,~~ in small packages.

A professional operator ~~who uses~~***using*** this derogation shall annually notify this activity***,*** to the competent ***authority in accordance with the instructions of that*** authority, with regard to the ***genera or*** species ~~and~~***concerned. Upon request of the competent authority, the professional operator concerned shall notify the respective*** quantities ***of PRM produced and marketed pursuant to this Article, with regard to the genera or species*** concerned***.***

2. The Commission ~~shall~~***may***, by means of implementing acts, adopt rules concerning the size, form, sealing and handling requirements concerning ***individual plants and*** the small packages referred to in paragraph 1***,*** point (d)***, and size, form, colour and content of the operator's label***.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).

Article 29

PRM *produced and* marketed ~~to and between gene banks,~~*by* organisations and networks *for the conservation of plant genetic resources*

1. By way of derogation from Articles 5 to ~~25, PRM~~***22, PRM intended for the conservation of plant genetic resources*** may be ***produced and*** marketed ~~to, or between, gene banks,~~***by non-profit*** organisations and networks***, having a purpose defined in their articles of association or other equivalent document of conserving*** ~~with a statutory objective, or an objective official notified to the competent authority, to conserve~~ plant genetic resources, ~~whereby any of the activities are carried out for non-profit purposes~~***to any natural or legal person who carries out conservation of that PRM and to farmers or non-professional users***.

~~It can be marketed as well from those gene banks, organisations and networks to persons who carry out conservation of that PRM as final consumers, for non-profit purposes.~~

~~In the cases provided for in the first and the second subparagraphs,~~***Such*** PRM shall fulfil the following requirements:

(aa) bear an operator's label with the indication 'Plant reproductive material for the conservation of plant genetic resources';

(a) be listed in a register kept by those ~~gene banks,~~ organisations and networks with ~~an~~ appropriate ~~description~~***related information*** of that PRM; ***and***

~~(b) be conserved by those gene banks, organisations and networks, and samples of that PRM be made available by them to the competent authorities upon request; and~~

(c) be practically free from quality pests and any defects likely to impair its quality as a reproductive material~~, and have satisfactory vigour and dimensions in respect of its usefulness as PRM, and, in the case of seeds, have satisfactory germination capacity~~.

2. The~~ gene banks,~~ organisations and networks shall ***annually*** notify ***this activity to*** the competent authority ~~of the use of the derogation referred to in paragraph 1 and~~***in accordance with the instructions of that authority with regard to*** the ***genera or*** species concerned. ***Upon request of the competent authority, the network or organisation concerned shall notify the respective quantities of PRM produced and marketed pursuant to this Article with regard to the genera or species concerned.***

3. The Commission may, by means of implementing acts, adopt rules concerning size, form and content of the operator's label.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).

Article 30

Seed exchanged in kind between farmers

1. By way of derogation from Articles 5 ~~–25,~~***to 22*** farmers may exchange ~~seeds~~***seed*** in kind, if such ~~seeds fulfill~~***seed fulfil*** all of the following conditions:

~~(1)~~***(a)***are produced in the respective farmer's own premises;

~~(2)~~***(b)***are derived from the respective farmer's own harvest; ***and***

~~(3)~~***(c)*** are not subject to a service contract ~~conducted by the respective~~***between the*** farmer ~~with~~***and*** a professional operator ~~performing seed production; and~~***for multiplication of seed.***

~~(4) the seed is used for dynamic management of farmer's own seed for the purpose of contributing to agro-diversity.~~

2. Such ~~seeds~~***seed*** shall fulfil all of the following requirements:

(a) ***they do*** not ~~to~~ belong to a ~~to~~ variety for which plant variety rights have been granted ***either*** in accordance with Regulation (EU) 2100/94 ***or with the national rules on plant variety rights of the Member State of production***;

(b) ~~to be~~***they are*** limited to small quantities, defined by the competent authorities for specific species per year and per farmer~~, without using commercial intermediaries or public offer of marketing; and~~***;***

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

(c) ~~to be~~***they are*** practically free from quality pests and any defects likely to impact their quality as ~~seeds, and shall have satisfactory germination capacity~~***seed***.

3. Member States shall ~~annually~~ notify to the Commission and the other Member States the ~~amounts~~***defined limitation concerning small quantities*** per species defined in accordance with paragraph 2, point (b)***, and any subsequent changes to those quantities***.

Article 30a

PRM of a generation prior to pre-basic category

1. By way of derogation from Articles 6 to 22, PRM of a generation prior to pre-basic seed or material may be produced and marketed for the purpose of its multiplication for the production of pre-basic seed or material, if that PRM fulfils all of the following conditions:

(a) the marketing is made directly from the professional operator responsible for the maintenance of the variety to the professional operator carrying out the production of pre-basic seed or material, with 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 indication 'Seed prior to pre-basic seed' or 'Material prior to pre-basic material'.

2. The Commission may, by means of implementing acts, adopt rules concerning size, form, colour and content of the operator's label as referred to in paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).

~~*Article 31*~~

~~**Breeder's seed**~~

~~1. By way of derogation from Articles 5–25, a competent authority may authorise operators to market seed of generations preceeding the pre-basic category to another operator, for the purpose of breeding new varieties (breeders' seed).~~

~~The competent authority shall determine the duration of the authorisation and quantities per species, when granting that authorisation.~~

~~2. The PRM referred to in paragraph 1 shall be accompanied by a label issued by the professional operator, with the indication 'breeder's seed', that shall be affixed, as applicable, on the container, bundle or package of that material.~~

~~It shall be sealed and bear a lot number to be used for identification purposes and control plot testing before it is used as pre-basic seed.~~

Article 32

PRM of ~~not yet registered~~ varieties *under registration*

1. By way of derogation from ~~Article 5~~***Articles 5, 9a and 9b***, a competent authority may authorise professional operators to produce and market~~, for the purposes of multiplication,~~ pre-basic ~~seeds, pre-basic material~~, basic***, certified and standard seed or*** ~~seeds and basic~~ material belonging to a variety ~~not yet~~***under registration for the purpose of having sufficient stock available for further multiplication once the variety is*** registered ~~in a national variety register, referred to in Article 44, if all of~~***, if*** the following requirements are fulfilled:

~~(a) the respective marketing sectors need to acquire that material or seeds in advance, so as to have sufficient stocks available, when the respective variety will be registered; and~~

(aa) the PRM belongs to a variety for which the competent authority has confirmed the submission of the application for variety registration in accordance with Article 58;

(ab) the PRM fulfils the respective requirements, other than varietal identity and varietal purity, of Articles 7 or 8 for the categories of pre-basic, basic, certified and standard seed or material;

(ac) the marketing is made between the authorised professional operator and the professional operators carrying out the multiplication, with no further marketing of that PRM thereafter; and

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

~~(c) the respective PRM belongs to a variety for which an application has been submitted for registration in a national variety register pursuant to Article 55.~~

~~Such~~***The*** authorisation ~~may be granted for a maximum period of 3-3years in the case of seeds, and 5 years in the case of PRM other than seeds, and for small quantities per species as specified by the competent authority~~***shall automatically expire if the application for variety registration is withdrawn or a decision pursuant to Article 67(1) or (2) is adopted***.

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

2. By way of derogation from Articles 5, ~~7~~***6a***, ~~10 -12, 15, 20, 23 and 24~~ ***and 9b***, a competent authority may authorise professional operators ~~for a maximum period of 3 years in the case of seeds, and 5 years in the case of PRM other than seeds, and for small quantities per species as determined by the competent authority,~~ to produce and market ~~PRM~~***standard seed or material of agricultural species and potato*** belonging to a variety ~~not yet registered in a national~~***under registration for the purpose of carrying out tests or trials to gather information on the cultivation or use of that*** variety ~~register referred to in Article 44, if all of~~***, if*** the following requirements are fulfilled:

(-a) the PRM belongs to a variety for which the competent authority has confirmed the submission of the application for variety registration in accordance with Article 58;

(-b) the PRM fulfils the respective requirements, other than varietal identity and varietal purity, of Article 8 for standard seed or material;

(a) ~~the authorised~~***that*** PRM is only used ~~for tests or trials carried out~~ by professional operators~~, in order to gather information~~ on the ~~cultivation or use of the variety concerned on farms~~***premises of specifically designated natural or legal persons***;

(b) the marketing is made ~~to those~~***by the authorised*** professional operators ***carrying out the tests and trials to the persons referred to in point (a)*** only, with no further marketing ***of that PRM*** thereafter~~, who produces a report on results of the tests or trials, in relation to the information on the cultivation or use of that variety;~~ ***to be allowed; and***

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

~~(d) the authorised PRM complies with the requirements of standard PRM for the respective species.~~

Such authorisation may be granted for limited quantities per species as determined by the competent authority as long as those quantities are not determined by the implementing acts referred to in paragraph 6a. That authorisation shall automatically expire if the application for variety registration is withdrawn or a decision pursuant to Article 67(1) or (2) is adopted.

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

2a. By way of derogation from Article 5, professional operators may produce and market standard seed or material of fruit plants and vine except vine rootstocks belonging to a variety under registration for the purpose of making new varieties available on the market without delay, if the following requirements are fulfilled:

(a) the PRM belongs to a variety for which the competent authority has confirmed the submission of the application for variety registration in accordance with Article 58;

(b) the PRM fulfils the respective requirements, other than varietal identity and varietal purity, of Article 8 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) that PRM bears a breeder's reference or the proposed denomination or a denomination deemed suitable pursuant to Article 54.

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 67(2).

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

2b. ***By way of derogation from Articles 5 and 9b, a competent authority may authorise professional operators to produce and market standard seed or material of varieties of vegetable plant species belonging to a variety under registration for the purpose of making new varieties available on the market without delay, if the following requirements are fulfilled:***

(a) ***the PRM belongs to a variety for which the competent authority has confirmed the submission of the application for variety registration in accordance with Article 58;***

(b) ***the PRM fulfils the respective requirements, other than varietal identity and varietal purity, of Article 8 for standard seed or material; and***

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

Such authorisation may be granted for limited quantities per species as determined by the competent authority as long as those quantities are not determined by the implementing acts referred to in paragraph 6a. That authorisation shall automatically expire if the application for variety registration is withdrawn or a decision pursuant to Article 67(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 may only be granted by the competent authority of the Member State where the application for registration has been submitted.

3. In order to obtain the authorisation referred to in paragraphs 1***, 2 and 2b*** ~~and 2~~, the professional operator shall submit to the competent ~~authorities~~***authority*** a request, ~~indicatingthe~~***indicating*** information about the following:

~~(a) the production of the stock of pre-basic seeds and material, and basic seeds and material, and certified seeds and material available before the variety registration and the envisaged tests and trials for the standard seeds and material;~~

(b) ***the species and*** the breeder's reference***, or the decided denomination, in accordance with Article 66, where applicable*** of the variety indicated in the application for registration;

~~(c) the procedure for the variety maintenance, where applicable;~~

~~(d) the authority before which the application for the registration of the variety is pending, and the reference assigned to that application;~~

(e) ***in case of authorisation as referred to in paragraph 1 and 2b, the sites***~~the site~~ where production ~~will~~***of PRM is to*** take place; and ***in case of authorisation as referred to in paragraph 2, the sites where tests and trials are to take place; and***

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

~~(f) the quantities of the material to be made available on the market.~~

4. The Member States whose competent authorities have granted the authorisation referred to in paragraphs 1***, 2 and 2b***~~ and 2~~ shall ~~annually~~***without delay*** inform the other Member States and the Commission thereof***, through the electronic portal referred to in Article 45***.

5. ~~PRM~~***Pre-basic, basic and certified seed or material*** referred to in ~~paragraphs 1 and 2~~***paragraph 1*** shall be accompanied by ~~a~~***an official*** label, ~~issued by the professional~~***and standard seed or material referred to in paragraph 1 shall be accompanied by an*** operator***'s label***, ***in both cases*** with the indication '~~Not yet listed~~ Variety~~-~~ ***under registration – stock for multiplication'***.

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

PRM referred to in paragraphs 2a and 2b shall be accompanied by an operator's label with the indication 'Variety under registration'.

6. The Commission may, by means of implementing acts, adopt rules concerning size, form, colour and content of the official label and the operator's label as referred to in paragraph 5. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).

6a. The Commission may, by means of implementing acts, lay down the amounts of limited quantities as referred to in paragraphs 2 and 2b. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).

7. Upon request of the competent authority, the professional operator using this derogation shall notify the quantities of PRM of the respective varieties produced and marketed pursuant to this Article.

Article 32a

Requirements for the production and marketing of commercial seed

1. By way of derogation from Articles 5, 6, 6a, 7, 8, 9a and 9b, seed of the genera or species included in column 3 of Annex I may be produced and marketed as commercial seed if they comply with the requirements referred to in Annex III, with the exception of varietal aspects.

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

2. The Commission is empowered in accordance with Article 75 to adopt delegated acts amending Annex I by adding genera or species to, or removing 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 respective genera or species.

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

4. The Commission may, by means of implementing acts, adopt rules concerning size, form, colour and content of the operator's label. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).

Article 33

Authorisation in cases of temporary difficulties in ~~the~~ supply

1. In order to remove temporary difficulties in the ~~general~~ supply of ~~PRM~~***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, by means of ~~an~~ implementing ~~act~~***acts***, may authorise ***one or more*** Member States***,*** for a maximum period of ~~1 year~~***18 months***, to allow the marketing of the categories of pre-basic, basic ~~or~~***,*** certified ***or standard seed or*** material ~~or seed, which~~***that*** fulfils one ***or both*** of the following conditions:

   (a) belongs to a variety not included in a national variety register~~; or~~ ***referred to in Article 44;***

   (b) complies with less stringent requirements than ~~the requirements~~***those*** referred to in Article 7(1) ***and (2) and Article 8(1) and (2)***.

   ~~Point (a) shall apply by way of derogation from Articles 5, and point (b) shall apply by way of derogation from Articles 7(1).~~

   ~~That~~***Those*** implementing ~~act~~***acts*** may set out the maximum quantities~~,~~ which may be ***produced and*** marketed per genera or species ***and the territories where that PRM may be produced and marketed***.

   ~~That~~***Those*** implementing ~~act~~***acts*** shall be adopted in accordance with the examination procedure referred to in Article 76(2).

2. PRM referred to in paragraph 1 shall be accompanied by ~~a~~***an official*** label ***as referred to in Article 15, or an operator's label as referred to in Article 16,*** that states~~, as applicable,~~ that the PRM ~~in question~~***concerned*** belongs to a non-registered variety or fulfils less stringent ~~quality~~ requirements than the ones referred to in Article 7(1) ***and (2) and Article 8(1) and (2)***. ***In the case where less stringent quality requirements concern reduced germination rate, the label referred to in this paragraph shall contain the germination rate of the respective seed lot.***

3. The Commission may decide, by means of ~~an~~ implementing ~~act~~***acts***, that the authorisation concerned has to be repealed or amended, if it concludes that is no longer necessary or proportionate to the objective of removing the temporary difficulties in the ~~general~~ supply of the PRM concerned. ~~That~~***Those*** implementing ~~act~~***acts*** shall be adopted in accordance with the examination procedure referred to in Article 76(2).

4. ***In the case of certified seed,*** Member States may, without obtaining the authorisation of the Commission referred to in paragraph 1, ***decide to*** allow, for a maximum period of ~~1 year,~~***18 months*** and for a limited amount of quantities per genera or species as necessary for ***the*** supply difficulties in question, the production and marketing of ~~seeds that fulfill~~***seed that fulfils*** germination rates reduced up to 15 percentage points compared to the ones set out pursuant to the implementing act referred to in Article ~~7(3)~~***7(4)***. ***In this case, the official label as referred to in paragraph 2 shall indicate 'reduced germination rate' and details on the actual germination rate of the seed. The Member States shall notify each such decision to the Commission and the other Member States mentioning the species and the germination rate of the seed.***

In the case of pre-basic and basic seed, Member States may, without obtaining the authorisation of the Commission referred to in paragraph 1, decide to allow, for a maximum period of 18 months and for a limited amount of quantities per genera or species as necessary for the supply difficulties in question, the production and marketing of seeds with reduced germination rates compared to the ones set out pursuant to the implementing act referred to in Article 7(4). In such cases, the official label shall indicate 'reduced germination rate' as well as the actual germination rate of the seed. The Member States shall notify each such decision to the Commission and the other Member States, specifying the species concerned and the germination rate of the seed.

Such seed may only be marketed in the territory of the Member State of production. It should be indicated on the label that it is for marketing in that territory only.

4a. The Commission may, by means of implementing acts, adopt rules concerning size, form, colour and content of the respective official label and operator's label as referred to in paragraphs 1 to 4. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).

Article 34

~~Provisional authorisation in urgency cases for~~ Marketing of ~~seeds not~~*seed* certified ~~as complying with applicable quality requirements~~ *on the basis of provisional analyses regarding germination in case of rapid supply needs*

1. ***For the purpose of making seed rapidly available on the market,*** competent authorities may ***temporarily*** authorise~~, for a maximum period of 1 month, the marketing of seeds as~~ ***professional operators to market*** pre-basic, basic or certified ~~seeds, before they have been certified~~***seed, if that seed is found*** to comply with ***all of*** the requirements referred to in Article 7 ***other than those*** concerning germination~~, maximum content of other species or purity, if it is necessary to make that seed rapidly available~~***. For the purpose of such temporary authorisation, the fulfilment of the requirements concerning germination shall be demonstrated*** on the ~~market to address urgent needs of supply~~***basis of a provisional analytical report***.

2. The authorisation referred to in paragraph 1 shall be granted ~~on the basis of a an analytical report on the seed, issued by~~***taking into account that*** the professional operator~~, attesting its compliance with the requirements concerning germination, content of other species or purity, adopted pursuant to Article 7(1).~~ ***has in place:***

   (a) the necessary procedures which ensure sufficient guarantees for the seed marketed, and identifying critical points of the process; and

   (b) procedures to ensure the traceability requirements set out in Article 42.

   ~~The name and address of the first recipient of the seeds shall be submitted to the competent authority by the professional operator.~~ The professional operator shall keep the ~~information on~~***name and address of the first recipients of the seed and*** the provisional analytical report ~~at the disposition of~~***, as referred to in paragraph 1, and make it available to*** the competent authority ***on request***.

3. The ~~seeds~~***seed*** referred to in paragraph 1 shall bear ~~a~~***an official*** label ***as referred to in Article 15,*** indicating '~~Provisional authorisation for marketing'marketing~~***Germination analysis not concluded***'.

Article 35

***Marketing of* PRM which is not ~~yet~~*finally* certified**

1. PRM which has been produced in the Union, ***and for which compliance with the production requirements referred to in Article 7(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 7, may be marketed with a reference to any of those categories, if all of the following requirements are fulfilled:

   (a) prior to the harvesting, a field inspection has been carried out by the competent authority, or the professional operator under ~~the~~ official supervision~~ of the competent authority, and that inspection has confirmed compliance of that PRM with the production requirements referred to in Article 7(1)~~;

   (b) it is in the process of being certified by the competent ~~autority~~***authority***, or by the professional operator under ~~the~~ official supervision~~ of the competent authority~~; and

   (c) ~~the requirements set out in paragraphs 2 to 5 are fulfilled.~~

   (ca) it shall be accompanied by an official label as referred to in Article 15 with the indication 'Seed/Material not finally certified'.

2. PRM referred to in paragraph 1 may be marketed only by the professional operator who has produced that PRM ***either*** to the professional operator who is to carry out the certification~~. Such PRM may not be further transferred to any other person before its final certification.~~ ***activities under official supervision pursuant to Article 10 or to the professional operator whose PRM is to be officially certified.***

~~3. PRM referred to in paragraph 1, shall be accompanied by a label, issued by the professional operator, with the indication 'Seeds/Material not yet finally certified'.~~

4. 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 certified pursuant to Article 7 ('***certifying competent authority') are different, the*** competent authority of ~~certification') are different, they~~***production*** shall ~~exchange~~***provide*** the relevant information concerning the production and marketing of that PRM ***to the certifying competent authority***.

~~5. PRM which has been harvested in a third country, but has not yet been certified as pre-basic, basic or certified material pursuant to Article 7, may be marketed in the Union by reference to any of those categories, if:~~

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

~~(b) the requirements set out in paragraph 1, points (a) and (b), paragraphs 2 and 3, are fulfilled, and the professional operators of the third county concerned have been subject to the official supervision of their competent authorities;~~

~~(c) the competent authorities of the Member State and the third country concerned exchange between themselves the relevant information concerning the marketing of that material; and~~

~~(d) on request, the competent authorities of the third country concerned provide all relevant production information to the competent authority of the Member State of certification.~~

~~For the purposes of this paragraph, references made in paragraphs 1 – 5 to the competent authority of production shall be construed as references made to the competent authority of the third country concerned, and references made therein to the requirements set out pursuant to Article 7(1) shall be construed as references made to equivalent requirements of the third country, as recognised pursuant to Article 39(2).~~

5a. The Commission may, by means of implementing acts, adopt rules concerning size, form, colour and content of the respective official label as referred to in paragraph 1(ca). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).

Article 36

More stringent production and *marketing* requirements

1a. Subject to a prior authorisation by the Commission as referred to in paragraph 1, Member States may adopt within their own territory more stringent requirements for the production and marketing of PRM than those laid down in Articles 7 or 8, provided that those more stringent requirements correspond to market demand and specific production conditions in, or agro-climatic needs of, that Member State.

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

1. ***In order to ensure uniform conditions for the implementation of paragraph 1a,*** the Commission ***may***, by means of implementing acts, ~~may~~ authorise ~~the Member States to impose, with regards to production and marketing of PRM, more stringent production or marketing requirements than those referred to in Articles 7 and 8, in all or part of the territory of the~~***a*** Member State ~~concerned, provided that those~~***to impose such*** more stringent requirements ~~correspond to specific production conditions in, and agro-climatic needs, of that Member State in regard to the respective PRM~~.

   Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).

2. In order to obtain the authorisation referred to in paragraph 1, Member States shall submit to the Commission a request setting out:

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

   (b) a justification on the necessity and proportionality of such requirements.

3. The authorisation referred to in paragraph 1 shall be granted only if the following conditions are fulfilled:

   (a) the implementation of the draft provisions, as referred to in paragraph 2, point (a), ensures the improvement of the identity and quality of the PRM concerned, and it is justified by the specific agricultural or climatic conditions of the Member State concerned; and

(b) the draft provisions are necessary and proportionate to the objective of the ~~measure~~***requirements*** referred to in paragraph 2, point (a).

4. Where applicable, each Member State shall, by … [one year after date of application of this Regulation], review the 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 either repeal those measures or amend them to comply with the production and marketing requirements set out in, and adopted pursuant to, Articles 7 and 8.

The Member State concerned shall inform the Commission and the other Member States of those actions.

~~The Commission may, by means of implementing acts, decide that the measures, as referred to in the first subparagraph, are to be repealed or amended, in case they are considered to be unnecessary and/or disproportionate to their objective. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).~~

Article 36a

Derogation from the production and marketing rules for certain species

1. By way of derogation from Articles 5 to 22, PRM may be produced in a Member State pursuant to paragraph 2 and subject to national rules pursuant to a request from that Member State demonstrating, on the basis of consultations with the professional operators concerned, that the following conditions are fulfilled:

(a) the cultivation of that 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 species would impose a disproportionate administrative burden on the competent authority of that Member State.

That PRM may only be marketed in the territory of that Member State with a label indicating that it is for marketing in that territory only.

2. The Commission may, by means of implementing acts, temporarily allow PRM belonging to certain species listed in Annex I to be produced and marketed in a Member State without being subject to the rules of Articles 5 to 22 as referred to in paragraph 1 of this Article.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).

Article 37

Emergency measures

1. Where ***there are detailed reasons based on new or additional scientific knowledge for considering that*** the production or marketing of PRM ~~is likely to constitute~~***constitutes*** a serious risk to human, animal or plant health, environment or cultivation of other species, and such risk ***has not been assessed pursuant to any other Union rules and*** cannot be contained satisfactorily by means of measures taken by the Member State concerned, the Commission shall take, without delay, by means of implementing acts, any appropriate ***and proportionate*** interim emergency measures. Such measures shall be limited in time. They may include provisions restricting or prohibiting the ***production and*** marketing of the PRM concerned~~ or laying down appropriate conditions for its production or marketing,~~**.** Depending on the gravity of the situation***, appropriate conditions for the production and marketing of PRM shall be established***.

Such measures may be taken on the Commission's own initiative or at the request of a Member State. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).

On duly justified imperative grounds of urgency to address a serious risk to human health, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 76(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 the appropriate 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 inform the other Member States and the Commission of the measures adopted, stating the grounds for its decision.

3. ~~The Commission may decide, by means of implementing acts, that the national interim emergency measures~~ ***Within 60 days from the information*** referred to in paragraph 2 ~~are to be repealed or amended, if it considers that those~~***of measures adopted, the Commission shall put the*** measures ~~are not justified in view of the respective risk as~~***adopted pursuant to paragraph 2 before the Committee*** referred to in ~~paragraph 1. Those implementing acts shall be adopted~~***Article 76(1)*** in accordance with the ~~examination~~***regulatory*** procedure referred to in Article 76(2)~~. The Member State concerned may maintain its~~ ***with a view to the extension, amendment or repeal of the*** national interim emergency ~~measures until the date of application of the implementing act(s) referred to in this paragraph.~~***measure.***

Article 38

Temporary experiments to seek improved alternatives to provisions of this Regulation

1. By way of derogation from Articles 2, ***3, 5, 6, 6a, 7, 8, 21 and 32a***~~5, 6, 7, 8 and 20~~, the Commission may, by means of implementing acts, decide on the organisation of temporary experiments to seek improved alternatives to provisions of this Regulation concerning the genera and species it applies to, the requirements for belonging to a registered variety, ***their mixtures,*** the production and marketing requirements for pre-basic, basic, certified and standard material or seed, and the obligation to belong to pre-basic, basic and certified material or seed.

Those experiments may take the form of technical or scientific trials examining the feasibility and appropriateness of new ~~requirements~~***provisions*** compared to the ones set out in Articles 2, ***3, 5, 6, 6a, 7, 8, 21 and 32a,***~~5, 6, 7, 8 and 20~~ of this Regulation.

2. The implementing acts referred to in paragraph 1 shall be adopted in accordance with the examination procedure referred to in Article 76(2) and shall specify one or more of the following elements:

(a) the genera or species concerned;

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

(c) the duration of the experiment;

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

Those acts shall adapt to the ~~evolution of techniques~~***scientific and technological developments*** for production of the PRM concerned, ~~as~~***and*** shall be based on any comparative trials carried out by the Member States.

3. The Commission shall review the results of those experiments and summarise them in a report, indicating, if necessary, the need to amend Articles 2, ***3, 5, 6, 6a, 7, 8, 21 or 32a***~~5, 6, 7, 8 or 20~~.

SECTION 8

IMPORTS FROM THIRD COUNTRIES

Article 39

Imports ~~on the basis of Union equivalence~~*of PRM*

1. PRM may only be imported from third countries, if it is established, pursuant to paragraph 2, that it fulfils requirements equivalent to those applicable to PRM produced and marketed in the Union.

~~However, no such import shall be allowed, and no such equivalence shall be recognised pursuant to paragraph 2, for the preservation mixtures such as those referred to in Article 22, and for PRM such as that subject to the derogations of Articles 26 - 30.~~

1aa. PRM belonging to preservation mixtures as referred to in Article 22 and PRM subject to the derogations of Articles 26, 28, 29, 30, 32a and 34 shall not be imported, and no such equivalence shall be recognised pursuant to paragraph 2 of this Article.

1a. By way of derogation from paragraph 1, seed as grown of vegetable species as referred to in column 1 of Annex I 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 is accompanied by a label pursuant to Article 40(2aa) and the identity of the seed is ensured;

(b) it is marketed only up to the place(s) of processing without further marketing;

(c) the import of that seed has been notified in advance by the professional operator to the competent authority.

The professional operator responsible for the imported seed as grown shall provide, upon 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 imported pursuant to this paragraph.

2. The Commission may recognise, by means of implementing acts, that PRM of specific genera, species or categories produced in a third country, or particular ~~areas~~***regions*** 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 the third country concerned;

(b) an audit carried out by the Commission in the third country concerned, showing that the PRM concerned fulfils requirements equivalent to those applicable to PRM produced and marketed in the Union ***when it concerns a first request to be recognised as equivalent***, ***and*** where that audit has been considered necessary by the Commission ***in other cases***; and

(c) in the case of ~~seeds~~***seed belonging to a species for which OECD Seed Schemes exist***, the fact that ~~this~~ the country concerned participates in the OECD Schemes for the Varietal Certification of Seed moving in International Trade and implements the methods of the International Seed Testing Association (ISTA), or, where applicable, ~~complies with~~***implements*** the rules of the Association of Official Seed Analysts (AOSA) ***or other internationally recognised organisations***.

2a. For ~~that~~***the*** purpose ***of paragraph 2***, the Commission shall examine:

(a) the third country's legislation on the species concerned;

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

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

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

(i) the conditions applied to the production sites from which PRM are exported to the Union comply with requirements that are equivalent to those referred to in this Article; and

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

The Commission may also carry out ***further*** audits to verify the compliance with points (b) to (d) of ~~the second subparagraph~~***this paragraph***.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).

3. The implementing ~~act~~***acts*** referred to in paragraph 2 may provide for one or more of the following elements, as appropriate for the respective PRM:

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

(b) in the case of ~~seeds~~***seed***, conditions relating to the issuance by the third country of a certificate provided by ~~the International Seed Testing Association~~***ISTA, or, where applicable, AOSA or other internationally recognised organisations***;

(c) conditions relating to ~~seed not yet finally certified~~***PRM subject to the derogation referred to in Article 35***;

(d) conditions relating to packaging, sealing and ~~marking~~***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 so 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.

4. The Commission may, by means of implementing acts, recognise that the controls on variety maintenance carried out in the third country afford the same guarantees as those provided for in Article 72(1), (2) and (4), if varieties registered in a national variety register or in the Union variety register are to be maintained in the third country concerned.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).

Article 40

Labelling ~~and information to be provided for the~~*of* PRM imported from third countries

1. Pre-basic, basic and certified ~~seeds~~***seed*** referred to in Article 39 ***from third countries*** may only be imported***, if it bears an OECD label or an official label issued by the competent authority of the*** ~~from~~ third ~~countries, if they are~~***country for species for which there is no OECD Seed Schemes available and, where applicable, is*** accompanied by ~~an OECD label~~***a certificate issued by ISTA or AOSA or other internationally recognised organisations as referred to in Article 39(3), point (b)***.

1a. Pre-basic, basic and certified material referred to in Article 39 ***from third countries*** may only be imported ~~from third countries~~ if it ~~is accompanied by~~***bears*** an official label issued by the competent authority of the third country concerned.

~~Those labels shall contain all of the following information:~~

~~(a) the indication 'meets EU rules and standards';~~

~~(b) the species, variety, category and lot number of the PRM concerned;~~

~~(c) the date of closure, in case of marketing in containers or packages;~~

~~(d) the third country of production and the respective competent authority;~~

~~(e) where applicable, the last third country from which the PRM is imported and the last third country where the PRM has been produced;~~

~~(f) in the case of seeds, the declared net or gross weight of the imported seeds or declared number of imported lots of seeds;~~

~~(g) the name of the person importing the PRM.~~

2. Standard seed and material referred to in Article 39 ***from third countries*** may only be imported ~~from third countries,~~ if it ~~is accompanied by~~***bears, where applicable, an OECD label issued by a professional operator or*** an operator's label ~~containing all of the following information:~~**.**

~~(a) the indication 'meets EU rules and standards';~~

~~(b) the species, variety, category and lot number of the PRM concerned;~~

~~(c) the date of closure, in case of marketing in containers or packages;~~

~~(d) the third country of production;~~

~~(e) where applicable, the last third country from which the PRM is imported and the last third country where the PRM has been produced;~~

~~(f) in the case of seeds, the declared net or gross weight of the imported seeds or declared number of imported lots of seeds;~~

~~(g) the name of the person importing the PRM.~~

2aa. Seed as grown of vegetable species as referred to in Article 39(1a) from third countries may only be imported if it bears an operator's label with the indication 'Seed as grown'.

2a. The Commission shall by means of implementing acts specify the format, colour, language, size and content of the labels referred to in paragraphs 1, 1a, 2 and 2aa.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).

~~3. PRM may only be imported into the Union after the electronic submission of the information referred to in paragraph 1 or 2 by the importer to the competent authority of the Member State of import.~~

~~4. Member States shall immediately notify the Information management system for official controls (IMSOC), referred to in Article 131 of Regulation (EU) 2017/625, of all established non-compliances of the imported PRM concerning the requirements of paragraphs 1 and 2.~~

Article 40a

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 41

Obligations of professional operators~~ producing PRM~~

Professional operators~~, which produce PRM,~~ shall:

(a) be established in the Union;

(b) be registered in the register ~~referred to~~***established by*** Article 65 of Regulation (EU) 2016/2031~~, in accordance with Article 66 of that~~ ***as applicable for this*** Regulation;

(c) be available personally, or designate another person, to liaise with the competent authorities for facilitating the 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 ~~(b)~~***(d)*** and provide them– for examination when requested by the competent authorities;

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

(g) keep updated information on the address of the premises and other locations***, including those of contracting third parties,*** used for the ~~production of PRM~~***activities defined in Article 3(2)***;

(h) make sure that competent authorities have access to the premises and other locations ~~of production~~***where the activities referred to in Article 3(2) take place***, including premises and fields of ~~third~~ contracting ***third*** 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 on request of the competent authorities any contracts with third parties***, in accordance with national and Union rules on confidentiality, access to information and private data protection***.

Article 41a

Procedure of registration

1. Professional operators to be registered in accordance with Article 41, point (b), shall submit an application for registration to the competent authority.

2. The application for registration shall include all of the following elements:

(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(2);

(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(2) for the purpose of the registration; and

(e) the commodity types, genera or species of the PRM concerned by the activities referred to in Article 3(2) carried out by the professional operator.

3. The competent authority shall, after examination of the application, register the professional operator without delay where the application for registration contains all of the elements set out in paragraph 2.

4. By way of derogation from paragraphs 1 and 2 of this Article, the competent authority shall register the professional operator without the submission of an application for registration if that operator is registered in accordance with the Directives referred to in Article 82 and if all of the elements set out in paragraph 2 of this Article are available to that competent authority. Where relevant, the professional operator concerned shall submit an update of those elements within a deadline set by the competent authority.

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

6. Where the competent authority becomes aware that the professional operator no longer carries out the activities referred to in Article 3(2), or that the elements 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 elements immediately or within a specified period of time.

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

7. 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 41b

Content of the register

The register shall contain the elements set out in Article 41a(2), points (a), (b), (d) and (e), and the following elements:

(a) the official registration number;

(b) where applicable, an indication for which of the activities referred to in Article 41a(2), point (c), the professional operator is authorised.

Article 41c

Derogation from obligations of professional operators

1. By way of derogation from Article 41, 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 and marketing of PRM intended to be used exclusively by, and marketed directly to non-professional users pursuant to Article 28;

(b) the production and marketing of PRM intended for the conservation of plant genetic resources by organisations and networks pursuant to Article 29;

(c) the exchange of seed in kind between farmers pursuant to Article 30.

2. Professional operators whose activities relating to PRM are limited to marketing directly to non-professional users as referred to in Article 28, without altering the content of the lots, packaging or labelling, are exempt from the obligations listed in Article 41, points (d), (e) and (g).

3. Organisations and networks involved in the conservation of plant genetic resources as referred to in Article 29 shall not be subject to the requirements of Article 41, points (d) and (e).

4. The Commission is empowered to adopt delegated acts in accordance with Article 75 amending paragraph 1 of this Article by adding other professional operators to be exempted from the obligation in Article 41, point (b), where registration would constitute an administrative burden for them disproportionate to the low risk related to their professional activities.

Article 41d

Availability of information of official registers

1. The Member State of the competent authority keeping the register referred to in Article 41, point (b), shall make available, upon reasoned request, the information contained therein to other Member States or the Commission.

2. ***The competent authority keeping the register shall make available, upon reasoned request, the information referred to in Article 41a(2), points (a) and (b), and Article 41b, point (b), concerning a particular registered operator to any natural or legal person established in the Union for that person's own use.***

3. ***This Article shall apply without prejudice to national and Union rules on confidentiality, access to information and private data protection.***

Article 42

Traceability

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

2. ~~For the purposes of paragraph 1,~~ Professional operators shall keep information ***or records*** allowing them to identify:

   (a) the professional operators~~, which~~ ***or other natural or legal persons who*** have supplied them with the ~~seeds and the material~~***PRM*** concerned;

   (b) the ~~persons~~***professional operators*** to whom they have supplied PRM and the PRM concerned~~, except in case of final users~~.

   On request, they shall 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 ~~3~~***at least 6*** years after ~~that material~~***the PRM*** has been respectively supplied to or by them.

Article 43

~~Annual~~ Notification of the ~~intended~~ production ~~and certification of pre-basic, basic and certified seed and material~~*for the purpose of marketing of PRM*

1. ~~Every~~***At least once a*** year, professional operators shall notify the competent authorities***, within a reasonable time in advance, and in accordance with the instructions of the competent authority,*** about:

(a) ~~their intention to produce pre-basic, basic and certified material or~~***the production of*** pre-basic, basic and certified seed~~, at least one month before the beginning of that production~~ ***and material***; and

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

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

2. Professional operators shall, upon request, submit to the competent authority a declaration concerning the quantities per species of standard seed and material, and commercial seed, that they produced for the purpose of its marketing in the Union.

CHAPTER IV
VARIETY REGISTRATION

SECTION 1
VARIETY REGISTERS

Article 44

Establishment of national variety registers

1. Each Member State shall establish and publish, in electronic format, and shall keep updated a single national register of varieties ('national variety register') containing ***at least***:

(a) all varieties registered pursuant to the procedure set out in Articles 55 ~~–68~~***to 68, including the varieties whose registration has been terminated pursuant to Article 71(1)***;

(aa) varieties for which an application has been submitted pursuant to Article 55 and have not yet been registered pursuant to Article 67, including the varieties whose application has been rejected or withdrawn as referred to in Annex VII, point (cb).

~~(b) the conservation varieties referred to in Article 26 and registered pursuant to Article 53.~~

1a. Any varieties additional to those referred to in paragraph 1 shall be indicated in the national variety register separately.

2. 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.

PRM belonging to a variety subject to paragraph 1, point (aa), may only be marketed pursuant to Article 32.

3. Following the establishment of their national variety registers, as well as following any of their updates, Member States shall~~ immediately~~ ***as soon as possible*** notify~~ them~~ to the Commission ***any elements of those registers, which are subject to this Regulation,*** for inclusion in the Union variety register referred to in Article 45.

4. ~~This Article, and Articles 45 to 74, may not apply to~~ Varieties which are ~~bred~~***intended*** solely as components of hybrid varieties ***and are not marketed as individual varieties are not required to be registered pursuant to this Article and Articles 45 to 74***.

Article 45

Establishment of a Union variety register

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

2. The Union variety register shall include the ~~varieties, registered in~~***elements of the*** national variety registers ~~and~~***as*** notified in accordance with Article 44***(3)***.

2a. The Union variety register ~~may~~***shall*** be accessible by an electronic portal ~~containing~~***established and managed by the Commission. That portal may enable access to*** other registers of plant ~~variety rights,~~***varieties, registers of*** forest reproductive material***, lists of selected clones and polyclonal material*** or other ~~plants~~***plant databases***.

Article 46

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 VII, concerning the varieties referred to in Article 44(1)~~, point (a)~~.

   ~~In the case of the conservation varieties referred to in Article 44(1), point (b), those registers shall indicate at least a brief summary of the officially recognised description, the initial region of their origin, their denomination and the person that maintains them.~~

2. The Commission is empowered to adopt a delegated act in accordance with Article 75, in order to amend Annex VII~~,~~ taking into account the technical and scientific developments, and on the basis of gained experience indicating the need of competent authorities or professional operators to obtain more precise information about the ~~registered~~ varieties ***referred to in Article 44(1)***.

Article 46a

Establishment of national lists of selected clones and polyclonal material

1. Each Member State shall establish and publish, in electronic format, and shall keep updated a single national list of selected clones and polyclonal material ('national list of selected clones and polyclonal material') of genera and species of fruit plants and vine as listed in Annex I.

   Those selected clones and that polyclonal material shall belong to a variety that has been registered in a national variety register referred to in Article 44.

2. Member States shall notify the list referred to in paragraph 1 to the Commission. The Commission shall publish it on the electronic portal referred to in Article 45(2a).

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 list referred to in paragraph 1. That application shall include:

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

(b) proposed denomination for the selected clone or polyclonal material in accordance with Article 54(2aa);

(c) the professional operator that has carried out the selection;

(d) the maintainer of the selected clone or polyclonal material, if different from the professional operator referred in point (c);

(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) description of the effective gains in relation to the overall performance of the relevant variety as regards agronomic or technological characteristics or characteristics related to 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 another Member State.

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

The Commission is empowered to adopt delegated acts, in accordance with Article 75, amending Annex VIIa in order to adapt that Annex to the scientific and technical developments and to the applicable international standards.

5. The national list of selected clones and polyclonal material shall include all information referred to in paragraph 3, as well as information on the variety to which they belong.

SECTION 2

REQUIREMENTS FOR REGISTRATION OF VARIETIES

Article 47

Requirements for registration in national variety registers

1. Varieties shall be registered in a national variety register in accordance with Articles 55 to 68, only if:

   (a) they have:

      (i) an official description showing compliance with the requirements of distinctness, uniformity and stability set out in Articles 48, 49 and 50***; and, in the case of vine, potato, and the genera and species of agricultural plants except for varieties used exclusively for turf grass purposes, listed in Annex I, they***~~, and~~ fulfil the requirements for satisfactory value for sustainable cultivation and use, as set out in Article 52; or

      (ii) an officially recognised description ~~pursuant to Article 53~~***referring to relevant characteristics of the species included in the protocols established by the Community Plant Variety Office (CPVO), or, in the absence of those protocols, in the guidelines of the International Union for the Protection of new Varieties of Plants (UPOV), or, in the absence of those guidelines, in other relevant national protocols***, if they are conservation varieties ***or local varieties***;

   (b) they bear a denomination deemed suitable pursuant to Article 54;

(c) where the varieties contain or consist of genetically modified organisms, the organism is authorised for cultivation in the ~~respective Member State pursuant to~~***Union, in accordance with*** Article 19 of Directive 2001/18/EC or Articles 7 ~~and~~***or*** 19 of Regulation (EC) 1829/2003, ~~or~~***and***, where applicable, ***Chapter III of Regulation (EU) …/…(Office of Publications, please insert reference to NGT Regulation ...), and, where applicable, that cultivation is not excluded*** in the ~~respective~~ Member State ***concerned*** in accordance with Article 26b of Directive 2001/18/EC;

(d) where the varieties contain or consist of a category 1 NGT plant as defined in Article ~~3(7)~~***3, point (7),*** of Regulation (EU) …/… (Office of Publications, please insert reference to NGT Regulation ...), 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;

~~(e) where the varieties contain or consist of a category 2 NGT plant as defined in Article 3(8) of Regulation (EU) …/… (Office of Publications, please insert reference to NGT Regulation), that plant has been authorised pursuant to Chapter III of that Regulation;~~

(f) where the varieties are tolerant to herbicides, they ~~are~~***may be*** subject to cultivation conditions ~~for the production of PRM and for any other purpose, adopted pursuant to paragraph 3 or, in the case they have not been adopted, as adopted by the competent authorities responsible for registration,~~ to avoid the development of herbicide resistance in weeds due to their use~~;~~***, and the competent authorities may determine the cultivation conditions for the territory of the Member State concerned.***

~~(g) where the varieties have particular characteristics other than the ones referred to in point (f) that may lead to undesirable agronomic effects, they are subject to cultivation conditions for the production of PRM and any other purpose, adopted pursuant to paragraph 3 or, in the case they have not been adopted, as adopted by the competent authorities responsible for their registration, to avoid those particular undesirable agronomic effects, such as the development of resistance of pests to the respective varieties or undesirable effects on pollinators.~~

A variety ~~may~~***shall*** not be registered with both an official description and an officially recognised description.

The officially recognised description referred to in point (a)(ii) 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.

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

1a. A variety shall not be listed in the national variety register as conservation variety or local variety if:

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

(b) the registration in the Union variety register as a variety with an official description was terminated pursuant to Article 71 within the last 2 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), or an application for Community plant variety rights or national plant variety rights is pending.

2. The Commission shall adopt, by means of implementing acts, specific requirements concerning~~:~~ ***distinctness, uniformity and stability per genera and species of varieties, as referred to in paragraph 1, point (a)(i), based on protocols established by the CPVO, or the applicable guidelines of UPOV, or other relevant national protocols, including for organic varieties suitable for organic production, as defined in Article 3 of Regulation (EU) 2018/848, where the requirements concerning uniformity may be adjusted for specific genera or species.***

~~(a) distinctness, uniformity and stability per genera or species of varieties, as referred to in paragraph 1, point (a), based on the applicable protocols of the International Union for the Protection of new Varieties of Plants (UPOV), protocols established by the CPVO, or other relevant technical and scientific evidence; and~~

~~(b) specific requirements concerning the distinctness, uniformity and stability per genera and species, as referred to in point (a), for organic varieties suitable for organic production, as defined in Article 3 of Regulation (EU) 2018/848, based on the applicable protocols established by UPOV or the CPVO, and in particular by adjusting the requirements concerning uniformity;~~

The Commission may adopt, by means of implementing acts, specific requirements concerning the characteristics and information that the officially recognised description referred to in paragraph 1, point (a)(ii), is to cover, if appropriate, for specific species.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).

They shall adapt the respective requirements to the development, where applicable, of international standards, and the new scientific and technical knowledge.

~~Until the requirements referred to in point 2(b) are established, the assessment of uniformity of varieties suitable for organic production, other than the varieties referred to in Article 68(1), shall be carried out on the basis of off-types. For self-pollinating species, a population standard of 10% and an acceptance probability of at least 90 % shall be applied. For open pollinated out-crossing species, a population standard of 20% shall be applied and an acceptance probability of at least 80 % shall be applied.~~

~~3. The Commission is empowered to adopt delegated acts in accordance with Article 75, supplementing this Regulation with the minimum cultivation conditions to be adopted by the competent authorities pursuant to paragraphs 1(f) and (g), concerning:~~

~~(i) measures in the field, including crop rotation;~~

~~(ii) monitoring measures;~~

~~(iii) the mode of notification of the conditions referred to in point (i) to the Commission and the other Member States;~~

~~(iv) rules for reporting from professional operators to the competent authorities concerning the application of the conditions referred to in point (i);~~

~~(v) the indication of the conditions referred to in point (i) in the national variety registers.~~

~~Those conditions shall be based on the latest scientific and technical knowledge.~~

~~4. For the purpose of registering a variety in its national variety register, a competent authority shall accept, without any further examination, an official description or an official examination of the requirements for value for sustainable cultivation and use, as referred to in paragraph 1, point (a)(i), which has been produced by a competent authority of another Member State.~~

Article 48

Distinctness

1. For the purposes of the official description~~,~~ referred to in Article 47(1), point ~~(a)~~***(a)(i)***, a variety shall be deemed 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 ~~commonly known~~***a matter of common knowledge*** on the date of the submission of the application established in accordance with Article 58.

2. The existence of another variety, as referred to in paragraph 1, shall be deemed to be ~~commonly known~~***a matter of common knowledge taking into account the respective UPOV guidelines***[28], ***in particular*** if one or more of the following conditions are complied with:

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

[28] *TG/1/3 GENERAL INTRODUCTION TO THE EXAMINATION OF DISTINCTNESS, UNIFORMITY AND STABILITY AND THE DEVELOPMENT OF HARMONIZED DESCRIPTIONS OF NEW VARIETIES OF PLANTS*

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

(b) an application for registration of the variety~~, or an application for granting a plant variety right in respect of that variety,~~ has been ~~filed in the Union~~***submitted in accordance with Article 55 of this Regulation and is under examination***; or

~~(c) an official description of that variety exists in the Union, it is commonly known worldwide, or the technical examination has been conducted pursuant to Article 59.~~

(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.

~~3. Where paragraph 2, point (c) applies, the person(s) responsible for the technical examinations shall make available to the competent authorities the official description of the variety examined by them.~~

Article 49

Uniformity

For the purposes of the official description***, as referred to in Article 47(1), point (a)(i)***, a variety shall be deemed to be uniform if, subject to the variation that may be expected from the particular features of its ~~reproduction and type~~***propagation***, it is sufficiently uniform in the expression of ~~the~~***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 50

Stability

For the purposes of the official description***, as referred to in Article 47(1), point (a)(i)***, a variety shall be deemed to be stable if the expression of the characteristics included in the examination for distinctness, as well as of any other characteristics used for the variety description, remains unchanged after repeated ~~reproduction~~***propagation*** or, in the case of ~~cycles of reproduction~~***a particular cycle of propagation***, at the end of each such cycle.

Article 51

Granted plant variety rights

1. If a variety has been granted a plant variety right pursuant to Article 62 of Regulation (EC) ~~No 2100/1994~~***No 2100/94*** or pursuant to ~~the legislation~~***national rules*** of a Member State, that variety shall be deemed to be distinct, uniform and stable for the purposes of the official description and to have a suitable denomination ~~for the purposes of~~***as referred to in*** Article 47(1), ~~point~~***points (a)(i) and*** (b).

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 have been found suitable pursuant to Article 60.

Article 52

Value for sustainable cultivation and use

1. For the ~~purposes of~~***purpose of fulfiling the requirements set out in*** Article 47(1), point ~~(c)~~***(a)(i)***, the value of a variety for sustainable cultivation and use ~~of a variety~~ shall be considered as 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 ~~a clear~~***an*** improvement for the sustainable cultivation and the uses which can be made of the crops, ~~other plants~~ or the products derived therefrom.

The characteristics referred to in the first subparagraph ~~are~~***may include*** the following, as appropriate***,*** for the species, regions, agro-ecological conditions and uses concerned:

(a) yield, including yield stability and yield under low-input conditions;

(b) tolerance/resistance to biotic stresses, including plant diseases caused by nematodes, fungi, bacteria, viruses, insects and other pests;

(c) tolerance/resistance to abiotic stresses, including adaptation to ~~climate change~~***climatic*** conditions;

(d) ~~more efficient~~***efficiency in the*** use of natural resources, such as water and nutrients;

(e) ~~reduced~~ need for external inputs, such as plant protection products and fertilisers;

(f) characteristics that enhance the sustainability of storage, processing and distribution;

(g) quality or nutritional characteristics~~.~~***;***

(h) ability to be cultivated in association with other species or varieties during all or part of the development cycle.

~~2. For the prupose of paragraph 1, Member States may collaborate with other Member States with similar agro-ecological conditions. Those Member States may establish shared facilities for carrying out the examination for value for sustainable cultivation and use.~~

3. The Commission is empowered to adopt delegated acts in accordance with Article 75, supplementing this Regulation by ***establishing the minimum requirements for***:

~~(a) establishing the minimum requirements for carrying out the examination referred to under paragraph 1;~~

(b) ~~establishing the methodologies for~~ assessing the characteristics listed under paragraph 1~~, points (a) to (g)~~;

(c) ~~establishing the standards for~~ the evaluation and the reporting of the results of the examination of the value for sustainable cultivation and use.

Those delegated acts shall adapt ~~the~~***those*** requirements~~, methodologies and standards of points (a) to (c)~~ to the applicable technical or scientific developments, and to any new Union policies or rules on sustainable agriculture.

Where ~~those~~***no such*** rules ~~are not yet~~***have been*** established, Member States may ~~adopt such~~***apply national*** rules ~~for~~***to*** their ~~respective~~ territories. They shall notify them to the Commission and ~~to~~ the other Member States.

~~The Commission may adopt, by means of implementing acts, a decision requesting a Member State to repeal or modify those rules, if they are deemed, on the basis of the available scientific and technical evidence, to be inappropriate for the examination of value for sustainable cultivation and use of a variety. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).~~

4. 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 an examination under organic conditions, or the examination of certain characteristics, including disease susceptibility, testing may be carried out under low-input conditions and with only the absolutely necessary for the completion of the testing treatments with pesticides and other external inputs.

~~*Article 53*~~

~~**Registration of conservation varieties**~~

~~1. By way of derogation from Articles 48, 49, 50, 52, 55(2), 56, 57, and 59 to 65, a conservation variety shall be registered in a national variety register if it complies with the following conditions:~~

~~(a) it has an officially recognised description, specifying the characteristics that qualify it as a conservation variety, in accordance with the definition in Article 3, point (29);~~

~~(b) it has an indication of its initial region of origin;~~

~~(c) it bears a denomination complying with Article 54;~~

~~(d) it is maintained in the Union.~~

~~2. A conservation variety shall be registered in the national variety register upon application by a professional operator established in the Union. That application shall include all the elements referred to in paragraph 1, points (a) to (d).~~

~~The competent authority shall accept or reject the registration of a conservation variety, after checking its compliance with paragraph 1.~~

~~3. A variety shall not be listed in the national variety register as conservation variety, if:~~

~~(a) it is already listed in the Union variety register with an official description, pursuant to Article 44(1), point (a), or it was deleted from the Union variety register as a variety with an official description within the last 2 years, or within 2 years from the expiry of the period granted pursuant to Article 71(2), or~~

~~(b) it is protected by a Community plant variety right as provided for in Regulation (EC) No 2100/94, or by a national plant variety right, or an application for such a right is pending.~~

~~4. The officially recognised description referred to in paragraph 1, point (a), shall be based on results of unofficial tests, 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 this purpose by Member States.~~

~~The Commission may, by means of implementing acts, specify the characteristics and information that that description should cover if appropriate for specific species. Such implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).~~

~~5. The person responsible for the maintenance of a conservation variety shall keep samples of it and, upon request, make them available to the competent authorities.~~

Article 54

Suitability of variety denominations

1. For the purposes of Article 47(1), point (b), the denomination of a variety shall not be deemed suitable if:

(a) its use in the territory of the Union is precluded by the prior right of a third party;

(b) it may commonly cause its users difficulties as regards recognition or reproduction;

(c) it is identical to, or may be confused with, a ~~variety~~ 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 of*** ~~or in~~ the Union ***or of a third country which is a member of UPOV, unless that*** variety ~~register~~***no longer remains in existence and its denomination has acquired no special significance***; or

(ii) under which ~~material of~~ another variety ***of the same or of a closely related species*** has been made available on the market in a Member State ***of the Union*** or in ***a third country which is a*** a member of ~~the International Union for the Protection of New Varieties of Plants,~~***UPOV, unless that variety no longer remains in existence and its denomination has acquired no special significance;***

~~unless variety referred to in point (i) or (ii) no longer remains in existence and its denomination has acquired no special significance;~~

(d) it is identical to, or may 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 legislation;

(e) it is liable to give offence in one of the Member States or is contrary to the public order; ***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, if a variety is already registered in other national variety registers, the denomination shall be deemed suitable~~,~~ only if it is identical to ~~that~~***the denomination*** appearing in those registers.

This paragraph 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) the rights of third parties impede the free use of that denomination in connection with the variety in question.

2a. ***In the case of conservation varieties referred to in Article 3, point (29), one or more commonly used synonyms may also be indicated in the national variety register. The denomination of conservation varieties which had been 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.***

2aa. ***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. That code shall be in line with the denomination requirements of paragraphs 1 and 2.***

~~3.~~ ~~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 paragraphs 1 and 2, the applicant shall submit an application for a new denomination. The competent authority shall decide on that application upon consultation with CPVO.~~

~~The competent authority may permit the previous denomination to be used temporarily.~~

3a. ***The Commission may, by means of implementing acts, adopt rules specifying the elements referred to in paragraphs 1 and 2, taking into account any applicable international standards, as well as the relevant guidelines on variety denominations developed by the CPVO. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).***

4. The Commission is empowered to adopt delegated acts in accordance with Article 75, supplementing this Regulation by setting out specific criteria concerning the suitability of variety denominations as regards:

(a) their relation to ~~trade marks~~***trademarks***;

(b) their relation to geographical indications or designations of origin for agricultural products;

(c) written consents of holders of prior rights to remove impediments to the suitability of a denomination;

~~(d) determination of whether a denomination is misleading or confusing as referred to in paragraph 1, point (f); and~~

(e) the use of a denomination in the form of a code~~.~~***;***

(f) the definition of closely related species as referred to in paragraph 1, point (c); and

(g) determination of whether a denomination is misleading, offensive or confusing as referred to in paragraph 1, points (e) and (f).

SECTION 3
PROCEDURE FOR REGISTRATION OF VARIETIES IN THE NATIONAL VARIETY REGISTERS

Article 55

Submission of application

Any ~~professional operator~~***natural or legal person*** established in the Union may~~ electronically~~ submit to the competent authority an application for registration of a variety in the national variety register.

~~The submission of that application may be subject to a fee paid by the applicant, as established by the competent authority.~~

Article 56

Contents of the application for registration of a variety

1. The application for registration of a variety in a national variety register shall ~~consist~~***at least include all elements referred to in Annex VII, accompanied by the necessary documentation, as well as all*** of the following ***elements, accompanied by the necessary documentation, as applicable***:

~~(a) a request for registration;~~

~~(b) the identification of the botanical taxon to which the variety belongs;~~

(c) ~~where applicable, the registration number of the applicant, its~~***the*** name and address ***of the applicant*** or, where ~~appropriate~~***applicable***, the names and addresses of the joint applicants, and the credentials of any procedural representative;

(ca) where applicable, the official registration number, as referred to in Article 41b, of the applicant(s) if they are professional operator(s);

~~(d) a proposed denomination;~~

~~(e) the name and address of the person responsible for the variety maintenance, and, where applicable, the registration number of that person;~~

(f) ~~a~~***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~~, and, if available, a completed technical questionnaire~~;

(fa) where the application concerns conservation varieties or local varieties, information related to the production of an officially recognised description;

~~(g) a description of the procedure of variety maintenance;~~

~~(h) the place of breeding of the variety and, if applicable, its particular region of origin;~~

(i) information on whether the variety ~~is~~***has been*** registered in another national variety ~~registerin- and on whether it is known to the applicant that~~***register or*** an application for registration in ~~one of those registers is pending~~***another national variety register has been submitted***;

(ia) 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;

(j) where the variety contains or consists of a genetically modified organism, 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 or ***Articles 7 or 19 of*** Regulation (EC) No 1829/2003, ~~or~~***and***, where applicable, ***Chapter III of Regulation (EU) …/…(Office of Publications, please insert reference to NGT Regulation ...), and, where applicable, that cultivation is not excluded*** in the~~ respective~~ Member State ***concerned*** in accordance with Article 26b of Directive 2001/18/EC;

~~(k) where the application concerns conservation varieties, information related to the production of an officially recognised description of the variety, a proof of that description and any document or publication supporting it;~~

~~(l) in the case of an application concerning varieties with a granted plant variety right pursuant to Regulation (EC) No 2100/94 or the legislation of a Member State, the proof that the variety is protected by such right, with the corresponding official description;~~

~~(m) in case the variety contains or consists of a category 1 NGT as defined in Article 3(7) of Regulation (EU) …/… of the European Parliament and of the Council[29] (Office of Publications, please insert reference to NGT Regulation), evidence that the 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 plant(s);~~

~~(n) in case the variety contains or consists of a category 2 NGT plant as defined in Article 3(8) of Regulation (EU) …/… (Office of Publications, please insert reference to NGT Regulation), indication of that fact;~~

(o) the intended use~~ or conditions of cultivation, if applicable pursuant to Article 47(2), of the variety.~~***;***

(p) in the case of varieties tolerant to herbicides, an indication of that fact, and the active substance to which the variety is tolerant.

~~[29] Regulation (EU) …./…. of the European Parliament and of the Council of … (…., p….).~~

2. The application for registration of a variety in a national variety register shall be accompanied by a sample~~ to be used for the examination of that variety~~. The competent authority of the respective Member State shall set a deadline for the submission of that sample and specify its quality and quantity.

Article 57

Formal examination of *the* application

1. The competent authority of the respective Member State shall register and examine each application referred to in Article 55 in order to establish whether it complies with the requirements laid down in Article 56.

2. If the application does not comply with the requirements laid down in Article 56, the competent authority shall give the applicant a possibility to rectify the application accordingly within a given time. If the application does not– meet these requirements by the expiry of ~~thatgiven~~***that given*** time, the competent authority shall reject the application ~~and terminate the variety registration~~.

Article 58

Date of application for registration

The date of the submission of the application for registration shall be the date on which the application~~, fully complying with the requirements laid down in Article 56,~~ is received by the competent authority of the respective Member State.

The competent authorities shall ~~immediately send to~~***inform*** the applicant~~ a confirmation~~ of the successful submission of the application, including information on the date of ***receipt of that application***~~that submission~~.

~~*Article 59*~~

~~**Technical examination of the variety**~~

~~1. Where, as a result of the formal examination, the application is found to comply with the requirements laid down in Article 56, a technical examination of the variety shall be carried out.~~

~~The technical examination shall be carried out by growing the variety, taking into account the intended use and conditions for cultivation of the variety. Other means, including the use of bio-molecular techniques, may be used as a supplementary tool, as appropriate for the purposes of the technical examination, the species concerned or the characteristics to be checked, as established pursuant to the implementing act referred to in Article 47(2) concerning distinctness, uniformity and stability.~~

~~The technical examination referred shall verify:~~

~~(a) the compliance with the requirements for distinctness, uniformity and stability of the variety, as laid down in Articles 48 to 50;~~

~~(b) whether the variety has value for sustainable cultivation and use, in accordance with Article 52, in the case of the varieties referred to in Article 47(1), point (a)(ii).~~

~~2. The technical examination referred to in paragraph 1 shall be carried out by the competent authorities in accordance with Article 60, unless the derogation referred to in Article 61(1) applies.~~

~~3. In case a formal report on the distinctness, uniformity and stability of the variety, produced by CPVO or another competent authority, is already available, the competent authority shall take into consideration the conclusions of that report for the purposes of concluding the technical examination.~~

~~4. The conduct of the technical examination referred to in paragraph 1 may be subject to a fee paid by the applicant, as established by the competent authority.~~

Article 59a

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 56, a technical examination of the variety, except for conservation and local varieties, shall be carried out to verify its compliance with the requirements of distinctness, uniformity and stability, as laid down in Articles 48, 49 and 50.

2. The technical examination shall be carried out by an examination office in accordance with Article 60.

The Commission may, by means of implementing acts, specify the way in which that examination office may collaborate with other natural or legal persons for the purpose of the technical examination.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(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 will conclude with the adoption of an examination report and, where applicable, an official description.

By way of derogation from the first subparagraph, 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 60, is already available, the competent authority may take into consideration or accept, without growing the variety, the results of that report or that official description.

4. In reference to the examination of requirements laid down in Articles 48, 49 and 50 other means, including bio-molecular techniques, may be used as a supplementary tool or as a compulsory tool if it is required in accordance with CPVO protocols, as appropriate for the purposes of the technical examination, the species concerned or the characteristics to be checked.

Article 59b

Technical examination of the value for sustainable cultivation and use

1. Where, as a result of the formal examination, the application is found to comply with the requirements referred to in Article 56, a technical examination of the variety, except for conservation and local varieties, shall be carried out in order to verify whether the variety has value for sustainable cultivation and use, in accordance with Article 52, in the case of the varieties referred to in Article 47(1), point (a)(i).

2. The technical examination shall be carried out by the competent authority.

The Commission may, by means of implementing acts, specify the way in which that competent authority may collaborate with natural or legal persons for the purpose of the technical examination.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(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.

By way of derogation from the first subparagraph, 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 entire, or part of the, examination for value for sustainable cultivation and use.

5. Other means, including bio-molecular techniques, may be used as a supplementary tool or as a compulsory tool if it is required in accordance with the respective national rules, as appropriate for the purposes of the technical examination, the species concerned or the characteristics to be checked.

Article 60

~~Audit of the competent authority's premises~~*Examination offices carrying out technical examination*

1. ~~The competent authority of the respective Member State may carry out~~ The technical examination ~~as regards compliance with the requirements for distinctness, uniformity and stability referred to in Articles 48 to 50 only after its premises and working arrangements, dedicated to this purpose,~~***pursuant to Article 59a shall be carried out only by the examination offices that*** have been found suitable ***by the CPVO for certain genera or species. That finding shall be based on the CPVO entrustment requirements*** for carrying out this examination ~~pursuant to an audit conducted by the CPVO or the Commission~~***. It shall also be based on regular audits taking place within specific periods, depending on the genera or species concerned***.

Examination offices that have been entrusted by the CPVO for certain genera or species, in accordance with Article 55(1) of Regulation (EC) No 2100/94, shall be considered suitable for carrying out the examination of the respective genera or species for the purposes of this Article.

~~On the basis of the audit referred to in the first subparagraph, the Commission may recommend to the competent authority, if appropriate, actions to ensure the suitability of the premises and organisation of the competent authorities. The Commission may carry out additional audits and, where applicable, recommend to the competent authorities corrective actions to ensure the suitability of their premises and organisation.~~

1a. ***Where, for certain genera or species, no examination offices in the Union have been found suitable in accordance with paragraph 1, the technical examination referred to in that paragraph may be carried out in the examination office of a third country, if that office has been found suitable by the CPVO for the respective genera or species.***

~~*Article 61*~~

~~Authorisation of the applicant to carry out technical examination for value for sustainable cultivation and use~~

~~1.~~ ~~By way of derogation from Article 59(2), the technical examination of whether the variety has a sustainable value for cultivation and use, in accordance with Article 52, or part of it, may be carried out by the applicant if:~~

~~(a)~~ ~~that applicant has been authorised by the competent authority of the respective Member State;~~

~~(b)~~ ~~the examination is carried out under the official supervision and guidance of the competent authority concerned; and~~

~~(c)~~ ~~the examination is carried out in the premises dedicated to that purpose.~~

~~2.~~ ~~Prior to granting the authorisation to carry out the technical examination on breeders' premises, the competent authority shall audit the premises, the resources and the organisational capacities of the applicant. That audit shall verify whether the premises, the laboratoriy facilities, the organisation and the carrying out of the growing trials are suitable for realising the technical examination on breeders' premises as regards compliance with the requirements of a value for sustainable cultivation and use referred to in Article 52.~~

~~3.~~ ~~The Commission is empowered to adopt delegated acts in accordance with Article 75, supplementing this Regulation by setting out the rules concerning the audit referred to in paragraph 2.~~

~~4.~~ ~~On the basis of the audit referred to in paragraph 2, the competent authority may recommend to the applicant, if appropriate, actions to ensure the suitability of the applicant's premises and organisation of the examination.~~

~~5.~~ ~~The competent authority may carry out additional audits to the one referred to in paragraph 2 and, where applicable, recommend to the applicant to perform, within a specific period of time, corrective actions concerning the its premises and the working arrangements. In case the competent authority concludes, following that period, that the applicant's premises and working arrangements are not suitable, it may withdraw or modify the authorisation referred to in paragraph 1.~~

~~*Article 62*~~

~~Additional rules on technical examination~~

~~1. The Commission is empowered to adopt delegated acts in accordance with Article 75, supplementing the requirements on the technical examination laid down in Article 59. Those delegated acts may concern:~~

~~(a) qualification, training and activities of staff of the competent authority or of the applicant, for the purposes of the technical examination referred to in Article 61;~~

~~(b) the necessary equipment, including laboratories for testing, necessary to carry out the technical examination;~~

~~(c) the establishment of a variety reference collection to compare the examined variety with other varieties to assess distinctness, and the storage management of such reference collection;~~

~~(d) the establishment of quality management systems, including record of activities and protocols or guidelines, to be used for the technical examination;~~

~~(e) the carrying out of growing trials and laboratory tests for particular genera or species, including bio-molecular techniques.~~

~~Those delegated acts adapt to the available international technical and scientific protocols.~~

~~2. Where no requirements have been adopted pursuant to paragraph 1, technical examinations shall be carried out in accordance with national protocols as regards the elements referred in paragraph 1, points (a) - (e).~~

Article 63

Confidentiality

1. Where, ~~during~~***for the purpose of*** the technical examination provided for in Article ~~59~~***59a***, an examination of the genealogical components appears to be necessary, the results of that examination and the description of ~~the genealogical~~***those*** components shall be treated as confidential~~, if the applicant requests so~~***. 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. In the case of varieties of PRM intended exclusively for the production of agricultural raw materials for industrial purposes, certain elements of the technical examination and the intended uses of those varieties, whose public disclosure may affect the competitive position of the applicant, shall be treated as confidential, if that applicant requests so.~~

3. This Article shall apply without prejudice to Article 8 of Regulation (EU) 2017/625.

~~*Article 64*~~

~~**Provisional examination report and provisional official description**~~

~~1. Following the technical examination provided for in Article 59, the competent authority shall produce a provisional examination report, as to the compliance with the distinctness, uniformity and stability requirements, and the characteristics of value for sustainable cultivation and use, as applicable, as referred to in Articles 48, 49, 50 and 52, and shall issue a provisional official description of the variety on the basis of that report.~~

~~2. The provisional examination report may refer to findings of other examination reports, produced on the relevant variety, by the competent authority concerned, other competent authorities or the CPVO.~~

~~3. The competent authority shall communicate the provisional examination report and the provisional official description of the variety to the applicant. The applicant may comment on these documents within 15 calendar days.~~

~~4. Where the competent authority does not consider that the provisional examination report constitutes a sufficient basis for a decision on the registration of the variety, it shall request from the applicant additional information, examinations or other actions, as appropriate, to ensure compliance of the variety with the requirements concerning distinctness, uniformity, stability and value for sustainable cultivation and/or use, as set out respectively in Articles 48, 49, 50 and 52.~~

Article 65

Examination report and ~~final~~ official description

1. ~~After taking into account any comments on the provisional~~***Following the technical*** examination ~~report and the provisional official description~~ provided ~~by the applicant~~***for in Article 59a and, where applicable, Article 59b***, the competent authority shall ~~issue a final~~***communicate a draft of the respective*** examination report ***to the applicant and give the applicant an opportunity to provide comments within a reasonable time***~~and a final official description on the distinctness, uniformity and stability of the variety and including a summary of the examantion results on value for sustainable cultivation and use~~.

2. After examining the comments of the applicant as 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 ~~authorities~~***authority*** shall, on reasoned request, make available the examination reports and the official description to third parties, subject to national or Union law on data protection and to rules on confidentiality.

Article 65a

Examination of conservation and local varieties

The competent authority shall examine the compliance of the proposed description of a conservation or local variety with the requirements of Article 47(1), point (a)(ii).

That examination may include a growing trial.

If that compliance is established, the competent authority shall officially recognise the respective description.

Article 66

Examination of the denomination of a variety

1. ~~After the formal examination of the application provided for in Article 57, and~~ Prior to the registration of a variety in a national variety register pursuant to Article 67, the competent authority shall ~~consult~~***take a decision on the variety denomination after consulting*** the CPVO on the ~~variety~~ denomination proposed by the applicant. ***That decision shall determine the suitability of the denomination on the basis of the facts applicable at the time of the proposal for that denomination. Where the denomination has not been proposed as referred to in Article 56(1), point (d), it may be proposed by the applicant at a later stage and at a reasonable time.***

2. ~~Thet~~***The*** CPVO shall submit to the competent authority a recommendation on the suitability of the variety denomination proposed by the applicant, in accordance with Article 54. ~~The competent authority shall inform the applicant on that recommendation.~~

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 a possibility 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 54, 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 67

Decision on the registration of a variety in the national variety register

1. If, on the basis of the procedure set out in Articles 55 to 66, it is concluded that the variety complies with the requirements set out in Article 47(1), ***and the requirements concerning variety maintenance in accordance with Article 72 are fulfilled,*** the competent authority of the respective Member State shall decide to register the variety in the national variety register.

2. The competent authority shall adopt a decision ~~refusing~~***rejecting*** registration in the national variety register, if:

   (a) it establishes that the respective requirements set out in Article 47(1) are not fulfilled; ~~or~~

   (b) the applicant has failed to comply with any of the ~~obligations~~***applicable requirements*** set out ~~for it~~ in Articles 55 to ~~64.~~***66;***

   (c) the requirements concerning variety maintenance in accordance with Article 72 are not fulfilled; or

   (d) the applicant has failed to pay any fee that has been set pursuant to Article 78a.

3. Decisions ~~refusing~~***rejecting*** the registration of a variety in the national variety register shall state the reasons justifying such ~~refusal~~***rejection***.

4. The competent authority shall communicate to the applicant the decision referred to in paragraphs 1 and 2.

5. The decisions referred to in paragraph 1 and 2 may be appealed ***against***, in accordance with the administrative rules of the Member State concerned. ~~Any appeal against a decision referred to in paragraph 1 shall have a suspensory effect on the registration of the respective variety.~~

~~6. The adoption of the decision referred to in paragraph 1 may be subject to a fee paid by the applicant, as established by the competent authority.~~

Article 68

Varieties registered pursuant to Directives 68/193/EEC, 2002/53/EC, 2002/55/EC and 2008/90/EC

1. By way of derogation from Articles ~~54~~***55*** to 67, the competent authorities shall immediately register in their national variety registers***, as applicable with an official description or an officially recognised description,*** all varieties officially accepted or registered before … [the date of ~~the entry into force~~***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 by those Articles.

Varieties accepted in accordance with Article 3 of Directive 2008/62/EC and Article 3(1) of Directive 2009/145/EC before… [OJ, please, insert the date of application of this Regulation] shall be immediately registered in the national variety registers as conservation varieties provided with an officially recognised description without applying the registration procedure set out by Articles 55 to 67 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 a conservation variety upon request by the applicant or the maintainer subject to the decision of the competent authority without applying the registration procedure set out by Articles 55 to 67 of this Regulation.

1a. The beginning of the period of registration of those varieties shall, without prejudice to Article 69(1), be the date on which they were registered pursuant to the Directives referred to in paragraph 1 of this Article. For varieties of vine, the beginning of the period of registration shall be … [the date of application of this Regulation].

~~2. By way of derogation from Article 53, varieties accepted in accordance with Article 3 of Directive 2008/62/EC and Article 3(1) of Directive 2009/145/EC before… [OJ, please, insert the date of the entry into force of this Regulation] shall be immediately registered in the national variety registers as conservation varieties provided with an officially recognised description without applying the registration procedure set out by that Article.~~

2a. Technical examinations within the meaning of Articles 59a and 59b, 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 Article 67 of this Regulation.

Article 68a

Varieties of species registered pursuant to national rules

By way of derogation from Articles 55 to 67, varieties of species listed in Annex I, which were not covered by the Directives referred to in Article 68(1) and are registered in a national variety register pursuant to national rules before [the date of application of this Regulation], shall be immediately registered in the relevant national variety registers without applying the rules set out in Articles 55 to 67.

SECTION 4

REGISTRATION PERIOD AND VARIETY MAINTENANCE

Article 69

Period of registration

1. The period of registration of a variety***, other than a conservation or local variety,*** in a national variety register ('period of registration') shall be 10 years. ***That period shall expire on 31 December of the last calendar year of the period of registration.***

   However, ~~that~~***the*** period of registration shall be 30 years for ***conservation and local varieties, as well as for*** varieties of ***genera and*** species of fruit plants and vine~~ propagating material~~, as listed ~~respectively in Parts C and D of~~***in*** Annex I. ***That period shall expire on 31 December of the last calendar year of the period of registration.***

   In the case of varieties consisting of, or containing, a genetically modified organism, the period of registration shall be limited to the period for which that genetically modified organism is authorised for cultivation pursuant to Directive 2001/18/EC or Regulation (EC) No 1829/2003***, and where applicable, Chapter III of Regulation (EU) …/…(Office of Publications, please insert reference to NGT Regulation ...), if that period is shorter than the respective periods referred to in subparagraphs 1 and 2.***

   ~~In the case of varieties consisting of, or containing, a category 2 NGT plant as defined in Article 3(8), of Regulation (EU) …/… (Office of Publications, please insert reference to NGT Regulation ...), the period of registration shall be limited to the period for which that plant is authorised pursuant to that Regulation.~~

2. The period of registration of a variety in a national variety register may be renewed for a further period of 10 years, or respectively 30 years, in accordance with the procedure and the conditions laid down in Article 70.

In the case of ~~a variety~~***varieties*** consisting of***,*** or containing***,*** a genetically modified organism, the renewal of the period of registration shall be limited to the period for which that genetically modified organism is authorised for cultivation pursuant to Directive 2001/18/EC or Regulation (EC) No 1829/2003***, and, where applicable, Chapter III of Regulation (EU) …/…(Office of Publications, please insert reference to NGT Regulation ...), and, where applicable, cultivation is not excluded, if that period is shorter than the respective periods referred to in subparagraph 1.***

~~3. The registration of a variety may be subject to an annual fee paid by the applicant, as established by the competent authority.~~

Article 70

Procedure and conditions for *renewal of* registration ~~renewal~~

1. Any person ***with a legitimate interest*** intending to renew the registration of a variety shall submit an application~~, no earlier than 12 months, and~~ no later than ~~6~~***24*** months, before the expiration of the period of registration as referred to in Article 69(1) ***and (2)***.

2. The application shall be submitted ~~electronically. It shall be~~***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 applicant has submitted sufficient evidence that~~ the variety continues to comply with the ~~respective~~ requirements of Article 47(1)***, other than the requirements concerning the value for sustainable cultivation and use***; and

   (b) the ~~competent authority of the respective Member State has established that there is a person responsible for the~~***requirements concerning*** variety maintenance in accordance with Article 72 ***are fulfilled***.

3a. ***Point (a) shall not apply to varieties referred to in Articles 68 and 68a, as long as the varieties remain true to their description.***

In the case of the varieties referred to in Article 47(1), point (a)(i), the competent authority may conduct a technical examination in accordance with Article 59a to determine whether the variety is uniform and stable, if evidence exists suggesting that such an examination is needed.

~~4. The competent authority may, on its own initiative, renew the registration of a variety, if it is still in large demand by the professional operators and farmers concerned, or it should be retained in the interest of conserving plant genetic resources.~~

Article 71

~~Removal from national~~*Termination of* variety ~~registers~~*registration*

1. The competent authority of the respective Member State shall ~~remove~~***terminate the registration of*** a variety***, if any of the following applies*** ~~from the national variety register, if~~:

(a) it concludes, on the basis of any new evidence, that the requirements for registration, as set out in Article 47(1)***, other than the requirements concerning value for sustainable cultivation and use,*** are no longer fulfilled;

(aa) it concludes, on the basis of any new evidence, that the requirements for registration, as set out in Article 47(1) had not been fulfilled at the time of registration;

(b) the applicant does not pay ***any of the fees***~~the fee~~ that the competent authority has established in accordance with ~~Articles 55, 59(4), 67(6) and 69(3)~~***Article 78a***;

(c) the ***variety is no longer maintained pursuant to the requirements in Article 72, or the natural or legal*** person responsible for the variety maintenance, as referred to in ***that*** Article~~ 72,~~ so requests, or that person has ceased to maintain the variety and no other person has become responsible for its maintenance;

~~(d) the variety is no longer maintained pursuant to requirements of Article 72;~~

~~(e) the variety is maintained in a third country, which has not provided assistance on the controls of that maintenance pursuant to Article 72(7);~~

(f) ***it has been found that*** at the time of the application, false or fraudulent data ~~were supplied~~***had been submitted*** on the basis of which the registration was decided;

(g) no application for renewal has been submitted by the deadline referred to in Article 70(1) and the ~~validity~~ period of registration referred to in Article 69(1) ***and (2)*** has expired~~.~~***; or***

(ga) the applicant has requested the termination of the registration (surrender)unless another natural or legal person has requested the continuation of that registration and has taken over the respective responsibilities of the applicant.

2. ~~On request by the applicant,~~ The competent authority may allow that a variety ~~removed from the national variety register~~***, the registration of which has been terminated*** in accordance with paragraph 1, point ***(c), (g) or (ga), is marketed***~~(g), continues to be made available on the market~~ until 30 June of the third year following the ~~removal from~~***termination in*** the register. ***Such decision shall be indicated in the national variety register.***

~~That request shall be submitted no later than the date of the expiration of the validity period of registration.~~

~~3. Following its removal from a national variety register, as referred to in paragraph 1, the variety concerned shall be immediately removed from the Union variety register, if it is not registered in any other national variety register.~~

3a. Following the termination of its registration, the variety shall remain in the national and the Union variety register as referred to in Articles 44 and 45 with an indication of its registration status, as referred to in point (cb) of Annex VII.

Article 72

Variety maintenance

1. Varieties registered in a national variety register shall be maintained by the applicant~~,~~ or by any other ***natural or legal*** person ~~notified by the applicant~~***in the Union, or in a third country that has been subject*** to the ~~competent authority. The competent authority shall authorise that other person to carry out the maintenance of the variety, if that person proves its capacity for that task, and the competent authority shall withdraw that authorisation if that person is no longer capable for that~~***implementing act referred to in Article 39(4) ("maintainer")***. The name and ~~registration number~~***address*** of that ***other natural or legal*** person shall be ~~notified by the applicant to~~***recorded by*** the competent authority of the Member State. ***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 the capability to carry out the maintenance.***

2. Variety maintenance shall take place in accordance with accepted practices concerning, as appropriate, genera, species or particular types of varieties.

3. The ~~persons referred to in paragraph 1~~***maintainer*** shall keep records concerning the variety maintenance. It shall at all times be possible for the competent authority to check the variety maintenance from those records. Those records shall also cover ***all the relevant***~~the production of pre-basic, basic, certified and standard material, and the~~ stages of production ~~prior to pre-basic material~~***of PRM, including the relevant categories***.

   A standard sample of the variety concerned shall be provided ***by the maintainer*** to the competent authority on request. ***In the case of vegetatively reproduced varieties, instead of a standard sample, the maintainer may demonstrate that it has living plants of that variety for the appropriate checks and maintenance.***

4. The competent authority shall carry out controls on the manner in which the variety maintenance is carried out and may, to this purpose, take samples of the ~~varieties~~***variety*** concerned. The frequency of those controls shall be based on the likelihood of non-compliance with paragraphs 1 to 3.

5. Where ~~a~~***the*** competent authority finds that the ~~person responsible for~~ variety ~~maintenance does not comply~~***is not maintained in accordance*** with paragraphs 1 to 3, it shall give ~~that person~~***the maintainer*** appropriate time to take corrective action or request another person to carry out ~~the variety~~***that*** maintenance. If no such action is taken within that time limit, the competent authority shall ~~remove~~***terminate the registration of*** the variety ~~from the national variety register~~ in accordance with Article ~~71~~***71(1), point (c)***.

6. 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 controls on variety maintenance. If no such assistance is provided within a reasonable period of time, or if it is concluded that the variety maintenance is not carried out in accordance with this Article, the respective competent authority shall ~~remove~~***request the maintainer to take corrective actions. If the corrective actions are not taken within reasonable time, the competent authority shall terminate the registration of*** the variety ~~from the national variety register~~ in accordance with Article ~~71~~***71(1), point (c)***.

7. Where variety maintenance takes place in a third country, the competent authorities of the Member State, in whose national variety register the variety has been registered, shall request the third country's authorities' assistance in the controls on variety maintenance, if such a maintenance has been subject to the recognition of equivalence referred to in Article ~~39(5)~~***39(4)***. If no such assistance is provided within a reasonable period of time, or if it is concluded that the variety maintenance is not carried out in accordance with this Article, the respective competent authority shall ~~remove~~***request the maintainer to take corrective actions. If the corrective actions are not taken within reasonable time, the competent authority shall terminate the registration of*** the variety ~~from the national variety register~~ in accordance with Article ~~71~~***71(1), point (c)***.

~~SECTION 5~~

~~KEEPING OF DOCUMENTATION AND SAMPLES~~

~~Article 73~~

~~Documentation on the national variety registers~~

~~The competent authority of the respective Member State shall keep a file on each variety registered in the national variety register, containing:~~

~~(a) the official description or the officially recognised description of the variety;~~

~~(b) the examination report; and~~

~~(c) any complementary examination report pursuant to Article 64(4).~~

~~In the case of an officially recognised description, the file shall only contain that description and the documents supporting it.~~

Article 74

***Standard* samples of the registered varieties**

1. The competent authorities shall keep ***standard*** samples of the varieties registered in the national variety registers and make them ~~accessible to any third party upon request~~***available to other competent authorities for official purposes***.

In the case of vegetatively reproduced varieties, instead of a standard sample, the competent authority or the maintainer may keep living plants of that variety.

2. The Commission may, by means of implementing acts, specify the size of those ***standard*** samples, the rules for their replacement, in the case where the quantity of the original ***standard*** sample is too limited or it is no longer adequate due to its use in other examinations, and their submission to other competent authorities. ~~That~~***Those*** implementing ~~act~~***acts*** shall be adopted in accordance with the examination procedure referred to in Article 76(2).

CHAPTER V
PROCEDURAL PROVISIONS

Article 75

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 Articles 2(3), ***6a(2),*** 7(3), 8(4), 10(2), 15(5), ~~20(2)~~***16(4)***, 22(2), ~~24(4), 27(3)~~***32a(2), 41c(4)***, 46(2), 47(3), 52(3)~~, 54(4), 61(3), and 62(1)~~ ***and 54(4)*** shall be conferred on the Commission for 5 years from the date of the entry into force of this Regulation.

   The delegation of power shall be tacitly extended for periods of 5 years, unless the European Parliament or the Council opposed such extension not later than three months before the end of each ~~period. The~~***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 5-year period.

3. The delegation of power referred to in Articles 2(3), ***6a(2),*** 7(3), 8(4), 10(2), 15(5), ~~20(2)~~***16(4)***, 22(2), ~~24(4), 27(3)~~***32a(2), 41c(4)***, 46(2), 47(3), 52(3)~~, 54(4), 61(3), and 62(1)~~ ***and 54(4)*** 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 on Better Law-Making of 13 April 2016.

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 Articles 2(3), ***6a(2),*** 7(3), 8(4), 10(2), 15(5), ~~20(2)~~***16(4)***, 22(2), ~~24(4), 27(3)~~***32a(2), 41c(4)***, 46(2), 47(3), 52(3)~~, 54(4), 61(3), and 62(1)~~ ***and 54(4)*** shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of 2 months of the 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 2 months at the initiative of the European Parliament or the Council.

Article 76

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[30]. 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.

   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 decides so or a simple majority of committee members requests it.

3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof shall apply.

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[30] 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).

CHAPTER VI

REPORTING, PENALTIES, *CONTROLS* AND AMENDMENTS OF REGULATIONS (EU) 2016/2031~~, 2017/625 AND 2018/848~~ *AND (EU) 2017/625*

Article 77

Reporting

1. By … [5 years after the date of application of this Regulation], and every ~~five~~ 5 years ~~there after~~***thereafter***, Member States shall transmit to the Commission a report on the following:

(a) ***annual*** quantities ***produced of seed and material belonging to pre-basic, basic, and***~~of~~ certified ~~and standard PRM and areas used for their~~***categories per genera or species, and any available data on the*** production ~~per year and~~***of standard seed and material per genera or*** species~~ with a specification of the quantities used for organic varieties suitable for organic production~~;

~~(b) quantities of marketed PRM of heterogeneous material and areas used for their production per year and species;~~

(c) ***annual*** quantities of ~~marketed~~***produced*** PRM of conservation varieties ***and local varieties per genera or***~~per year and~~ species;

(d) ***the*** number of professional operators using the derogations for ***production and*** marketing to ~~final~~***non-professional*** users in accordance with Article 28, ***and the genera or***~~the~~ species concerned~~ and total quantities of PRM per species~~;

(e) ***the*** number of~~ gene banks,~~ organisations and networks ~~with a statutory or other declared objective to conserve~~***using the derogation for production and marketing of PRM for the conservation of*** plant genetic resources, in accordance with Article 29 and the ***genera or*** species concerned;

~~(f) the quantities as defined per species for the seeds exchanged in kind between farmers, in accordance with Article 30;~~

(g) the quantities authorised per ***genera or*** species for PRM~~ intended for tests and trials for the breeding of new varieties~~, in accordance with Article ~~31~~***32(2) and (2b)***;

(h) ***the*** quantities of PRM per genera ~~and~~***or*** species ~~for which~~***that is allowed to be marketed in accordance with*** Article 33(4)~~ has been applied~~;

~~(i) quantities of PRM per genera and species imported from third countries, in accordance with Article 39;~~

(j) ***number and types of violations for which*** penalties ***were*** imposed ***annually*** in accordance with Article 78;

(k) number of professional operators ~~established in their territory~~***registered in accordance with Article 41, point (b)***.

2. The Commission shall, by means of implementing acts, specify the technical formats for reporting made pursuant to paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).

Article ~~19~~77a

Non-compliance of PRM with production and marketing requirements

In the case where~~ official~~ controls carried out ***by the competent authority*** during the ***production and*** marketing of PRM show ~~that pre-basic, basic, certified seeds or material, or standard seeds or material, have not been produced or marketed within the Union in compliance~~***non-compliance*** with the respective requirements referred to in ~~Articles 7 or 8, or in the case where the varietal identity and purity of the PRM were not confirmed in the control plot testing in accordance with Article 24~~***this Regulation***, the competent ~~authorities~~***authority*** shall ensure that the professional operator ~~concerned~~ takes the necessary corrective actions ~~concerning the PRM concerned~~***with regard to that PRM*** and its premises and production methods, as appropriate. Those actions shall aim at achieving one or more of the following elements:

(a) the PRM concerned complies with the respective requirements;

(b) the PRM concerned is withdrawn from the market or is used as material other than PRM; ***or***

(c) with the exception of standard seed or standard material, the PRM concerned is produced or marketed under a lower category, in accordance with the requirements applicable for that category~~;~~**.**

~~(d) the professional operator is sanctioned by additional means to the withdrawal or modification of the authorisation referred to in Article 11.~~

Article 78

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 of any subsequent amendment affecting them.

2. Member States shall ensure that financial penalties for violations of this Regulation, perpetrated through fraud are equal, in accordance with national law, at least either to the acquired economic advantage for the professional operator or to a percentage of the professional operator's turnover.

Article 78a

Fees

Member States may collect fees for their acts provided for under this Regulation.

Article 79

Amendments of Regulation (EU) 2016/2031

In Article 37 of Regulation (EU) 2016/2031~~, paragraph 4 is replaced by the following~~:

(1) paragraph 2 is replaced by the following:

'2. The Commission shall, by means of an implementing act, establish 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 in paragraph 7 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, by means of an implementing act, where appropriate, set 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 to this Regulation.;*** ———————

**** Regulation (EU) .... of the European Parliament and of the Council of ... [the final title of the PRM Regulation] (OJ L ..., ELI:...).'***

(3) paragraph 7 is replaced by the following:

'7. Where Article 36, point (e), is only fulfilled for one or more of the categories referred to in Article 6(1) of [PRM Regulation]+, or, as applicable, in one or more of the specific cases referred to in Article 6(2) of that Regulation, or for other plants for planting, if the respective phytosanitary risk requires so, the list referred to in paragraph 2 of this Article shall set out those categories, refer to those specific cases or refer to the other plants for planting, stating that the prohibition of introduction and movement provided for in paragraph 1 of this Article only applies to those categories or in those specific cases.'

Article 80

Amendments of Regulation (EU) 2017/625

Regulation (EU) 2017/625 is amended as follows:

(1) in Article 1, paragraph 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) …/….’***;’

(2) in Article 3, the following point is added:

‘(52) ‘plant reproductive material’ means plant reproductive material as defined in Article 3(1) of Regulation (EU) …/… of the European Parliament and the Council(*)+’;

_____

(*) Regulation (EU) …/… of the European Parliament and of the Council …. (OJ …, p…). [footnote that will be in that regulation goes here]

[+ OJ: Please insert in the text the number of this Regulation and insert the number, date, title and OJ reference of this Regulation in the footnote.]’

(3) the following article– is inserted after Article 22:

‘Article 22a

Specific rules on official controls and for 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) ~~specific requirements for the performance of such official controls on~~ 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, by means of implementing acts, lay 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 12(1) of Regulation (EU) …/… ***of the European Parliament and of the Council****++

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

_____

**** Regulation (EU) .... of the European Parliament and of the Council of ... [the final title of the PRM Regulation] (OJ L ..., ELI:...).'***

++_____ OJ: Please insert in the text the number of this Regulation ***and insert the number, date, title and OJ reference of this Regulation in the footnote.]***

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) in Article 40(1), the following point is added:~~

~~'(c) laboratories which are accreditated by the International Seed Testing Association to carry out analyses, tests and diagnoses on seed samples'samples.'~~

Article 80a

Derogation from the rules on official controls and other official activities laid down in Regulation (EU) 2017/625

Article 6, Article 11, Article 37(4), point (e), and Articles 109 to 113 of Regulation (EU) 2017/625 shall not apply to controls or other activities within the scope of this Regulation.

Competent authorities shall perform audits of official laboratories as provided in Article 39(1) of Regulation (EU) 2017/625 unless they find these audits redundant if 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 the official laboratory runs a quality assurance system fulfilling the requirements of the ISTA Standards.

~~*Article 81*~~

~~**Amendment of Regulation (EU) 2018/848**~~

~~Regulation (EU) 2018/848 is amended as follows:~~

~~(1) Article 3 is amended as follows:~~

~~(a) point (17) is replaced by the following:~~

~~‘(17)~~

~~‘plant reproductive material’ means plant reproductive material as defined in Article 3(1) of Regulation (EU) …/… of the European Parlament and Council(*)+;’;~~

~~(*) Regulation (EU) …/… of the European Parliament and of the Council …. (OJ …, p…). [footnote that will be in that regulation goes here]~~

~~[+ OJ: Please insert in the text the number of this Regulation and insert the number, date, title and OJ reference of this Regulation in the footnote.]’~~

~~(b) point (18) is replaced by the following:~~

~~‘(18)~~

~~‘organic heterogeneous material’ means heterogeneous material as defined in Article 3(27) of Regulation (EU) …/…(*)++ , produced in accordance with this Regulation;’~~

~~(*) Regulation (EU) …/… of the European Parliament and of the Council …. (OJ …, p…). [footnote that will be in that regulation goes here]~~

~~[++ OJ: Please insert in the text the number of this Regulation.]’~~

~~(2) Article 13 is deleted.~~

~~(3) The second paragaph of Point 1.8.4. of Part I of Annex II to Regulation (EU) 2018/848 is replaced by the following: “ All multiplication practices, except plant tissue cultures, cell cultures, germplasm, meristems, chimaeric clones, micro-propagated material, shall be carried out under certified organic management”.~~

CHAPTER VII
FINAL PROVISIONS

Article 82

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 are repealed.

References to those repealed acts shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex VIII.

Article 82a

Transitional provisions

PRM produced before … [the date of application of this Regulation] in accordance with the Directives referred to in Article 82 or with national rules may continue to be marketed until exhaustion of the respective stocks. Such PRM may continue to be marketed with the appropriate label issued pursuant to those Directives, or pursuant to national rules.

Article 82b

Evaluation and reporting

1. By [5 years after the day of entry into application of this Regulation], the Commission shall submit to the European Parliament and to the Council a report of the application of Articles 28 and 30 of this Regulation.

2. The report shall examine the effect of the derogations contained in those Articles 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 if seed exchanged in kind have been sold to professional users. That report shall also examine the possible prevalence of infringements of intellectual property rights, including in particular plant variety rights.

3. That report shall be based on information and data, where these are available, and as submitted by the Member States and professional operators or associations.

4. The report can, as the Commission may see necessary, cover the application of other provisions of this Regulation than the Articles mentioned in paragraph 1.

5. The report shall be accompanied, if appropriate, by a legislative proposal to amend this Regulation.

Article 83

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 … [~~36~~***60*** months from the date of the entry into force of this Regulation-].

~~However,~~

~~(a) Article 40(4) shall apply from three days after the entry into force of this Regulation;~~

~~(b) Article 52 shall apply from ... [60 months from the date of the entry into force of this Regulation] for the species listed in Parts B and C of Annex I. It shall be binding in its entirety and directly applicable in all Member States.~~

It shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

ANNEX I

GENERA AND SPECIES, ~~AND THEIR RESPECTIVE USES,~~ AS REFERRED TO IN ARTICLE 2, *6a AND 32a*

1	2	*3*
Intended use of PRM belonging to the genera and species	**Genera or species may be produced and marketed only as category pre-basic, basic or certified PRM in accordance with Article 6a**	***Genera or species may be produced and marketed as commercial seed in accordance with Article 32a***
Agricultural plants		
Agrostis canina L.	1	
Agrostis capillaris L.	1	
Agrostis gigantea Roth	1	
Agrostis stolonifera L.	1	
Alopecurus pratensis L.	1	
Arachis hypogaea L.	1	***1***
Arrhenatherum elatius (L.) P. Beauv. ex J. Presl & C. Presl	1	
Avena nuda L.	1	

1	2	*3*
Intended use of PRM belonging to the genera and species	**Genera or species may be produced and marketed only as category pre-basic, basic or certified PRM in accordance with Article 6a**	***Genera or species may be produced and marketed as commercial seed in accordance with Article 32a***
Avena sativa L. (includes *A. byzantina* K. Koch)	1	
Avena strigosa Schreb.	1	
Beta vulgaris L. partim	1	
Biserrula pelecinus L.	***1***	***1***
Brassica juncea (L.) Czern.	1	
Brassica napus L. var. *napobrassica* (L.) Rchb.	1	
Brassica napus L. ~~var~~. **subsp**. *napus* **(L.)**	1	
~~*Brassica nigra* (L.) W. D. J. Koch~~		
Brassica oleracea L. convar. *acephala* (DC.) Alef. var. *medullosa* Thell. + var. *varidis* L.	1	
Brassica rapa L. ~~var. *silvestris* (Lam.) Briggs~~ **subsp. *campestris* (l.) A. R. Clapham**	1	
Bromus catharticus Vahl **var. *elatus* (É. Desv.) Planchuelo**	1	

1	2	*3*
Intended use of PRM belonging to the genera and species	**Genera or species may be produced and marketed only as category pre-basic, basic or certified PRM in accordance with Article 6a**	***Genera or species may be produced and marketed as commercial seed in accordance with Article 32a***
Bromus sitchensis Trin.	1	
***Camelina sativa* (L.) Crantz**	***1***	
Cannabis sativa L.	1	
Carthamus tinctorius L.	1	
Carum carvi L.	1	
***Cicer arietinum* L.**	***1***	***1***
***Cichorium intybus* L.**	***1***	
Cynodon dactylon (L.) Pers.	1	***1***
Dactylis glomerata L.	1	
***Fagopyrum esculentum* Moench**	***1***	
Festuca arundinacea Schreb.	1	

1	2	*3*
Intended use of PRM belonging to the genera and species	**Genera or species may be produced and marketed only as category pre-basic, basic or certified PRM in accordance with Article 6a**	***Genera or species may be produced and marketed as commercial seed in accordance with Article 32a***
Festuca filiformis Pourr**.**	1	***1***
Festuca ovina L.	1	
Festuca pratensis Huds.	1	
Festuca rubra L.	1	
Festuca trachyphylla (Hack.) ~~Krajina~~ **Hack.**	1	***1***
Galega orientalis Lam.	1	
Glycine max (L.) Merr. partim	1	
Gossypium **L.** ~~spp.~~	1	
Hedysarum coronarium L.	1	***1***
Helianthus annuus L.	1	
Hordeum vulgare L.	1	

1	2	*3*
Intended use of PRM belonging to the genera and species	**Genera or species may be produced and marketed only as category pre-basic, basic or certified PRM in accordance with Article 6a**	***Genera or species may be produced and marketed as commercial seed in accordance with Article 32a***
Lathyrus cicera L.	***1***	***1***
***Lathyrus sativus* L.**	***1***	
***Lens culinaris* Medik.**	***1***	***1***
Linum usitatissimum L.	1	
~~*Lolium × boucheanum* Kunth~~		
Lolium multiflorum Lam.	1	
Lolium perenne L.	1	
Lolium x-hybridum Hausskn.	***1***	
Lotus corniculatus L.	1	
Lupinus albus L.	1	
Lupinus angustifolius L.	1	

1	2	*3*
Intended use of PRM belonging to the genera and species	**Genera or species may be produced and marketed only as category pre-basic, basic or certified PRM in accordance with Article 6a**	***Genera or species may be produced and marketed as commercial seed in accordance with Article 32a***
Lupinus luteus L.	1	
Medicago doliata Carmign.	***1***	***1***
~~*Medicago italica* (Mill.) Fiori~~		
~~*Medicago littoralis* Rohde ex Loisel.~~		
Medicago lupulina L.	1	
Medicago murex Willd.	***1***	***1***
Medicago polymorpha L.	***1***	***1***
~~*Medicago rugosa* Desr.~~		
Medicago sativa L.	1	
~~*Medicago* × *varia* T. Martyn~~		
Medicago sativa L. nothosubsp. *varia* (Martyn) Arcang	***1***	

1	2	*3*
Intended use of PRM belonging to the genera and species	**Genera or species may be produced and marketed only as category pre-basic, basic or certified PRM in accordance with Article 6a**	***Genera or species may be produced and marketed as commercial seed in accordance with Article 32a***
~~*Medicago scutellata* (L.) Mill.~~		
Medicago truncatula Gaertn.	***1***	***1***
Onobrychis viciifolia Scop.	1	***1***
Ornithopus compressus L.	***1***	***1***
Ornithopus sativus Brot.	***1***	***1***
Oryza sativa L.	1	
***Panicum miliaceum* L.**	***1***	
Papaver somniferum L.	1	
Phacelia tanacetifolia Benth.	1	
Phalaris aquatica L.	1	***1***
Phalaris canariensis L.	1	

1	2	*3*
Intended use of PRM belonging to the genera and species	**Genera or species may be produced and marketed only as category pre-basic, basic or certified PRM in accordance with Article 6a**	***Genera or species may be produced and marketed as commercial seed in accordance with Article 32a***
Phleum nodosum L.	1	***1***
Phleum pratense L.	***1***	
Pisum sativum L. partim	***1***	
Plantago lanceolata L.	***1***	
Poa annua L.	***1***	***1***
Poa nemoralis L.	***1***	
Poa palustris L.	***1***	
Poa pratensis L.	***1***	
Poa trivialis L.	***1***	
Raphanus sativus L. var. *oleiformis* Pers.	***1***	
Secale cereale L.	***1***	

1	2	*3*
Intended use of PRM belonging to the genera and species	**Genera or species may be produced and marketed only as category pre-basic, basic or certified PRM in accordance with Article 6a**	***Genera or species may be produced and marketed as commercial seed in accordance with Article 32a***
Sinapis alba L.	***1***	
Sorghum bicolor (L.) Moench subsp. *bicolor*	1	
Sorghum ~~*bicolor* (L.) Moench subsp.~~ ***x*** *drummondii* (Steud.)~~ de Wet ex Davidse~~ **Millsp. & Chase**	***1***	
Sorghum bicolor (L.) Moench subsp. *bicolor x Sorghum* ~~*bicolor* (L.) Moench subsp.~~ ***x*** *drummondii* (Steud.)~~ de Wet ex Davidse~~ **Millsp. & Chase**	***1***	
~~*Sorghum bicolor* (L.) Moench × *Sorghum sudanense* (Piper) Stapf.~~		
~~*Sorghum sudanense* (Piper) Stapf.~~		
Trifolium alexandrinum L. ~~Beersem~~	1	
Trifolium fragiferum L.	***1***	***1***
Trifolium glanduliferum Boiss.	***1***	***1***

1	2	*3*
Intended use of PRM belonging to the genera and species	**Genera or species may be produced and marketed only as category pre-basic, basic or certified PRM in accordance with Article 6a**	***Genera or species may be produced and marketed as commercial seed in accordance with Article 32a***
Trifolium hirtum All.	***1***	***1***
Trifolium hybridum L.	1	
Trifolium incarnatum L.	1	
Trifolium isthmocarpum Brot.	***1***	***1***
Trifolium michelianum Savi	***1***	***1***
Trifolium pratense L.	1	
Trifolium repens L.	1	
Trifolium resupinatum L.	1	
Trifolium squarrosum L.	***1***	***1***
Trifolium subterraneum L.	***1***	***1***
Trifolium vesiculosum Savi	***1***	***1***

1	2	*3*
Intended use of PRM belonging to the genera and species	**Genera or species may be produced and marketed only as category pre-basic, basic or certified PRM in accordance with Article 6a**	***Genera or species may be produced and marketed as commercial seed in accordance with Article 32a***
Trigonella foenum-graecum L.	1	***1***
Trisetum flavescens (L.) P. Beauv.	1	
Triticum aestivum L. subsp. *aestivum*	1	
Triticum aestivum L. subsp. *spelta* (L.) Thell.	***1***	
Triticum ~~*turgidum* L. subsp.~~ *durum* ~~(~~Desf.~~) van Slageren~~	***1***	
Vicia benghalensis L.	***1***	***1***
Vicia faba L. **var. minuta (hort. Ex Alef.) Mansf.** partim	1	
Vicia pannonica Crantz	1	***1***
Vicia sativa L.	1	
Vicia villosa Roth	1	
x-Festulolium Asch. & Graebn.	***1***	

1	2	*3*
Intended use of PRM belonging to the genera and species	**Genera or species may be produced and marketed only as category pre-basic, basic or certified PRM in accordance with Article 6a**	***Genera or species may be produced and marketed as commercial seed in accordance with Article 32a***
x-Triticosecale Wittm. ex A. Camus	***1***	
Zea mays L. (partim)	1	
Potato		
Solanum tuberosum L.	1	
Vegetable plants		
Allium cepa L.		
Allium fistulosum L.		
Allium porrum L.		
Allium sativum L.		
Allium schoenoprasum L.		
Anthriscus cerefolium (L.) Hoffm.		

1	2	*3*
Intended use of PRM belonging to the genera and species	**Genera or species may be produced and marketed only as category pre-basic, basic or certified PRM in accordance with Article 6a**	***Genera or species may be produced and marketed as commercial seed in accordance with Article 32a***
Apium graveolens L.		
Asparagus officinalis L.		
Beta vulgaris L. (partim)		
***Brassica napus* L. var. *napobrassica* (L.) Rchb.**		
Brassica oleracea L. (partim)		
Brassica rapa L. partim		
Capsicum annuum L.		
Cichorium endivia L.		
Cichorium intybus L.		
Citrullus lanatus (Thunb.) Matsum. et Nakai		
Cucumis melo L.		

1	2	*3*
Intended use of PRM belonging to the genera and species	**Genera or species may be produced and marketed only as category pre-basic, basic or certified PRM in accordance with Article 6a**	***Genera or species may be produced and marketed as commercial seed in accordance with Article 32a***
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.		

1	2	*3*
Intended use of PRM belonging to the genera and species	**Genera or species may be produced and marketed only as category pre-basic, basic or certified PRM in accordance with Article 6a**	***Genera or species may be produced and marketed as commercial seed in accordance with Article 32a***
Phaseolus vulgaris L.		
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. **var. *major* Harz** partim		
Zea mays L. partim		

1	2	*3*
Intended use of PRM belonging to the genera and species	**Genera or species may be produced and marketed only as category pre-basic, basic or certified PRM in accordance with Article 6a**	***Genera or species may be produced and marketed as commercial seed in accordance with Article 32a***
Fruit plants		
***Actinidia* Lindl.**		
Castanea sativa Mill.		
Citrus L.		
Corylus avellana L.		
Cydonia oblonga Mill.		
Ficus carica L.		
Fortunella Swingle		
Fragaria L.		
Juglans regia L.		
Malus Mill.		

1	2	*3*
Intended use of PRM belonging to the genera and species	**Genera or species may be produced and marketed only as category pre-basic, basic or certified PRM in accordance with Article 6a**	***Genera or species may be produced and marketed as commercial seed in accordance with Article 32a***
Olea europaea L.		
Pistacia ~~*vera*~~ L.		
~~*Poncirus* Raf.~~		
Prunus armeniaca L.		
Prunus avium (L.) L.		
Prunus cerasus L.		
Prunus domestica L.		
Prunus ~~*amygdalus Batsch*~~ ***dulcis*** **(Mill.) D.A. Webb**		
Prunus persica (L.) Batsch		
Prunus salicina Lindl**.** ~~ey~~		
Pyrus L.		

1	2	*3*
Intended use of PRM belonging to the genera and species	**Genera or species may be produced and marketed only as category pre-basic, basic or certified PRM in accordance with Article 6a**	***Genera or species may be produced and marketed as commercial seed in accordance with Article 32a***
Ribes L.		
Rubus L.		
Vaccinium L.		
Vine		
Vitis L.		

Annex II

REQUIREMENTS FOR THE PRODUCTION AND MARKETING OF PRE-BASIC, BASIC AND CERTIFIED ~~SEEDS~~*SEED* AND MATERIAL AS REFERRED TO IN ARTICLE 7

PART A

REQUIREMENTS FOR THE PRODUCTION AND MARKETING OF PRE-BASIC, BASIC AND CERTIFIED ~~SEEDS~~*SEED* OF AGRICULTURAL AND VEGETABLE SPECIES*, AND TRUE POTATO SEED*

1. ~~General~~ Requirements for the production of pre-basic, basic and certified ~~seeds~~*seed of agricultural and vegetable species, and true potato seed*

A. Sowing or planting:

(a) The variety ***and identity*** of the seed sown, including where applicable mother plants, shall be ~~identified through an official label or a label issued~~***determined by the competent authority or*** by the professional operator, and shall be recorded to ensure its traceability. ~~The label, or the records on the mother plant, shall be retained by the professional operator until the issuance of the official label of the marketed seed.~~

(b) The previous cropping of the field shall ~~be compatible~~***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 ~~such~~ plants~~,~~ which may have remained from previous cropping (volunteers).

(c) The ***seed or*** mother plants ~~or seed~~***, where applicable,*** shall be planted and/or ~~sowed~~***sown*** in a way~~, which assures:~~ ***that ensures***

~~(i)~~ sufficient distance from pollen sources of the same ***genus,*** species and/or different varieties, from any undesirable foreign pollination, ~~so as~~ to avoid cross pollination with other crops, where applicable~~; and~~.

~~(ii) an appropriate source and level of pollination to ensure the subsequent reproduction, where applicable.~~

~~(d) The quality of soil, substrates, mother plants and the immediate environment shall be inspected to avoid presence of pests or their vectors, in accordance with Regulation (EU) 2016/2031.~~

~~(e) The machines and any equipment used shall be inspected, and weed or seed from other species or varieties shall be removed.~~

~~(f) Where appropriate, the production of seeds shall take place separately from the cultivation of seeds belonging to the same genera or species intended for the production of food or feed, to ensure the fulfillment of the requirements applicable only for the PRM concerned.~~

(g) Where applicable, ~~in vitro~~***plants derived from in vitro*** propagation may ~~also~~ be used for the ~~reproduction of seeds~~***production of seed***.

B. Field cultivation:

(a) The field crop shall have sufficient varietal identity and varietal purity.

~~(a)~~ It shall be ensured that plants of other species, other varieties, ~~appearing as varietal impurity,~~***or plants that are*** obviously differing from the variety in one or more characteristics from the variety description ('off-type'), in the field, are absent. Where this is not possible due to the characteristics of the species concerned, they shall be present up to the lowest possible level.

In the case of presence of off-types or other plant species ~~or varieties~~ during the cultivation stage~~, or during seed processing,~~ appropriate treatment and/or elimination shall be applied ~~to ensure varietal identity and purity of the seed, and to avoid the presence of any undesirable species~~.

~~(b) The plants shall be treated or excluded as a source of PRM in case of positive test results or visual symptoms of pests, in accordance with Regulation (EU) 2016/2031, or defects.~~

~~(c) PRM, including, where applicable, mother plants, shall be maintained in a way to ensure the identity of the variety. That maintenance shall be based on the official description or the officially recognised description of the variety.~~

~~(d)~~ ~~The mother plants shall be maintained in all phases of production, under conditions to enable the production of seeds, and permit their identification with the official description of their variety.~~

(e) All crops in the field shall be inspected officially or under official supervision at their relevant growth stage(s), at the relevant frequency and with the relevant methods, as appropriate, for the species concerned to verify the respective requirements. ~~The methods for inspections shall be in accordance with the applicable international standards.~~ 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 ~~discarded~~***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 ~~bulk or as individual plants, as appropriate, to ensure~~***a way that ensures*** its identity~~ and~~***,*** purity and~~ a correct~~ traceability.

(b) A sample of seed shall be taken ***officially or under official supervision*** from each ~~sealed~~ lot. The sample size and the sampling intensity, equipment and method shall be appropriate for the species concerned~~ and in accordance with the applicable international standards~~.

(c) ~~All seed samples~~***The seed sample*** shall be ~~subjected to~~***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 in acordance with the applicable international standards. Testing shall include, where appropriate, retesting of germination rate after a certain period appropriate to the species concerned.~~

~~(d) All the seed lots belonging to the pre-basic, basic category, or certified category if it will be used for the production of further seed generations, and at least 5% of the seed lots belonging to a certified category that will be no longer multiplied, are subject to control plot-testing by the operator, under official supervision, to verify the compliance with:~~

~~(i) their varietal identity;~~

~~(ii) the standards of the minimum varietal purity; and~~

~~(iii) the plant health requirements.~~

~~Seed lots belonging to the pre-basic, basic, or certified category shall be subject to risk-based official post-control testing to verify the compliance with the previous requirements. The samples used for the official post-control tests shall be taken officially.~~

~~Control plot-testing shall be carried out in accordance with the applicable international standards.~~

~~Appropriate bio-molecular methods may be utilised.~~

2. Requirements for the marketing of ~~seeds~~*pre-basic, basic and certified seed of agricultural and vegetable species, and true potato seed*

The seed shall fulfil ~~all of~~ the following quality requirements, depending on the characteristics of each genus or species and the category concerned:

(a) have a minimum ***sufficient*** germination ~~to allow an appropriate number of plants per square metre after sowing, and consequently to secure the yield and quality of the production~~***that shall be confirmed through retesting***;

(b) have a maximum ***allowed*** content of hard seed ~~to allow an appropriate number of plant per square metre~~;

(c) have a minimum ***sufficient analytical*** purity ~~to secure the highest level of varietal identity~~***, and, where applicable, have a maximum allowed presence of soil or extraneous matter***;

(d) have ~~a maximum~~***an appropriate*** moisture content~~ to ensure the preservation of the material during processing, storage and making available on the market~~;

(e) have a maximum ***allowed*** content of ~~seeds~~***seed*** of other genera or species~~ to ensure the lowest presence of undesirable plants in the lot~~;

~~(f) have a minimum vigour, defined dimension and specific grading to ensure the appropriateness of the material and the sufficient homogeneity of the lot for sowing or planting;~~

~~(g) have a maximum presence of earth or extraneous matter to prevent fraudulent practices and technical impurities; and~~

(h) be ***practically*** free from ~~specific~~***significant*** defects and damages~~ to ensure the quality and health of the material~~.

PART Aa

REQUIREMENTS FOR THE PRODUCTION AND MARKETING OF PRE-BASIC, BASIC AND CERTIFIED SEED OF FRUIT PLANT SPECIES AND VINE

1. Requirements for the production of pre-basic, basic and certified seed of fruit plant species and vine

A. Sowing or planting:

(a) The variety and identity of mother plants shall be determined by the competent authority or by the professional operator, and shall be recorded to ensure their traceability.

(b) The mother plants and, where appropriate, the pollinator plants shall be planted in a way that there is sufficient distance from other plants of the same genus, species, and/or different varieties, determined by the botanical characteristics, to ensure protection from any undesirable foreign pollination, to avoid cross pollination with other crops.

(c) Where applicable, 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 shall be disposed of at all stages of cultivation in order to ensure trueness to the identity of the variety, or for plants not belonging to a variety, to ensure the trueness to the identity of the species to which they belong, their sufficient purity and efficient production.

(b) Mother plants and pollinator plants shall be excluded as a source of seed in case of significant defects likely to impair the quality of seed.

(c) Mother plants shall be cultivated, in all stages of development, in such a way to enable the production of seeds 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.

(d) Mother plants and pollinator plants shall be inspected officially or under official supervision at their relevant growth stage(s), at the relevant frequency and with the relevant methods as appropriate for the genera or species concerned to verify 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) The 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 intensity, equipment and method of sampling shall be appropriate for the genera or species concerned.

(c) Testing shall be carried out in accordance with the methods, equipment and growing media appropriate for the genera or species concerned, to ensure that the quality requirements have been fulfilled.

2. Requirements for the marketing of pre-basic, basic and certified seed of fruit plant species and vine

The seed shall fulfil the following quality requirements, depending on the characteristics of each genus or species, and the category concerned:

(a) have minimum sufficient germination;

(b) be practically free from significant defects and damages.

PART B

REQUIREMENTS FOR THE PRODUCTION AND MARKETING OF PRE-BASIC, BASIC AND CERTIFIED MATERIAL OF AGRICULTURAL~~ AND~~, VEGETABLE *AND FRUIT PLANT* SPECIES *AND VINE, INCLUDING SELECTED CLONES AND POLYCLONAL MATERIAL*

1.* Requirements for the production of pre-basic, basic and certified material *of agricultural, vegetable and fruit plant species and vine, including selected clones and polyclonal material

A. Sowing or planting:

(a) The ***variety and*** identity of the material~~, including, where applicable,~~ mother plants or seed sown, shall be determined ~~through an official label or a label issued~~***by the competent authority or*** by the professional operator, and ***shall be*** recorded~~ by the professional operator~~ to ensure ~~its~~***their*** traceability. ~~The label of the material after the marketing of that material, or the records on the mother plant, shall be kept by the professional operator.~~

(b) The material***, mother plants or seed*** shall be planted ***or sown*** in a way that~~:~~

~~(i) the pre-basic material is maintained in facilities that ensure freedom from infection through aerial vectors and any other possible sources~~***ensures its viability and quality*** throughout the production process~~;~~**.**

~~(ii) there is sufficient distance from other plants of the same genera or species, determined on the basis of botanical characteristics and breeding techniques of each species, and as appropriate for the category of the material, to ensure protection from any undesirable foreign pollination and to avoid cross pollination with other crops; and~~

~~(iii) planting densities are adequate to allow plants to be observed individually.~~

~~(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) Where applicable, plants derived from in vitro propagation may be used for the production of material.

B Field cultivation:

(aa) The field crop shall have sufficient varietal identity and varietal purity.

~~(a) During all stages of cultivation, propagating and planting material shall be kept separate from each other.~~

~~(b) PRM satisfying the requirements for a given category shall not be mixed with material of other categories.~~

(c) Off-types and deformed or damaged ***mother*** plants ***and material*** shall be disposed of at all stages of cultivation.

~~(d) Mother plants shall be treated or excluded as a source of PRM in case of positive test results or visual symptoms of pests, in accordance with Regulation (EU) 2016/2031 or defects.~~

(e) Mother plants ***and material*** shall be ~~maintained~~***cultivated,*** in all ~~phases of cultivation, under conditions~~***stages of development, in such a way*** to enable the production of ~~PRM~~***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, ~~that~~***the*** verification~~ of compliance with the official description or the officially recognised description~~ shall concern the species to which those mother plants ***and material*** belong.

(f) Mother plants ***and material*** shall be inspected ***officially or under official supervision*** at their relevant growth stage(s), at the relevant frequency and with the relevant methods***,*** as appropriate for the genera or species concerned ***to verify the respective requirements***.

C. Harvesting and post-harvesting:

(a) The material shall be harvested in a way that ensures its identity, purity and traceability.

~~(g)~~***(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 in accordance with the applicable international standards~~.

~~(h)~~***(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 in accordance with the applicable international standards,~~ to ensure that the quality requirements have been fulfilled.

~~C Harvesting and post-harvesting for species and genera belonging to Part E of Annex I (seed potatoes):~~

~~(a) The material shall be harvested in bulk or as individual plants, as appropriate, to ensure its identity, health and traceability.~~

~~(b) A sample of tubers shall be taken from each sealed lot. The sample size and the sampling intensity, equipment and method shall be appropriate for the species concerned and in accordance with the applicable international standards.~~

~~(c) All tubers samples shall be subjected to laboratory testing, to ensure the fulfilment of the quality and phytosanitary 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 in accordance with the applicable international standards.~~

~~(d) All the lots belonging to the pre-basic or basic category, and at least 5% of the lots belonging to a certified category, shall be subject to control plot-testing by the operator, under official supervision of the competent authority, to verify the compliance with:~~

~~(i) their varietal identity;~~

~~(ii) the standards of the minimum varietal purity;~~

~~(iii) their germination capacity;~~

~~(iv) the plant health requirements.~~

~~Lots belonging to the pre-basic, basic, or certified category shall be subject to risk-based official post-control testing to verify the compliance with the previous requirements. The samples used for the official post-control tests shall be taken officially.~~

~~Control plot-testing shall be carried out in accordance with the applicable international standards.~~

~~Appropriate bio-molecular methods may be utilised.~~

2. Requirements for the marketing of pre-basic, basic and certified material *of agricultural, vegetable and fruit plant species and vine, including selected clones and polyclonal material*

The material shall fulfil ~~all of~~ the following requirements, depending on the characteristics of each genus or species**,** and the category concerned:

(a) have minimum ***sufficient*** vigour~~ or germination rate, defined dimension,~~ and, where applicable, specific grading~~, to ensure the appropriateness of the material and sufficient homogeneity of the lot for planting~~;

(b) be practically free from ~~specific~~***significant*** defects ***and damages***.

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 Ba

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 shall be determined by the competent authority or the professional operator, and shall be recorded to ensure its traceability.

(b) The material shall be planted in a way that ensures its viability and quality throughout the production process

(c) Where applicable, 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) Plants shall be cultivated, in all stages of development, in such a way to enable the production of PRM, and to permit their identification and verification of compliance with the official description of their variety.

(d) Plants shall be inspected officially or under official supervision at their relevant growth stage(s), at the relevant frequency and with the relevant methods.

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 size and the sampling intensity, equipment and method shall be appropriate for determining the fulfilment of the quality requirements. 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.

2. Requirements for the marketing of pre-basic, basic and certified seed potatoes and other material of potatoes

The seed potatoes shall fulfil the following requirements, depending on the category concerned:

(a) have sufficient vigour, defined dimension, and specific grading;

(b) be practically free from significant defects and damages.

~~**PART C**~~

~~**REQUIREMENTS FOR THE PRODUCTION, REGISTRATION AND MARKETING OF SELECTED CLONES, MULTICLONAL MIXTURES AND POLYCLONAL PRM OF PRE-BASIC, BASIC AND CERTIFIED MATERIAL AS REFERRED TO IN ARTICLE 9 (1)**~~

~~**1. Requirements for the production of pre-basic, basic and certified selected clones, multiclonal mixtures and polyclonal PRM**~~

~~A Planting:~~

~~(a) The identity of the selected clone, multiclonal mixture or polyclonal PRM shall be determined through an official label or a label issued by the profesional operator and recorded by the professional operator to ensure its traceability. The label of the material or the records, on the respective mother plants for the production of each selected clone and the respective genotypes for the production of the polyclonal PRM, shall be kept by the professional operator after the marketing of that PRM.~~

~~(b) The material shall be planted in a way that:~~

~~(i) there is sufficient distance from other plants of the same genera or species, determined on the basis of botanical characteristics for each species and as appropriate for the category of the material, to ensure protection from any undesirable foreign pollination and to avoid cross pollination with other crops;~~

~~(ii) planting densities are adequate to allow each plant to be observed individually.~~

~~(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.~~

~~B Field cultivation:~~

~~(a) During all stages of cultivation, propagating and planting material shall be kept separate from each other.~~

~~(b) Reproductive material satisfying the requirements of a given category shall not be mixed with material of other categories.~~

~~(c) Off-types and deformed or damaged plants shall be disposed of at all stages of cultivation in order to ensure varietal identity and purity, or, in the case of rootstocks not belonging to a variety, trueness to the identity of the species, and efficient production.~~

~~(d) The respective mother plants and the respective genotypes shall be excluded as a source of PRM in case of defects.~~

~~(e) The respective mother plants and the respective genotypes shall be maintained in all phases of cultivation, under conditions to enable the production of PRM, 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 not belonging to a variety, that verification of compliance with the official description or the officially recognised description shall concern the species to which those mother plants belong.~~

~~(f) Mother plants shall be inspected at their relevant growth stage(s), at the relevant frequency and with the relevant methods as appropriate for the genera or species concerned.~~

~~(g) The 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 intensity, equipment and method of sampling shall be appropriate for the genera or species concerned and in accordance with the applicable international standards.~~

~~(h) Testing shall be carried out in accordance with the methods, equipment and growing media appropriate for the genera or species concerned, and in accordance with the applicable international standards, to ensure that the quality requirements have been fulfilled.~~

~~(i) In the case of multiclonal mixtures, the mixture of selected clones constituting the multiclonal mixture shall be made before the final packaging of that PRM and shall include identical proportions of all selected clones that constitute the multiclonal mixture.~~

~~(j) In the case of polyclonal PRM, the mixture of genotypes constituting the polyclonal PRM shall be made before the final packaging of that PRM and shall include identical proportions of all genotypes that constitute the polyclonal PRM.~~

~~2. Requirements for the registration of a selected clone, multiclonal mixture and polyclonal PRM~~

~~(a) The applicant shall submit an application to the competent authority indicating:~~

~~(i) species and, as applicable, variety to which the selected clone, multiclonal mixture or polyclonal PRM belongs, whereby the variety shall be registered in a national variety register referred to in Article 44;~~

~~(ii) proposed denomination and synonyms;~~

~~(iii) where applicable, description of the composition of the multiclonal mixture or polyclonal PRM;~~

~~(iv) the maintainer of the selected clone, multiclonal mixture or polyclonal PRM;~~

~~(v) reference to the description of the main characteristics of the variety to which the selected clone, multiclonal mixture or polyclonal PRM belongs;~~

~~(vi) description of the main VSCU characteristics of the selected clone, multiclonal mixture or polyclonal PRM;~~

~~(vii) the estimated genetic gain of the selected clone, multiclonal mixture or polyclonal PRM in relation to the overall performance of the relevant variety;~~

~~(viii) information on whether the selected clone, multiclonal mixture or polyclonal PRM is already registered in a register of another Member State.~~

~~(b) The selected clone, multiclonal mixture or polyclonal PRM shall fulfil the following requirements as appropriate for the type of material concerned in order to be registered:~~

~~(i)~~ ~~the polyclonal PRM shall be selected in a single field trial containing a representative sample of the overall genetic diversity of the variety according to an experimental design based on internationally accepted methods. In the case of polyclonal PRM of vine that design shall be based on methods prescribed by the International organisation of vine and wine;~~

~~(ii)~~ ~~in the case of vine propagating material, the polyclonal PRM shall be composed of 7 to 20 distinct genotypes;~~

~~(iii)~~ ~~the trueness of the selected clone, each selected clone of the multiclonal mixture, each genotype of the polyclonal PRM to the identity of the variety shall be ensured through the observation of the phenotypic characteristics and, where appropriate, through molecular analysis pursuant to internationally accepted standards.~~

~~The competent authority shall decide on the registration only after it concludes that the points (i) - (iii) as applicable for the type of material are fulfilled.~~

~~(c)~~ ~~The requirements for the marketing of pre-basic, basic and certified material as set out in Part B point 2 shall apply accordingly.~~

~~PART D~~

~~REQUIREMENTS FOR THE PRODUCTION AND MARKETING OF PRE-BASIC, BASIC AND CERTIFIED SEED OF FRUIT PLANTS, VINE AND SEED POTATOES~~

~~1. Requirements for the production of pre-basic, basic and certified seed of fruit plants, vine and seed potatoes~~

~~A~~ ~~Sowing or planting:~~

~~(a)~~ ~~The mother plants and, where appropriate, the pollinator plants shall be planted in a way that:~~

~~(i) there is sufficient distance from other plants of the same genera or species, determined by the botanical characteristics and breeding techniques and as appropriate for the category of the material, to ensure protection from any undesirable foreign pollination and to avoid cross pollination with other crops; and~~

~~(ii) planting densities are adequate to allow plants to be observed individually.~~

~~(b) 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.~~

~~B Field cultivation:~~

~~(a) During all stages of cultivation, propagating and planting material shall be kept separate from each other.~~

~~(b) Reproductive material satisfying the requirements of a given category shall not be mixed with material of other categories.~~

~~(c) The flowering mother plant shall be subject to self-pollination or cross-pollination with pollen from the surrounding pollinator plants, as appropriate for the genera or species concerned.~~

~~(d) Off-types and deformed or damaged plants shall be disposed of at all stages of cultivation in order to ensure trueness to the identity of the variety, or for plants not belonging to a variety, to ensure the trueness to the identity of the species to which they belong, their sufficient purity and efficient production.~~

~~(e) Mother plants and pollinator plants shall be excluded as a source of seeds in case of defects.~~

~~(f) Mother plants shall be maintained in all phases of cultivation, under conditions to enable the production of seeds. Mother plants and pollinator plants shall be maintained in all phases of cultivation, under conditions permitting 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, that verification of compliance with the official description or the officially recognised description shall concern the species to which those mother plants and pollinator plants belong.~~

~~(g) Mother plants and pollinator plants shall be inspected at their relevant growth stage(s), at the relevant frequency and with the relevant methods as appropriate for the genera or species concerned.~~

~~(h) The 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 intensity, equipment and method of sampling shall be appropriate for the genera or species concerned and in accordance with the applicable international standards.~~

~~(i) Testing shall be carried out in accordance with the methods, equipment and growing media appropriate for the genera or species concerned, and in accordance with the applicable international standards, to ensure that the quality requirements have been fulfilled.~~

~~2. Requirements for the marketing of pre-basic, basic and certified seed of fruit plants, vine and seed potatoes~~

~~The seed shall fulfil all of the following quality requirements, depending on the characteristics of each genus or species and the category concerned:~~

~~(a) belong to the variety and, in the case of seeds not belonging to a variety, to the species;~~

~~(b) have minimum vigour, defined dimension, and, where applicable, specific grading, to ensure the appropriateness of the material and sufficient homogeneity of the lot for planting; and~~

~~(c)~~ ~~be practically free from specific defects and damages to ensure the quality of the seeds.~~

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

(a) The identity of the ~~in vitro or in vivo~~***in vitro or in vivo*** material, as applicable, shall be determined ~~through a label and~~***by the competent authority or by the professional operator and shall be*** recorded to ensure its traceability. ~~The label of the material shall be kept.~~

~~(b)~~ ~~Material that has been sampled from in vivo material shall be sanitised.~~

B In vitro production

(a) The ~~clone(s)~~***material*** that originate from the material referred to under point A.(a) shall be produced by ~~in vitro~~***in vitro*** propagation.

~~(b)~~ ~~During all stages of cultivation, propagating and planting material shall be kept separate from each other.~~

~~(c)~~ ~~Clone(s) satisfying the requirements of a given PRM category shall not be mixed with clone(s) of other categories.~~

(d) The number of successive propagation cycles by ~~in vitro~~***in vitro*** propagation shall be restricted, as appropriate, for the genera or species concerned.

(e) ~~Clone(s)~~***The material*** shall be ~~maintained~~***cultivated,*** in all ~~phases of production, under conditions to enable the production of PRM, and permitting their~~***stages of development, in such a way to permit its*** identification and verification of compliance with the official description or the officially recognised description of their variety. ~~In the case of clone(s) not belonging to a variety, that verification of compliance with~~***Where*** the official description or ~~the~~ officially recognised description ***cannot be used because of the particular growing stage of the plant, biomolecular techniques 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 ~~those clone(s) belong~~***that material belongs***.

(f) ~~Clone(s)~~***The material*** shall be inspected ~~at their relevant growth stage(s),~~ at the relevant frequency and with the relevant methods***,*** as appropriate***,*** for the genera or species concerned ***to verify the respective requirements***.

~~(g) The 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 intensity, equipment and method of sampling shall be appropriate for the genera or species concerned and in accordance with the applicable international standards.~~

~~(h) Testing shall be carried out in accordance with the methods, equipment and growing media appropriate for the genera or species concerned, and in accordance with the applicable international standards, to ensure that the quality requirements have been fulfilled.~~

2. Requirements for the marketing of pre-basic, basic and certified material produced by in vitro propagation

The ~~in vitro or in vivo~~***in vitro*** material shall fulfil ~~all of~~ the following requirements, depending on the characteristics of each genus or species ~~and the category~~ concerned:

~~(a) belong to the variety and, in the case of material not belonging to a variety, belong to the species indicated on the label by:~~

~~(i) observing the phenotypic characteristics of the in vivo material referred to under point A.(a);~~

~~(ii) producing in vivo plants from the in vitro material referred to under point A.(a) and observing the phenotypic characteristics of those plants;~~

~~(iii) producing in vivo plants from the clone(s) referred to under point B.(a) and observing the phenotypic characteristics of those plants; and~~

~~(iv) where appropriate, molecular analysis of the in vitro material referred to under point A.(a) and/or the clone(s) referred to under point B.(a);~~

(b) have ~~minimum~~***sufficient*** vigour, defined dimension, and, where applicable, specific grading~~, to ensure the appropriateness of the material and sufficient homogeneity of the lot for planting~~;

(c) be practically free from ~~specific~~***significant*** defects and damages.

Annex III

REQUIREMENTS FOR THE PRODUCTION AND MARKETING OF STANDARD SEED AND MATERIAL AS REFERRED TO IN ARTICLE 8

PART A

REQUIREMENTS FOR THE PRODUCTION AND MARKETING OF STANDARD SEED OF AGRICULTURAL AND VEGETABLE SPECIES*, AND TRUE POTATO SEED*

1. ~~General~~ Requirements for the production of standard seed *of agricultural and vegetable species, and true potato seed*

A Sowing or planting:

(a) The variety ***and identity*** of the seed sown, including where applicable, mother plants, shall be determined ***and recorded*** to ensure its traceability. ~~The label of the material, or the records on the mother plant, shall be kept at least for 2 years.~~

(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 ~~such~~ plants, which may have remained from previous cropping (volunteers).

(c) The ***seed or*** mother plants~~ or seed~~***, where applicable,*** shall be planted ~~and /or sowed~~***and/or sown*** in a way that ~~there is:~~***ensures***

~~(i)~~ sufficient distance from pollen sources of the same ***genus,*** species and/or~~ the~~ different varieties,~~ in accordance with isolation rules determined on the basis of botanical characteristics for each species and breeding techniques, to ensure protection~~ from any undesirable foreign pollination~~ and~~***,*** to avoid cross pollination with other crops, where applicable~~; and~~***.***

~~(ii) an appropriate source and level of pollination to ensure the subsequent reproduction, where applicable.~~

~~(d) The quality of soil, substrates, mother plants and the immediate environment shall be inspected to avoid presence of pests or their vectors, in accordance with Regulation (EU) 2016/2031.~~

~~(e) Appropriate attention shall be paid to the machines and any equipment used to ensure absence of weed or other species, which are difficult to distinguish in laboratory tests.~~

~~(f) Where appropriate, the production of seeds shall take place separately from the cultivation of seeds belonging to the same genera or species intended for the production of food or feed, to ensure health of the material concerned.~~

(g) Where applicable, ~~in vitro~~***plants derived from in vitro*** propagation may~~ also~~ be used for the ~~reproduction of seeds~~***production of seed***.

B Field ~~production~~***cultivation***:

(a) The field crop shall have sufficient varietal identity and varietal purity.

(a) It shall be ensured that ~~off-types~~***plants of other species, other varieties, or plants that are obviously differing from the variety in one or more characteristics from the variety description ('off-type')***, in the field, are absent. Where this is not possible due to the characteristics of the species concerned, they shall be present up to the lowest possible level.

In the case of presence of off-types or other plant species~~, or varieties,~~ during the cultivation stage~~, or during seed processing,~~ appropriate treatment and/or elimination shall be applied~~ to ensure varietal identity and purity of the seed, and to avoid the presence of any undesirable species~~.

~~(b) The plants shall be treated or excluded as a source of PRM in case of positive test results or visual symptoms of pests, in accordance with Regulation (EU) 2016/2031 or defects.~~

~~(c) PRM, including, where applicable, mother plants, shall be maintained in a way to ensure the identity of the variety. That maintenance shall be based on the official description or the officially recognised description of the variety.~~

~~(d) The mother plants shall be maintained in all phases of production, under conditions to enable the production of seeds, and permitting their identification and verification of compliance with the official description of their variety.~~

(e) All crops in the field shall be ~~inspected~~***checked*** at their relevant growth stage(s), at the relevant frequency~~ and with the relevant methods~~, as appropriate, for the species concerned to verify the respective requirements.~~ The methods for inspections shall be such to ensure the reliability of the observations. If it is not possible to remove or separate non-compliant plants during the growing phase, the entire field shall be discarded for seed production, unless the undesirable seeds can be mechanically separated at a later stage.~~

C Harvesting and post-harvesting:

(a) The seed shall be harvested in ~~bulk or as individual plants, as appropriate, to ensure~~***a way that ensures*** its identity, purity and traceability.

(b) A sample of seed shall be taken from each lot and tested~~ in a laboratory~~ to ensure the fulfilment of the quality requirements for the respective species~~, including germination. Testing shall include, where appropriate, retesting of germination rate after a certain period appropriate to the species concerned.~~

~~(c) Seed lots shall be subject to risk-based official post-control-testing to verify the compliance with:~~

~~(i) their varietal identity;~~

~~(ii) the standards of the minimum varietal purity;~~

~~(iii) their germination capacity; and~~

~~(iv) the plant health requirements.~~

~~The samples used for the official post-control tests shall be taken officially.~~

~~Appropriate bio-molecular methods may be utilised.~~

2. Requirements for *the* marketing of standard seed *of agricultural and vegetable species, and true potato seed*

The seed shall fulfil~~ all of~~ the following quality requirements, depending on the characteristics of each genus or species:

(a) have~~ at least~~ a minimum ***sufficient*** germination~~, to allow an appropriate number of plants per square metre after sowing, and consequently to secure the yield and quality of the production~~ ***that shall be confirmed through retesting***;

(b) have~~ at most~~ a maximum ***allowed*** content of hard seed~~, to allow an appropriate number of plants per square metre~~;

(c) have~~ at least~~ a minimum ***sufficient analytical*** purity ***and, where applicable, have a maximum allowed presence of soil or extraneous matter***~~, to secure the highest level of varietal identity~~;

(d) have ~~at most a maximum~~***an appropriate*** moisture content~~, to ensure the preservation of the material during processing, storage and making available on the market~~;

(e) have~~ at most~~ a maximum ***allowed*** content of ~~seeds~~***seed*** of other genera or species~~, to ensure the lowest presence of undesirable plants in the lot~~;

~~(f) have sufficient vigour, defined dimension and specific grading, to ensure appropriateness of the material and sufficient homogeneity of the lot for sowing or planting;~~

~~(g) have a maximum presence of earth or extraneous matter, to prevent fraudulent practices and technical impurities; and~~

(h) be ***practically*** free from ~~specific~~***significant*** defects and damage~~ to ensure the quality and health of the material~~.

PART Aa

REQUIREMENTS FOR THE PRODUCTION AND MARKETING OF STANDARD SEED OF FRUIT PLANT SPECIES AND VINE

1. Requirements for the production of standard seed of fruit plant species and vine

A. Sowing or planting:

(a) The variety and identity of mother plants shall be determined and recorded to ensure its traceability.

(b) The mother plants and, where appropriate, the pollinator plants shall be planted in a way that there is sufficient distance from other plants of the same genus, species, and/or different varieties, determined by the botanical characteristics, to ensure protection from any undesirable foreign pollination, to avoid cross pollination with other crops.

(c) Where applicable, 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 shall be disposed of at all stages of cultivation in order to ensure trueness to the identity of the variety, or for plants not belonging to a variety, to ensure the trueness to the identity of the species to which they belong, their sufficient purity and efficient production.

(b) Mother plants and pollinator plants shall be excluded as a source of seed in case of significant defects likely to impair the quality of seed.

(c) Mother plants shall be cultivated, in all stages of development, in such a way 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.

(d) Mother plants and pollinator plants shall be checked at their relevant growth stage(s), at the relevant frequency, as appropriate, for the genera or species concerned to verify 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 from each lot and tested to ensure the fulfilment of the quality requirements for the respective genera or species.

2. Requirements for the marketing of standard seed of fruit plant species and vine

The seed shall fulfil the following quality requirements, depending on the characteristics of each genus or species concerned:

(a) have minimum sufficient germination;

(b) be practically free from significant defects and damages.

PART B

REQUIREMENTS FOR THE PRODUCTION AND MARKETING OF STANDARD MATERIAL OF AGRICULTURAL ~~AND~~, VEGETABLE *AND FRUIT PLANT* SPECIES *AND VINE, INCLUDING POLYCLONAL MATERIAL*

~~With the exception of point (b)(i) thereof, Part B of Annex II shall apply accordingly for the production and marketing of standard material.~~

1. Requirements for the production of standard material of agricultural, vegetable and fruit plant species and vine, including polyclonal material

A. Sowing or planting:

(a) The variety and identity of the material, mother plants or seed sown shall be determined and shall be recorded to ensure their traceability.

(b) The material, mother plants or seed shall be planted or sown in a way that ensures it viability and quality throughout the production process.

(c) Where applicable, 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 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 and material plants belong.

(d) Mother plants and material shall be checked at their relevant growth stage(s), at the relevant frequency, as appropriate, for the genera or species concerned to verify the respective requirements.

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 plant species and vine, including polyclonal material

The material shall fulfil the following requirements, depending on the characteristics of each genus or species concerned:

(a) have minimum sufficient vigour and, where applicable, specific grading;

(b) be practically free from significant defects and damages.

(c) 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 Ba

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 shall be determined and recorded to ensure its traceability.

(b) The material shall be planted in a way that ensures its viability and quality throughout the production process.

(c) Where applicable, 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) Plants shall be cultivated, in all stages of development to permit their identification and verification of compliance with the official description or the officially recognised description of their variety.

(d) Plants shall be checked at their relevant growth stage(s), at the relevant frequency.

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 shall fulfil the following requirements:

(a) have sufficient vigour, defined dimension, and specific grading;

(b) be practically free from significant defects and damages.

~~PART C~~

~~REQUIREMENTS FOR THE REGISTRATION, PRODUCTION AND MARKETING OF SELECTED CLONES, MULTICLONAL MIXTURES AND POLYCLONAL PRM OF STANDARD MATERIAL AS REFERRED TO IN ARTICLE 9 (1)~~

~~Vine rootstocks may not be marketed as standard material.~~

~~Part C of Annex II shall apply accordingly for the registration, production and marketing of selected clones, multiclonal mixtures and polyclonal PRM of standard material.~~

~~**PART D**~~

~~**REQUIREMENTS FOR THE PRODUCTION AND MARKETING OF STANDARD SEED OF FRUIT PLANTS, VINE AND SEED POTATOES**~~

~~Part D of Annex II shall apply accordingly for the production and marketing of standard seed of fruit plants, vine and seed potatoes.~~

PART E

REQUIREMENTS FOR THE PRODUCTION AND MARKETING OF STANDARD MATERIAL PRODUCED BY IN VITRO PROPAGATION

~~Part E of Annex II shall apply accordingly 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

(a) The identity of the in vitro or in vivo material, as applicable, shall be determined and shall be recorded to ensure its traceability.

B. In vitro production

(a) The material that originate from the material referred to under point A.(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 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 growing stage of the plant, biomolecular techniques 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 at the relevant frequency, as appropriate, for the genera or species concerned to verify the respective requirements.

2. Requirements for the marketing of standard material produced by in vitro propagation

The in vitro material shall fulfil the following requirements, depending on the characteristics of each genus or species concerned:

(a) have sufficient vigour, defined dimension, and, where applicable, specific grading;

(b) be practically free from significant defects and damages.

~~Annex IV~~

~~GENERA AND SPECIES WHICH MAY ONLY BE PRODUCED AND MARKETED AS PRE-BASIC, BASIC OR CERTIFIED SEED OR MATERIAL, IN ACCORDANCE WITH ARTICLE 20(1)~~

~~PART A~~

~~GENERA AND SPECIES TO BE USED FOR THE PRODUCTION OF AGRICULTURAL CROPS, OTHER THAN VEGETABLES WHICH MAY ONLY BE PRODUCED AND MARKETED AS PRE-BASIC, BASIC OR CERTIFIED SEED~~

~~Agrostis canina L.~~

~~Agrostis capillaris L.~~

~~Agrostis gigantea Roth.~~

~~Agrostis stolonifera L.~~

~~Alopecurus pratensis L.~~

~~Arachis hypogaea L.~~

~~Arrhenatherum elatius (L.) P. Beauv. ex J. Presl & C. Presl.~~

~~Avena nuda L.~~

~~Avena sativa L.(including A. byzantina K. Koch.)~~

~~Avena strigosa Schreb.~~

~~Beta vulgaris L.~~

~~Brassica juncea (L.) Czern.~~

~~Brassica napus L. var. napobrassica (L.) Rchb.~~

~~Brassica napus L. var. napus~~

~~Brassica nigra (L.) W.D.J. Koch~~

~~Brassica oleracea L. convar. acephala (DC.) Alef. var. medullosa Thell. + var. varidis L.~~

~~Brassica rapa L.~~

~~Bromus catharticus Vahl~~

~~Bromus sitchensis Trin.~~

~~Cannabis sativa L.~~

~~Carthamus tinctorius L.~~

~~Carum carvi L.~~

~~Cynodon dactylon (L.) Pers.~~

~~Dactylis glomerata L.~~

~~Festuca arundinacea Schreb.~~

~~Festuca filiformis Pourr.~~

~~Festuca ovina L.~~

~~Festuca pratensis Huds.~~

~~Festuca rubra L.~~

~~Festuca trachyphylla (Hack.) Krajina~~

~~xFestulolium Asch. et Graebn.~~

~~Galega orientalis Lam.~~

~~Glycine max (L.) Merrill~~

~~Gossypium L.~~

~~Hedysarum coronarium L.~~

~~Helianthus annuus L.~~

~~Hordeum vulgare L.~~

~~Linum usitatissimum L.~~

~~Lolium × boucheanum Kunth~~

~~Lolium multiflorum Lam.~~

~~Lolium perenne L.~~

~~Lotus corniculatus L.~~

~~Lupinus albus L.~~

~~Lupinus angustifolius L.~~

~~Lupinus luteus L.~~

~~Medicago lupulina L.~~

~~Medicago sativa L.~~

~~Medicago × varia T. Martyn~~

~~Onobrychis viciifolia Scop.~~

~~Oryza sativa L.~~

~~Papaver somniferum L.~~

~~Phacelia tanacetifolia Benth.~~

~~Phalaris aquatica L.~~

~~Phalaris canariensis L.~~

~~Phleum nodosum L.~~

~~Phleum pratense L.~~

~~Pisum sativum L.~~

~~Poa annua L.~~

~~Poa nemoralis L.~~

~~Poa palustris L.~~

~~Poa pratensis L.~~

~~Poa trivialis L.~~

~~Raphanus sativus L.~~

~~Secale cereale L.~~

~~Sinapis alba L.~~

~~Solanum tuberosum L.~~

~~Sorghum bicolor (L.) Moench~~

~~Sorghum bicolor (L.) Moench × Sorghum sudanense (Piper) Stapf.~~

~~Sorghum sudanense (Piper) Stapf.~~

~~Trifolium alexandrinum L.~~

~~Trifolium hybridum L.~~

~~Trifolium incarnatum L.~~

~~Trifolium pratense L.~~

~~Trifolium repens L.~~

~~Trifolium resupinatum L.~~

~~Trigonella foenum-graecum L.~~

~~Trisetum flavescens (L.) P. Beauv.~~

~~xTriticosecale Wittm. ex A. Camus.~~

~~Triticum aestivum L.~~

~~Triticum durum Desf.~~

~~Triticum spelta L.~~

~~Vicia faba L.~~

~~Vicia pannonica Crantz .~~

~~Vicia sativa L.~~

~~Vicia villosa Roth.~~

~~Zea mays L.~~

~~PART B~~

~~GENERA AND SPECIES WHICH MAY ONLY BE PRODUCED AND MARKETED AS PRE-BASIC, BASIC OR CERTIFIED MATERIAL~~

~~Solanum tuberosum L.~~

~~Annex V~~

~~PRODUCTION AND MARKETING REQUIREMENTS FOR PRESERVATION MIXTURES AS REFERRED TO IN ARTICLE 22~~

1. ~~Source area~~

~~Competent authorities may designate specific source areas for the preservation mixtures, with which such mixtures are naturally associated. For that purpose, they shall take into account information from plant genetic resource authorities or organisations recognised for this purpose by the Member States.~~

~~Where the source area is located in more than one Member State, it shall be identified by a common agreement of all Member States concerned.~~

~~2. Species~~

~~The species and, where relevant, subspecies, used in preservation mixtures shall be:~~

~~(a) typical for the habitat type of the source area;~~

~~(b) of importance for the preservation of the natural environment in the context of conservation of genetic resources, as components of the mixture;~~

~~(c) adequate for the purpose of recreating the habitat type of the source area.~~

~~The preservation mixture shall not contain the species Avena fatua, Avena sterilis and Cuscuta spp.~~

~~The maximum content of Rumex spp., other than Rumex acetosella and Rumex maritimus, shall not exceed 0,05 % by weight.~~

~~3. Authorisation of professional operators~~

~~Professional operators shall be authorised prior to the production of preservation mixtures.~~

~~The professional operator shall submit an application for the authorisation referred to in Article 22(1), including all of the following elements:~~

~~(a) name and address of the professional operator;~~

~~(b) harvesting method: whether the mixture is directly harvested or multiplied;~~

~~(c) components as species and, where relevant, subspecies and varieties of the preservation mixture; which are typical for the habitat type of the source area site and which are, as components of the mixture, of importance for the preservation of the natural environment in the context of the conservation of genetic resources;~~

~~(d) quantity of the mixture to which the authorisation is to apply;~~

~~(e) source area of the mixture;~~

~~(f) collection site, and in the case of a multiplied preservation mixture, in addition, the multiplication site;~~

~~(g) habitat type of the source area of the mixture; and~~

~~(h) year of collection.~~

~~The application shall be accompanied by the information necessary to verify compliance with requirements set out in point 4 in the case of directly harvested preservation mixtures, or point 5 in the case of multiplied preservation mixtures.~~

~~Competent authorities may issue an authorisation which shall include the authorisation date and the scope of the authorisation, according to the operator application and the compliance of the requirements, and the restriction to marketing in the source area.~~

~~Professional operators before the beginning of each production season shall notify the quantity of seed of preservation mixtures, for which the authorisation is intended, together with size and location of the intended collection site or sites and the date or dates of collection.~~

~~4. Production of directly harvested preservation mixtures~~

~~Directly harvested preservation mixtures shall comply the following requirements:~~

~~(a) a seed mixture that has been collected at the source area ('directly harvested preservation mixture') shall be collected at a site which has not been sown in the 40 years previous to the date of the authorisation;~~

~~(b)~~ ~~the percentage of the components of the directly harvested preservation mixture that are species and, where relevant, subspecies, shall be adequate for the purpose of recreating the habitat type of the source area;~~

~~(c)~~ ~~the maximum content of species and, where relevant, subspecies which do not comply with point (b) shall not exceed 1 % by weight;~~

~~(d)~~ ~~the competent authorities may carry out visual inspections on the collection site during the period of growth at intervals appropriate, and during the collection activities, to ensure that the mixture complies with the requirements provided for this preservation mixtures; they shall document the results thereof.~~

~~(e)~~ ~~tests shall be carried out officially, or under the official supervision of the competent authority, to check that the preservation mixture complies with the requirements provided; such tests shall be carried out in accordance with current international methods, or, where such methods do not exist, in accordance with any appropriate methods;~~

~~(f)~~ ~~samples shall be drawn from homogenous lots, and shall be sufficient to carry out the test referred to in point (e).~~

~~**5. Production of multiplied preservation mixtures**~~

~~Preservation mixtures seeds may be also multiplied by an authorized operator in accordance with the following process:~~

~~(a)~~ ~~seed of individual species is taken at the source area, or is a directly harvested preservation mixtures purchased to other operator;~~

~~(b)~~ ~~the seed referred to in point (a) is multiplied outside the source area as single species. Multiplication may take place for five generations;~~

~~(c)~~ ~~the seeds of those species are then mixed to create a mixture which is composed of those genera, species and, where relevant, subspecies which are typical for the habitat type of the source area;~~

~~(d)~~ ~~this mixture may also include seed from species listed in Part A of Annex I that has been produced conventionally, if it complies with point (c);~~

~~(e)~~ ~~the collected seed from which the preservation mixture is multiplied shall have been collected in its source area at a collection site which has not been sown in the 40 years previous to the date of the authorization by the operator, referred to in point 3.~~

~~(f)~~ ~~the seed of the multiplied preservation mixture shall be of species and, where relevant, subspecies which are typical for the habitat type of the source area and which are, as components of the mixture, of importance for the preservation of the natural environment in the context of conservation of genetic resources;~~

~~(g)~~ ~~the germination rate of the components referred to in point (f) shall be sufficient for the purpose of recreating the habitat type of the source area;~~

~~(h)~~ ~~the maximum content of species and, where relevant, subspecies which do not comply with point (g) shall not exceed 1 % by weight;~~

~~(i)~~ ~~components of a multiplied preservation mixture which are seeds of species listed in Part A of Annex I shall, before mixing, comply at least with the requirements for standard seed for the concerned species;~~

~~(j)~~ ~~tests shall be carried out officially or under official supervision of the Member State to check that the preservation mixture complies with the requirements provided. Such tests shall be carried out in accordance with current international methods, or, where such methods do not exist, in accordance with any appropriate methods;~~

~~(k)~~ ~~samples shall be drawn from homogenous lots, and shall be sufficient to carry out the test referred to in point (j).~~

~~Annex VI~~

~~REQUIREMENTS FOR PRODUCTION AND MARKETING OF PRM OF HETEROGENEOUS MATERIAL AS REFERRED TO IN ARTICLE 27(2)~~

~~A. Notification of heterogeneous material~~

~~PRM of heterogeneous material as referred to in Article 27 (2) may be marketed following a notification of the heterogeneous material by the professional operator to the competent authorities, made my means of a dossier containing:~~

~~a) the contact details of the applicant;~~

~~b) the species and denomination of the heterogeneous material;~~

~~c) the description of the heterogeneous material as referred in point B~~

~~d) a declaration by the applicant concerning the truth of the elements in points (a), (b) and (c).~~

~~e) a representative sample~~

~~The notification shall be sent by registered letter or by any other means of communication accepted by the competent authorities with confirmation of receipt requested. Three months after the date shown on the return receipt provided that no additional information was requested or that non formal refusal for reasons of incompleteness of the notification was communicated to the supplier, the competent authority shall be deemed to have acknowledged the notification and its content, and the heterogeneous material shall be included in the heterogeneous material register.~~

~~B. Description of the heterogeneous material~~

~~1. The description of heterogeneous material shall include all of the following elements:~~

~~(a) a description of its characteristics, including:~~

~~(i) the phenotypic characterisation of the key characters which are common to the material, together with the description of the heterogeneity of the material, by characterising the phenotypic diversity observable between individual reproductive units;~~

~~(ii) documentation of its relevant characteristics, including agronomic aspects such as yield, yield stability, suitability for low input systems, performance, resistance to abiotic stress, disease resistance, quality parameters, taste or colour;~~

~~(iii) any available results from tests concerning the characteristics referred to in point (ii);~~

~~(b) a description of the type of technique used for the breeding or production method of the heterogeneous material;~~

~~(c) a description of the parental material used to breed or produce the heterogeneous material and own production control programme used by the operator concerned with a reference to the practices as referred to in point B.2.(a) and, if applicable, in point B.2.(c);~~

~~(d) a description of the on-farm management and selection practices with a reference to point B.2.(b) and, if applicable, of the parental material with a reference to point B.2.(c);~~

~~(e) a reference to the country of breeding or production, with information on the year of production and description of the pedo-climatic conditions.~~

~~2. The heterogeneous material may be generated by one of the following techniques:~~

~~(a) crossing of several different types of parental material, using crossing protocols to produce diverse heterogeneous material by bulking of the progeny, repeatedly re-sowing and exposing the stock to natural and/or human selection, provided that this material shows a high level of genetic diversity;~~

~~(b) on-farm-management practices, including selection, establishing or maintaining material, which is characterized by a high level of genetic diversity;~~

~~(c) any other technique used for breeding or production of heterogeneous material, taking into account particular features of propagation.~~

~~C. Requirements concerning the identity of PRM lots of heterogeneous material~~

~~PRM of heterogeneous material shall be identifiable on the basis of all of the following elements:~~

~~(a) the initial material and the production scheme used in the crossing for creation of the heterogeneous material, as provided for in point B.2.(a) or, if applicable, in point B.2.(c), or the history of the material and the on-farm management practices, including whether the selection has occurred naturally and/or through human intervention, in the cases of points B.2.(b) and point B.2.(c);~~

~~(b) the country of breeding or production; and~~

~~(c) characterisation of the common key characters and of the phenotypic heterogeneity of the material.~~

~~D. Requirements concerning the sanitary quality, analytical purity and germination of PRM of heterogeneous material~~

~~1. PRM of heterogeneous material shall comply with the requirements for the analytical purity and germination requirements for seed and the quality requirements for other material of the lowest category for the respective species.~~

~~The plants shall be treated or excluded as a source of PRM, in case of defects or positive test results or visual symptoms of pests in accordance with Regulation (EU) 2016/2031.~~

~~2. By way of derogation from point D.1, professional operators may place on the market PRM of heterogeneous material which does not satisfy the conditions with respect to germination, provided that the operator indicates the germination rate of the PRM concerned on the label or directly on the package.~~

~~**E. Requirements for packaging and labelling of PRM of heterogeneous material**~~

~~1. PRM of heterogeneous material shall be contained in small packages and in maximum quantities as defined in point H. However, they may be contained in other packages or containers, only if these are closed in such a manner that they cannot be opened without leaving evidence of tampering on the package or container.~~

~~2. The professional operators shall affix on packages or containers of PRM of heterogeneous material a label in at least one of the official languages of the Union.~~

~~That label shall:~~

~~(i) be legible, printed or written on one side, newly issued and easily visible;~~

~~(ii) include the information set out in point G of this Annex, except where that information is printed or written directly on the package or the container; and~~

~~(iii) be yellow, with a green diagonal cross.~~

~~3. In the case of small, transparent packages, the label may be placed inside the package provided it is clearly legible.~~

~~4. By way of derogation from points E.1 and E.2, PRM of heterogeneous material contained in closed and labelled packages and containers may be sold to final users in unmarked and unsealed packages up to the maximum quantities provided for in point H, if on request, the purchaser is informed in writing at the time of delivery, about the species, the denomination of the heterogeneous material and the reference number of the lot.~~

~~**F. Maintenance of heterogeneous material**~~

~~1. Where maintenance is possible, the professional operator who has notified the heterogeneous material to the competent authorities, shall preserve the main characteristics of the material at the time of its notification, by maintaining it as long as it remains on the market.~~

~~2. That maintenance shall be undertaken in accordance with accepted practices adapted to the maintenance of such heterogeneous material. The professional operator responsible for the maintenance shall keep records of duration and content of maintenance.~~

~~3. At all times, the competent authorities shall have access to all records kept by the professional operator responsible for the material, in order to check its maintenance. The professional operator shall keep those records for 5 years after the moment the heterogeneous material is not marketed anymore.~~

~~G. Content of the label of the packages~~

~~PRM of heterogeneous material shall be marketed in packages bearing a label containing the following elements:~~

~~(1) the denomination of the heterogeneous material, together with the phrase 'heterogeneous material';~~

~~(2) the indication 'EU rules and standards';~~

~~(3) the name and address of the professional operator responsible for affixing the label, or its registration code;~~

~~(4) country of production;~~

~~(5) lot reference number given by the professional operator responsible for affixing the labels;~~

~~(6) month and year of closing, following the term: 'closed';~~

~~(7) species, indicated at least under its botanical name, which may be given in abridged form and without the authors' names;~~

~~(8) declared net or gross weight, or declared number of PRM, except for small packages;~~

~~(9) where weight is indicated and pelleting substances or other solid additives are used, the nature of the additive and also the approximate ratio between the weight of pure seeds and the total weight; and~~

~~(10) the germination rate, if applicable.~~

~~H. Maximum quantities of PRM of heterogeneous material in small packages~~

~~Species~~	~~Maximum net mass (kg)~~
~~Fodder plants~~	~~10~~
~~Beet~~	~~10~~
~~Cereals~~	~~30~~
~~Oil and fiber plants~~	~~10~~
~~Potato~~	~~30~~
~~Vegetable:~~	
~~Legumes~~	~~5~~
~~Onions, chervil, asparagus, spinach beet or chard, red beet or beetroot, turnips, water melon, gourd, marrows, carrots, radishes, scorzonera or black salsify, spinach, corn-salad or lamb's lettuce~~	~~0,5~~
~~All other vegetable species~~	~~0,1~~

Annex VII

CONTENTS OF THE NATIONAL AND UNION VARIETY REGISTERS AS REFERRED TO IN ARTICLE 46

The national variety registers and the Union variety register shall contain all of the following elements***, where applicable***:

(a) the ***scientific*** name of the genus or species to which the variety belongs;

(aa) the common name of the genus or species to which the variety belongs;

(b) ***the breeder's reference and/or*** the denomination of the variety and~~, for varieties marketed before the entry into force of this Regulation, where applicable, other alternative denominations~~ ***known synonyms*** used for that variety;

(c) the name ***of the applicant*** and, where applicable, the ~~reference number,~~***name*** of the applicant***'s representative***;

(ca) the application date;

(cb) the status of the variety, including indication whether the variety is registered, its registration is terminated, or surrendered by the applicant, or with an application pending for registration, or an application that has been withdrawn by the applicant or rejected by the competent authority;

(d) the date of the registration of the variety and~~, where applicable, of the renewal of the registration~~ ***any change of its status according to point (cb)***;

(e) ***the date of termination of the registration and, where applicable,*** the date of the end of ~~validity of registration~~***marketing pursuant to Article 71(2)***;

(f) a~~ reference to the link of the file, where~~ ***link to*** the official description of the variety, or~~, if applicable,~~ the officially recognised description of the variety~~, can be found~~;

(g) ~~in the case of varieties with officially recognised description and, if appropriate,~~ an indication ~~of~~***whether it is a conservation or local variety and in that case*** the region~~(s), where the variety has historically been grown and to which it is naturally adapted (‘region(s)~~ of origin~~²)~~;

(h) the name***, address and, where applicable, the official registration number*** of the ~~person responsible for the maintenance of a variety~~***maintainer***;

(i) ***for the Union register,*** the name of the Member States having established the relevant national variety register(s);

(j) the ~~reference~~***unique variety identifier*** under which the variety has been registered in the national variety register(s);

(k) ~~where applicable,~~ the indication that the variety is an 'organic variety suitable for organic production' ***according to Regulation (EU) 2018/848***;

(l) where applicable, the indication that the variety contains, or consists of, a genetically modified organism ***as defined in Article 2, point (2), of Directive 2001/18/EC, excluding organisms obtained through the techniques of genetic modification listed in Annex I B to that Directive***;

(m) ~~where applicable,~~ the indication that the variety is a component variety of another registered variety;

(n) ~~where applicable,~~ the indication that PRM belonging to the variety is only produced and marketed ~~in~~***as*** rootstocks;

~~(o) where applicable, a reference to the link of the file, where the results of the examinations for value for sustainable cultivation and use, as referred to in Article 52, can be found;~~

(p) ~~where applicable,~~ an indication of the reproduction method of the variety, including information on whether it is ~~a hybrid or a synthetic variety,~~***:***

(i) a hybrid;

(ii) a synthetic variety; or

(iii) a vegetatively or seed propagated variety in case of species with both types of propagation;

(q) ~~where applicable, the~~ indication ~~that~~***whether*** the variety contains, or consists of a category 1 NGT plant within the meaning of Article ~~3(7)~~***3, point (7),*** of Regulation (EU) …/… (Office of Publications, please insert reference to NGT Regulation) and the identification number(s) referred to in Article 9(1), point (e) of [NGT Proposal] assigned to the category 1 NGT plant(s) it has been derived from;

~~(r) where applicable, the indication that the variety contains, or consists of a category 2 NGT plant within the meaning of Article 3(8) of Regulation (EU) …/… (Office of Publications, please insert reference to NGT Regulation);~~

(s) ~~where applicable,~~ indication ~~that~~***whether*** the variety is herbicide tolerant ~~and indication of the applicable cultivation conditions~~;

~~(t) where applicable, indication that the variety has certain characteristics, other than the one referred to in point (s), and indication of the applicable cultivation conditions.~~

(u) types or uses of the variety, including winter or spring type, turf grass uses, or industrial, or food or feed uses.

Annex VIIa

TECHNICAL REQUIREMENTS FOR THE REGISTRATION OF SELECTED CLONES AND POLYCLONAL MATERIAL

The selected clone or polyclonal material shall fulfil the following requirements, as applicable to the type of material concerned, in order to be registered:

(a) ***the polyclonal material is selected in a single field trial containing a representative sample of the overall genetic diversity of the variety according to an experimental design based on internationally accepted methods; in the case of polyclonal material of vine propagating material, that design is based on methods prescribed by the International Organisation of Vine and Wine;***

(b) ***in the case of vine propagating material, the polyclonal material is composed of 7 to 20 distinct genotypes;***

(c) ***the trueness of the selected clone and of each genotype of the polyclonal material to the identity of the variety to which they belong is ensured through the observation of the phenotypic characteristics and, where appropriate, through molecular analysis pursuant to internationally accepted standards;***

(d) ***the selected clone or polyclonal material is maintained in accordance with internationally accepted practices.***

Annex VIII

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