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### WORKING DOCUMENT

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From: General Secretariat of the Council  
To: Delegations

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Subject: Meeting of the Working Party on Genetic Resources and Innovation in  
Agriculture (Seeds, Propagating and Planting Materials; PRM) on 26 and  
27 March 2025 - Meeting document on agenda item 1

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In view of the meeting of the Working Party on Genetic Resources and Innovation in Agriculture (Seeds, Propagating and Planting Materials; PRM) on 26 and 27 March 2025, delegations will find in Annex drafting suggestions from the Presidency concerning Articles 2 and 3, as well as the Presidency revised text on Articles 15 to 38 and Annex V of the proposal on the production and marketing of plant reproductive material in the Union.

Deletions are marked with ~~strike through~~ and additions are marked with **bold and underline** in comparison with the previous Presidency's revised text as in document 11303/2024.

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

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Polish Presidency drafting suggestions on Articles 2 and 3, and Presidency revised text on Articles 15 to 38 and Annex V in view of the meeting of the Working Party on Genetic Resources and Innovation in Agriculture (Seeds, Propagating and Planting Materials) on 26 and 27 March 2025

Article 2, paragraph 4

NEW

**[(i) PRM marketed by non-profit organisations and networks other than gene banks, with a purpose defined in their articles of association or other equivalent document of conserving plant genetic resources, to any natural or legal person, under the condition that those organisations and networks have notified their activity to the competent authority and the respective PRM is identified as such through appropriate labelling;]**

## Article 3

### NEW proposal

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

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## SECTION 5

### LABELLING REQUIREMENTS

#### *Article 15*

#### Official label

1. Pre-basic, basic and certified **seed and** material ~~and seed~~ shall be identified, and their compliance with this Regulation shall be attested, through an official label, issued 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; or

(b) the professional operator, under the official supervision of the competent authority, when the professional operator is authorised to carry out such printing **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. ~~The professional operator may carry out the printing or affixing of the label through a contracted third party.~~

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

4a. The official label may **contain some of the information in digital form** ~~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 **the following**:

(a) the **digital** recording and collection of **actions leading to the issuance and printing of official labels** ~~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 the information referred to in point (a);

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

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

~~Only following the adoption of such delegated act, ‘an electronic official label’ may be issued.~~ **Information may only be provided in the official label in digital form once such delegated acts have entered into application.**

~~6. By way of derogation from paragraphs 1 to 5, pre-basic, basic 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. ~~PRM other than pre-basic, basic and certified categories, marketed under the professional operator’s responsibility,~~ **Standard seed and material** shall be identified through an operator’s label-

2. ~~T~~**h**at label shall attest**s** that the PRM referred to in paragraph 1 **their** complies **compliance** with the 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,~~ to the outside of the individual plant, bundle, package or container.

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

- [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 operator's labels;

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

(b) the technical arrangements for the issuance of electronic operator's labels and its the format **and content** of those labels.

~~Only following the adoption of such delegated act, 'an electronic label' may be issued.~~  
**Information may only be provided in the operator's label in digital form once such delegated acts have entered into application.**

#### *Article 17*

#### **Content and characteristics of labels**

1. The official label and the operator's label, shall be written in at least one of the official ~~Union~~ languages **of the Union**. ~~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, unused, and easily visible.  
**2a. Adhesive label may be used where there is no risk that it can be re-used. In the case of official labels, the use of adhesive labels shall be authorised by the competent authority.**
3. Where applicable, the official label and the operator's label, apart from the elements **to be adopted pursuant to** ~~mentioned in paragraph 4, shall~~ **may** include in any **an appropriate** 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 **related to production and marketing requirements, other than the ones set out in this Regulation;** ~~or~~
- ~~(f) any other official information obliged by the competent authority.~~

Such information shall be presented **in a legible way** in letters not larger than those used for the content of the official label or the operator's label as referred to in paragraph 4. ~~That additional official information shall be related only to production and marketing requirements or to labelling requirements~~

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

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

- (a) [...]
- (b) [...]
- (c) [...]
- (d) [...]
- (e) [...]
- (f) [...]
- (g) [...]
- (h) [...]
- (i) [...]

- (j) [...]
- (k) [...]
- (l) [...]
- (m) [...]
- (n) [...]

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

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

#### *Article 18*

#### **Reference to lots**

[...]

#### *Article 19 to become Article 77a*

#### **Non-compliance of PRM with production and marketing requirements**

In the case where official controls carried out **by the competent authority** during the production and marketing of PRM show that ~~pre-basic, basic, certified seed or material, or standard seed or material, have not been produced or marketed within the Union in~~ **its non-compliance** with the respective requirements referred to in Articles 7, 8, or 9, or in the case where, the varietal identity and varietal purity of the PRM were not confirmed in the control plot testing in accordance with Article 24 **this Regulation**, the competent authority~~s~~ shall ensure that the professional operator ~~concerned~~ takes the necessary corrective actions ~~concerning~~ **with regard to the that** 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 to become Article 6a*

### **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 indicated in column 5 **[X]** of Annex I may **only** be produced and marketed as standard **pre-basic, basic or certified** 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 or material.~~
2. The Commission is empowered to adopt a delegated acts in accordance with Article 75 in order to amend column 5 **[X]** of Annex I.

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

- (a) there is a need for higher ~~equ~~ guarantees for the quality of PRM belonging to that genus or species; and-
- (b) the costs of the certification activities, necessary to produce and market the respective PRM as pre-basic, basic and certified seed or material are proportionate:
  - (i) to the purpose of ensuring food and feed security, or ensuring high value of industrial processing; or
  - (ii) to the economic, **phytosanitary and environmental** benefits deriving from the highest standards concerning identity and quality of the PRM, resulting from the

compliance with the requirements for pre-basic, basic and certified PRM compared to those for standard ~~seed~~ **PRM**.

That **The assessment of** proportionality **referred to in the first subparagraph of point (b)** shall be based on an overall assessment of the following elements in combination:

- (i)** the importance of the respective genus or species for the Union food and feed security;
- (ii)** the volume of its production in the Union;
- (iii)** its demand by the professional operators and operators of the food/feed industry;
- (iv)** the costs of the production of pre-basic, basic and certified PRM compared to the cost of production of other PRM of the same genus or species; and
- (v)** the economic, phytosanitary and environmental benefits derived from the production and marketing of pre-basic, basic and certified ~~seed or material~~ **PRM** compared to **those for standard** ~~other~~ PRM of the same genus or species.

The delegated acts referred to in the first subparagraph shall ~~add~~ **remove** a genus or a species ~~to~~ **from** column 5 **[X]** of Annex I, if one of the conditions set out in the second subparagraph, point (b), points (i) and (ii), is not 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, mixtures of standard seed or mixtures of certified and standard~~ **S**eed of various genera or species listed in Annex I, as well as of different varieties of those genera or species **belonging to any of the categories referred to in Article 6(1)** ~~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, fulfill the~~

requirements of Articles 5 to 8 and 20, and the requirements of this Article. **as a mixture of those genera, species or varieties.**

**1a.** Mixtures **referred to in paragraph 1** of seeds may also be produced from **include commercial** seed subject to **Article 32a and seed certified on the basis of provisional analysis regarding germination subject to** Article 34.

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

- (a) an official label, where the mixture consists only of certified seed or of **categories referred to in Article 6(1), points (a), (b) and (c), or** seed subject to Article 34; or
- (b) an operator's label, in all other cases.

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

**1c.** For the purposes of the second subparagraph, point (a), ~~the~~ professional operators shall submit to the competent authority, **upon request,** the list of constituent species and varieties **components** of the mixture and their ratios, for verification of eligibility of those varieties **components**.

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

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

**3aa.** 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.

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.~~

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

~~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 **mixtures** 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, **the** rules concerning:

- (a) the mixing equipment and procedure;
- (aa) sealing, packaging, **including maximum size of small packages**, and labelling; ~~and~~
- (ab) content, size, colour and form of the official label and operator's label; **and**
- ~~[(b) maximum lot sizes for particular species and varieties.]~~
- (c) in case of mixtures referred to in paragraph 3a, possible applicable use.**

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

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

*Article 22*

**Preservation mixtures**

1. By way of derogation from Articles **5 to 12, 14 and** 21(1) **to (4)**, Member States may **decide to authorise** **allow** the production and marketing, **in their territories, or part of those territories**, of ~~seed intended for, or used in a mixture~~ of various genera or species listed in Annex I, as well as 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 region ('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.~~

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

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

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

**(aa) the designation of the region of origin;**

**(ab) the use of certain species in preservation mixtures;**

**(ac) the authorisation of professional operators;**

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

(b) ~~authorisation requirements for~~ **the production of** multiplied preservation mixtures;

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

(d) [...]

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

**(f) the reporting obligations for professional operators; and**

**(g) inspection, sampling, testing and other activities carried out by the competent authority.**

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

2a. The Commission may, by means of implementing acts, adopt specific requirements concerning **packaging**, sealing, content, size, colour and form of the ~~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 to become Article 17a*

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

- ~~1. Lots of pre basic, basic and certified seed shall be repackaged, re sealed and re labeled in accordance with this Article, Articles 14 and 15.~~
- ~~2. The re packaging, re sealing and re labelling of a seed lot shall be conducted by the competent authority or the professional operator under the official supervision of the competent authority as referred to in Article 14(4)~~
  - (a) [...]
  - (b) [...]
3. ~~To ensure that the quality of the seed lots is maintained during the re packaging,~~ The professional operator carrying out re-packaging, re-sealing and re-labelling of seed lots **PRM**, shall take all steps to ensure that during the **that** operation of re-packaging, the identity, and varietal purity **and homogeneity** 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 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 of the lot.~~

~~Those records shall be kept in a form allowing identification and verification 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 shall also keep the replaced label, its content or digital equivalent of each original 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 state the original seed lot reference number and in the case of mixtures or merging of lots, a new seed lot reference number shall be assigned and indicated on the label. Records of this new seed lot reference number shall be kept in accordance with the provisions of paragraph 4.~~

~~6. [...]~~

~~7. [...]~~

Article 24 to become Article 9a in the new Section 2a “Specific requirements for control plot tests for seed”

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

1. Control plot tests shall be carried out by the competent authorities in order to verify that the lots of pre-basic, basic and certified seed, except **for lots of seed lots for of potatoes, vine and fruit and vine species**, placed on the market comply with the requirements relating to their varietal identity and varietal purity.

Those tests shall consist of a visual comparison between the control plot sown from a reference **standard** sample ~~of the variety~~ and a plot sown from a sample of seed representative of the seed lot **under testing**. ~~The~~ **That** sample ~~of the seed lot~~ shall be taken upon **during the** certification or ~~during the marketing of~~:

- a) **a** lots of pre-basic, basic and certified seed intended for the production of a new generation of seed (pre-control); or
- b) **of a lot 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.

a) [...]

b) [...]

2. ~~The proportion of these~~ **Those** control plot tests **shall apply for to all lots of** pre-basic, **and basic seed**, and **In the case of** certified seed, **the proportion of the** lots **to be tested** shall be determined on the basis of a risk analysis concerning possible non-compliance of the seed 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~~ **The** samples **from of a tested** seed lots **of seed** referred to in paragraph 1 **shall be** taken by the competent authority. **That sampling may be carried out** ~~or using~~ an automatic sampling device officially approved by the competent authority.
4. [...]

4. ~~5.~~ Where the results of control plot testing referred to in paragraph 1 are not conclusive as to the **For the purpose of control of** varietal identity and varietal purity, biochemical and bio-molecular techniques recognised in accordance with Article 7(4), point (~~g~~**b**), may be used as a supplementary tool.
- 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:
- (a)** withdraw or prohibit further multiplication and marketing of the ~~concerned~~ **seed lot concerned**; ~~or~~
  - (b)** ensure that ~~it~~ **the seed lot concerned** complies with the applicable requirements; ~~or~~
  - (c)** ~~impose~~ **take** other appropriate corrective actions.
- 5b. The Commission may, by means of implementing acts in accordance with Article 76(2) set out rules concerning the control plot tests of **lots of pre-basic, basic and certified** 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 **elements**:
- (a) criteria for the conduct of the risk analysis referred to in paragraph 2;
  - (b) the testing procedure;
  - (c) the ~~way of~~ evaluation of **the** results of the tests;
  - (d) ~~the proportion of the seed lots or the frequency rates.~~

*Article 25 to become Article 9b in the new Section 2a "Specific requirements for control plot tests for seed"*

### **Control plot tests for standard seed**

1. ~~During the marketing~~ **Control plot tests shall be carried out by the competent authorities in order to verify that the marketed** ~~of lots of standard seed, the competent authorities shall carry out control plot tests (post-control) to check whether the seed lots, except~~ **for lots**

of seed lots of potatoes, vine and ~~from fruit and vine species~~, comply with the respective requirements relating to their varietal identity and varietal purity requirements.

Those tests shall consist of a visual comparison between the control plot sown from a reference standard sample ~~of the variety~~ and a plot sown from a sample of seed ~~representative of the seed lot~~ under testing. ~~The~~ That sample of the seed lot shall be taken during the marketing of the lots.

2. Those control plot tests shall apply to ~~the~~ the proportion of lots of standard seed ~~the control plot tests shall be determined on the basis of a risk analysis concerning possible non-compliance of the respective standard seed with those~~ the respective requirements.
3. ~~On the basis of the risk analysis referred to in paragraph 2, the control plot tests referred to in paragraph 1 shall be carried out by using~~ The samples from a tested of seed lots referred to in paragraph 1 shall be taken by the competent authority. That sampling may be carried out ~~or~~ using an automatic sampling device officially approved by the competent authority.
4. ~~In the case~~ For the purpose of control of varietal identity and varietal purity, ~~the use of~~ biochemical and bio-molecular techniques recognised in accordance with Article 7(4) 8(5), 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, if feasible:
  - (a) withdraw or prohibit further multiplication and marketing of the concerned seed lot concerned; ~~or ensure that it complies with the applicable requirements;~~ or
  - (b) ~~impose~~ take 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 standard seed lots per genera or species. Those rules shall be adapted to the development of scientific and technical knowledge and international standards, and may be established per particular genera or species. They may concern the 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 Articles ~~20~~ **6a**, **and 9b**, 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 notify this activity, ~~with regard to the species and quantities concerned when submitting the declaration~~ **in accordance with** referred to in Article 43, last subparagraph.

### *Article 27*

#### **PRM of heterogeneous material**

- ~~1~~ As referred to in Article 5(3), PRM of heterogeneous material shall be produced and marketed within the Union without belonging to a variety. The heterogeneous material shall be notified to and registered by the competent authority prior to its 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) and Article 8(1), (2), 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 heterogeneous material, 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, on the basis of the experience gained from the checks carried out by the competent authorities;~~
  - ~~(c) improve the rules on maintenance of heterogeneous material, on the basis 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 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, 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 producing PRM of heterogeneous material intended for marketing shall ensure traceability of the PRM of heterogeneous material by recording and keeping 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;~~
- ~~(c) the description of the characteristics of the notified heterogeneous material;~~
- ~~(d) the location where the notified heterogeneous material was initially bred and production location;~~
- ~~(e) the 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, 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 non-professional users

1. By way of derogation from Articles 5(1) ~~to 12, and 14-15 to 17a~~ and 20, PRM ~~with the exception of seed potatoes,~~ intended to be used **exclusively** by non-professional users may be produced, and marketed ~~to 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 PRM for non-professional user - not certified' or, in the case of seed, 'Seed for non-professional user;~~
  - (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~~ **followed by the indication 'variety not registered pursuant to Article 44** of Regulation (EU) .../... of the European Parliament and of the Council<sup>1</sup>, **and complying with Article 54** 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, kept by the professional operator. This and that private documentation shall be is~~ made available by the professional operator ~~upon request to the competent authority~~ **upon request;**

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<sup>1</sup> 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;~~
- (i) **in the case of PRM other than seed, shall have satisfactory sufficient vigour and dimensions in respect of its usefulness as PRM;** and;
- (ii) **in the case of seed, shall have satisfactory minimum sufficient germination as applicable for the lowest possible category of the respective species 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, or in small packages, clearly distinct~~ **distinguishable** from those **packages** used for any pre-basic, basic, certified and standard seed **PRM**.

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

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

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

#### *[Article 29*

### **PRM marketed by organisations and networks for the conservation of plant genetic resources**

1. By way of derogation from Articles 5 ~~to 15 and 19– 25~~, PRM may be marketed, ~~for~~ **by** non-profit purposes, ~~by~~ organisations and networks **other than gene banks, having a purpose defined in their articles of association or other equivalent document** ~~with a statutory~~

~~objective, of ensuring the conservation~~ **conserving** of plant genetic resources, **to any natural or legal** persons who carry ~~ies~~ out conservation of that PRM and to farmers or non-professional users.

~~In these cases, this~~ **Such** 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~~ **PRM** for the conservation of plant genetic resources';
- (a) be listed in a register kept by those organisations and networks with appropriate related information of that PRM;
- (b) be conserved by those 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.

2. The 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.

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

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

### *Article 30*

#### **~~Seed exchanged in kind between farmers~~**

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

- ~~(a) are produced in the respective farmer's own premises;~~
- ~~(b) are derived from the respective farmer's own harvest; and~~

~~(c) are not subject to a service contract between the farmer and a professional operator for multiplication of seed.~~

~~(4) [...]~~

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

~~(a) they do not belong to a 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) 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 authorities, without using commercial intermediaries or public offer of marketing; and~~

~~(c) they are practically free from quality pests and any defects likely to impact their quality as seed.~~

~~3. Member States shall notify to the Commission and the other Member States the 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**

~~[...]~~

### *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 annually inform the other Member States and the Commission thereof.~~

### *Article 32*

#### **PRM of varieties under registration for which an application for registration has been submitted**

1. By way of derogation from Articles 5, **24 and 25**, 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 belonging to a variety,~~ **for which the competent authority has confirmed the successful submission of the application for variety registration in accordance with Article 58 not yet registered in a national variety register, referred to in Article 44 for the purpose of having sufficient stock available for further multiplication once the variety is registered**, if all of the following requirements are fulfilled:
  - (a) [...]
  - (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 **that** PRM thereafter; **and**
  - ~~(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 **limited** period and for small quantities per species as as determined by the competent authority. That authorisation shall automatically expire when a decision pursuant to Article 67(1) or (2) 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, ~~6a, 10-12, 15, 23 and 24~~ **25**, 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 ~~certified or standard seed or material belonging to a variety~~ **for which the competent authority has confirmed the successful submission of the application for variety registration in accordance with Article 58** ~~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) that PRM is only used ~~for tests or trials carried out~~ by professional operators on the premises of specifically designated **natural or legal** persons ~~in order to gather information on the cultivation or use of the variety concerned;~~
  - (b) the marketing is made by 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;
  - (c) there is no risk that such an authorisation will lead to insufficient identification or quality of the marketed PRM;
  - (ea) ~~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) [...]

~~(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 **limited** 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**(1) or (2)** 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 information about the following:

(a) [...]

- (b) **the species and** the breeder's reference ~~and species~~ of the variety indicated in the application for registration;
- (c) [...]
- (d) the Member State and authority before which the application **referred to in Article 58 has been submitted** 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 sites where production ~~will~~ **is to** take place, and in case of authorisation as referred to in paragraph 2, the sites where tests and trials ~~will~~ **are to** 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 **for standard seed and material**;
- (f) [...]

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

5. Pre-basic, basic and certified seed or material referred to in paragraph 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 **under registration** - stock for multiplication'.

~~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 s~~Standard seed or material referred to in paragraph 2 shall be accompanied by an operator's label as referred to in Article 16(2)(gb), with the indication 'Not yet registered - Variety **under registration** - 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

##### **Requirements for the Pproduction and marketing of commercial seed**

1. By way of derogation from Articles 5, **6, 6a, 7, 8**, 24 and 25, seed of the genera or species included in column 7 **[Y]** of Annex I may be produced and marketed as commercial seed if **the they comply with the** requirements referred to in **Annex III, with the exception of varietal aspects** 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~~ **by adding** genera ~~and~~ **or** species ~~to, in that Annex by adding or removing genera or species from,~~ column 7 **[Y]** of that Annex.

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

~~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 operator's label pursuant to Article 15, with the indication 'Commercial seed'.
- 5. The Commission may, by means of implementing acts, adopt rules concerning size, form, colour and content of the operator's label. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).**

### *Article 33*

#### **Authorisation in cases of temporary difficulties in the supply**

1. In order to remove temporary difficulties in the supply of pre-basic, basic, certified or standard seed or material that may occur in the Union due to adverse climatic conditions or other unforeseen circumstances, the Commission, by means of ~~an~~ implementing acts, may authorise one or more Member States, for a maximum period of 18 months, to allow the marketing of the categories of pre-basic, basic, certified or standard seed or material ~~or seed~~ that fulfils 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]~~;
- (b) complies with less stringent requirements than those ~~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 Articles 5, and point (b) shall apply by way of derogation from Articles 7(1) and (2) and Article 8(1) and (2).~~

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

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

2. PRM referred to in paragraph 1 shall be accompanied by an official label as referred to in Article 15(1a), ~~point (e)~~, or an operator's label as referred to in Article 16(2), ~~point (i)~~, that states that the PRM ~~in question~~ **concerned** belongs to a non-registered variety or fulfils less stringent ~~quality~~ requirements than the ones referred to in Article 7(1) and (2) and Article 8(1) and (2). ~~{In the case where these 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 acts, that the authorisation concerned has to be repealed or amended, if it concludes that is no longer necessary or proportionate to the objective of removing the temporary difficulties in the supply of the PRM concerned. ~~That~~ **Those** implementing acts 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 18 months and for a limited amount of quantities per genera or species as necessary for supply difficulties in question, the production and marketing of seed that fulfil germination rates reduced up to 15 percentage points compared to the ones set out pursuant to the implementing act referred to in Article 7(4). In this case, the official label as referred to in paragraph 2 shall indicate 'reduced germination rate' and details on the actual germination rate of the seed. The Member States ~~will~~ **shall** notify each authorisation to the Commission and the other Member States mentioning the species and the germination rate of the seed.
5. **The Commission may, by means of implementing acts, adopt rules concerning size, form, colour and content of the respective official label and operator's label as referred to in paragraphs 1 to 4. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).**

**Marketing of seed ~~not finally certified~~ on the basis of provisional analyses regarding as complying with germination rate requirements in case of rapid supply needs**

1. **For the purpose of making seed rapidly available on the market,** ~~Competent authorities may temporarily authorise professional operators for a maximum time period defined by the competent authority to market seed as pre-basic, basic or certified seeds, and mixtures thereof, before they seed or, if applicable, the seed components prior to mixing, have been certified to~~ **if that seed is found to** comply with **all of** the requirements referred to in Article 7. **For the purpose of such temporary authorisation, the fulfilment of the requirements concerning germination shall be demonstrated on the basis of a provisional analytical report,** ~~if it is necessary to make that seed rapidly available on the market. 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 taking into account that the professional operator has in place:
  - (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; **and**
  - (b) ~~procedures to ensure the fulfilment 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 professional operator shall keep the name and address of the first recipients of the seed and the results of the preliminary **provisional** analytical tests **report**, as referred to in paragraph 1, and make it available to the competent authority on request.

3. The seed referred to in paragraph 1 shall bear an official label as referred to in Article 15(1a), ~~point (e),~~ indicating ‘Germination **analysis not concluded** rate not finally certified’.

**Marketing of [PRM] which is not yet finally certified**

1. [PRM] which has been produced in the Union, **and for which compliance with the production requirements referred to in Article 7(1) and (2) has been confirmed** but has not yet been **finally** certified as pre-basic, basic or certified seed [or material] pursuant to Article 7, may be marketed with a reference to any of those categories, if all of the following requirements are fulfilled:
  - (a) prior to the harvesting, a field inspection has been carried out by the competent authority, or the professional operator under the official supervision of the competent authority, ~~and that inspection has confirmed compliance of that PRM with the production requirements referred to in Article 7(1), (2);~~
  - (b) it is in the process of being certified by the competent authority, or by the professional operator under the official supervision of the competent authority; and
  - (c) ~~the requirements set out in paragraphs 2 to 5 are fulfilled.~~
  - (d) it shall be accompanied by an official label as referred to in Article 15 with the indication ‘Seed[/Material] not finally certified’.**
2. PRM referred to in paragraph 1 may be marketed only by the professional operator who has produced that PRM to the professional operator who is to carry out the ~~final processing or~~ certification activities under **official** supervision pursuant to Article 10.
3. ~~PRM referred to in paragraph 1, shall be accompanied by an official label as referred to in Article 15(1a), point (d), with the indication ‘Seeds/Material not yet finally certified’.~~
4. If the competent authority **of the territory**, where the PRM has been harvested (‘competent authority of production’), and the competent authority **of the territory** where the PRM is certified pursuant to Article 7 (‘**certifying** competent authority ~~of certification~~’) are different, the competent authority of production shall provide the relevant information concerning the production and marketing of that PRM to the certifying competent authority.

~~5. 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 country 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;~~
- ~~(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 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).]~~

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

#### *Article 36*

### **More stringent production and marketing requirements**

- 1a. Member States may ~~impose~~ **adopt** within their own territory more stringent requirements for the production [and marketing] of PRM than those laid down in ~~the~~ **Articles 7 or 8 Annexes II or III**, **provided that those more stringent requirements correspond to market demand and specific production conditions in, and agro-climatic needs of, that Member State.**

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

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

1. [...]

2. [...]

3. [...]

4. [...]

### *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 constitutes a serious risk to human, animal or plant health, environment or cultivation of other species, and such risk has not been assessed pursuant to any other Union rules and cannot be contained satisfactorily by means of measures taken by the Member State concerned, the Commission shall take, without delay, by means of implementing acts, any appropriate and proportionate interim emergency measures. Such measures shall be limited in time. They may include provisions restricting or prohibiting the **production and** marketing of the PRM concerned. Depending on the gravity of the situation, appropriate conditions for the production and marketing of PRM shall be established.

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

On duly justified imperative grounds of urgency to address a serious risk to human health, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 76(3).

2. Where a Member State officially informs the Commission of the need to take emergency measures and the Commission has not acted in accordance with paragraph 1, that Member State may adopt the appropriate interim emergency measures. Those measures may include provisions restricting, prohibiting or laying down appropriate conditions for the production or marketing of PRM within the territory of that Member State, depending on the gravity of the situation. The Member State concerned shall immediately inform the other Member States and the Commission of the measures adopted, stating the grounds for its decision.
3. Within ~~30~~ **60** ~~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.

#### *Article 38*

#### **Temporary experiments to seek improved alternatives to provisions of this Regulation**

1. By way of derogation from Articles 2, 3, 5, 6, **6a**, 7, **and** 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~~ **provisions** compared to the ones set out in Articles 2, **3**, 5, 6, **6a**, 7, **and** 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, 6a, 7, or 8, ~~9 or 20~~.

## ANNEX V

### PRODUCTION AND MARKETING REQUIREMENTS FOR PRESERVATION MIXTURES AS REFERRED TO IN ARTICLE 22

#### **1. ~~Region of origin~~**

~~Competent authorities may designate specific 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 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:~~

- ~~(a) naturally occur in the region of origin;~~
- ~~(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 region of origin.~~

#### **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 method: whether the mixture is directly harvested or multiplied;~~
- ~~(c) components as species and, where relevant, subspecies of the preservation mixture; which are typical for the habitat type of the 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) [...]~~

~~(e) 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 region of origin of the mixture;~~

~~(h) [...]~~

~~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 region of origin.~~

~~Professional operators shall notify to the competent authority the quantity of seed of preservation mixtures, together with size and location of the 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 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;~~

~~(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 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, 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 region of origin, or is a directly harvested preservation mixtures purchased from another 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 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) ~~[...]~~
- (e) ~~the collected seed from which the preservation mixture is multiplied shall have been collected in its 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) [...]~~
- ~~(g) the germination rate of the components referred to in point (c) shall be sufficient for the purpose of recreating the habitat type of the 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 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).~~
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