Council of the
European Union

Brussels, 18 June 2024
(OR. en)

11303/24

Interinstitutional File:
2023/0227(COD)

AGRI 525
AGRILEG 321
SEMENCES 144
PHYTOSAN 163
FORETS 201
CODEC 1565
IA 146

WORKING DOCUMENT

From:	Presidency
To:	Delegations
Subject:	Proposal for a Regulation of the 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) - Presidency revised text

Delegations will find in Annex the Presidency revised text on the above-mentioned proposal.

Deletions are marked with ~~strikethrough~~ and additions are marked in **bold and underline** in comparison with the Commission proposal.

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, 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,

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

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

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Rules for the production and marketing of plant reproductive material ('PRM') of agricultural crops, 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([1]); 66/402/EEC([2]); 68/193/EEC([3]); 2002/53/EC([4]); 2002/54/EC([5]); 2002/55/EC([6]); 2002/56/EC([7]); 2002/57/EC([8]); 2008/72/EC([9]) and 2008/90/EC([10]) (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.

---

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

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

3 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).

4 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).

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

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

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

8 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).

9 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).

10 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 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, quality and diversity of PRM appears to be of outmost importance to achieve the transition to sustainable food systems called for in the Farm to Fork Strategy[11], 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 biodiversity and to meet increasing farmers' and consumers' expectations related to quality and sustainability of PRM.

[11] 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 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 agricultural crops, vegetables, fruit plants or vine. 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 capable of, and intended for, producing entire plants. This Regulation should, therefore, cover seeds, as well as all other forms of plants at any growth stage, capable of and intended for producing entire plants.

(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[12] +.

(11) This Regulation should not cover propagating material of ornamental plants, because after consultations with Member States and stakeholders it has been concluded that Council Directive 98/56/EC ([13]) still adequately covers the needs of that sector.

(12) This Regulation should cover neither PRM exported to third countries, nor PRM used solely for official testing, 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 for their own private use and outside their trade. 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.

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

(15) However, it is appropriate to exempt, where necessary, rootstocks from the requirement to belong to a variety, as although of a significant value, they frequently do not fall under the definition of a variety.

---

[12] 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.

[13] 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).

(16) In order to ensure the identity, quality and transparency and to enable informed choices by the users, PRM should as a general rule be produced or marketed under predefined categories. Those categories should reflect different generation stages and quality levels, and, on the basis of the internationally established terminology, be named 'pre-basic', 'basic', 'certified' and 'standard' seed, and 'pre-basic', 'basic', 'certified' and 'standard' material, in the case of PRM other than seeds, and .

(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 ([14]) ('OECD Seed Schemes'), the seed potato standards of the United Nations Economic Commission for Europe (UNECE) and the rules on seed sampling and testing of the International Seed Testing Association (ISTA).

(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') and should be attested by an official label.

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

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

(20) Professional operators should be authorised by the competent authority to perform certification under official supervision of PRM belonging to certain species and categories 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.

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

(22) In view of the large diversity of PRM, professional operators should be able to market the PRM lots in the form of individual plants, packages, bundles or containers, or in bulk.

(23) Rules should be adopted for the labelling of PRM to ensure the appropriate identification of that material per category through the attestation of compliance with the respective requirements concerning pre-basic, basic, certified and standard seed and material.

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

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

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

(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.

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

(29) Seeds are frequently marketed in varietal mixtures of same species or species mixtures. However seeds of genera or species, covered by this Regulation, should be allowed to be produced and marketed in mixtures only with seeds of the genera or species covered by this Regulation. This is necessary to ensure that the respective production and marketing standards are respected. However, Member States should have the possibility to allow the production and marketing of a mixture of seeds covered by this Regulation, with seeds not belonging to genera or species covered by this Regulation, for the purposes of conservation of genetic resources and preservation of the natural environment. This is is because those species are the ones most appropriate for the purpose of that preservation. Rules should be set out concerning those mixtures to ensure their identity and quality.

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

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

(32) Certain types of varieties do not fulfil the established requirements concerning distinctness, uniformity and stability. However, they are important for the conservation and sustainable use of plant genetic resources. They are traditionally grown or new locally produced varieties under specific local conditions and adapted to those conditions. They are characterised, in particular, by reduced uniformity due to a high 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 ([15]). 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 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 to comply with the requirements for standard material for the species concerned. That PRM belonging to conservation varieties should therefore be labelled with the indication 'Conservation varieties'. Those varieties should also be registered, to enable their control by the competent authorities and guarantee the informed choices for their users and the effectiveness of official controls.

[15] 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 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 be marketed to final users without having to comply with the 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 for consumer offer, while respecting the general quality requirements. Moreover, for reasons of transparency and better control, rules should be set out for the packaging and labelling of PRM intended for final users only. For the same reason, professional operators using this derogation for marketing to final users should notify that activity to the competent authorities.

(35) Many gene banks, 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 which is marketed to them, or among them, derogates from the established production and marketing requirements, and that instead it complies with less stringent rules.

(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 a derogation from the established requirements is provided for the exchanges of small quantities of seeds between farmers. Such derogation could apply if those seeds do not belong to a variety for which plant variety rights have been granted in accordance with Council Regulation (EU) 2100/94([16]). Member States should be allowed to define those small quantities for specific species per year, in order to ensure that there is no misuse of such derogation impacting the marketing of seeds.

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

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

(37) According to the PRM marketing Directives, derogations from the established requirements are allowed for the marketing of PRM belonging to not yet registered varieties; of varieties that have not yet been fully tested; of 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.

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

(38a) **To facilitate the advancement of agricultural diversity and innovation within the Union, varieties that are developed need to be assessed concerning their commercial viability, cultivation potential, and use for and within the Union. For this reason, derogations from the established requirements are allowed. Marketing of these unregistered varieties is conditionally authorized, strictly in quantities deemed minimal yet sufficient for conducting comprehensive tests and the tests are also authorised in time duration. Each lot must be accompanied by appropriate labelling, clearly indicating its intended use for testing purposes only. This approach ensures that there is no misuse of such derogation impacting the marketing of seeds.**

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

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

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

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

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

(41) In order to ensure transparency and more effective controls on the production and marketing of PRM, professional operators should be registered. It is appropriate that they register in the registers established by Member States pursuant to Regulation (EU) 2016/2031 of the European Parliament and of the Council ([17]), 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.

(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.

(43) Experience has shown that the reliability and quality of the marketed PRM can be jeopardised where it is impossible to trace material not complying with the applicable standards. It is therefore necessary to establish a comprehensive traceability system allowing withdrawals from the market or the submission of information to users of PRM or competent authorities. For that reason, the keeping of information and records on transfers from and to professional users should be mandatory for the professional operators. However, such record keeping is not appropriate for marketing in retail.

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

(45) Varieties should be registered in a national variety register, to ensure informed choices by their users and more effective official controls.

---

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

(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 varieties. The existence of those two different descriptions is necessary to separate the two categories of varieties, whereby the first one is based on DUS testing results, while the other one is based on historical data concerning the use of the variety and practical experience. In addition, such approach can offer the necessary information about the characteristics of the varieties and their identity.

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

(48) Herbicide tolerant varieties are varieties that have been bred to be intentionally tolerant to herbicides, in order to be cultivated in combination of 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 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 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, new varieties of all genera or species 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. Among those aspects are their 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'). 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 appropriate that their registration is subject to adjusted DUS, and in particular as regards the requirements concerning uniformity. Furthermore, in order for that such varieties to be better 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.

(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 technical examination, confidentiality, provisional examination report and provisional official description, examination report and final official description, examination of the denomination of a variety and decision on the registration of a variety in the national variety register.

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

(54) Rules should be set out concerning the technical examination of varieties, in order to conclude whether they are distinct, uniform and stable. Due to the importance of that examination for the variety breeding sector and the fact that it leads to the production of an official description, that technical examination should be carried out only by the competent authority.

(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, the competent authority should be in charge of the testing arrangements. 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 should be audited by the Community Plant Variety Office (‘CPVO’).The premises of the applicants where the examination for the satisfactory value for sustainable cultivation and use takes place under official supervision, should be audited by the respective competent authorities, to ensure compliance with the applicable requirements.

(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 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 person, 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.

(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 persons notified by the applicant to the competent authority, pursuant to certain requirements and subject to official controls by the competent authorities.

(60) Rules should be set out concerning the content of the national variety registers and the Union variety register, and the keeping of samples 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.

(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.

(62) Regulation (EU) 2017/625 of the European Parliament and of the Council[18] 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[19].

(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.

(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.

---

[18] 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).

[19] 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).

(65) In order to adapt the list of genera and species of PRM, subject to the scope of this Regulation, to the developments related to the significance of area and value of production, food/feed security and number of Member States where it is cultivated, 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 material and seeds.

(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.

(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.

(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.

(71) In order to adapt the rules on variety denomination to the technical and scientific developments, and follow up on the experience gained from the application of those rules, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of supplementing this Regulation by setting out specific criteria concerning the suitability of variety denominations.

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

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

(74) It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[20]. 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.

[20] OJ L 123, 12.5.2016, p. 1.

(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[21].

(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, 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 of PRM, and adapt the respective rules to the experience gained from the application of the provisions of this Regulation, implementing powers should be conferred to the Commission for adopting specific requirements for all or certain species of PRM, concerning the merging or splitting of lots in relation to the origin of PRM lots, their identification, records on that operation and labelling following the merging or splitting of PRM lots.

(78) In order to ensure uniform conditions for the implementation of this Regulation, 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.

---

[21] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers, OJ L 55, 28.2.2011, p. 13–18.

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

(80) In order to ensure uniform conditions for the implementation of this Regulation and follow up on any practical experience gained by the application of the respective rules, implementing powers should be conferred to the Commission for adopting specific provisions concerning mixtures of seeds.

(81) In order to ensure uniform conditions for the implementation of this Regulation with respect to retail marketing of PRM, 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 small packages for seeds and the packages and bundles for other PRM marketed to final users.

(82) In order to ensure uniform conditions for the implementation of this Regulation and to address urgent 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, the marketing of PRM of the categories of pre-basic, basic or certified material or seed subject to less stringent requirements, or to derogate from the requirement to belong to a variety, and with respect to repealing and amending that authorisation.

(83) In order to ensure uniform conditions for the implementation of this Regulation, and ensure some flexibility to Member States to adopt national measures adapted to their agro-climatic conditions and higher quality standards, implementing powers should be conferred to the Commission for authorising the Member States to adopt, with regards to production and marketing of PRM, more stringent 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.

(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 the production or marketing of PRM is likely to constitute a serious risk to human, animal or plant health, the environment or cultivation of other species, and such risk 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.

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

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

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

(88) In order to ensure uniform conditions for the implementation of this Regulation, and to adapt its provisions to the evolving applicable protocols of the International Union for the Protection of new Varieties of Plants (UPOV) or protocols established by the CPVO, and the relevant technical and scientific developments, implementing powers should be conferred to the Commission for adopting specific requirements concerning distinctness, uniformity and stability per genera or species of varieties.

(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 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.

(90) Since the objective of this Regulation, namely to ensure a harmonised approach with regard to the production and marketing of PRM, cannot be sufficiently achieved by the Member States but can rather, by reason of its effects, complexity and international character, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 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 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 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, iden**ti**ty 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.

   ~~Its requirements concern, respectively, all types of PRM, only seeds, or only material other than seeds.~~

   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 all users** ~~for professional operators and final users~~;

(b) to ensure 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**ing** Annex I, in order to adapt it 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 referred to in the first subparagraph shall add genera or species to the list in Annex I if they fulfil at least two of the following elements **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) **the PRM is**~~are~~ marketed in at least two Member States.

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

4. This Regulation does not apply to:

(a) propagating material of ornamental plants ~~as defined in Article 2 of~~ **subject to** Directive 98/56/EC **with the exception of turf grass seed**;

(b) forest reproductive material **(FRM) subject to** ~~as defined in Article 3 of~~ Regulation (EU) .../… of the European Parliament and of the Council[22]+;

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

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

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

(f) PRM [with the exception of seed potatoes] transferred in any way, not aimed at its commercial exploitation but subject to service contracts for the purposes of cleaning, disinfection, treatment, packaging, labelling, transport, processing and storage, provided that the provider of services does not acquire title to that PRM ~~seed~~ and its traceability is ensured;

[22] 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.

(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 for the conservation of plant genetic resources in gene banks.

Article 3

Definitions

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

(1) 'plant reproductive material' ('PRM') means plants **for planting** as defined in Article 2(**4**~~1~~) of Regulation (EU) 2016/2031, capable of, and intended for**:**~~,~~

(a) ~~producing~~**the propagation or the multiplication of** entire 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 [breeding]**;

(b) marketing;

(c) maintenance of varieties **registered in accordance with article 47 (1) (a) (i)**;

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

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

(3) 'marketing' means the following actions ~~conducted by a professional operator~~ **in relation to PRM**: sale, holding, transfer for free, or offering for sale **including online** or any other way of transferring or distribution within, or import into, the Union**, with the exception of those listed in article 2 (4)[(e) and (f)];**

(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, is true to the description of the 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**. It is applicable to [vine and fruit] species in which this intra-varietal variability has been able to occur**;

(7) ‘polyclonal ~~plant reproductive material~~ **selections**’ means ~~a group of several distinct individual plant progenies derived from different genotypes, each of which is true to the description of the variety to which it belongs~~ **[vine propagating material obtained from a selection, made through quantitative genetics tools, of a group of at least 7 genotypes from the same experimental set of a specific ancient variety, containing most of its intra-varietal diversity;]**

~~(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 authoriti~~t~~y’ 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, 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, **commonly known fruit variety or rootstock not belonging to a variety.** ~~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~~;**. [The officially recognised description shall be recognised by the competent authority as a sufficiently complete description to ensure the identification and distinctness of these conservation varieties];**

[*or*

'officially recognised description' means a written description of a conservation variety, commonly known fruit variety or rootstock not belonging to a variety, which has been prepared in accordance with Article 53(4), includes relevant characteristics that qualify a variety as a conservation variety and is recognised by a competent authority;]

(12) 'variety maintenance' means the actions taken for ~~controlling~~ **ensuring** varietal purity and identity with the aim to ensure that **the expression of the characteristics which are included in the examination for distinctness as well as any others used for the variety description, remain unchanged after repeated propagation or, in the case of a particular cycle of propagation, at the end of each such cycle**~~a variety remains in accordance with its description over subsequent cycles of reproduction;~~**.**

(13) 'seeds' means seeds in the botanical sense;

(14) ‘pre-basic seed’ means seed that **[has been produced under the responsibility of the maintainer according to accepted practices for the maintenance of the variety, [mainly]from breeder’s seed],** belongs to ~~a~~ generation**s** 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 **[under the responsibility of the maintainer according to accepted practices for the maintenance of the variety],** 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, 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 satisfies the respective conditions laid down in ~~Part A of~~ Annex III;

(17a) ‘commercial seed’ means seed which

(a) is identifiable as belonging to a species, which is not heterogeneous material within the meaning of Article 3(27); and

(b) has been found by means of official examination, or examination under official supervision, to satisfy the relevant conditions laid down in Annex II, with the exception of the requirement to belong to a variety registered in a national variety register as referred to in Article 44;

(17b) [‘Mother Plant’] means an identified plant intended for propagation.

(17c) [‘Pre-basic mother plant’] means a mother plant intended for the production of pre-basic material or lower categories.

(17d) [‘Basic mother plant’] means a mother plant intended for the production of basic material or lower categories.

(17e) [‘Certified mother plant’] means a mother plant intended for the production of certified material or lower categories.

(17f) [‘Standard mother plant’] means a mother plant intended for the production of standard material.

(17g) [‘multiplication’] means the process of increasing the quantity of PRM;

(17h) [‘renewal of a mother plant’] means replacing a mother plant by a plant vegetatively produced from it;

(18) ‘pre-basic material’ means PRM, other than seeds, that **has been produced, under the responsibility of the maintainer according to the accepted practices for the maintenance of the identity of the variety and of the clone and for its phytosanitary status,** belongs to ~~a~~ generation**s** 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**, [under the responsibility of the maintainer according to the accepted practices for the maintenance of the identity of the variety and of the clone and for its phytosanitary status],** 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, [if intended to be used for the production of rootstocks, by certified seeds from basic or certified material of rootstocks],** 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; **[In case it corresponds to vine, it shall not be produced from preceding generations of certified material];**

(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 authorised professional operator that pre-basic, basic or certified seed or material complies with the applicable requirements, and where at least one or more of the relevant inspections, sampling, testing or label printing **and affixing** have 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 ([23]), excluding organisms obtained through the techniques of genetic modification listed in Annex I B to Directive 2001/18/EC;

(25a) 'NGT plant' as defined in Article 3(3) of Regulation (EU) (…)

[23] 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).

(26) ‘lot’ means a unit of PRM, identifiable by its homogeneity of composition and origin **or origins, in the case of seed mixtures**;

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

(a) presents common phenotypic characteristics;

(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) ‘**non-professional**~~final~~ user’ means any 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~~**either**:

(a) **a traditional conservation variety that is:**

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

(ii) characterised by **reduced uniformity due to** a ~~high~~ **certain** level of genetic and phenotypic~~al~~ diversity between individual reproductive units, **except in the case of vegetatively propagated material**;

[(b) a newly bred conservation variety that is:

(i) newly locally bred and derived from participatory on-farm selection, and is bred for adaptation to local agro-climatic conditions and farming systems; and

(ii) 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 material;]

(c) a reregistered variety for conservation purposes that:

(i) was deleted or expired from the Union variety register for a least two years; and

[(ii) is adapted to specific local conditions;]

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

(a) they are not Union quarantine pests, protected zone quarantine pests, or 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 harvesting activities]**; 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 quality pests on the respective PRM is so low that those pests do not affect adversely the quality of that PRM;

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

(33) ‘farmer’ means **any person acquiring or using PRM for the professional production of food, feed or for industrial processing**~~farmer as defined in Article 3(1) of Regulation (EU) 2021/2115 of the European Parliament and of the Council~~ ~~[24]~~;

~~[24] 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 **plant that can be clearly distinguished from the** ~~not corresponding to the description of the~~ variety or species to which it is supposed to belong pursuant to this Regulation **in the expression of any characteristic included in its variety description, 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 a nationally recognised centre with an official mission for conserving genetic resources under appropriate conditions to ensure the continued availability of these resources for research, breeding, education and training, including pre-breeding for improved plant varieties or material delivery for a sustainable and resilient agricultural system; the key principles at the core of the operation of a gene bank are to safeguard the conservation of the genetic material and the facilitation of access;

(35b) 'seed as grown' means unprocessed seed, produced in a third country or in the Union, intended to be processed in the Union in order to comply with the requirements 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 **the relevant provisions** ~~Articles 36, 37, 40, 41, 42, 49, 53 and 54~~ 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.~~,~~

1a. By way of derogation from paragraph 1, PRM of all~~except~~ the following cases **may be produced and marketed within the Union without belonging to a variety**:

(a) **[**as rootstocks, 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 **non-professional**~~final~~ 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 difficulties of PRM in accordance with Article 33;

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

1b. PRM produced and marketed in the following cases shall not be registered as a variety:

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

(b) as heterogeneous material in accordance with Article 27;

(c) as PRM of a variety for which an application for registration has not yet been submitted in accordance with Article 31a;

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

(e) 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 material or seed;

(b) basic material or seed;

(c) certified material or seed;

(d) standard 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 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** (**eb**~~d~~) **of that paragraph** in the following cases:

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

(b) marketing to a **non-professional**~~final~~ user in accordance ~~to~~ **with** Article 28;

(c) marketing ~~to and between~~**by organizations and**~~conservation~~ networks as referred to in 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 variety for which an application for registration has not yet been submitted in accordance with Article 31a;

(eb) PRM of a generation prior to pre-basic seed or material produced and marketed for the purpose of multiplication for the production of pre-basic, basic, certified or standard seed or material. This PRM shall be accompanied by an operator's label pursuant to Article 16, with the indication 'PRM from maintenance'.

SECTION 2

Requirements for the production and marketing of pre-basic, basic, certified and standard 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 is practically free from quality pests;

   (b) it is ~~produced and marketed~~:

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

      (ii) **produced an 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).

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 is practically free from quality pests;

(b) it is ~~produced and marketed~~:

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

(ii) **produced and marketed** in accordance with the requirements set out in Part B**, Ba, C or E** 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 **Annex II** to the developments of international technical and scientific standards and may concern the requirements for the following:]

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

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

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

(d) sowing and planting, and production ~~in the field,~~ 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;

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

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

(i) marketing of pre-basic, basic and certified material produced by 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~~**to E** 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~~**may** concern one or more of the following elements

(a) ~~specific~~ **intended** uses of the genera, species or the types of the PRM concerned;

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

(c) conditions for sowing or planting;

(ca) previous cropping and isolation distances;

(d) **[open** field **or in greenhouse** cultivation**]**;

(e) **[**harvesting and post-harvesting**]**;

~~(e)~~**(ea)** germination rates, purity and content of other **species**~~PRM~~ **among which *Avena fatua***, moisture, vigour, presence of **soil**~~earth~~ or extraneous matter;

~~(e)~~**(eb)** 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;

~~(d)~~**(ec)** 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;

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

(f) conditions for the production of fruit plants, vine or seed potatoes from seeds.

Those implementing acts shall be adopted in accordance with the examination procedure set out in Article 76(2), in order to adapt to the developments of the relev~~e~~**a**nt international technical and scientific standards. **The first such implementing act shall be adopted not later than [*36 months from the date of the entry into force of this Regulation/any other date*].**

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:

      (i) under the responsibility of the professional operator;

      (ii) 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:

      (i) under the responsibility of the professional operator;

      (ii) in accordance with the requirements set out in Part B**, Ba, C 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 adapt the requirements referred to in paragraphs 1 and 2 to the scientific and technical developments and to the applicable international standards. Those amendments shall concern the following:

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

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

(c) requirements for marketing of standard seeds;

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

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

(f) requirements for the marketing of standard material;

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

(ga) requirements for marketing of selected clones and polyclonal PRM of standard material;

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

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

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

(a) ~~specific~~**intended** uses of the genera, species or the types of the PRM concerned;

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

(c) conditions for sowing or planting;

(ca) previous cropping and isolation distances;

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

(e) harvesting and post-harvesting;

(f) germination rates, purity and content of other **species**~~PRM~~ **among which *Avena fatua***, moisture, vigour, presence of **soil**~~earth~~ 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 **(true)** seeds from fruit plants**, from seed potatoes** or vine;

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

Those implementing acts shall be adopted in accordance with the examination procedure set out in Article 76(2), in order to adapt to the developments of the relevent international technical and scientific standards. **The first implementing act shall be adopted not later than *[36 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. **Vine rootstocks may not be produced or marketed as standard material.**

2. ~~Clones,~~ ~~s~~**S**elected 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 **selected** clones **and polyclonal PRM** 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 **IIIa** ~~II, Part B, Part C point 2~~.

3. ~~Clones, s~~**S**elected 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 3

Authorisation of professional operators and official supervision of the competent authorities

Article 10

Authorisation of professional operators to carry out certification under official supervision

1. ~~A professional operator may, upon application, be authorised by the competent authority to perform all or certain activities required for certification of PRM under official supervision of the competent authority for pre-basic, basic and certified material or seeds, and to issue an official label for them~~**Competent authorities may decide that professional operators, upon application to the competent authority, may be authorised to perform all or certain activities required for certification of PRM [, except for control plot testing,] under official supervision of the competent authority for pre-basic, basic and certified material or seeds, and to print and affix an official label for them**.

   ~~In order to be granted such authorisation and depending on the activities to be authorised for, the professional operator shall~~**Where a competent authority provides the possibility for operators to apply for carrying out certain activities required for certification under official supervision, the professional operator shall, in order to be granted such an authorisation and depending on the activities to be authorised for, comply with 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 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 equipment to carry out the testing referred to in Annex II, or use laboratories **performing according to 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~~**by setting out criteria to be fulfilled by the professional operators in order for them to comply with the conditions set out in**~~:~~

[~~(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) **of this Article and procedures to ensure that those criteria are met.**

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), 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

1. For the purposes of the certification **activities** under official supervision, the competent authorities 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.**

   The~~y~~ **competent authorities** shall also organise training and examinations of 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 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 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.

3. The Commission may, by means of implementing acts, specify the requirements for the ~~audits~~ **evaluations**, training, 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 **1 and the** ~~and minimum portion of the crops and the lots of PRM, to be subject to inspections, sampling and testing, as referred to in paragraph 2~~ **minimum portion of the crops and the lots of PRM to be subject to inspections, sampling and testing as referred to in paragraph 2**;

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

(c) 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 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 REQUIREMENTS

Article 13

Lots

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

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 23.**

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 of certified seed or material, t**he merging operation may only be undertaken in a facility and by persons authorised **in accordance with Article 10** by 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 23.**

~~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 **shall**~~may~~, 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~~ **re-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 in ~~fastened~~ packages, bundles or containers, bearing a sealing device and ~~marking~~ **a label**. ~~In the case of PRM other than seeds, it may also be marketed in the form of individual plants.~~ **PRM other than seed and seed potatoes may be marketed 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~~ **re-sealed** 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 resealing,** the date of **production** ~~refastening~~ and the details of the responsible competent authority shall be stated on the label referred to in Article 15.

4. ~~Lots of pre-basic, basic or certified~~ PRM may be re-packaged, re-labelled, and re-sealed**. In the case of pre-basic, basic or certified seed or material, it may only be done** ~~only~~ **by persons authorised by the competent authority for this specific purpose in accordance with Article 10** ~~under official control or under the official supervision of the competent authority~~.

5. By way of derogation from paragraph 1, seed~~s~~ **and pre-basic, basic or certified seed potatoes** may be marketed from a professional operator directly to a farmer in bulk.

That professional operator shall be authorised for that purpose by the competent authority. It shall ~~inform~~ **keep records** ~~the competent authority in advance~~ of such activity and of the lot from which such seed **or seed potatoes** come~~s~~. **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 of transfer and lot identification.**]**

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 seed~~s~~ **and seed potatoes** in bulk. Those implementing acts **may include specific derogations when technical and biological reasons 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

1. Pre-basic, basic and certified material and seed~~s~~ 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.

1a. The official label referred to in paragraph 1 shall also attest compliance of the respective PRM with the requirements in Article 7 other than the derogations from part of those requirements provided for in Article 32(1) and (2), Article 32(2) and Articles 33, 34 and 35. In particular, it shall be used for:

(a) pre-basic, basic or certified PRM for which an application for registration has been submitted for the purpose of multiplication referred to in Article 32(1);

(b) certified PRM for which an application for registration has been submitted for the purpose of carrying out tests or trials to gather information on the cultivation or use of that variety referred to in Article 32(2);

(c) pre-basic, basic, certified seed and material authorised in cases of temporary difficulties in the supply referred to in Article 33;

(d) seed not finally certified as complying with germination rate requirements in the case of rapid supply needs referred to in Article 34; and

(e) PRM other than seed potatoes which is not yet certified referred to in Article 35.

2. The official label shall be issued by the competent authority and bear a serial number**,** given by the competent authority. **That label shall ensure the unique identification and traceability of the respective lot.**

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 **such printing** ~~certification under official supervision in accordance with Article 10~~**; the professional operator may carry out the printing of the label through a contracted third party.**

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 the person acting under the responsibility of the professional operator~~. **The professional operator may carry out the printing or affixing of the label through a contracted third party.**

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 be issued in electronic format (electronic official label).

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

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

(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)**;

(c) the technical arrangements for the issuance of electronic official labels **and their format and content of those labels**.

Only f~~F~~ollowing the adoption of such delegated act, ~~the official label may also be issued in an electronic form (~~'**an** electronic official label'~~)~~ **may be issued**.

6. By way of derogation from paragraphs 1 to 5, pre-basic, basic ~~material and seed basic material and seed~~ and certified material and seed, imported from third countries pursuant to Article 39, shall be marketed in the Union with the respective OECD label that was accompanying them at import**, or with another official label if so provided for by applicable international standards**.

Article 16

Operator's label

1. ~~Standard material and standard seed~~ **PRM other than pre-basic, basic and certified categories, marketed under the professional operator´s responsibility,** shall be identified through an operator's label.

2. That label shall attest that **the PRM referred to in paragraph 1** ~~standard material or standard seed~~ complies with the ~~relevant~~ production and marketing requirements, referred to in **this Regulation,** ~~Article 8,~~ on the basis of inspections, sampling and testing carried out by the professional operator. **In particular, it shall be used for:**

(aa) PRM of a generation prior to pre-basic seed or material produced and marketed for the purpose of multiplication, as referred to in Article 6(2)(eb);

(ab) standard material or standard seeds as referred to in Article 8~~,~~;

(ac) standard material of selected clones and polyclonal PRM as referred to in Article 9;

(b) mixtures referred to in Article 21(1), if they include standard material;

(ba) mixtures referred to in Article 21(3a);

(c) preservation mixtures referred to in Article 22;

(d) repackaged and relabelled seeds referred to in Article 23, if they contain standard seeds;

(e) PRM belonging to conservation varieties referred to in Article 26;

(f) PRM of heterogeneous material referred to in Article 27;

(g) PRM marketed by certain organizations and networks referred to in Article 29;

(ga) PRM of a variety for which an application for registration has not yet been submitted referred to in Article 31a;

(gb) standard seed or material of not yet registered varieties referred to in Article 32(1) and (2);

(h) PRM of not yet registered fruit and vine varieties referred to in Article 32(2a);

(i) standard seed or material authorised in cases of temporary difficulties in the supply referred to in Article 33,;

(l) standard seed and material imported from third countries referred to in Article 39(1) if it includes standard material;

(m) seed as grown referred to in Article 39(1a).

The operator´s label shall also be used for PRM marketed to non-professional users referred to in Article 28, unless the professional operator selects to use an official label in case the PRM is marketed as pre-basic, basic or certified seed or material.

3. 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 operator, ~~on~~ **to** the outside of ~~a~~ **the individual plant,** bundle, package or container.

3a. The Commission is empowered to adopt delegated acts in accordance with Article 75, supplementing this Article by establishing rules on:

(a) the recording and collection of digital data on the activities carried out by professional operators in order to issue the electronic labels;

(b) the technical arrangements for the issuance of electronic labels and the format of those labels.

Only following the adoption of such delegated act, 'an electronic label' may be issued.

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. **Competent authorities may request the professional operator concerned that the label is also written in another official Union language.**

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, **not reusable,** printed on one side, ~~not having been used previously~~ **unused**, and easily visible.

3. **Where applicable,** ~~Any space of~~ the official label ~~or~~**and** the operator's label, apart from the elements mentioned in paragraph 4, **shall include in any space, additional information concerning:**

(a) seed treatments according to Regulation (EU) 1107/2009;

(b) new genomic techniques in accordance with Regulation (EU) …/… [*NGT Regulation*];

(c) organic production in accordance with Regulation (EU) 2018/848;

(d) plant health in accordance with Regulation (EU) 2016/2031;

(e) any other applicable Union rules; or

(f) any other official information obliged by the competent authority.

~~may be used for 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 **official** information ~~shall be strictly factual, it shall not represent advertising material, and~~ shall be related only to ~~the~~ production and marketing requirements or to labelling requirements ~~for genetically modified organisms or category 1 NGT plants as defined in Article 3(7) of Regulation (EU) …/… (Office of Publications, please insert reference to NGT Regulation ...).~~

4. The Commission shall, by means of implementing acts, specify the content, size, colour and form of the official **label** or operator's label, as applicable, 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 implementing act shall be adopted in accordance with the examination procedure referred to in Article 76(2).

5. The competent authority may ~~authorise~~**allow** the professional operator**s** to indicate **at the periphery of the official label** 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 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.~~

Article 19

Non-compliance of PRM with production and marketing requirements

In the case where official controls carried out during the **production and** marketing of PRM show that pre-basic, basic, certified seed~~s~~ or material, or standard seed~~s~~ or material, have not been produced or marketed within the Union in compliance with the respective requirements referred to in Articles 7**,** ~~or~~ 8, **or 9,** 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~~, **the varietal identity and varietal purity of the PRM were not confirmed in the control plot testing in accordance with Article 24,** the competent authorities shall ensure that the professional operator concerned takes the necessary corrective actions concerning the PRM concerned 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;

(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 20

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

1. PRM belonging to the genera or species as ~~listed~~**indicated** in **column 5 of** Annex I~~V~~ **may be produced and marketed as standard seed or material. PRM belonging to the other genera or species of Annex I and are not indicated in column 5,** may only be produced and marketed as pre-basic, basic or certified seed~~s~~ or material.

2. The Commission is empowered to adopt a delegated act in accordance with Article 75 in order to amend **column 5 of** Annex I~~V~~.

   The delegated act referred to in the first subparagraph shall **remove**~~add~~ a genus or a species **from**~~to~~ **column 5 of** Annex I~~V~~ if both **of** the following conditions are fulfilled:

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

   (b) the costs of the certification activities, necessary to produce and market the respective **PRM**~~seed~~ 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 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 **PRM** ~~seed~~ compared to those for standard seed.

That proportionality 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 **PRM**~~seed~~ compared to the cost of production of other ~~seed~~**PRM** of the same genus or species; and the economic**, phytosanitary and environmental** benefits derived from the production and marketing of pre-basic, basic and certified seed **or material** compared to other ~~seed~~**PRM** of the same genus or species.

The delegated act referred to in the first subparagraph shall **add**~~remove~~ a genus or a species ~~from~~**to** **column 5 of** Annex I~~V~~, if one of the conditions set out in the second subparagraph, point (b), points (i) and (ii), is **not**~~no longer~~ fulfilled.

SECTION 6

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

Article 21

Mixtures of seeds

1. Mixtures of certified seed**,**~~ or~~ mixtures of standard seed **or mixtures of certified and 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 **without prejudice to Regulation (EU) No 1143/2014 of the European Parliament and of the Council**, may be produced and marketed in the Union, if **the seeds, prior to mixing,**~~they~~ fullfill the requirements of **Articles 5 to 8 and 20, and the requirements of** this Article.

Mixtures of seeds may also be produced from seed subject to Article 34.

The seeds included in those mixtures shall be accompanied by:

(a) an official label, where the mixture consists only of certified seed~~s~~ **or of seed subject to Article 34**; or

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

For the purposes of the second subparagraph, point (a), the professional operators shall submit to the competent authority the list of constituent **species and** varieties of the mixture and their ratios, for verification of eligibility of those varieties.

2. Mixtures of seeds referred to in paragraph 1 may only be produced by professional operators, which are authorised for that purpose by the competent authority. In order to receive an authorisation for the production of such mixtures, professional operators 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~~**traceability** of seed mixtures and their intended use.

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

The mixing operation shall be carried **out** in a manner to ensure that there is no risk of presence of seeds 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.~~

3a. [By way of derogation from paragraph 1, seed intended for, or used in, mixtures may be produced and marketed in accordance with the rules in this paragraph if the mixture is used for one or more of the following purposes:

(a) creation of flower strips through or around agricultural fields;

(b) catch crops, nitrogen fixing crops or cover crops used in the fields when the intended production does not take place.

Those mixtures may include genera or species not listed in Annex I without prejudice to Regulation (EU) No 1143/2014 of the European Parliament and of the Council.

That derogation shall only apply if the professional operators comply with the following conditions:

(a) they are authorised by the competent authority for this purpose;

(b) they keep records of the species, if applicable, the varieties, quantities and uses concerned, which shall be made available to the competent authority on request; and

(c) they ensure that the components of the mixtures that are listed in Annex I comply with the respective quality requirements of at least standard seed and where applicable, the requirements concerning varietal identity.

Those seed lots shall be accompanied by an operator's label with the indication of the applicable uses, as selected pursuant to points (a) or (b) of the third subparagraph, and with reference to a website or any other area where more information is available about the composition and the use of that mixture.]

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, rules concerning:

(a) the mixing equipment and procedure;

(aa) sealing, packaging and labelling; and

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

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

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

Article 22

Preservation mixtures

1. By way of derogation from Article 21(1), Member States may authorise the production and marketing of **seed intended for, or used in** a mixture ~~of seeds~~ of various genera or species listed in ~~Part A of~~ Annex I, as well as **of** ~~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 of the European Parliament and of the Council**, 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~~**region** ('~~source area~~**region of origin**') contributing to the conservation of genetic resources or the restoration of the natural environment;

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

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

Preservation mixtures of seeds referred to in paragraph 1 may only be produced by professional operators who are authorised for that purpose by the competent authority.

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

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

(b) authorisation requirements for ~~crop-grown~~ **multiplied** preservation mixtures;

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

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

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

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 sealing, content, size, colour and form of the official label and operator's label, packaging, as well as the content of certain species. 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.

Article 23

Re-packaging, re-sealing and re-labelling of seed lots

1. ~~Seed l~~**L**ots of pre-basic, basic and certified seed shall be repackaged**, re-sealed** and re**-**labeled in accordance with this Article, Articles 14 and 15~~, where this is necessary for splitting or merging of lots~~.

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

~~(a)~~ the **competent authority or** the professional operator under the official supervision of the competent authority **as referred to in Article 14(4)**~~; 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. **To ensure that the quality of the seed lots is maintained during the re-packaging,** ~~T~~**t**he professional operator ~~and the seed sampler~~ carrying out re-packaging**, re-sealing** and re-labelling of seed lots, shall take all steps to ensure that during the operation of re-packaging, the identity and varietal purity of the seed lot is maintained, no contamination occurs, and the resulting seed lot is as homogeneous as possible. **In the case of mixtures, the ratio of the different original seed lots within a mixture shall be maintained during the repackaging process.**

3a. The competent authority may subject the seed lots to laboratory testing to ensure that the new lot complies with the requirements of this Regulation.

4. The professional operators ~~and the seed sampler~~ shall keep records, when re-packaging**, re-sealing** and re-labelling seed lots, for 3 years after the respective re-labelling**, re-sealing** and re-packaging. The information contained in the records shall include:

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

(b) the reference number of the repackaged or relabeled seed lot;

(c) the weight of the original seed lot;

(d) the weight of the re-packaged or relabeled seed lot;

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

Those records shall be kept in a form allowing ~~to~~ **identification**~~y~~ and verif**ication**~~y~~ **of** the authenticity of the original seed 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 **original** seed lot. The professional operator~~s or the seed sampler~~ shall also keep the **replaced** label, **its content or digital equivalent** ~~which was replaced,~~ of each **original**~~component~~ seed lot **for at least 3 years after the respective re-sealing**. **In the case the professional operator chooses to keep the content of the replaced label instead of the label itself, the retainment may take the form of storage of the information contained in the official label in a computerised database, provided that this includes the information that is needed to guarantee the traceability.**

The new labels shall ~~either~~ state the original seed lot reference number **and in the case of mixtures or merging of lots,** ~~or~~ a new seed lot reference number **shall be** assigned **and indicated on the label** ~~by the competent authority~~. **Records of this new seed lot reference number shall be kept in accordance with the provisions of paragraph 4.**

~~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 24

Control plot tests for pre-basic, basic and certified seeds

1. ~~After the production of pre-basic, basic and certified seeds,~~ **Control plot tests shall be carried out by** the competent authorities **in order to verify that the lots of pre-basic, basic and certified seeds, except seed lots for fruit and vine species, placed on the market comply with the requirements relating to their** ~~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 of seed of the variety to ascertain that the characteristics of varieties have remained unchanged in the process of production and to verify the~~ varietal identity ~~and~~ **and varietal** purity, ~~their quality of individual seed lots~~.

Those tests shall consist of a visual comparison between the control plot sown from a reference sample of the variety and a plot sown from a sample of seed representative of the seed lot. The sample of the seed lot shall be taken upon certification or during the marketing of lots of pre-basic, basic and certified seed intended for the production of a new generation of seed (pre-control) or of seed of a generation no longer intended for further multiplication (post-control). Those tests shall take place during the growing season following the drawing of the sample.

~~Those tests shall be used for assessing:~~

~~a) whether the requirements for the next categories or generations are fulfilled. When, as a result of such tests of the immediately descending category or 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;~~

~~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.~~

2. The proportion of these control plot tests for pre-basic, basic and certified seed **lots** shall be determined on the basis of a risk analysis concerning possible non-compliance of the seed~~s~~ with the respective requirements.

3. On the basis of the risk analysis referred to in paragraph 2, **the** control plot tests shall be carried out **by using samples of seed lots referred to in paragraph 1 taken by the competent authority or using an automatic sampling device officially approved by the competent authority.** ~~through samples taken by the competent authority from the harvested seed~~.

~~4. The Commission is empowered to adopt delegated acts in accordance with Article 75, supplementing this Regulation by setting out rules for the control plot tests of seeds per genera or species. Those rules shall adapt to the development of scientific and technical knowledge and international standards, and may be established per particular genera, species or categories. They may concern the following:~~

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

~~(b) the testing procedure;~~

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

~~5.~~ **4.** ~~In the case of control of varietal identity and purity, the use of bio-molecular techniques~~ **Where the results of control plot testing referred to in paragraph 1 are not conclusive as to the varietal identity and varietal purity, biochemical and bio-molecular techniques recognised in accordance with Article 7(4), point (g),** may be used as a supplementary tool ~~where the results of the conrol plot tests referred to in paragraph 1 are non conclusive~~.

5a. 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 withdraw or prohibit further multiplication and marketing of the concerned seed lot or ensure that it complies with the applicable requirements or impose other appropriate corrective actions.

5b~~6~~. The Commission may, by means of implementing acts in accordance with Article 76(2)~~-~~set out rules concerning the control plot tests of 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, species or category. They may concern the following:

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

(b) the testing procedure;

(c) the way of evaluation of results of the tests;

(d) the proportion of the seed lots or the frequency rates.

Article 25

Control plot tests for standard seed~~s~~

1. ~~After~~ **During** the marketing of **lots of** standard seed~~s~~, the competent authorities shall carry out control plot tests **(post-control)** to check whether the seed~~s~~ **lots, except seed lots from fruit and vine species,** comply with the respective 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 from a reference sample of the variety and a plot sown from a sample of seed representative of the seed lot. The sample of the seed lot shall be taken during the marketing of the lots.**

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

3. **On the basis of** ~~Based on~~ the risk analysis **referred to in paragraph 2,** ~~of non-compliance with the respective rules,~~ the control plot tests referred to in paragraph 1 shall be carried out ~~anually,~~ by using samples **of seed lots referred to in paragraph 1** taken by the competent authority **or using an automatic sampling device officially approved 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.~~

4. In the case of control of varietal identity and **varietal** purity, the use of **biochemical and** bio-molecular techniques **recognised in accordance with Article 7(4), point (g),** may be used as a supplementary tool where the results of the control plot tests referred to in paragraph 1 are non conclusive.

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 prohibit further multiplication and marketing of the concerned seed lot or ensure that it complies with the applicable requirements or impose other appropriate corrective actions.

6. The Commission may, by means of implementing acts in accordance with Article 76(2), set out rules concerning the control plot tests of 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 criteria for the conduct of the risk analysis referred to in paragraph 2.

SECTION 7

DEROGATIONS FROM THE REQUIREMENTS OF ARTICLES 5 TO 25

Article 26

PRM belonging to conservation varieties

1. By way of derogation from Article 20, PRM belonging to a conservation variety registered in a national variety register referred to in Article 44(1), point (b), may 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.

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

3. A professional operator who uses this derogation shall ~~annually~~ notify ~~to the competent authority~~ this activity, with regard to the species and quantities concerned **when submitting the declaration referred to in Article 43, last subparagraph**.

Article 27

PRM of heterogeneous material

1 ~~By way of derogation from~~ **As referred to** in Article 5**(3)**, PRM of heterogeneous material **shall** ~~may~~ be produced and marketed within the Union without belonging to a variety. The heterogeneous material shall be notified to and register**ed** by the competent authority prior to its ~~production and/or~~ marketing, in accordance with the requirements set out in Annex VI.

1a PRM of heterogeneous material other than organic heterogeneous material as referred to in Article 3(18) of Regulation (EU) 2018/848 shall only be produced and marketed within the Union if it is not vegetatively propagated and belongs to a genus or species set out in column 6 of Annex I.

1b. The Commission is empowered to adopt a delegated act in accordance with Article 75 in order to amend column 6 of Annex I.

The delegated act referred to in the first subparagraph shall add a genus or a species to column 6 of Annex I, if a reliable method exist to distinguish varieties of the genus or species from heterogeneous material of that genus or species.

The delegated act referred to in the first subparagraph shall remove a genus or a species from column 6 of Annex I, if that condition is no longer fulfilled.

2. By way of derogation from Articles 7(1), (**2**~~3~~) and Article 8(1), (**2**~~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 heterogeneo**u**~~y~~s **material**~~PRM~~, on the basis of experience gained by the application of the respective rules;

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

(c) improve the rules on mai**n**tenance of heterogen**e**ous **material**~~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~~ **with the intention** 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 **six months,** ~~a time determined by the competent authority, the PRM of heterogeneous material may be marketed~~ **the PRM of heterogeneous material may be marketed. The heterogeneous material shall only be notified once to the competent authority for registration.**

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 **ensure traceability of the PRM of heterogeneous material by** ~~also~~ record**ing** and keep**ing** 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 **description of the** characteris**tics**~~ation~~ of the notified heterogeneous material;

(d) the **location** ~~breeding location~~ **where** ~~of the PRM of~~ **the notified** heterogeneous material **was initially bred** and production location;

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

(f) the name of the professional operators who have supplied the initial propagating material (source material) used for the production of heterogeneous material.

The professional operator shall keep that information for 6 years.

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 **4**~~1~~, shall be registered by the competent authorities in a dedicated **national** register ('heterogeneous material register').

The competent authorities shall keep, update and publish that **national** register, and notify immediately its content and updates to the Commission **for inclusion in a single register of heterogeneous material composed of all the national heterogeneous material registers. The single register of heterogeneous material shall be published in the electronic portal referred to in Article 45(2), second subparagraph. Organic heterogeneous material shall be indicated as such.**

7a. By way of derogation from paragraph 1 and 2, the competent authorities shall immediately register in their national heterogeneous material register all organic heterogeneous material officially listed before … [*the date of application of this Regulation*] in the lists established by their Member States pursuant to Article 13 of Regulation (EU) 2018/848 without applying the registration procedure set out by this Article.

Article 28

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

1. By way of derogation from Articles 5**(1)** - 12, ~~14,~~ 15 and 20, PRM**, with the exception of seed potatoes, intended to be used 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 an operator's label **as referred to in Article 16(2), second subparagraph,** with the denomination of the PRM and the indication 'Plant reproductive material for ~~final~~ **non-professional** users~~ – not officially certified~~' or, in the case of seed~~s~~, 'Seed~~s~~ for ~~final~~ non-professional users~~ – not officially certified~~';

   (b) in case not belonging to a variety registered in a national **or in the Union** variety register referred to in Article 44 **and 45:**~~,~~

      (i) to use a denomination [starting with the Prefix "Art. 28 of Regulation (EU) .../… of the European Parliament and of the Council[25] followed by any given denomination in order to clearly differentiate] from varieties registered in national or Union variety registers; and

      (ii) 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;

---

[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.

(c) to be 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 seed~~s~~, shall have satisfactory germination capacity;

(ca) to be kept separate and identifiable from the PRM not intended for non-professional user during the production and marketing process; and

(d) to be marketed **as individual plants or trays, or in the case of seed and tubers,** ~~as individual plants, or, in the case of seeds and tubers,~~ in small packages **clearly distinct from those used for any pre-basic, basic, certified and standard seed.**

A professional operator~~,~~ **producing or repackaging PRM intended for non-professional users~~,~~** who uses this derogation shall **annually**~~annually~~ notify this activity to the competent authority **in accordance with the instuctions of the competent authority**, with regard to the species **[and denomination]** ~~and quantities~~ concerned**.**

2. The Commission shall, by means of implementing acts, adopt rules concerning the size, form, sealing and handling requirements concerning the small packages referred to in paragraph 1**,** point (d).

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

Article 29

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

1. By way of derogation from Articles 5 **- 15 and 19 - 25**, PRM may be marketed, **for non-profit purposes**, ~~to, or between,~~ **by** ~~gene banks,~~ organisations and networks with a statutory objective, ~~or an objective official notified to the competent authority, to conserve~~ **of ensuring the conservation** of plant genetic resources~~,~~ ~~whereby any of the activities are carried out for non-profit purposes.~~

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

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

(aa) bear an operator's label as referred to in Article 16(2), point (g), 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 **related information** ~~description~~ of that PRM;

(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 notify the competent authority of the use of the derogation referred to in paragraph 1 and the species**, if listed in Annex I,** concerned.

Article 30

Seed exchanged in kind between farmers

1. By way of derogation from Articles 5 **to** 25 farmers may exchange seed~~s~~ in kind, if such seed~~s~~ fulfil~~l~~ 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 **between the** ~~conducted by the respective~~ farmer ~~with~~**and** a professional operator **for multiplication of seed**~~performing seed production.; and~~

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

2. Such seed~~s~~ 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~~,~~**;**

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

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

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 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 31a

PRM of a variety for which an application for registration has not yet been submitted

1. By way of derogation from Articles 5 –25, a competent authority may temporarily authorise a professional operator to market small quantities of PRM belonging to a variety for which an application for registration in a national variety register has not yet been submitted in accordance with Article 55, for the purpose of testing the potential for the cultivation or use of that variety in the Union.

The competent authorities shall determine the small quantities of the concerned PRM to be authorised for each professional operator and the duration of that authorisation, as well as the duration of the tests.

2. The PRM referred to in paragraph 1 shall be accompanied by an operator's label pursuant to Article 16(2)(ga), with the indication 'unregistered variety – value testing'.

3. The Member States whose competent authorities have granted the authorisation shall anually inform the other Member States and the Commission thereof.

Article 32

PRM of ~~not yet registered~~ varieties for which an application for registration has been submitted

1. By way of derogation from Article 5, a competent authority may authorise professional operators **before the PRM has been certified to comply with the requirements referred to in Article 7 or 8 concerning varietal identity and varietal purity,** to produce and market, for the purposes of multiplication, **pre-basic, basic, certified and standard seed or material**~~pre-basic seeds, pre-basic material, basic seeds and basic material~~ belonging to a variety not yet registered in a national variety register, referred to in Article 44, if all of 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 marketing is made to professional operators carrying out the multiplication in order to have sufficient stock available for further multiplication once the respective variety is registered, with no further marketing of PRM thereafter;

(ab) there are indications that PRM complies with the requirements pursuant to Article 7 or 8 concerning varietal identity and varietal purity, which shall be attested by the technical questionnaire provided by the professional operator;

(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 authorisation may be granted **for a period and** ~~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 **as determined** ~~specified~~ by the competent authority. **That authorisation shall automatically expire when a decision pursuant to Article 67 is adopted concerning the registration of the respective variety or if the application for registration of the respective variety is withdrawn.**

2. By way of derogation from Articles 5, ~~7,~~ 10 -12, 15, ~~20,~~ 23 and 24, a competent authority may authorise professional operators **before the PRM has been certified to comply with the requirements referred to in Article 7 or 8 concerning varietal identity and varietal purity,** ~~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 **certified or standard seed or material**~~PRM~~ belonging to a variety not yet registered in a national variety register referred to in Article 44 **for the purpose of carrying out tests or trials to gather information on the cultivation or use of that variety**, if all of the following requirements are fulfilled:

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

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

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

(ca) there are indications that PRM complies with the requirements pursuant to Article 7 or 8 concerning varietal identity and varietal purity, which shall be attested by the technical questionnaire provided by the professional operator; and

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

(e) 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 authorisation may be granted for a period and for small quantities per species as determined by the competent authority. That authorisation shall automatically expire when a decision pursuant to Article 67 is adopted concerning the registration of the respective variety or if the application for registration of the respective variety is withdrawn.

2a. By way of derogation from Article 5, professional operators may produce and market standard material of fruit plants and vine belonging to a variety not yet registered in a national variety register as referred to in Article 44 before the PRM has been certified to comply with the requirements referred to in Article 8 concerning varietal identity and varietal purity, if all of the following requirements are fulfilled:

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

(b) that PRM complies with the requirements pursuant to Article 8 concerning varietal identity and varietal purity, which shall be attested by the technical questionnaire provided by the professional operator;

(c) that PRM bears a denomination deemed suitable pursuant to Article 54; and

(d) that PRM belongs to a variety for which an application has been submitted for registration in a national variety register pursuant to Article 55.

That PRM shall not be produced and marketed anymore when a decision pursuant to Article 67 is adopted concerning the registration of the respective variety or if the application for registration of the respective variety is withdrawn.

3. In order to obtain the authorisation referred to in paragraphs 1 and 2, the professional operator shall submit to the competent authorities a request, indicating ~~the~~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 breeder's reference **and species** of the variety indicated in the application for registration;

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

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

(da) the quantities of the PRM and the respective category to be made available on the market;

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

(ea) in case of authorisation as referred to in paragraph 1, the envisaged production of the stock of pre-basic, basic, certified, or standard seed and material available before the variety registration and, in case of authorisation as referred to in paragraph 2, the envisaged tests and trials;

~~(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 and 2 shall **without delay**~~annually~~ inform the other Member States and the Commission thereof.

5. ~~PRM~~**Pre-basic, basic and certified seed or material** referred to in paragraph~~s~~ 1 **shall be accompanied by an official label as referred to in Article 15(1a)(a) and standard seed or material referred to in paragraph 1 shall be accompanied by an operator's label referred to in Article 16(2)(gb), with the indication 'Not yet registered variety – stock for multiplication'**~~and~~**.**

Certified seed or material referred to in paragraph 2 shall be accompanied by an official label as referred to in Article 15(1a)(a) and standard seed or material referred to in paragraph 2 shall be accompanied by a**n operator's** label **as referred to in Article 16(2)(gb)**, ~~issued by the professional operator,~~ with the indication 'Not yet **registered**~~listed~~ variety **– tests and trials**'.

PRM referred to in paragraph 2a shall be accompanied by an operator's label as referred to in Article 16(2)(h) with the indication 'Not yet registered fruit variety' or 'Not yet registered vine variety', as applicable.

Article 32a

Production and marketing of commercial seed

1. By way of derogation from Articles 5, 24 and 25 seed of the genera or species included in column 7 of Annex I may be produced and marketed as commercial seed if the requirements referred to in Article 7 are fulfilled with the exception of the requirement of varietal identity and varietal purity.

2. By way of derogation from Article 5, seed of the genera or species newly added to Annex I via a delegated act pursuant to Article 2(3) and for which fewer than [30 varieties] are registered in the Register of Community Plant Variety Rights pursuant to Regulation (EU) 2100/94 when the delegated act enters into force may also be produced and marketed as commercial seed.

When seed of the genera or species newly added to Annex I may be produced and marketed as commercial seed pursuant to this paragraph, the Commission shall indicate column 7 of Annex I for these species or genera when adopting the delegated act referred to in the first subparagraph.

3. The Commission is empowered in accordance with Article 75 to adopt delegated acts, amending Annex I to the breeding and economic developments of the genera and species in that Annex by adding or removing genera or species from column 7 of that Annex.

The delegated act shall add genera or species to column 7 of Annex I if they fulfil at least one of the two following elements:

(a) the number of varieties registered in the Union variety register pursuant to Article 45 does not meet the needs of the operators concerned;

(b) the value of the genera or species mainly lies within multifaceted purposes that extend beyond traditional food and feed production.

The delegated act referred to in the first subparagraph shall remove genera or species from column 7 of Annex I if they no longer fulfil both of the elements set out in the second subparagraph.

4. Seeds referred to in paragraph 1 and 2 shall be accompanied by an official label pursuant to Article 15, with the indication 'Commercial seed'.

Article 33

Authorisation in cases of temporary difficulties in the supply

1. In order to remove temporary difficulties in the ~~general~~ supply of **pre-basic, basic, certified or standard seed or material**~~PRM~~ that may occur in the Union due to adverse climatic conditions or other unforeseen circumstances, the Commission, by means of an implementing act, may authorise **one or more** Member States**,** for a maximum period of 1**8 months**~~year~~, to allow the marketing of the categories of pre-basic, basic~~ or~~**,** certified **or standard** material or seed **that**~~, which~~ fulfils~~ one of the following~~ **one or both of the following conditions**:

   (a) belongs to a variety not included in a national **[or the Union]** variety register **referred to in Article 44 [and 45]**; ~~or~~

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

   Point (a) shall apply by way of derogation from Article~~s~~ 5, and point (b) shall apply by way of derogation from Articles 7(1) **and (2) and Article 8(1) and (2)**.

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

   That implementing act 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**n official** label **as referred to in Article 15(1a), point (c), or an operator's label as referred to in Article 16(2), point (i),** that states~~, as applicable,~~ that the PRM in question 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 those 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, 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 implementing act shall be adopted in accordance with the examination procedure referred to in Article 76(2).

4. Member States may, without obtaining the authorisation of the Commission referred to in paragraph 1, allow, for a maximum period of 1**8 months**~~year,~~ and for a limited amount of quantities per genera or species as necessary for supply difficulties in question, the production and marketing of seed~~s~~ that fulfil~~l~~ 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~~**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 will notify each authorisation to the Commission and the other Member States mentioning the species and the germination rate of the seed.**

Article 34

~~Provisional authorisation in urgency cases for m~~Marketing of seed~~s~~ not finally certified as complying with ~~applicable quality~~ germination rate requirements in case of rapid supply needs

1. Competent authorities may authorise **professional operators**~~, for a maximum period of 1 month, the~~ **for a maximum time period defined by the competent authority to** market~~ing of~~ seed~~s~~ as pre-basic, basic or certified seed~~s~~**, and mixtures thereof,** before the~~y~~ **seed or, if applicable, the seed components prior to mixing** have been certified to comply with the requirements referred to in Article 7 concerning germination~~, maximum content of other species or purity~~, if it is necessary to make that seed rapidly available on the market~~ to address urgent needs of supply~~. **Such seed shall comply with the requirements adopted pursuant to Article 7(1) concerning germination, which shall be attested by preliminary analytical tests on the seed performed by the professional operator.**

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

   (a) the necessary procedures which ensure sufficient guarantees for the seed marketed, particularly in relation to performing the preliminary analysis of the seed and identifying critical points of the process;

   (b) procedures to ensure the fulfillment of the requirements concerning the identification of lots pursuant to Article 13; and

   (c) 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 the provisional analytical report at the disposition of the competent authority.~~

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

3. The seed~~s~~ referred to in paragraph 1 shall bear a**n official** label **as referred to in Article 15(1a), point (c),** indicating '**Germination rate not finally certified**~~Provisional authorisation for marketing'marketing~~'.

Article 35

Marketing of PRM which is not yet certified

1. PRM which has been produced in the Union, but has not yet been 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)**, (2)**;

   (b) it is in the process of being certified by the competent aut**h**ority, 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.

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

3. PRM referred to in paragraph 1, shall be accompanied by a**n official** label **as referred to in Article 15(1a), point (d)**, ~~issued by the professional operator,~~ with the indication 'Seeds/Material not yet finally certified'.

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

[5. ~~PRM~~**Seed** which has been harvested in a third country, but has not yet been certified as pre-basic, basic or certified **seed** 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 countr**y** 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 **seed**; ~~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**; and**~~.~~

(e) where applicable, the OECD label and in other cases another official label attesting compliance with points (b), (c) and (d).

For the purposes of this paragraph, references made in paragraphs 1 **to 4**~~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).]

Article 36

More stringent production and marketing requirements

1a. Member States may impose within their own territory more stringent requirements for the production and marketing of PRM than those laid down in the Annexes II or III.

Those more stringent measures shall not impose, or result in, any prohibitions or restrictions on the movement of products between Member States.

1b. Member States shall immediately inform the Commission and other Member States of measures taken by them in accordance with paragraph 1a.

~~1. The Commission, 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 Member State concerned, provided that those 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 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 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**s** 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 marketing of the PRM concerned**.** ~~or laying down appropriate conditions for its production or marketing,~~ ~~d~~**D**epending 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. **Within 30 working days, the Commission shall put the measures adopted pursuant to paragraph 2 before the Committee referred to in Article 76(1) in accordance with the regulatory procedure referred to in Article 76(2) with a view to the extension, amendment or repeal of the national interim protective measure.** ~~The Commission may decide, by means of implementing acts, that the national interim emergency measures referred to in paragraph 2 are to be repealed or amended, if it considers that those measures are not justified in view of the respective risk as referred to in paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2). The Member State concerned may maintain its national interim emergency measures until the date of application of the implementing act(s) referred to in this paragraph.~~

Article 38

Temporary experiments to seek improved alternatives to provisions of this Regulation

1. By way of derogation from Articles 2, **3,** 5, 6, 7, 8**, 9** 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, 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 compared to the ones set out in Articles 2, 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 for production of the PRM concerned, as 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, 7, 8**, 9** or 20.

SECTION 8

IMPORTS FROM THIRD COUNTRIES

Article 39

Imports on the basis of Union equivalence

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, **for PRM subject to the derogations of Articles 22, and 26 - 30** 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~~.

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

(a) it shall be accompanied by a label pursuant to Article 40(2), points (b)–(g), with the indication 'seed as grown' and the identity of the seed is ensured;

(b) there is no further marketing prior to processing other than to the first place of destination which will be the place of processing;

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

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** ~~by the Commission~~; and

(c) in the case of seeds **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 **the**~~that~~ 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~~ **this** ~~sub~~paragraph.

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

3. The implementing act 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, conditions relating to the issuance by the third country of a certificate provided by the ~~International Seed Testing Association~~ **ISTA, or, where applicable, the AOSA or other internationally recognised organisations**;

(c) conditions relating to ~~seed not yet finally certified~~ **PRM subject to the derogations referred to in Articles 31 - 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 PRM imported from third countries

1. Pre-basic, basic and certified seed~~s~~ referred to in Article 39 **from third countries** may only be imported ~~from third countries~~, if they ~~are~~ **bear** ~~accompanied by~~ an OECD **Seed Schemes** label **('OECD label')**~~label~~ **or an official label issued by the competent authority of the third country for species for which there is no OECD Seed Schemes available and, where applicable, is accompanied by 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 may only be imported **into the Union** from third countries if it **bears** ~~is accompanied by~~ an official label issued by the competent authority of the third country concerned.

1b. The~~ose~~ **official** labels**, including the OECD label**, **referred to in paragraph 1 and 1a**, shall **at least** contain ~~all of~~ the following **official** information:

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

(b) the species, variety, category and**,** lot **reference number and label serial** number of the PRM concerned;

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

(d) the third country **or, where applicable region,** 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**, if applicable, the** declared number of ~~imported~~ lots of seeds **imported into the Union**;

(fa) in the case of material, the declared number of plants declared number of bundles, or declared net or gross weight imported into the Union;

(fb) In the case of seeds, information regarding seed treatments with plant protection products or other treatments.

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

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

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

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

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

(d) the third country or**, where applicable region,** 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**, if applicable, the** declared number of imported lots of seeds;

(fa) in the case of material, the declared number of imported plants or, if applicable, the declared number of imported bundles;

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

(ga) In the case of seeds, information regarding seed treatments with plant protection products or other treatments.

2a. The Commission shall by means of an implementing act specify the format, color, language, size and additional content of the official label issued by the competent authority of the third country in case there is no OECD Seed schemes available referred to in paragraph 1, the official label referred to in paragraph 1a and of the operator´s labels referred to in paragraph 2.

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.~~ **The professional operator responsible for the imported PRM, shall inform the respective competent authority in advance of the arrival of the consignment and provide the information referred to in paragraph 1 or 2 through the information management system for official controls (IMSOC) referred to in Article 131 of Regulation (EU) 2017/625.**

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.

5. The Commission is empowered in accordance with Article 75 to adopt delegated acts, amending paragraphs 1b and 2, in order to align these provisions to technical and scientific developments of international standards.

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 **as** referred to **in** Article 65**(1) and (2)** of Regulation (EU) 2016/2031, **and** in accordance with Article 66 of that Regulation, **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 (**d**~~b~~) 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 **activities defined in Article 3(2)** ~~production of PRM~~;

(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 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**, without prejudice to national and Union rules on confidentiality, access to information and private data protection**.

Networks and organisations involved in the conservation of plant genetic resources as referred to in Article 29 shall not be subject to the requirements of points (b), (d) - (f), (i) and (j).

A professional operator whose activities relating to PRM are limited to sale to non-professional users, without producing PRM, altering the content of the lots, packaging, individual plants or labelling, is exempt from the obligations listed in points (b), (d) - (f) and (i).

Farmers who exchange seed in kind shall not be subject to the requirements of points (b), (d) - (f) and (i).

Article 68 of Regulation (EU) 2016/2031 shall apply accordingly.

Article 41a

Registration of professional operators

1. The registration of the professional operators referred to in Article 41(b), shall, where applicable, include the elements detailed in Article 66(2) of Regulation (EU) 2016/2031 and in addition to this, specifically for the professional operators referred to in Article 3(2) who shall be registered pursuant to Article 41:

(a) a statement concerning the intention of the professional operator to exercise one or more of the activities referred to in Article 3(2), supplemented with the intended use of the PRM and the species involved;

(b) a statement concerning which activities the professional operator intends to carry out under official supervision; and

(c) a statement concerning the intention to print official labels or operator's labels pursuant to Article 15, 16, 21, 22, 23, 26 to 29 and 32 to 35.

2. The Commission is empowered to adopt delegated acts in accordance with Article 75 concerning one or two of the following:

(a) amending this Regulation by adding further categories of professional operators to be exempted from the application of paragraph 1, where registration would constitute a disproportionate administrative burden, disproportionate to the low risk related to their professional activities;

(b) supplementing this Regulation by setting out particular requirements for the registration of certain categories of professional operators, taking into account the nature of the activity or of the PRM concerned.

3. When the registered professional operator no longer performs the activities it is registered for, it shall rectify or ask for withdrawal of its registration according to the instructions of the competent authority.

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

Article 42

Traceability

1. Professional operators **who are registered according to Article 41(b),** shall ensure that PRM is traceable at all stages of production and marketing.

2. For the purposes of paragraph 1, professional operators shall keep information **or records** allowing them to identify:

   (a) the professional operators **or other persons**, ~~which~~ **who** have supplied them with the **PRM**~~seeds and the material~~ concerned;

   (b) the **professional operators or the** persons to whom they have supplied PRM and the PRM concerned, except in case of ~~final users~~**non-professional 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 persons referred to in paragraph 2 for **at least** ~~3 years after that material~~ **6 years after the PRM** has been respectively supplied to or by them.

Article 43

~~Annual n~~Notification of the ~~intended~~ production and certification of pre-basic, basic and certified seed, commercial seed and material and, of the production of standard seed and material

~~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) the~~ir intention to~~ produc**tion of** pre-basic, basic and certified **seed and material, and commercial seed** ~~material or pre-basic, basic and certified seed, at least one month before the beginning of that production~~; and

(b) the production of pre-basic, basic and certified **seed and material, and commercial seed** ~~material~~ that started in p**r**evious years and continues in the year concerned.

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

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 for the purpose of its marketing in the Union.

[…]

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”.

[…]

ANNEX I
GENERA AND SPECIES, ~~AND THEIR RESPECTIVE USES,~~ AS REFERRED TO IN ARTICLES 2, 20 (1), 27 AND 32b

~~PART A~~
~~Genera and species to be used for the production of agricultural crops, other than vegetables~~

~~*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. (includes *A. byzantina* K. Koch)~~

~~*Avena strigosa* Schreb.~~

~~*Beta vulgaris* L. partim~~
~~*Biserrula pelecinus* 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. var. *silvestris* (Lam.) Briggs~~

~~*Bromus catharticus* Vahl~~

~~*Bromus sitchensis* Trin.~~

~~*Cannabis sativa* L.~~

~~*Carthamus tinctorius* L.~~

~~*Carum carvi* L.~~

~~*Cynodon dactylon* (L.) Pers.~~

~~*Dactylis glomerata* L.~~

~~*Festuca arundinacea* Schreber~~

~~*Festuca filiformis* Pourr~~

~~*Festuca ovina* L.~~

~~*Festuca pratensis* Huds.~~

~~*Festuca rubra* L.~~

~~*Festuca trachyphylla* (Hack.) Krajina~~

~~*Galega orientalis* Lam.~~

~~*Glycine max* (L.) Merr. partim~~

~~*Gossypium* spp.~~

~~*Hedysarum coronarium* L.~~

~~*Helianthus annuus* L.~~

~~*Hordeum vulgare* L.~~

~~*Lathyrus cicera* L.~~

~~*Linum usitatissimum* L.~~

~~*Lolium multiflorum* Lam.~~

~~*Lolium perenne* L.~~

~~*Lolium x hybridum* Hausskn~~

~~*Lotus corniculatus* L.~~

~~*Lupinus albus* L.~~

~~*Lupinus angustifolius* L.~~

~~*Lupinus luteus* L.~~

~~*Medicago doliata* Carmign.~~

~~*Medicago italica* (Mill.) Fiori~~

~~*Medicago littoralis* Rohde ex Loisel.~~

~~*Medicago lupulina* L.~~

~~*Medicago murex* Willd.~~

~~*Medicago polymorpha* L.~~

~~*Medicago rugosa* Desr.~~

~~*Medicago sativa* L.~~

~~*Medicago sativa* L. *nothosubsp. varia* (Martyn) Arcang.~~

~~*Medicago scutellata* (L.) Mill.~~

~~*Medicago truncatula* Gaertn.~~

~~*Onobrychis viciifolia* Scop.~~

~~*Ornithopus compressus* L.~~

~~*Ornithopus sativus* Brot.~~

~~*Oryza sativa* L.~~

~~*Papaver somniferum* L.~~

~~*Phacelia tanacetifolia* Benth.~~

~~*Phalaris aquatica* L.~~

~~*Phalaris canariensis* L.~~

~~*Phleum nodosum* L.~~

~~*Phleum pratense* L.~~

~~*Pisum sativum* L. partim~~

~~*Plantago lanceolata* L.~~

~~*Poa annua* L.~~

~~*Poa nemoralis* L.~~

~~*Poa palustris* L.~~

~~*Poa pratensis* L.~~

~~*Poa trivialis* L.~~

~~*Raphanus sativus* L. var. *oleiformis* Pers.~~

~~*Secale cereale* L.~~

~~*Sinapis alba* L.~~

~~*Sorghum bicolor* (L.) Moench subsp. *bicolor*~~

~~*Sorghum bicolor* (L.) Moench subsp. *bicolor* x *Sorghum bicolor* (L.) Moench subsp. *drummondii* (Steud.) de Wet ex Davidse~~

~~*Sorghum bicolor* (L.) Moench subsp. *drummondii* (Steud.) de Wet ex Davidse~~

~~*Trifolium alexandrinum* L. Berseem~~

~~*Trifolium fragiferum* L.~~

~~*Trifolium glanduliferum* Boiss.~~

~~*Trifolium hirtum* All.~~

~~*Trifolium hybridum* L.~~

~~*Trifolium incarnatum* L.~~

~~*Trifolium isthmocarpum* Brot.~~

~~*Trifolium michelianum* Savi~~

~~*Trifolium pratense* L.~~

~~*Trifolium repens* L.~~

~~*Trifolium resupinatum* L.~~

~~*Trifolium squarrosum* L.~~

~~*Trifolium subterraneum* L.~~

~~*Trifolium vesiculosum* Savi~~

~~*Trigonella foenum-graecum* L.~~

~~*Trisetum flavescens* (L.) P. Beauv.~~

~~*Triticum aestivum* L. subsp. *aestivum*~~

~~*Triticum aestivum* L. subsp. *spelta* (L.) Thell.~~

~~*Triticum turgidum* L. subsp. *durum* (Desf.) van Slageren~~

~~*Vicia benghalensis* L.~~

~~*Vicia faba* L. partim~~

~~*Vicia pannonica* Crantz~~

~~*Vicia sativa* L.~~

~~*Vicia villosa* Roth~~

~~*xFestulolium* Asch. & Graebn~~

~~*xTriticosecale* Wittm. ex A. Camus~~

~~*Zea mays* L. partim~~

~~PART B~~
~~Genera and species to be used for the production of vegetables~~

~~*Allium cepa* L.~~

~~*Allium fistulosum* L.~~

~~*Allium porrum* L.~~

~~*Allium sativum* L.~~

~~*Allium schoenoprasum* L.~~

~~*Anthriscus cerefolium* (L.) Hoffm.~~

~~*Apium graveolens* L.~~

~~*Asparagus officinalis* L.~~

~~*Beta vulgaris* L. partim~~

~~*Brassica 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.~~

~~*Cucumis sativus* L.~~

~~*Cucurbita maxima* Duchesne~~

~~*Cucurbita pepo* L.~~

~~*Cynara cardunculus* L.~~

~~*Daucus carota* L.~~

~~*Foeniculum vulgare* Mill.~~

~~*Lactuca sativa* L.~~

~~*Petroselinum crispum* (Mill.) Nyman ex A. W. Hill~~

~~*Phaseolus coccineus* L.~~

~~*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. partim~~

~~*Zea mays* L. partim~~

~~Hybrids resulting from the crossing of species referred in this Part.~~

~~**PART C**~~

~~**Genera and species to be used for the production of fruit plants**~~

~~*Castanea sativa* Mill.~~

~~*Citrus* L.~~

~~*Corylus avellana* L.~~

~~*Cydonia oblonga* Mill.~~

~~*Ficus carica* L.~~

~~*Fortunella* Swingle~~

~~*Fragaria* L.~~

~~*Juglans regia* L.~~

~~*Malus* Mill.~~

~~*Olea europaea* L.~~

~~*Pistacia vera* L.~~

~~*Poncirus* Raf.~~

~~*Prunus amygdalus* Batsch~~

~~*Prunus armeniaca* L.~~

~~*Prunus avium* (L.) L.~~

~~*Prunus cerasus* L.~~

~~*Prunus domestica* L.~~

~~*Prunus persica* (L.) Batsch~~

~~*Prunus salicina* Lindley~~

~~*Pyrus* L.~~

~~*Ribes* L.~~

~~*Rubus* L.~~

~~*Vaccinium* L.~~

~~**PART D**~~
~~**Genera and species to be used for the production of vine**~~

~~*Vitis* L.~~

~~**PART E**~~
~~**Genera and species to be used for the production of potatoes**~~

~~*Solanum tuberosum* L.~~

1	2	3	4	5	6	7
Species **and hybrids thereof**	Intended use			**May be produced and marketed as standard PRM**	**May be produced and marketed as heterogeneous material other than organic heterogeneous material (Article 27)**	May be produced and marketed without belonging to a variety (commercial seed; Article 32b)
	Agricultural crop and potato (1)	Vegetable (2)	Fruit plant, [hop] and vine (3)			
Abelmoschus esculentus **Mönch**		**x**		**(2)**	**(2)**	
Actinidia **Lindl.**			**x**	**(3)**	**(3)**	
Agrostis canina L.	x					(1)
Agrostis capillaris L.	x					(1)
Agrostis gigantea Roth	x					(1)
Agrostis stolonifera L.	x					(1)
Allium cepa L.		x		(2)	(2)	
Allium fistulosum L.		x		(2)	(2)	
Allium porrum L.		x		(2)	(2)	

1	2	3	4	5	6	7
Species **and hybrids thereof**	Intended use			**May be produced and marketed as standard PRM**	**May be produced and marketed as heterogeneous material other than organic heterogeneous material (Article 27)**	May be produced and marketed without belonging to a variety (commercial seed; Article 32b)
	Agricultural crop and potato (1)	Vegetable (2)	Fruit plant, [hop] and vine (3)			
Allium sativum L.		x		(2)	(2)	
Allium schoenoprasum L.		x		(2)	(2)	
Alopecurus pratensis L.	x					(1)
***Amelanchier alnifolia* (Nutt.)**			**x**	**(3)**	**(3)**	
Anthriscus cerefolium (L.) Hoffm.		x		(2)	(2)	
Apium graveolens L.		x		(2)	(2)	
Arachis hypogaea L.	x				(1)	(1)
***Aronia melanocarpa* (Michx.) Elliott**			**x**	**(3)**	**(3)**	

1	2	3	4	5	6	7
Species **and hybrids thereof**	Intended use			**May be produced and marketed as standard PRM**	**May be produced and marketed as heterogeneous material other than organic heterogeneous material (Article 27)**	May be produced and marketed without belonging to a variety (commercial seed; Article 32b)
	Agricultural crop and potato (1)	Vegetable (2)	Fruit plant, [hop] and vine (3)			
***Aronia mitschurinii* A.K. Skvortsov & Maitulina**			**x**	**(3)**	**(3)**	
Arrhenatherum elatius (L.) P. Beauv. ex J. Presl & C. Presl	x					(1)
Asparagus officinalis L.		x		(2)	(2)	
Avena nuda L.	x				(1)	
Avena sativa L. (includes *A. byzantina* K. Koch)	x				(1)	
Avena strigosa Schreb.	x				(1)	
Beta vulgaris L. partim	x	x		(2)	(1), (2)	
Biserrula pelecinus L.	x			(1)	(1)	(1)

1	2	3	4	5	6	7
Species **and hybrids thereof**	Intended use			**May be produced and marketed as standard PRM**	**May be produced and marketed as heterogeneous material other than organic heterogeneous material (Article 27)**	May be produced and marketed without belonging to a variety (commercial seed; Article 32b)
	Agricultural crop and potato (1)	Vegetable (2)	Fruit plant, [hop] and vine (3)			
***Brachypodium* P. Beauv.**	**x**			**(1)**	**(1)**	**(1)**
Brassica juncea (L.) Czern.	x				(1)	(1)
Brassica napus L. var. *napobrassica* (L.) Rchb.	x	**x**		**(2)**	(1), **(2)**	
Brassica napus L. var. *napus* (L.) Rchb	x				(1)	
Brassica nigra (L.) W.D.J. Koch	x				(1)	(1)
Brassica oleracea L. convar. *acephala* (DC.) Alef. var. *medullosa* Thell. + var. *varidis* L.	x				(1)	

1	2	3	4	5	6	7
Species **and hybrids thereof**	Intended use			**May be produced and marketed as standard PRM**	**May be produced and marketed as heterogeneous material other than organic heterogeneous material (Article 27)**	May be produced and marketed without belonging to a variety (commercial seed; Article 32b)
	Agricultural crop and potato (1)	Vegetable (2)	Fruit plant, [hop] and vine (3)			
Brassica oleracea L. partim		x		(2)	(2)	
Brassica oleracea* L. var. *capitata* fo. *alba* subfo. *Conica		**x**		**(2)**	**(2)**	
Brassica rapa L. partim		x		(2)	(2)	
***Brassica rapa* subsp. oleifera (DC.) Metzg**	**x**				**(1)**	
Brassica rapa L. var. *silvestris* (Lam.) Briggs	x				(1)	(1)
***Brassica rapa* subsp. *chinensis* (L.) Hanelt**		**x**		**(2)**	**(2)**	

1	2	3	4	5	6	7
Species **and hybrids thereof**	Intended use			**May be produced and marketed as standard PRM**	**May be produced and marketed as heterogeneous material other than organic heterogeneous material (Article 27)**	May be produced and marketed without belonging to a variety (commercial seed; Article 32b)
	Agricultural crop and potato (1)	Vegetable (2)	Fruit plant, [hop] and vine (3)			
Bromus catharticus Vahl	x					(1)
Bromus sitchensis Trin.	x					(1)
***Bromus stamineus* E. Desv**	**x**					(1)
***Camelina sativa* Crantz**	**x**				**(1)**	
Cannabis sativa L.	x					
Capsicum annuum L.		x		(2)	(2)	
Carthamus tinctorius L.	x				(1)	
Carum carvi L.	x				(1)	
Castanea sativa Mill.			x	(3)	(3)	

1	2	3	4	5	6	7
Species **and hybrids thereof**	Intended use			**May be produced and marketed as standard PRM**	**May be produced and marketed as heterogeneous material other than organic heterogeneous material (Article 27)**	May be produced and marketed without belonging to a variety (commercial seed; Article 32b)
	Agricultural crop and potato (1)	Vegetable (2)	Fruit plant, [hop] and vine (3)			
***Ceratonia siliqua* L.**			**x**	(3)	(3)	
***Cicer arietinum* L.**	**x**	**x**		**(2)**	**(1), (2)**	**(1)**
Cichorium endivia L.		x		(2)	(2)	
Cichorium intybus L.	**x**	x		**(1),** (2)	**(1),** (2)	
Citrullus lanatus (Thunb.) Matsum. et Nakai		x		(2)	(1)	
Citrus L.			x	(3)	(3)	
***Coriandrum sativum* L.**		**x**		**(2)**	**(2)**	
***Cornus mas* L.**			**x**	**(3)**	**(3)**	
Corylus avellana L.			x	(3)	(3)	

1	2	3	4	5	6	7
Species **and hybrids thereof**	Intended use			**May be produced and marketed as standard PRM**	**May be produced and marketed as heterogeneous material other than organic heterogeneous material (Article 27)**	May be produced and marketed without belonging to a variety (commercial seed; Article 32b)
	Agricultural crop and potato (1)	Vegetable (2)	Fruit plant, [hop] and vine (3)			
Cucumis melo L.		x		(2)	(2)	
Cucumis sativus L.		x		(2)	(2)	
Cucurbita maxima Duchesne		x		(2)	(2)	
***Cucurbita moschata* Duchesne**		**x**		**(2)**	**(2)**	
Cucurbita pepo L.	**x**	x		**(1)**, (2)	**(1),** (2)	
Cydonia oblonga Mill.			x	(3)	(3)	
Cynodon dactylon (L.) Pers.	x					(1)
Cynara cardunculus L.		x		(2)	(2)	

1	2	3	4	5	6	7
Species **and hybrids thereof**	Intended use			**May be produced and marketed as standard PRM**	**May be produced and marketed as heterogeneous material other than organic heterogeneous material (Article 27)**	May be produced and marketed without belonging to a variety (commercial seed; Article 32b)
	Agricultural crop and potato (1)	Vegetable (2)	Fruit plant, [hop] and vine (3)			
Dactylis glomerata L.	x					
Daucus carota L.		x		(2)	(2)	
***Deschampsia cespitosa* L.**	**x**					**(1)**
Diospyros kaki			**x**	**(3)**	**(3)**	
Diplotaxis tenuifolia		**x**		**(2)**	**(2)**	
***Eruca vesicaria* subsp. *sativa* (L.) Cav.**		**x**		**(2)**	**(2)**	
***Fagopyrum esculentum* Moench**	**x**				**(1)**	
Festuca arundinacea Schreb.	x					

1	2	3	4	5	6	7
Species **and hybrids thereof**	Intended use			**May be produced and marketed as standard PRM**	**May be produced and marketed as heterogeneous material other than organic heterogeneous material (Article 27)**	May be produced and marketed without belonging to a variety (commercial seed; Article 32b)
	Agricultural crop and potato (1)	Vegetable (2)	Fruit plant, [hop] and vine (3)			
Festuca filiformis Pourr	x					(1)
Festuca ovina L.	x					(1)
Festuca pratensis Huds.	x					
Festuca rubra L.	x					
Festuca trachyphylla (Hack.) Krajina	x					(1)
Ficus carica L.			x	(3)	(3)	
Foeniculum vulgare Mill.		x		(2)	(2)	
Fortunella Swingle			x	(3)	(3)	
Fragaria L.			x	(3)	(3)	

1	2	3	4	5	6	7
Species **and hybrids thereof**	Intended use			**May be produced and marketed as standard PRM**	**May be produced and marketed as heterogeneous material other than organic heterogeneous material (Article 27)**	May be produced and marketed without belonging to a variety (commercial seed; Article 32b)
	Agricultural crop and potato (1)	Vegetable (2)	Fruit plant, [hop] and vine (3)			
Galega orientalis Lam.	x				(1)	
Glycine max (L.) Merr. partim	x	**x**		**(2)**	(1), **(2)**	(1)
Gossypium L. ~~spp.~~	x				(1)	
Hedysarum coronarium L.	x				(1)	(1)
Helianthus annuus L.	x				(1)	
***Hippophae rhamnoides* L.**			**x**	**(3)**	**(3)**	
Hordeum vulgare L.	x				(1)	
***[Humulus lupulus* L.]**			**x**	**(3)**	**(3)**	
***Ipomoea batatas* (L.)**		**x**		**(2)**	**(2)**	

1	2	3	4	5	6	7
Species **and hybrids thereof**	Intended use			**May be produced and marketed as standard PRM**	**May be produced and marketed as heterogeneous material other than organic heterogeneous material (Article 27)**	May be produced and marketed without belonging to a variety (commercial seed; Article 32b)
	Agricultural crop and potato (1)	Vegetable (2)	Fruit plant, [hop] and vine (3)			
Lam.						
Juglans regia L.			x	(3)	(3)	
***Koeleria macrantha* (Ledeb.) Schult.**	**x**			**(1)**		**(1)**
Lactuca sativa L.		x		(2)	(2)	
Lathyrus cicera L.	x			(1)	(1)	(1)
***Lathyrus sativus* L.**	**x**				**(1)**	
***Lens culinaris* Medik**	**x**	**x**		**(2)**	**(1), (2)**	**(1)**
***Lens esculenta* Moench**	**x**				**(1)**	**(1)**
Linum usitatissimum L.	x				(1)	
Lolium multiflorum Lam.	x					

1	2	3	4	5	6	7
Species **and hybrids thereof**	Intended use			**May be produced and marketed as standard PRM**	**May be produced and marketed as heterogeneous material other than organic heterogeneous material (Article 27)**	May be produced and marketed without belonging to a variety (commercial seed; Article 32b)
	Agricultural crop and potato (1)	Vegetable (2)	Fruit plant, [hop] and vine (3)			
Lolium perenne L.	x					
~~*Lolium x boucheanum* Kunth~~						
Lolium x hybridum Hausskn.	x					
***Lonicera caerulea* var. *kamtschatica* Sevast.**			**x**	**(3)**	**(3)**	
Lotus corniculatus L.	x					(1)
***Lotus tenuis* Waldst. & Kit.**	**x**				**(1)**	
Lupinus albus L.	x				(1)	(1)
Lupinus angustifolius L.	x				(1)	(1)

1	2	3	4	5	6	7
Species **and hybrids thereof**	Intended use			**May be produced and marketed as standard PRM**	**May be produced and marketed as heterogeneous material other than organic heterogeneous material (Article 27)**	May be produced and marketed without belonging to a variety (commercial seed; Article 32b)
	Agricultural crop and potato (1)	Vegetable (2)	Fruit plant, [hop] and vine (3)			
Lupinus luteus L.	x				(1)	(1)
Malus Mill.			x	(3)	(3)	
Medicago doliata Carmign.	x			(1)		(1)
Medicago littoralis Rohde ex Loisel.	x			(1)		(1)
Medicago lupulina L.	x					(1)
Medicago murex Willd.	x			(1)		(1)
Medicago polymorpha L.	x			(1)		(1)
Medicago rugosa Desr.	x			(1)		(1)
Medicago sativa L.	x					

1	2	3	4	5	6	7
Species **and hybrids thereof**	Intended use			**May be produced and marketed as standard PRM**	**May be produced and marketed as heterogeneous material other than organic heterogeneous material (Article 27)**	May be produced and marketed without belonging to a variety (commercial seed; Article 32b)
	Agricultural crop and potato (1)	Vegetable (2)	Fruit plant, [hop] and vine (3)			
Medicago scutellata (L.) Mill.	x			(1)		(1)
Medicago tornata ~~*italica*~~ (L.) Mill.	x			(1)		(1)
Medicago truncatula Gaertn.	x			(1)		(1)
Medicago x varia T. Martyn	x					
***Mespilus germanica* L.**			**x**	**(3)**	**(3)**	
Olea europaea L.			x	(3)	(3)	
Onobrychis viciifolia Scop.	x					(1)

1	2	3	4	5	6	7
Species **and hybrids thereof**	Intended use			**May be produced and marketed as standard PRM**	**May be produced and marketed as heterogeneous material other than organic heterogeneous material (Article 27)**	May be produced and marketed without belonging to a variety (commercial seed; Article 32b)
	Agricultural crop and potato (1)	Vegetable (2)	Fruit plant, [hop] and vine (3)			
Ornithopus compressus L.	x			(1)	(1)	(1)
Ornithopus sativus Brot.	x			(1)	(1)	(1)
Oryza sativa L.	x				(1)	
***Panicum miliaceum* L.**	**x**				**(1)**	
Papaver somniferum L.	x					(1)
***Pastinaca sativa* L.**		**x**		**(2)**	**(2)**	
***Persea americana* Mill.**			**x**	**(3)**	**(3)**	
Petroselinum crispum (Mill.) Nyman ex A. W. Hill		x		(2)	(2)	
Phacelia tanacetifolia	x				(1)	(1)

1	2	3	4	5	6	7
Species **and hybrids thereof**	Intended use			**May be produced and marketed as standard PRM**	**May be produced and marketed as heterogeneous material other than organic heterogeneous material (Article 27)**	May be produced and marketed without belonging to a variety (commercial seed; Article 32b)
	Agricultural crop and potato (1)	Vegetable (2)	Fruit plant, [hop] and vine (3)			
Benth.						
Phalaris aquatica L.	x					(1)
Phalaris canariensis L.	x				(1)	
Phaseolus coccineus L.	**x**	x		(2)	**(1),** (2)	
Phaseolus vulgaris L.	**x**	x		(2)	**(1),** (2)	
Phleum nodosum L.	x					(1)
Phleum pratense L.	x					
Pistacia L.			x	(3)	(3)	
Pisum sativum L. partim	x	x		(2)	(1), (2)	
Plantago lanceolata L.	x					~~(1)~~

1	2	3	4	5	6	7
Species **and hybrids thereof**	Intended use			**May be produced and marketed as standard PRM**	**May be produced and marketed as heterogeneous material other than organic heterogeneous material (Article 27)**	May be produced and marketed without belonging to a variety (commercial seed; Article 32b)
	Agricultural crop and potato (1)	Vegetable (2)	Fruit plant, [hop] and vine (3)			
Poa annua L.	x					(1)
Poa nemoralis L.	x					(1)
Poa palustris L.	x					(1)
Poa pratensis L.	x					(1)
Poa trivialis L.	x					(1)
~~***Poncirus*** **Raf.**~~			~~**x**~~			
Prunus armeniaca L.			x	(3)	(3)	
Prunus avium (L.) L.			x	(3)	(3)	
Prunus cerasus L.			x	(3)	(3)	
Prunus domestica L.			x	(3)	(3)	

1	2	3	4	5	6	7
Species **and hybrids thereof**	Intended use			**May be produced and marketed as standard PRM**	**May be produced and marketed as heterogeneous material other than organic heterogeneous material (Article 27)**	May be produced and marketed without belonging to a variety (commercial seed; Article 32b)
	Agricultural crop and potato (1)	Vegetable (2)	Fruit plant, [hop] and vine (3)			
Prunus ~~*amygdalus*~~ *dulcis* ~~(Miller)~~ D.A. Webb			x	(3)	(3)	
Prunus persica (L.) Batsch			x	(3)	(3)	
Prunus salicina Lindl. ~~ey~~			x	(3)	(3)	
***Punica granatum* L.**			**x**	**(3)**	**(3)**	
Pyrus L.			x	(3)	(3)	
Raphanus sativus L. Partim		x		(2)	(2)	
Raphanus sativus L. var. *oleiformis* Pers.	x				(1)	
Rheum rhabarbarum L.		x		(2)	(2)	

1	2	3	4	5	6	7
Species **and hybrids thereof**	Intended use			**May be produced and marketed as standard PRM**	**May be produced and marketed as heterogeneous material other than organic heterogeneous material (Article 27)**	May be produced and marketed without belonging to a variety (commercial seed; Article 32b)
	Agricultural crop and potato (1)	Vegetable (2)	Fruit plant, [hop] and vine (3)			
Ribes L.			x	(3)	(3)	
Rubus L.			x	(3)	(3)	
***Sambucus nigra* L.**			**x**	**(3)**	**(3)**	
Scorzonera hispanica L.		x		(2)	(2)	
Secale cereale L.	x				**(1)**	
***Selenicereus undatus* D. R. Hunt**			**x**	**(3)**	**(3)**	
Sinapis alba L.	x				(1)	(1)
Solanum lycopersicum L.		x		(2)	(2)	
Solanum melongena L.		x		(2)	(2)	

1	2	3	4	5	6	7
Species **and hybrids thereof**	Intended use			**May be produced and marketed as standard PRM**	**May be produced and marketed as heterogeneous material other than organic heterogeneous material (Article 27)**	May be produced and marketed without belonging to a variety (commercial seed; Article 32b)
	Agricultural crop and potato (1)	Vegetable (2)	Fruit plant, [hop] and vine (3)			
Solanum tuberosum L	x					
Sorghum bicolor (L.) Moench subsp. *bicolor*	x				(1)	
Sorghum bicolor (L.) Moench subsp. *drummondii* (Steud.) de Wet ex Davidse	x				(1)	
Sorghum bicolor (L.) Moench subsp. *bicolor x Sorghum bicolor* (L.) Moench subsp. *drummondii* (Steud.) de Wet ex Davidse	x				(1)	

1	2	3	4	5	6	7
Species **and hybrids thereof**	Intended use			**May be produced and marketed as standard PRM**	**May be produced and marketed as heterogeneous material other than organic heterogeneous material (Article 27)**	May be produced and marketed without belonging to a variety (commercial seed; Article 32b)
	Agricultural crop and potato (1)	Vegetable (2)	Fruit plant, [hop] and vine (3)			
~~*Sorghum bicolor* (L.) Moench x *Sorghum sudanense* (Piper) Stapf.~~						
~~*Sorghum sudanense* (Piper) Stapf.~~						
Spinacia oleracea L.		x		(2)	(2)	
Trifolium alexandrinum L. ~~Berseem~~	x					(1)
Trifolium fragiferum L.	x			(1)		(1)
Trifolium glanduliferum Boiss.	x			(1)		(1)
Trifolium hirtum All.	x			(1)		(1)

1	2	3	4	5	6	7
Species **and hybrids thereof**	Intended use			**May be produced and marketed as standard PRM**	**May be produced and marketed as heterogeneous material other than organic heterogeneous material (Article 27)**	May be produced and marketed without belonging to a variety (commercial seed; Article 32b)
	Agricultural crop and potato (1)	Vegetable (2)	Fruit plant, [hop] and vine (3)			
Trifolium hybridum L.	x					(1)
Trifolium incarnatum L.	x					(1)
Trifolium isthmocarpum Brot.	x			(1)		(1)
Trifolium michelianum Savi	x			(1)		(1)
Trifolium pratense L.	x					
Trifolium repens L.	x					
Trifolium resupinatum L.	x					(1)
Trifolium squarrosum L.	x			(1)		(1)
Trifolium subterraneum L.	x			(1)		(1)

1	2	3	4	5	6	7
Species **and hybrids thereof**	Intended use			**May be produced and marketed as standard PRM**	**May be produced and marketed as heterogeneous material other than organic heterogeneous material (Article 27)**	May be produced and marketed without belonging to a variety (commercial seed; Article 32b)
	Agricultural crop and potato (1)	Vegetable (2)	Fruit plant, [hop] and vine (3)			
Trifolium vesiculosum Savi	x			(1)		(1)
Trigonella foenum-graecum L.	x				(1)	(1)
Trisetum flavescens (L.) P. Beauv.	x					(1)
Triticum aestivum L. subsp. *aestivum*	x				(1)	
Triticum aestivum L. subsp. *spelta* (L.) Thell.	x				(1)	
***Triticum dicoccon* (Shrank) Thell.**	**x**				**(1)**	**(1)**

1	2	3	4	5	6	7
Species **and hybrids thereof**	Intended use			**May be produced and marketed as standard PRM**	**May be produced and marketed as heterogeneous material other than organic heterogeneous material (Article 27)**	May be produced and marketed without belonging to a variety (commercial seed; Article 32b)
	Agricultural crop and potato (1)	Vegetable (2)	Fruit plant, [hop] and vine (3)			
***Triticum monococcum* L.**	**x**				**(1)**	**(1)**
Triticum turgidum L. subsp. *durum* (Desf.) van Slageren	x				(1)	
Vaccinium L.			x	(3)	(3)	
Valerianella locusta (L.) Laterr.		x		(2)	(2)	
Vicia benghalensis L.	x			(1)	(1)	(1)
***Vicia ervilia* (L.) Willd.**	**x**				**(1)**	
Vicia faba L. partim	x	x		(2)	**(1), (2)**	(1)
***Vicia narbonensis* L.**	**x**			**(1)**	**(1)**	

1	2	3	4	5	6	7
Species **and hybrids thereof**	Intended use			**May be produced and marketed as standard PRM**	**May be produced and marketed as heterogeneous material other than organic heterogeneous material (Article 27)**	May be produced and marketed without belonging to a variety (commercial seed; Article 32b)
	Agricultural crop and potato (1)	Vegetable (2)	Fruit plant, [hop] and vine (3)			
Vicia pannonica Crantz	x				(1)	(1)
Vicia sativa L.	x				(1)	(1)
Vicia villosa Roth	x				(1)	(1)
***Vigna unguiculata* (L.) Walp.**		**x**		**(2)**	**(2)**	
Vitis L.			x	(3)	(3)	
x Festulolium Asch. & Graebn	x					(1)
x Triticosecale Wittm. ex A. Camus	x				(1)	
Zea mays L. partim	x	x		(2)	(1), (2)	

ANNEX II

REQUIREMENTS FOR THE PRODUCTION AND MARKETING OF PRE-BASIC, BASIC AND CERTIFIED SEEDS AND MATERIAL AS REFERRED TO IN ARTICLE 7

Table of contents

Section 1 General requirements:

PART A seeds of agricultural and vegetable species

PART Aa seed of fruit plant species, vine and true seed potatoes

PART B material of agricultural, vegetable and fruit plant species, and vine

PART Ba seed potatoes

Section 2 Specific requirements:

PART C material of selected clones and polyclonal selection

PART E material produced by in vitro propagation

SECTION 1

GENERAL REQUIREMENTS

PART A

REQUIREMENTS FOR THE PRODUCTION AND MARKETING OF ~~PRE-BASIC, BASIC AND CERTIFIED~~ SEEDS OF AGRICULTURAL AND VEGETABLE SPECIES

1. ~~General r~~Requirements for the production of pre-basic, basic and certified seeds

A. Sowing or planting:

(a) The variety of the seed sown, including where applicable mother plants, shall be identified through an official label or a label issued 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 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 mother plants or seed shall be planted and/or sowed in a way, which assures:

(i) sufficient distance from pollen sources of the same 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 **not** intended for **seed production**~~the production of food or feed~~, to ensure the fulfillment of the requirements applicable only for the PRM concerned.

(g) Where applicable, *in vitro* propagation may also be used for the reproduction of seeds.

B. Field cultivation:

(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 **significant** defects **likely to impair the quality of the seeds**.

~~(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 **cultivated, in all stages of development in such a way**~~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. **Where the official description cannot be used because of the particular growing stage of the plant, biomolecular techniques may be used.**

(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 shall be **rejected**~~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 its identity**,** ~~and~~ purity and ~~a correct~~ traceability.

(b) A sample of seed 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 seed samples shall be subjected to laboratory testing, 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 t~~**T**he seed lots belonging to the pre-basic, basic ~~category~~, or certified category ~~if it~~**that** 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 **risk-based official pre- and post-**control plot-testing by the **competent authority**~~operator, under official supervision,~~ to verify the compliance with:

(i) their varietal identity; **and**

(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

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 germination ~~to allow an appropriate number of plants per square metre after sowing, and consequently to secure the yield and quality of the production~~;

(b) have a maximum content of hard seed to allow an appropriate number of plant per square metre;

(c) have a minimum purity to secure the highest level of varietal identity;

(d) have a maximum moisture content to ensure the preservation of the material during processing, storage and making available on the market;

(e) have a maximum content of seeds 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 **soil**~~earth~~ or extraneous matter ~~to prevent fraudulent practices~~ and technical impurities; and

(h) be free from specific defects and damages to ensure the quality and health of the material.

PART AaD

REQUIREMENTS FOR THE PRODUCTION AND MARKETING OF PRE-BASIC, BASIC AND CERTIFIED SEED OF FRUIT PLANTS SPECIES, VINE AND TRUE SEED OF POTATOES

1. Requirements for the production of pre-basic, basic and certified seed of fruit plants species, vine and true seed potatoes

A. Sowing or planting:

(aa) the variety of the seed sown, including where applicable mother plants, shall be identified through an official label or a label issued by the professional operator and shall be recorded to ensure its traceability. The label of the seed, 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;

(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 **not** intended for **seed production**food or feed purposes.

B. Field cultivation:

(a) During all stages of cultivation, **PRM**~~propagating and planting material~~ shall be kept separate from each other.

(b) **PRM**~~Reproductive material~~ satisfying the requirements of a given category shall not be mixed with ~~material~~**PRM** 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 **significant** defects **likely to impair the quality of seeds**.

(f) Mother plants shall be **cultivated, in all stages of development, in such a way**~~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~~ **and to** permit~~ting~~ their identification and verification of compliance with the official description or the officially recognised description of their variety. **Where the official description cannot be used because of the particular growing stage of the plant, biomolecular techniques may be used.** 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 plant~~s~~ species, vine and true 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 **germination**~~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 **significant**~~specific~~ defects and damages to ensure the quality of the seeds.

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

1. Requirements for the production of pre-basic, basic and certified material of agricultural, vegetable and fruit plant species, and vine

A. Sowing or planting:

(a) The 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 professional operator, and recorded by the professional operator to ensure its 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 shall be **grafted or** planted 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 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 **not** intended for **PRM production**~~food or feed purposes~~.

B. Field cultivation:

(a) During all stages of cultivation, **PRM**~~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 plants 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 **significant** defects **likely to impair the quality of the material**.

(e) Mother plants shall be **cultivated, in all stages of development, in such a way**~~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. **Where the official description cannot be used because of the particular growing stage of the plant, biomolecular techniques may be used.** 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.

~~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 <u>of agricultural, vegetable and fruit plant species, and vine</u>

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 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 **<u>significant</u>**~~specific~~ defects **<u>likely to impair the quality of the material</u>**.

PART Ba

REQUIREMENTS FOR THE PRODUCTION AND MARKETING OF SEED POTATOES

1. Requirements for the production of pre-basic, basic and certified seed potatoes

A. Sowing or planting:

(a) The identity of the material, including, where applicable, mother **tubers**~~plants~~ or seed sown, shall be determined through an official label or a label issued by the professional operator, and recorded by the professional operator to ensure its 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 shall be planted in a way that:

(i) the pre-basic **minituber**~~material~~ is maintained in facilities that ensure freedom from infection through aerial vectors and any other possible sources throughout the production process; **and**

~~(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 **the seed potatoes**~~material~~ shall take place separately from the cultivation of ~~material belonging to the same genera or species~~ **seed potatoes not** intended for **PRM production**~~food or feed purposes~~.

B. Field cultivation:

(a) During all stages of cultivation, **PRM**~~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 plants **or tubers** 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 **significant** defects **likely to impair the quality of the material**.

(e) Mother plants shall be **cultivated, in all stages of development, in such a way**~~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. **Where the official description cannot be used because of the particular growing stage of the plant, biomolecular techniques may be used.** 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 **potato**~~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 **seed potatoes**~~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 **potato**~~the species concerned~~, and in accordance with the applicable international standards.

(d) ~~All t~~**T**he lots belonging to the pre-basic**,** ~~or~~ basic **or** ~~category, and at least 5% of the lots belonging to a~~ certified category, shall be subject to **risk-based pre- and post-**control plot-testing by the **competent authority**~~operator, under official supervision of the competent authority~~, to verify the compliance with:

(i) their varietal identity; **and**

(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 seed potatoes

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 ~~vigour or~~ germination rate, defined dimension, and, ~~where applicable,~~ specific grading, to ensure the appropriateness of the **tubers**~~material~~ and sufficient homogeneity of the lot for planting;

(b) be practically free from **significant**~~specific~~ defects **likely to impair the quality of the material**.

SECTION 2

SPECIFIC REQUIREMENTS

PART C

REQUIREMENTS FOR THE PRODUCTION~~, REGISTRATION~~ AND MARKETING OF SELECTED CLONES~~, MULTICLONAL MIXTURES~~ AND POLYCLONAL SELECTION~~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 selections~~PRM~~

A. Planting:

(a) The identity of the selected clone~~, multiclonal mixture~~ or polyclonal **selection**~~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 **selection**~~PRM~~, shall be kept by the professional operator after the marketing of that PRM **for at least five years**.

(b) The material shall be **grafted or** 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 **not** intended for **PRM production**~~food or feed purposes~~.

B. Field cultivation:

(a) During all stages of cultivation, **PRM**~~propagating and planting material~~ shall be kept separate from each other.

(b) **PRM**~~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 **specific** defects **likely to impair the quality of the material**.

(e) The respective mother plants and the respective genotypes shall be **cultivated, in all stages of development, in such a way**~~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. **Where the official description cannot be used because of the particular growing stage of the plant, biomolecular techniques may be used.** 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 **selections**~~PRM~~, the mixture of genotypes constituting the polyclonal **selections**~~PRM~~ shall be made before the final packaging of that PRM and shall include identical proportions of all genotypes that constitute the polyclonal **selections**~~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* material, as applicable, shall be determined through a label **or records** and recorded to ensure its traceability. The label **or records** of the material shall be kept **for at least five years by the professional operator**.

~~(b) Material that has been sampled from *in vivo* material shall be sanitised.~~

B. *In vitro* production

(a) The clone(s) that originate from the material referred to under point A.(a) shall be produced by *in vitro* propagation.

(b) During all stages of cultivation, **PRM**~~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* propagation shall be restricted, as appropriate, for the genera or species concerned.

(e) Clone(s) shall be **cultivated, in all stages of development, in such a way**~~maintained in all phases of production, under conditions to enable the production of PRM, and~~ **to** permit~~ting~~ their identification and verification of compliance with the official description or the officially recognised description of their variety. **Where the official description cannot be used because of the particular growing stage of the plant, biomolecular techniques may be used.** In the case of clone(s) 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 clone(s) belong.

(f) Clone(s) 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.

2. Requirements for the marketing of pre-basic, basic and certified material produced by *in vitro* propagation

The *in vitro* or *in vivo* material **derived from *in vitro*** 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 **or minitubers** 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 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 **significant**~~specific~~ defects ~~and damages~~ **likely to impair the quality of the material**.

ANNEX III

REQUIREMENTS FOR THE PRODUCTION AND MARKETING OF STANDARD SEED AND MATERIAL AS REFERRED TO IN ARTICLE 8

Table of contents

Section 1 General requirements:

PART A seeds of agricultural and vegetable species

PART Aa seed of fruit plant species, vine and true seed of potatoes of conservation varieties

PART B material of agricultural, vegetable and fruit plant species, and vine

PART Ba seed potatoes of conservation varieties

Section 2 Specific requirements:

PART C material of selected clones and polyclonal selection

PART E material produced by in vitro propagation

SECTION 1

GENERAL REQUIREMENTS

PART A

REQUIREMENTS FOR THE PRODUCTION AND MARKETING OF ~~STANDARD~~ SEED OF AGRICULTURAL AND VEGETABLE SPECIES

1. ~~General r~~Requirements for the production of standard seed

A. Sowing or planting:

(a) The variety of the seed sown, including where applicable, mother plants, shall be determined to ensure its traceability. The label of the **seed**~~material~~, or the records on the mother plant, shall be kept at least for 2 years **by the professional operator**.

(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 mother plants or seed shall be planted and /or sowed in a way that there is:

(i) sufficient distance from pollen sources of the same 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 **not** intended for **seed production**~~the production of food or feed~~, to ensure health of the material concerned.

(g) Where applicable, *in vitro* propagation may also be used for the reproduction of seeds.

B. Field production:

(a) It shall be ensured that off-types, 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 **significant** defects **likely to impair the quality of the seed**.

~~(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 **cultivated, in all stages of development, in such a way**~~maintained in all phases of production, under conditions to enable the production of seeds, and~~ **to** permit~~ting~~ their identification and verification of compliance with the official description of their variety.**Where the official description cannot be used because of the particular growing stage of the plant, biomolecular techniques may be used.**

(e) All crops in the field shall be **checked**~~inspected~~ 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 **rejected**~~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 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; **and**

(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 marketing of standard 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 germination~~, to allow an appropriate number of plants per square metre after sowing, and consequently to secure the yield and quality of the production~~;

(b) have at most a maximum content of hard seed, to allow an appropriate number of plants per square metre;

(c) have at least a minimum purity, to secure the **appropriate**~~highest~~ level of varietal identity;

(d) have at most a maximum moisture content, to ensure the preservation of the material during processing, storage and making available on the market;

(e) have at most a maximum content of seeds 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 **soil**~~earth~~ or extraneous matter, to prevent fraudulent practices and technical impurities; and

(h) be free from **specific**~~specific~~ defects and damage to ensure the quality and health of the material.

PART Aa

REQUIREMENTS FOR THE PRODUCTION AND MARKETING OF SEED OF FRUIT PLANT SPECIES, VINE AND TRUE SEED OF POTATOES FROM CONSERVATION VARIETIES

~~Part D of Annex II shall apply accordingly for the production and marketing of standard seed of fruit plants, vine and seed potatoes.~~

1. Requirements for the production of standard seed of fruit plant species, vine, and true seed potatoes from conservation varieties

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 **not** intended for **seed production**~~food or feed purposes~~.

B. Field cultivation:

(a) During all stages of cultivation, ~~propagating and planting material~~**PRM** shall be kept separate from each other.

(b) ~~Reproductive material~~**PRM** 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 **cultivated, in all stages of development, in such a way**~~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~~**to** permit~~ting~~ their identification and verification of compliance with the official description or the officially recognised description of their variety. **Where the official desciption or officially recognised description cannot be used because of the particular growing stage of the plant, biomolecular techniques may be used.** 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.

(fa) All crops in the field shall be inspected 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.

~~(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 standard seed of fruit plant species, vine, and true seed of potatoes from conservation varieties

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 **significant**~~specific~~ defects and damages to ensure the quality of the seeds.

PART B

REQUIREMENTS FOR THE PRODUCTION AND MARKETING OF ~~STANDARD~~ MATERIAL OF AGRICULTURAL, ~~AND~~ VEGETABLE AND FRUIT PLANT SPECIES AND VINE

~~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 species, and vine

A. Sowing or planting:

(a) The 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 professional operator, and recorded by the professional operator to ensure its 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 shall be planted 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 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 **not** intended for **PRM production**~~food or feed purposes~~.

B. Field cultivation:

(a) During all stages of cultivation, ~~propagating and planting material~~**PRM** 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 plants 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 **significant** defects **likely to impair the quality of the PRM**.

(e) Mother plants shall be **cultivated, in all stage of development, in such a way** ~~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. **Where the official desciption cannot be used because of the particular growing stage of the plant, biomolecular techniques may be used.** 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.

(ea) All crops in the field shall be inspected 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.

~~(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.~~

~~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 standard material of agricultural, vegetable and fruit species, and vine

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 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 **likely to impair the quality of the material**.

PART Ba

SEED POTATOES OF CONSERVATION VARIETIES

The following provisions shall apply to seed potatoes produced and marketed pursuant to the derogation referred to in Article 26 concerning conservation varieties.

1. Requirements for the production of standard seed potatoes of conservation varieties

A. Sowing or planting:

(a) The identity of the material, including, where applicable, mother **tubers**~~plants~~ or seed sown, shall be determined through an official label or a label issued by the professional operator, and recorded by the professional operator to ensure its 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 shall be planted 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 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 **the** ~~material~~ **seed potatoes** shall take place separately from the cultivation of ~~material belonging to the same genera or species~~ **seed potatoes not** intended for **PRM production**~~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) ~~PRM~~**Seed potatoes** satisfying the requirements for a given category shall not be mixed with material of other categories.

(c) Off-types and deformed or damaged plants **or tubers** shall be disposed of at all stages of cultivation.

(d) Mother **tubers**~~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 **significant** defects **likely to impair its quality**.

(e) Mother plants shall be **cultivated, in all stages of development** ~~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. **Where the official desciption cannot be used because of the particular growing stage of the plant, biomolecular techniques may be used.** ~~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.

C. Harvesting and post-harvesting:

(a) The **seed potatoes**~~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 **potato**~~the species concerned~~, and in accordance with the applicable international standards.

(d) The lots belonging to the standard category~~, and the lots belonging to a certified category,~~ shall be subject to risk-based official ~~pre- and~~ postcontrol plot-testing by the competent authority, to verify the compliance with:

(i) their varietal identity; and

(ii) the standards of the minimum varietal purity.

~~The samples used for the official post-control tests shall be taken officially.~~

2. Requirements for the marketing of standard ~~material~~seed potatoes of conservation varieties

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 vigour ~~or germination rate,~~ defined dimension **for the specific variety**, and~~, where applicable,~~ specific grading, to ensure the appropriateness of the ~~material~~ **tubers** and sufficient homogeneity of the lot for planting;

(b) be practically free from **significant**~~specific~~ defects **likely to impair the quality of the seed potatoes**.

SECTION 2

SPECIFIC REQUIREMENTS

PART C

REQUIREMENTS FOR THE ~~REGISTRATION,~~ PRODUCTION AND MARKETING OF SELECTED CLONES~~, MULTICLONAL MIXTURES~~ AND POLYCLONAL SELECTIONS~~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.~~

1. Requirements for the production of standard PRM of selected clones~~, multiclonal mixtures~~ and polyclonal ~~PRM~~selections

A. Planting:

(a) The identity of the selected clone~~, multiclonal mixture~~ or polyclonal **selections**~~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 **for at least five years**.

(b) The material shall be **grafted or** 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 **not** intended for **PRM production**~~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 **significant** defects.

(e) The respective mother plants and the respective genotypes shall **be cultivated, in all stages of development, in such a way** ~~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. **Where the official desciption or officially recognised description cannot be used because of the particular growing stage of the plant, biomolecular techniques may be used.** 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.

(ea) All crops in the field shall be inspected 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.

~~(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 **selections**~~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 **selection**~~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 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 through a label and 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) that originate from the material referred to under point A.(a) shall be produced by *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* propagation shall be restricted, as appropriate, for the genera or species concerned.

(e) Clone(s) shall be **cultivated, in all stages of development, in such a way**~~maintained in all phases of production, under conditions~~ to enable the production of PRM, and permitting their identification and verification of compliance with the official description or the officially recognised description of their variety. **Where the official desciption or officially recognised description cannot be used because of the particular growing stage of the plant, biomolecular techniques may be used.** In the case of clone(s) 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 clone(s) belong.

(ea) All clones in the field shall be inspected 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.

~~(f) Clone(s) 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.~~

2. Requirements for the marketing of standard material produced by *in vitro* propagation

The *in vitro* or *in vivo* 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 **or minitubers** 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 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 defects and damages.

ANNEX IIIa

REQUIREMENTS FOR THE REGISTRATION OF SELECTED CLONES AND POLYCLONAL SELECTIONS AS REFERRED TO IN ARTICLE 9

(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 **selections**~~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 **selections**~~PRM~~;

(iv) the maintainer of the selected clone~~, multiclonal mixture~~ or polyclonal **selections**~~PRM~~;

(v) reference to the description of the main characteristics of the variety to which the selected clone~~, multiclonal mixture~~ or polyclonal **selections**~~PRM~~ belongs;

(vi) description of the main VSCU characteristics of the selected clone~~, multiclonal mixture~~ or polyclonal **selections**~~PRM~~;

(vii) the estimated genetic gain of the selected clone~~, multiclonal mixture~~ or polyclonal **selections**~~PRM~~ in relation to the overall performance of the relevant variety;

(viii) information on whether the selected clone~~, multiclonal mixture~~ or polyclonal **selections**~~PRM~~ is already registered in a register of another Member State.

(b) The selected clone~~, multiclonal mixture~~ or polyclonal **selections**~~PRM~~ shall fulfil the following requirements as appropriate for the type of material concerned in order to be registered:

(i) the polyclonal **selections**~~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 t~~**T**hat design shall be based on methods prescribed by the International ~~o~~**O**rganisation of ~~v~~**V**ine and ~~w~~**W**ine;

(ii) ~~in the case of vine propagating material, t~~**T**he polyclonal **selections**~~PRM~~ shall be composed of 7 to 20 distinct genotypes;

(iii) the trueness of the selected clone~~, each selected clone of the multiclonal mixture,~~ **or** each genotype of the polyclonal **selections**~~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.

~~**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~~Region of origin

Competent authorities may designate specific ~~source areas~~**regions of origin** 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~~**region of origin** 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~~**naturally occur in** the **region of origin**~~source area~~;

(b) **be** of importance for the preservation of the natural environment in the context of conservation of genetic resources, as components of the mixture;

(c) **be** adequate for the purpose of recreating the habitat type of the ~~source area~~**region of origin**.

~~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) **production**~~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~~**region of origin** 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~~**region of origin** of the mixture;

(f) **for directly harvested mixtures, the** collection site, and in the case of a multiplied preservation mixture, **the collection site of each component and** in addition, the multiplication site; **and**

(g) habitat type of the ~~source area~~**region of origin** 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 **professional** operator**'s** application and the compliance of the requirements, and the restriction to marketing in the ~~source area~~**region of origin**.

Professional operators ~~before the beginning of each production season~~ shall notify **to the competent authority** 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 **at the end of each production season**.

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~~**region of origin** ('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 **first collection**~~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~~**region of origin**;

(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 **appropriate** 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 **professional** operator in accordance with the following process:

(a) seed of individual species is taken at the ~~source area~~**region of origin**, or is a directly harvested preservation mixtures purchased ~~to~~**from** **an**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~~**region of origin, 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**;

~~(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~~**region of origin** at a collection site which has not been sown in the 40 years previous to the date of the authorization by the **professional** 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 (**c**~~f~~) shall be sufficient for the purpose of recreating the habitat type of the ~~source area~~**region of origin**;

(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 **of agricultural or vegetable crops** listed in ~~Part A of~~ Annex I shall, before mixing, comply at least with the requirements **concerning germination and purity** 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 (**1**~~2~~) may be marketed following a notification of the heterogeneous material by the professional operator to the competent authorities, made ~~m~~**b**y means of a dossier containing:

a) the contact details of the applicant;

b) the species**, indicated by its scientific name and its common name** and denomination of the heterogeneous material;

c) the description of the heterogeneous material as referred **to** in point B**;**

d) a declaration by the applicant concerning the truth of the elements in points (a), (b) and (c)**;**~~.~~

e) **if the competent authority requires so,** a representative sample **according to the instructions of the competent authority;**

ea) where applicable, information whether the PRM was or will be produced in accordance with Regulation (EU) 2018/848.

~~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 **or tolerance** to abiotic **or biotic** 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 program~~me~~ 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 **the final breeding stage**~~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 **and**~~or~~ production; and

(c) characterisation of the common key characters and of the phenotypic heterogeneity of the material.

D. Requirements concerning quality pests, 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.

1a. The heterogenous material shall be practically free from quality pests and any defects likely to impair its quality as reproductive material.

~~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~~**Seed** of heterogeneous material shall be contained in **closed** 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. **Seedlings of heterogeneous material shall be contained in trays.**

2. The professional operators shall affix on packages, **trays** or containers of PRM of heterogeneous material a**n** **operator's** label in at least one of the official languages of the Union.

That **operator's** 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~~**if** th**e**~~at~~ information **set out in point G** 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 **operator's** 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**, trays or containers** bearing a**n operator's** label containing the following elements:

(1) the denomination of the heterogeneous material, together with the phrase 'heterogeneous material' **or 'organic heterogeneous material' where applicable**;

(2) the indication 'EU rules and standards';

(2a) in case of seedlings, the indication 'produced from seed of heterogeneous material';

(3) the name and address of the professional operator responsible for affixing the label, **and**~~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 **on**';

(7) species, indicated ~~at least under~~ **by** its ~~botanical~~**scientific** name, which may be given ~~in abridged form and~~ without the authors' names**, and its common name in at least one official Union language**;

(8) declared net ~~or gross~~ weight **or number of seeds**, or declared number of PRM **other than seeds**, ~~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)**
Seed of ~~F~~**f**odder plants	10
Beet **seed**	10
Cereals **seed**	30
Seed of ~~O~~**o**il and fiber plants	10
True seed ~~P~~**p**otato	~~30~~ **10**
Vegetable **seed**:	
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

[…]