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NOTE

From:	Presidency
On:	10 June 2025
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 the annex the Presidency revised text on Articles 1 to 40 and Annexes I, II, III, IIIa, V and VI of the above-mentioned proposal. The order of the articles has been changed in accordance with the Presidency's proposal.

Deletions are marked with ~~strikethrough~~ and additions are marked with **bold and underline** in comparison with the Belgian Presidency's revised text (document 11303/24), with the exception of Article 3(29), (29a), (29b) and (36) where the Hungarian Presidency's revised text (document 15979/1/24 REV 1) was used as a basis for the revision.

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)

CHAPTER I
GENERAL PROVISIONS

Article 1

Subject matter

This Regulation lays down rules for the production **with a view to marketing**, and **the** 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, identity and quality requirements, certification, labelling, packaging, imports, professional operators, and the registration of varieties.

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

Article 2

Scope and objectives

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

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

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 of PRM, and its availability ~~for~~ **to** all 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, amending Annex I, in order to adapt ~~it~~ **that Annex** to the developments of technical and scientific knowledge, and the economic data concerning production and marketing of genera and species, by adding genera and species to or removing them from that Annex for one or more uses.

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

- (a) represent a significant area of production of PRM ~~for~~ **and** the respective crop~~],~~ and a significant value of marketed PRM ~~for~~ **and** 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 marketed in at least two Member States.

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

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

4. This Regulation does not apply to:

- (a) ~~propagating material~~ **PRM** of **species listed in Annex I, intended for** ornamental plants **purposes** subject to **in accordance with** Directive 98/56/EC, with the exception of turf grass seed;
- (b) forest reproductive material (FRM) subject to Regulation (EU) .../... of the European Parliament and of the Council¹;
- (c) PRM solely intended for export to third countries, under the condition that it is identified as such;
- (d) PRM transferred in any way, whether free of charge or not, between non-professional users for their own private use and outside their ~~commercial~~ **professional** activities;
- (e) PRM used solely for **inspection**, sampling, ~~official testing~~, **for the purpose of this Regulation**, or testing, **officially or** under official supervision, breeding, ~~official inspections~~, exhibitions or ~~research for scientific purposes~~, under the condition **that** 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 **processing** **including** cleaning, disinfection, treatment, packaging, **as well as** ~~labelling~~, transport,

¹ 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.

~~processing or~~ and storage, provided that the provider of services does not acquire title to that PRM and its traceability is ensured;

- (g) PRM supplied under certain conditions to providers of services for the production of certain agricultural raw materials, intended for industrial purposes, or PRM produced for that purpose, provided that:
 - (i) the provider of services does not acquire title to either that PRM or the product of the harvest;
 - (ii) the traceability of that PRM is ensured; and
 - (iii) the supplier of that PRM has provided the competent authority with a copy of the relevant parts of the contract made with the provider of services including the standards and conditions met by the PRM provided;
- (h) PRM used **by gene banks** for the conservation of plant genetic resources ~~in gene banks~~;
- [(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;]**
- j) organic heterogenous material produced in accordance with Regulation (EU) 2018/848.**

Article 3

Definitions

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

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

- (a) **the production** ~~the propagation or the multiplication~~ of entire plants **or parts of plants**; or
- (b) the production of fruits, vegetables or other crops;
- (2) ‘professional operator’ means any **natural or legal** person, other than a competent authority, governed by public or private law, involved professionally in and legally responsible for one or more of the following activities in the Union concerning PRM:
 - (a) production with a view to marketing ~~[breeding]~~;
 - (b) marketing;
 - (c) maintenance of varieties ~~registered in accordance with~~ **pursuant to** ~~Article 47~~ **72** ~~(1)~~ ~~(a)-(i)~~;
 - (d) [...]
 - (e) ~~laboratory analysis, field inspections,~~ **sampling, laboratory testing,** storage, ~~drying,~~ processing, ~~treating,~~ packaging, sealing, **or** labelling ~~sampling or testing~~;
- (3) ‘marketing’ means the following actions in relation to PRM: sale, holding **with a view to sale**, transfer for free, or offering for sale including online, ~~or any other way of transferring 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 **of a vine or fruit species** 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 selections **PRM**’ means ~~{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;}~~ **material belonging to a group of several distinct different individual plant progenies derived from different genotypes, each of which is true to the description of the variety to which it belongs;**
- (8) [...]
- (9) ‘competent authority’ means the central or regional authority of a Member State, or, where applicable, the corresponding authority of a third country, responsible for the organisation of official controls, registration, certification and other official activities concerning the production and marketing of PRM, or any other authority to which 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. [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~~ **new local 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 ensuring varietal purity and identity with the aim to ensure that **the variety remains unchanged in** the expression of **its relevant** 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.;

- (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 generations preceeding the generation of the basic seed, is intended for the production ~~and certification~~ of pre-basic, basic or certified seed, and has been found by means of official certification, or certification under official supervision, to satisfy the respective conditions laid down in 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 Annex II;
- (16) 'certified seed' means seed that has been produced from pre-basic, basic or preceding generations of certified seed, **is intended for the production of further generations of certified seed or for any other purpose cultivation,** and which has been found by means of official certification, or certification under official supervision, to satisfy the respective conditions laid down in Annex II;
- (17) 'standard seed' means seed, other than pre-basic, basic or certified seed, ~~and~~ **that** satisfies the respective conditions laid down in 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) ~~{ 'm~~**M**~~other p~~**l**~~ant' }~~ means an identified plant intended for propagation **the production of PRM;**

- (17c) {~~p~~**P**re-basic mother plant'} means a mother plant intended for the production of seed or material of the pre-basic category seed or material or lower categories;-
- (17d) {~~b~~**B**asic mother plant'} means a mother plant intended for the production of seed or material of the basic category seed or material or lower categories;-
- (17e) {~~c~~**C**ertified mother plant'} means a mother plant intended for the production of seed or material of the certified category seed or material or lower categories;-
- (17f) {~~S~~**S**tandard 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 generations preceding 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 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 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],~~ is intended for the production of further generations of certified material or for any other

purposes cultivation, and has been found by means of official certification, or certification under official supervision, to satisfy the respective conditions laid down in 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 satisfies the respective conditions laid down in 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;
- (23) ‘certification under official supervision’ means attestation by **an** specifically authorised professional operator that pre-basic, basic or certified seed or material complies with the applicable **respective** requirements, and where at least one ~~or more~~ of the relevant inspections, sampling, testing or label printing and affixing ~~have~~ **has** been carried out by that professional operator, under the official supervision of the competent authority;
- (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 ⁽²⁾, excluding organisms obtained through the techniques of genetic modification listed in Annex I B to Directive 2001/18/EC;
- (25a) ‘NGT plant’ **means NGT plant** as defined in Article 3(3) of Regulation (EU) (...)
- (26) ‘lot’ means a ~~unit~~ **defined quantity** of PRM, identifiable by its **homogeneous constituents** ~~homogeneity of composition and origin or origins, in the case of seed mixtures~~;

² Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

(27) ~~‘**organic** 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; **and**~~

~~**(e) has been produced in accordance with Regulation (EU) 2018/848;**~~

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

[(29) ‘conservation variety’ means ~~either~~ **a variety that:**

(a) ~~a landrace or variety that is:~~

(i) **is** traditionally grown under specific local conditions in the Union, and adapted to those conditions; and

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

~~(iii) has an officially recognised description.~~

(b) **was deleted or expired from the Union variety register for at least two years and is adapted to specific local conditions.**

(29a) ‘commonly known fruit variety’ means a variety that is commonly known within the meaning of Directive 2008/90/EC and was already is still marketed before at the entry into force date of application of this Regulation, pursuant to Directive 2008/90/EC, in the territory of a Member State;

[(29b) b) ‘a **new** locally newly developed variety (**amateur variety**)’ **means a variety** that is:

(i) **a variety of fruit and vegetable species;**

- (ii) newly, locally derived bred ~~from participatory on-farm selection~~, and is ~~developed for~~ adapted to local agro-climatic conditions and farming systems;
- (iii) characterised by reduced uniformity due to a certain level of genetic and phenotypic diversity between individual reproductive units, except in the case of species that are vegetatively propagated; and
- (iv) ~~has an officially recognised description.~~
- (v) is intended for non-professional users.

(c) ~~a reregistered variety for conservation purposes that:~~

- (i) ~~was deleted or expired from the Union variety register for at least two years;~~
~~and~~
- (ii) ~~has an official description.]~~

(30) 'quality pests' means pests fulfilling all of the following criteria:

- (a) they are ~~not~~ neither Union quarantine pests, protected zone quarantine pests, nor regulated non-quarantine pests ('RNQPs') within the meaning of Regulation (EU) 2016/2031, nor pests subject to the measures adopted pursuant to Article 30(1) of that Regulation;
- (b) they occur during PRM production or ~~storage~~ ~~[post-harvesting activities]~~; and
- (c) their presence has an unacceptable impact on the quality of the PRM, and an unacceptable economic impact as regards the use of that PRM in the Union;

(31) 'practically free from quality pests' means that the extent to which ~~a situation where the presence of quality pests~~ are present on the respective PRM is so sufficiently low to ensure ~~that those pests do not affect adversely the~~ acceptable quality and usefulness of that PRM;

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

[(32a) 'true potato seed' means seed of *Solanum tuberosum* L.]

(33) 'farmer' means any natural or legal person who exercises an agricultural activity professionally ~~acquiring or using PRM for the professional production of food, feed or for industrial processing;~~

- (34) ‘off-type’ means, a plant that can be clearly distinguished from the variety ~~or species~~ to which it is supposed to belong pursuant to this Regulation in the expression of any **relevant** characteristic ~~included in its variety description~~, taking into consideration the particular features of its propagation;
- (35) [...]
- ~~[(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~~ **an organisation officially recognised in accordance with national rules, with an objective, set out in the organisation’s articles of association or other equivalent document, of conserving plant genetic resources for the continued public availability of those resources for research and breeding;**~~]~~
- (35b) ‘seed as grown’ means unprocessed seed **of vegetable species**, produced in a third country ~~or in the Union~~, **and imported into the Union for the purpose of being processed and marketed** ~~intended to be processed in the Union in order to comply~~ **in accordance** with the ~~requirements of this Regulation~~;
- (36) ‘standard sample’ means a sample of PRM of a variety that ~~is kept by the competent authority~~, represents that variety, and is used **by the competent authority** as reference to check the varietal identity, purity and maintenance ~~of~~ **for** the purpose of this Regulation.

Article 4

Compliance with Regulation (EU) 2016/2031

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

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

CHAPTER II

REQUIREMENTS CONCERNING VARIETIES, CATEGORIES OF PRM, LABELLING, AUTHORISATIONS, HANDLING, IMPORTS AND DEROGATIONS

SECTION 1

General requirements for the production and marketing of PRM

Article 5

Belonging to a registered variety

1. Only PRM belonging to a variety registered in a national variety register referred to in Article 44 may be produced and marketed within the Union.
- 1a. By way of derogation from paragraph 1, PRM of all the following cases may be produced and marketed within the Union without belonging to a registered variety registered in accordance with Article 44:
 - (a) {as rootstocks for fruit plants, provided that the material is, if produced and marketed with a reference, contained in an appropriate labelling, to the species to which they belong;}
 - (b) [...]
 - [(c) as PRM intended for marketed to non-professional users in accordance with Article 28;]
 - [(d) as PRM produced and marketed by conservation organisations, and networks for the conservation of plant genetic resources in accordance with Article 29;]
 - [(e) as seed exchanged in kind between farmers in accordance with Article 30;]
 - (f) [...]
 - (g) [...]

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

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

~~{(hb) which is subject to an application for registration in accordance with the derogation set out in Article 32;}~~

1b. **By way of derogation from paragraph 1,** PRM produced and marketed in the following cases shall not ~~be registered~~ **belong** as **to** a **registered** 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 **under registration** 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 **seed** ~~material~~ or **material** seed;

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

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

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

Where a reference is made in this Regulation to categories concerning PRM, that determination shall be based on the ranking **of** the order of points (a) to (d), with point (a) indicating the highest rank and point (d) the lowest one.

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

~~(a) — marketing of PRM of as [organic] heterogeneous material in accordance with Article 27;~~

~~[(b) marketing to a of PRM intended for non-professional user in accordance with Article 28;]~~

~~[(c) — marketing PRM produced and marketed by conservation organisations and networks as referred in accordance with to in Article 29;]~~

~~[(d) — as seed exchanged in kind between farmers in accordance with Article 30;]~~

~~(e) [...]~~

~~(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' in accordance with Article 30a;~~

~~[(f) PRM as commercial seed in accordance with Article 32a;]~~

~~[(g) preservation mixtures produced in accordance with Article 22.]~~

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 ~~5-2~~ ~~[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~~ ~~2~~ ~~[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~~ ~~2~~ ~~[X]~~ of Annex I if both of the following conditions are fulfilled:

- (a) there is a need for higher ~~eg~~ 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 ~~2~~ **IX** of Annex I, if one of the conditions set out in the second subparagraph, point (b), points (i) and (ii), is not fulfilled.

SECTION 2

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

Article 7

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

1. Pre-basic, basic and certified seed may only be produced and marketed within the Union, if all the following conditions are fulfilled:
 - (a) ~~the pre-basic, basic or certified seed~~ **it** is practically free from quality pests;
 - (b) it is:
 - (i) marketed following official certification by the competent authorities, or certification by the professional operator under official supervision;
 - (c) ~~ii~~ **it is** produced and marketed in accordance with the requirements set out in Part A and Aa of Annex II, and its compliance with those requirements is attested by the official label referred to in Article 15(1).

2. Pre-basic, basic and certified material may only be produced and marketed within the Union, if all the following conditions are fulfilled:
- (a) ~~the pre-basic, basic or certified material~~ **it** is practically free from quality pests;
 - (b) it is:
 - (i) ~~produced~~ **marketed** following official certification by the competent authorities, or certification by the professional operator under official supervision;
 - (c ii) **it is** 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 ~~that~~ Annex II to the **scientific and technical** developments of international technical and scientific **applicable international** standards, and may **shall** concern the requirements for **one or more of** the following **elements**:}
- (a) **production** (sowing, and planting **and field cultivation**) and ~~production~~ 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;
 - (d) **production** (sowing, and planting **and field cultivation**) and ~~production~~ 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 and polyclonal PRM;
 - (ga) marketing of pre-basic, basic and certified material of **clones**, selected clones and polyclonal mixtures **PRM**;

- (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 shall adopt implementing acts specifying the production and marketing requirements referred to in ~~Part A to E~~ of Annex II for certain genera, species or categories of PRM, and, where appropriate, for certain grades, classes, generations or other subdivisions of the category concerned. Those requirements ~~may~~ **shall** concern one or more of the following elements **for all or certain species:**

- (a) **specific rules for one or more of the** intended uses of the genera, species or the types of the PRM concerned;
- (b) production methods of PRM, including sexual and asexual reproduction and *in vitro* propagation;
- (c) conditions for sowing or planting;
- (ca) previous cropping and isolation distances;
- (d) {open field or ~~in~~ greenhouse cultivation};

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

- (e) {harvesting and post-harvesting};
- (ea) germination rates, purity and content of other species ~~among which *Avena fatua*,~~ moisture, vigour, presence of soil or extraneous matter;
- (eb) **methods of** certification ~~methods~~ of PRM, including the application of bio-molecular or other technical methods, as well as their approval and use, and the listing of approved methods in the Union;
- (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;
- (ed) conditions for the production of (~~true~~) seeds-from fruit plants, ~~from seed~~ potatoes {for 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). They may be amended in order to adapt them to the scientific and technical developments of the relevant and applicable international technical and scientific standards. Those implementing acts may additionally set out specify more stringent production and marketing requirements to be applicable in certain parts of the Union territory, if so required by the agro-climatic conditions, risk of spreading of noxious weeds, or other special conditions and needs of certain areas.

The first such Implementing acts for each of the requirements listed above 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;
 - (c ii) it is produced and marketed in accordance with the requirements set out in Part A and Aa of Annex III, and its compliance with those requirements is attested by the operator's label referred to in Article 16.
2. Standard material may only be produced and marketed within the Union, if all the following conditions are fulfilled:
 - (a) it is practically free from quality pests;
 - (b) it is produced and marketed:

- (i) under the responsibility of the professional operator ~~with the exception of vine that may be produced or marketed as standard material only following examination by the competent authority;~~
- (c) ~~it is produced and marketed~~ 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. [...]

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

- (a) ~~requirements for production (sowing, and planting, and field cultivation) and production of standard seeds;~~
- (b) **harvesting and post-harvesting of standard seed;**
- (c) ~~requirements for marketing of standard seeds;~~
- (d) ~~requirements for production (sowing, and planting, and field cultivation) and production 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 and polyclonal PRM of standard material category;~~
- (ga) ~~requirements for marketing of clones, selected clones and polyclonal PRM of standard material category;~~
- (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 adopt implementing acts specifying the production and marketing requirements referred to in ~~Part A to E~~ of Annex III for certain genera or species of standard ~~seed or material~~ **PRM**. Those requirements shall concern one or more of the following elements **for all or certain species**:

- (a) **specific rules for one or more of the** intended uses of the genera, species or the types of the PRM concerned;
- (b) production methods of PRM, including sexual and asexual reproduction and *in vitro* propagation;
- (c) conditions for sowing or planting;
- (ca) previous cropping and isolation distances;
- (d) **open** field or greenhouse cultivation;

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

- (e) harvesting and post-harvesting;
- (f) germination rates, purity and content of other species ~~among which *Avena fatua*~~, moisture, vigour, presence of soil or extraneous matter;
- (g) the application of bio-molecular or other technical methods, as well as their approval and use, and the listing of approved methods in the Union;
- (h) the conditions for rootstocks and other parts of plants of genera or species other than those listed in Annex I, or their hybrids, if propagating material of the genus or species listed in Annex I or their hybrids is grafted onto them;
- (i) conditions for the production of ~~(true)~~ seeds from fruit plants, ~~from seed~~ potatoes ~~for 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). **They may be amended** in order to adapt **them** to the **scientific and technical** developments of the relevant **and applicable** international ~~technical and scientific~~ standards. **Those**

implementing acts may additionally set out specify more stringent production and marketing requirements to be applicable in certain parts of the Union territory, if so required by the agro-climatic conditions, risk of spreading of noxious weeds, or other special conditions and needs of certain areas.

The first such Implementing acts for each of the requirements listed above shall be adopted not later than [36 months from the date of the entry into force of this Regulation/any other date].

Article 9

~~Production, marketing and registration of selected clones and polyclonal PRM~~

1. ~~In addition to the requirements referred to in Articles 4 to 43, pre-basic, basic, certified and standard material of selected clones 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. ~~Selected clones 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 selected clone and polyclonal PRM, as set out in Annex IIIa.~~

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

SECTION 2a

Specific requirements for control plot tests for seed

Article 9a (former Article 24)

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~~ **with** a reference **standard** sample ~~of the variety~~ and a plot sown ~~from~~ **with** a sample of seed ~~representative of the seed~~ **the** 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 **or category** 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 **no later than** 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 (~~geb~~), 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.~~

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~~ **with** a reference **standard** sample of the variety and a plot sown ~~from~~ **with** 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 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, **if feasible,** 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~~ **following elements:-**

- (a) criteria for the conduct of the risk analysis referred to in paragraph 2;**
- (b) the testing procedure;**
- (c) the evaluation of the results of the tests.**

SECTION 3

Authorisation of professional operators and official supervision ~~of~~ **by** the competent authorities

Article 10

Authorisation of professional operators to carry out certification under official supervision

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

In such a case, a professional operator may, upon application, be authorised by the
~~c~~Competent authorities may decide that professional operators, upon application to the competent authority, may be authorised to perform all or certain activities required for **the** certification of PRM, ~~except for control plot testing as referred to in Article 24 9a,~~ under official supervision ~~of~~ **by** the competent authority for pre-basic, basic and certified material or seeds, and to print and affix an official label ~~for~~ **on** them.

~~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, I~~in order to be granted such an authorisation and depending on the activities

to be authorised for, **the professional operator shall** comply, **where so applicable for the authorised activities**, with **all of** the following conditions:

- (a) possess the necessary knowledge for complying with the requirements referred to in Article 7;
- (b) be qualified to carry out the inspections referred to in Annex II **in accordance with international standards** or employ personnel qualified for such inspections;
- (c) employ qualified personnel for carrying out the sampling referred to in Annex II, or conclude contracts with other professional operators employing qualified personnel for those activities;
- (d) employ specialised personnel and **possess the necessary** equipment to carry out the testing referred to in Annex II, or use laboratories performing according to **International Seed Testing Association (ISTA)** rules or other international standards where applicable, employing qualified personnel for those activities;
- (e) have identified, and have the capability to monitor, the critical points of the production process which may influence the quality and identity of the PRM, and keep records of the results of that monitoring;
- (f) have in place systems to ensure the fulfilment of the requirements concerning the identification of lots pursuant to Article 13;
- (g) have in place systems to ensure the fulfilment of the traceability requirements set out in Article 42.

2. The Commission is empowered to adopt delegated acts in accordance with Article 75, supplementing paragraph 1 ~~by setting out criteria to be fulfilled by the professional operators in order for them to comply with the conditions set out in~~ **as regards the following elements:**

~~[(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), **or if the PRM produced or marketed by that operator has been repeatedly found to be in non compliance with the provisions of the Regulation,** the competent authority shall request that operator to take corrective actions within a specified period of time.

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

Article 12

Official supervision by the competent authorities

1. For the purposes of the certification activities under official supervision, the competent authorities shall conduct 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, **and the adverse consequences of that non-compliance.**

The competent authorities shall also organise trainings and examinations **for** 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 **PRM** with the requirements referred to in Article 7.

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

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

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

- (a) the risk criteria as referred to in paragraph 1 and minimum portion of the crops and the lots of PRM to be subject to **field** inspections, sampling and testing as referred to in paragraph 2;
- (b) [...]
- (c) use of 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 referred to in this Article due to the use of those quality assurance systems.

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

SECTION 4

HANDLING AND LABELLING REQUIREMENTS

Article 13

Lots

- 1. PRM shall be **produced and** marketed **with reference to a** in lots. ~~The content of each lot shall be sufficiently homogeneous and~~ **It shall be** identifiable by its **their** unique lot reference number ensuring traceability.
- 2. ~~During processing, packaging, storage, or at delivery, If~~ Lots of PRM may be merged into a new lot only if they belong to the same variety. 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~~ **17a**.

Where lots consisting of different ~~certification~~ categories are merged, the new lot shall belong to the category of the component of the lowest category. In the case of pre-basic, basic or ~~certified~~ seed or material, the merging operation may only be undertaken ~~in a facility and by persons authorised in accordance with Article 10 by the competent authority for this specific purpose~~ **the professional operator under the official supervision of the competent authority.**

3. ~~During processing, packaging, storage, or at delivery, if~~ 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~~ **17a**.
4. [...]
5. The Commission shall, by means of implementing acts, adopt specific requirements for all or certain species of PRM, concerning the maximum size of lots, their identification, ~~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 **as individual plants or in sealed** packages, bundles or containers, **or as individual plants** bearing a sealing device and a label. **However,** 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 sealed in such a way, that they cannot be opened without destroying that seal or leaving traces demonstrating that the package, bundle or container has been opened. The effectiveness of the 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 sealing cannot be reused.

3. In the case of pre-basic, basic or certified seed and material, those packages, bundles and containers shall be 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 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 re-sealed, the date of resealing, ~~the date of production~~ and the details of the responsible competent authority shall be stated on the label referred to in Article 15.
4. 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 by ~~persons authorised~~ **the professional operator under the official supervision** by **of** the competent authority ~~for this specific purpose in accordance with Article 10.~~
5. ~~{By way of derogation from paragraph 1,~~ **certified** ~~seed 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 keep records of such activity and of the lot from which such seed ~~or seed potatoes~~ come. Those records shall be made available to the competent authority on request.

Where seed is loaded directly into the farmer's machinery or trailer **marketed in bulk to a farmer**, the professional operator ~~and the farmer concerned~~ shall ensure traceability of that seed by issuing and retaining documents indicating the species and variety, quantity, the ~~time~~ **date** of transfer and lot ~~identification~~ **reference number**.~~}~~

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

SECTION 5

LABELLING REQUIREMENTS

Article 15

Official label for pre-basic, basic and certified PRM

1. Pre-basic, basic and certified **seed and** material ~~and 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 **unique** 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~~ **official** labels **with information in a digital form**;
 - (b) the establishment of a centralised platform that connects the Member States and the Commission to facilitate the processing of, access to, and use of 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 **in digital form** 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 **seed and** material ~~and seed~~, imported from third countries pursuant to Article 39, ~~shall~~ **may** be marketed in the Union with the respective OECD **Seed Schemes** label **(‘OECD label’)** that was accompanying them at import, or with ~~another~~ **an** official label **issued by the competent authority of the third country for seed of species for which there is no OECD Seed Schemes available** ~~if so provided for by applicable international standards~~ **or for PRM other than seed.**

Article 16

Operator’s label for standard PRM

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~~~~that 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, **or printed indelibly on the 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 **digital** recording and collection of ~~digital~~ data on the activities carried out by professional operators in order to issue ~~the electronic~~ **operator's** labels **with information in a digital form**;
- (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 **in a digital form** 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 **newly issued**, 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 paragraphs 3 and 4, and other than advertising material, placed in an area of a size not larger than 20 % of the total area of the official label, bearing the title 'Non official information'. Such information shall be in letters not larger than those used for the content of the official label as referred to in paragraph 4.

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

(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 17a (former Article 23)

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, t~~The professional operator carrying out re-packaging, re-sealing and re-labelling of a seed lots of PRM, lots or part of them it, 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, and 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.~~

In the case of pre-basic, basic and certified seed and material, 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).

- 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. In addition to the provision of Article 42, ~~T~~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 18

~~Reference to lots~~

[...]

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~~ Seed 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) and complying prior to mixing with the respective requirements of Articles 7 or 8** ~~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, or consist of, 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, upon request, 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 to be part of those mixtures.

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 be eligible for 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.~~

Those 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; and**
- (d) denomination of mixtures.**

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

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

Article 22

Preservation mixtures

1. By way of derogation from 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 mixtures 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 by direct collection** ~~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~~ **by multiplication;**
 - (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; and**
 - (h) conditions for the production and marketing of seed intended for mixtures.**

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

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

SECTION 7

DEROGATIONS FROM THE REQUIREMENTS OF ARTICLES 5 TO ~~25~~ 22

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 **only** be produced and marketed in the Union as standard seed or material, if it complies with all the requirements concerning standard seed and material for the respective species, as referred to in Article 8.
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 **and mixtures of seed**, 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 **complying with Article 54 and** [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"~~³, **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**;~~
- (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;~~
- (ea) ~~to be kept separate and identifiable from the PRM not intended for non-professional user during the production and marketing process; and~~

³ Regulation (EU) .../... of the European Parliament and of the Council (OJ..., p....).
 + OJ: Please insert in the text the number of the Regulation contained in document (... (COD)) and insert the number, date, title and OJ reference of that Regulation in the footnote.

- (d) ~~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, **as well as the quantities produced and marketed,** 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, colour and content of the operator's label.**

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

Article 29

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

1. ~~By way of derogation from Articles 5 to 15 and 19 to 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 ~~carryies~~ **carry** 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~~

~~(e) — 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 30a

PRM of a generation prior to pre-basic category

1. By way of derogation from Articles 6 to 22, PRM of a generation prior to pre-basic seed or material may be produced and marketed for the purpose of its multiplication for the production of pre-basic seed or material, if that PRM fulfils all of the following conditions:
 - a) the marketing is made directly from the professional operator responsible for the maintenance of the variety to the professional operator carrying out the production of pre-basic seed or material, with no further marketing of that PRM thereafter; and
 - b) it is accompanied by an operator's label bearing the denomination of the variety and the indication 'Seed prior to pre-basic seed' or 'Material prior to pre-basic material'.
2. The Commission may, by means of implementing acts, adopt rules concerning size, form, colour and content of the operator's label as referred to in paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).

Article 31

Breeder's seed

[...]

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

- 1a. By way of derogation from Articles 5, 9a and 9b, and pursuant to the paragraphs below, a competent authority may authorise professional operators to produce and market PRM of a variety for which the competent authority has confirmed the successful submission of the application for variety registration in accordance with Article 58 for the following purposes:**
- a) multiplication of stocks in accordance with paragraph 1;**
 - b) tests and trials in accordance with paragraph 2;**
 - [c) production and marketing of fruit plants and vine in accordance with paragraph 2a.]**

1. By way of derogation from Articles 5, ~~24 9a and 25 9b~~, 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 **PRM fulfilling the respective requirements, other than varietal identity and varietal purity, of Articles 7 or 8 for the categories of** ~~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 **limited** 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 9b**, 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 **PRM fulfilling the respective requirements, other than varietal identity and varietal purity, of Article 8 for** ~~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~~ **for which an application for variety registration has been accepted pursuant to Article 58** before the PRM has been ~~certified~~ **confirmed** 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 **or rejected.**]

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),~~ **in both cases** with the indication 'Not yet registered ~~v~~ 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 ~~v~~ 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.~~

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

Requirements for the Production and marketing of commercial seed

1. By way of derogation from Articles 5, **6, 6a, 7, 8,** 24 **9a** and **25-9b,** seed of the genera or species included in column **7-3 IV** 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 **7-3 IV** 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 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 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 **other than those concerning germination. 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 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 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 [for 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 **either** to the professional operator who is to carry out the ~~final processing or~~ certification activities under **official** supervision pursuant to Article 10 **or to the professional operator whose PRM is to be officially certified.**
3. ~~PRM referred to in paragraph 1, shall be accompanied by 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).

More stringent production and marketing requirements

- 1a. **Subject to a prior authorisation by the Commission as referred to in paragraph 1,** 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 or agro-climatic needs of, that Member State.**

Those more stringent measures shall ~~apply to PRM originating from other Member States or~~ not impose, or result in, any prohibitions or restrictions on the movement of products **originating from, or destined to, other** ~~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. In order to ensure uniform conditions for the implementation of paragraph 1a, the Commission may, by means of implementing acts, authorise a Member State to impose such more stringent requirements.**

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.

Article 36a

[Derogation from the production rules for certain species]

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

- a) the cultivation of that species in the requesting Member State is insignificant, in terms of economic value and area of cultivation, due to the agro-climatic conditions in that Member State; and
- b) the certification and control of the production of PRM of that species would impose a disproportionate administrative burden on the competent authority of that Member State.

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

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

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

Article 37

Emergency measures

1. Where there are detailed reasons based on new or additional scientific knowledge for considering that the production or marketing of PRM 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~~, 21 and 32a, the Commission may, by means of implementing acts, decide on the organisation of temporary experiments to seek improved alternatives to provisions of this Regulation concerning the genera and species it applies to, the requirements for belonging to a registered variety, their mixtures, the production and marketing requirements for pre-basic, basic, certified and standard material or seed, and the obligation to belong to pre-basic, basic and certified material or seed.

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

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.
- 1aa.** ~~However, for PRM~~ **belonging to preservation mixtures as referred to in Article 22 and PRM** subject to the derogations of Articles ~~22, and 26, 27, [28], 29, [30], [30a], [32], 32a and 34~~ no such import shall **not** be **imported** allowed, and no such equivalence shall be recognised pursuant to paragraph 2 **of this Article**.
- 1a. By way of derogation from paragraph 1, seed as grown of vegetable species **as referred to in column X 1 of Annex I** may be imported into the Union for the purpose of being processed and marketed as standard seed without the need to comply with **the** requirements ~~as~~ referred to in that paragraph. Such seed shall comply with the following conditions:
 - (a) ~~it shall be~~ **is** accompanied by a label pursuant to Article 40(~~2aa~~), ~~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~~ **it is marketed only up to the place(s) of processing without further marketing;**
 - (c) the import of that seed has been notified in advance by the professional operator ~~in the EU~~ to the competent authority.

[The EU professional operator responsible for the imported PRM shall provide upon request of the competent authority, information on the conditions under which the multiplication took place, the place of processing, and the varieties to which the seed belongs.]

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 regions of a third country, fulfils requirements equivalent to those applicable to PRM produced and marketed in the Union, on the basis of all of the following:
- (a) a thorough examination of the information and data provided by the third country concerned;
 - (b) an audit carried out by the Commission in the third country concerned, showing that the PRM concerned fulfils requirements equivalent to those applicable to PRM produced and marketed in the Union {when it concerns a first request to be recognised as equivalent}, and where that audit has been considered necessary by the Commission in other cases; and
 - (c) in the case of seeds belonging to a species for which OECD Seed Schemes exist, the fact that 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, implements the rules of the Association of Official Seed Analysts (AOSA) or other internationally recognised organisations.
- 2a. For the purpose of paragraph 2, the Commission shall examine:
- (a) the third country's legislation on the species concerned;
 - (b) the structure of the competent authorities of the third country and its control services, the powers available to them, the guarantees that can be provided with regard to the application and enforcement of the legislation of the third country applicable to the sector concerned, and, where applicable, the reliability of the official certification procedures;
 - (c) the performance by the competent authorities of the third country of adequate official controls concerning the identification and quality of the PRM of the species concerned;
 - (d) the guarantees given by the third country that:

- (i) the conditions applied to the production sites from which PRM are exported to the Union comply with requirements that are equivalent to those referred to in this Article; and
- (ii) those production sites are subject to regular and effective controls by the competent authorities of the third country.

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

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

3. The implementing acts referred to in paragraph 2 may provide for one or more of the following elements, as appropriate for the respective PRM:
 - (a) conditions relating to inspections in the production site, carried out in third countries;
 - (b) in the case of seeds, conditions relating to the issuance by the third country of a certificate provided by the ISTA, or, where applicable, the AOSA or other internationally recognised organisations;
 - (c) conditions relating to ~~PRM~~ subject to the derogations referred to in Articles ~~34~~—35;
 - (d) conditions relating to packaging, sealing and labelling of PRM;
 - (e) conditions relating to the production, identity and marketing of PRM, in addition to the ones provided for by the third country's legislation, if 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 of the PRM imported from third countries

1. Pre-basic, basic and certified seeds referred to in Article 39 from third countries may only be imported, if ~~they~~ **it** bears ~~an OECD Seed Schemes label~~ (‘OECD 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 **from third countries** may only be imported ~~into the Union from third countries~~ if it bears an official label issued by the competent authority of the third country concerned.
- ~~1b. The official labels, including the OECD label, referred to in paragraph 1 and 1a, shall at least contain 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;~~
 - ~~(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;~~
 - ~~(f) in the case of seeds, the declared net or gross weight of the seeds or, if applicable, the declared number of 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) — [...]~~

2. Standard seed and material referred to in Article 39 **from third countries** may only be imported ~~into the Union from third countries~~, if it **bears,** ~~is accompanied by an **where applicable, an** OECD label **issued by a professional operator** 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;~~

~~(d) — the third country or, where applicable region, of production;~~

~~(e) — where applicable, the last third country from which the PRM is imported;~~

~~(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) — [...]~~

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

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

2a. The Commission shall by means of ~~an~~ implementing acts specify the format, colour, language, size and ~~additional~~ content of the ~~official labels~~ issued by the competent authority of the third country in case there is no OECD Seed schemes available referred to in

paragraphs 1, **1a**, the official label referred to in paragraph 1a, and of the operator's labels referred to in paragraph 2 **and 2aa**.

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

Article 40a

[Information provided for PRM imported from third countries]

3. ~~The professional operator responsible for the imported PRM~~ **may only by imported into the Union after the electronic notification is delivered**, ~~shall inform~~ **by the professional operator** 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. **The rules of the delegated act referred to in Article 45(4) of Regulation (EU) 2017/625 shall apply accordingly.**
- 3a. In addition to the information pursuant to paragraph 3, the professional operator responsible for the imported PRM shall immediately and directly inform the competent authority of the place of destination as referred to in Article 44(3), point (e), of Regulation (EU) 2017/625 about the arrival of the consignment.**
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.]~~

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~~ies~~ 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.~~

ANNEX I

GENERA AND SPECIES, AS REFERRED TO IN ARTICLES 2, ~~6a 20 (1), 27~~ AND ~~32a 32b~~

1	2	3
Intended use of PRM belonging to the genera and species	Genera or species may be produced and marketed only as category: pre-basic, basic or certified PRM in accordance with Article 6a*	Genera or species may be produced and marketed as commercial seed in accordance with Article 32a
Agricultural plants		
<i>Agrostis canina</i> L.	1	+
<i>Agrostis capillaris</i> L.	1	+
<i>Agrostis gigantea</i> Roth	1	+
<i>Agrostis stolonifera</i> L.	1	+
<i>Alopecurus pratensis</i> L.	1	+
<i>Arachis hypogaea</i> L.	<u>1</u>	1
<i>Arrhenatherum elatius</i> (L.) P. Beauv. ex J. Presl & C. Presl	1	+

1	2	3
Intended use of PRM belonging to the genera and species	Genera or species may be produced and marketed only as category: pre-basic, basic or certified PRM in accordance with Article 6a*	Genera or species may be produced and marketed as commercial seed in accordance with Article 32a
<i>Avena nuda</i> L.	1	
<i>Avena sativa</i> L. (includes <i>A. byzantina</i> K. Koch)	1	
<i>Avena strigosa</i> Schreb.	1	
<i>Beta vulgaris</i> L. partim	1	
{ <i>Biserrula pelecinus</i> L.}	1	1
<i>Brachypodium</i> P. Beauv.	±	±
<i>Brassica juncea</i> (L.) Czern.	1	±
<i>Brassica napus</i> L. var. <i>napobrassica</i> (L.) Rchb.	1	
<i>Brassica napus</i> L. var. <u>subsp.</u> <i>napus</i> (L.) Rchb.	1	
{ <i>Brassica nigra</i> (L.) W. D. J. Koch }	±	±
<i>Brassica oleracea</i> L. convar. <i>acephala</i> (DC.) Alef. var. <i>medullosa</i> Thell. + var. <i>varidis</i> L.	1	

1	2	3
Intended use of PRM belonging to the genera and species	Genera or species may be produced and marketed only as category: pre-basic, basic or certified PRM in accordance with Article 6a*	Genera or species may be produced and marketed as commercial seed in accordance with Article 32a
<i>Brassica rapa</i> subsp. <i>oleifera</i> (DC.) Metzg.	±	
<i>Brassica rapa</i> L. var. <i>silvestris</i> (Lam.) Briggs <u>subsp. <i>campestris</i> (L.) A. R. Clapham</u>	1	±
<i>Bromus catharticus</i> Vahl <u>var. <i>elatus</i> (É. Desv.) Planchuelo</u>	1	±
<i>Bromus sitchensis</i> Trin.	1	±
<i>Bromus stamineus</i> E. Desv.	±	±
<i>Camelina sativa</i> (<u>L.</u>) Crantz	1	
<i>Cannabis sativa</i> L.	1	
<i>Carthamus tinctorius</i> L.	1	
<i>Carum carvi</i> L.	1	
<i>Cicer arietinum</i> L.	1	1
<i>Cichorium intybus</i> L.	1	

1	2	3
Intended use of PRM belonging to the genera and species	Genera or species may be produced and marketed only as category: pre-basic, basic or certified PRM in accordance with Article 6a*	Genera or species may be produced and marketed as commercial seed in accordance with Article 32a
Cucurbita pepo L.	±	
Cynodon dactylon (L.) Pers.	1	1
Dactylis glomerata L.	1	
Deschampsia cespitosa (L.) P. Beauv.	±	±
Fagopyrum esculentum Moench	1	
Festuca arundinacea Schreb.	1	
Festuca filiformis Pourr.	1	1
Festuca ovina L.	1	±
Festuca pratensis Huds.	1	
Festuca rubra L.	1	
Festuca trachyphylla (Hack.) Krajina <u>Hack.</u>	1	{1}

1	2	3
Intended use of PRM belonging to the genera and species	Genera or species may be produced and marketed only as category: pre-basic, basic or certified PRM in accordance with Article 6a*	Genera or species may be produced and marketed as commercial seed in accordance with Article 32a
<i>Galega orientalis</i> Lam.	1	
<i>Glycine max</i> (L.) Merr. partim	1	+
<i>Gossypium</i> L.	1	
<i>Hedysarum coronarium</i> L.	1	1
<i>Helianthus annuus</i> L.	1	
<i>Hordeum vulgare</i> L.	1	
<i>Koeleria macrantha</i> (Ledeb.) Schult.	+	+
<i>Lathyrus cicera</i> L.	1	1
<i>Lathyrus sativus</i> L.	1	
<i>Lens culinaris</i> Medik.	1	1
<i>Lens esculenta</i> Moench	+	+

1	2	3
Intended use of PRM belonging to the genera and species	Genera or species may be produced and marketed only as category: pre-basic, basic or certified PRM in accordance with Article 6a*	Genera or species may be produced and marketed as commercial seed in accordance with Article 32a
<i>Linum usitatissimum</i> L.	1	
<i>Lolium multiflorum</i> Lam.	1	
<i>Lolium perenne</i> L.	1	
<i>Lolium x-hybridum</i> Hausskn.	1	
<i>Lotus corniculatus</i> L.	1	+
<i>Lotus tenuis</i> Waldst. & Kit. <u>ex Willd.</u>	+	
<i>Lupinus albus</i> L.	1	+
<i>Lupinus angustifolius</i> L.	1	+
<i>Lupinus luteus</i> L.	1	+
{ <i>Medicago doliata</i> Carmign.}	1	1
<i>Medicago tornata</i> (L.) Mill. <u>italica</u> (Mill.) Fiori	+	+

1	2	3
Intended use of PRM belonging to the genera and species	Genera or species may be produced and marketed only as category: pre-basic, basic or certified PRM in accordance with Article 6a*	Genera or species may be produced and marketed as commercial seed in accordance with Article 32a
Medicago littoralis Rohde ex Loisel.	±	±
<i>Medicago lupulina</i> L.	1	±
{ <i>Medicago murex</i> Willd.}	1	1
<i>Medicago polymorpha</i> L.	1	1
Medicago rugosa Desr.	±	±
<i>Medicago sativa</i> L.	1	
Medicago scutellata (L.) Mill.	±	±
{ <i>Medicago truncatula</i> Gaertn.}	1	1
Medicago x varia T. Martyn <u>sativa L. nothosubsp. varia (Martyn) Arcang</u>	1	
<i>Onobrychis viciifolia</i> Scop.	1	{1}
{ <i>Ornithopus compressus</i> L.}	1	1

1	2	3
Intended use of PRM belonging to the genera and species	Genera or species may be produced and marketed only as category: pre-basic, basic or certified PRM in accordance with Article 6a*	Genera or species may be produced and marketed as commercial seed in accordance with Article 32a
<i>Ornithopus sativus</i> Brot.	1	1
<i>Oryza sativa</i> L.	1	
<i>Panicum miliaceum</i> L.	1	
<i>Papaver somniferum</i> L.	1	±
<i>Phacelia tanacetifolia</i> Benth.	1	±
<i>Phalaris aquatica</i> L.	1	1
<i>Phalaris canariensis</i> L.	1	
<i>Phaseolus coccineus</i> L.	±	
<i>Phaseolus vulgaris</i> L.	±	
<i>Phleum nodosum</i> L.	1	1
<i>Phleum pratense</i> L.	1	

1	2	3
Intended use of PRM belonging to the genera and species	Genera or species may be produced and marketed only as category: pre-basic, basic or certified PRM in accordance with Article 6a*	Genera or species may be produced and marketed as commercial seed in accordance with Article 32a
<i>Pisum sativum</i> L. partim	1	
{ <i>Plantago lanceolata</i> L.}	1	
{ <i>Poa annua</i> L.}	1	1
<i>Poa nemoralis</i> L.	1	+
{ <i>Poa palustris</i> L.}	1	+
<i>Poa pratensis</i> L.	1	+
<i>Poa trivialis</i> L.	1	+
<i>Raphanus sativus</i> L. var. <i>oleiformis</i> Pers.	1	
<i>Secale cereale</i> L.	1	
<i>Sinapis alba</i> L.	1	+
<i>Sorghum bicolor</i> (L.) Moench subsp. <i>bicolor</i>	1	

1	2	3
Intended use of PRM belonging to the genera and species	Genera or species may be produced and marketed only as category: pre-basic, basic or certified PRM in accordance with Article 6a*	Genera or species may be produced and marketed as commercial seed in accordance with Article 32a
<i>Sorghum bicolor</i> (L.) Moench subsp. x <i>drummondii</i> (Steud.) de Wet ex Davidse <u>Millsp. & Chase</u>	1	
<i>Sorghum bicolor</i> (L.) Moench subsp. <i>bicolor</i> x <i>Sorghum bicolor</i> (L.) Moench subsp. x <i>drummondii</i> (Steud.) de Wet ex Davidse <u>Millsp. & Chase</u>	1	
<i>Trifolium alexandrinum</i> L.	1	+
<i>Trifolium fragiferum</i> L.	1	1
{ <i>Trifolium glanduliferum</i> Boiss.}	1	1
{ <i>Trifolium hirtum</i> All.}	1	1
<i>Trifolium hybridum</i> L.	1	+
<i>Trifolium incarnatum</i> L.	1	+
{ <i>Trifolium isthmocarpum</i> Brot.}	1	1

1	2	3
Intended use of PRM belonging to the genera and species	Genera or species may be produced and marketed only as category: pre-basic, basic or certified PRM in accordance with Article 6a*	Genera or species may be produced and marketed as commercial seed in accordance with Article 32a
<i>Trifolium michelianum</i> Savi	1	1
<i>Trifolium pratense</i> L.	1	
<i>Trifolium repens</i> L.	1	
<i>Trifolium resupinatum</i> L.	1	±
<i>Trifolium squarrosum</i> L.	1	1
<i>Trifolium subterraneum</i> L.	1	1
<i>Trifolium vesiculosum</i> Savi	1	1
<i>Trigonella foenum-graecum</i> L.	1	1
<i>Trisetum flavescens</i> (L.) P. Beauv.	1	±
<i>Triticum aestivum</i> L. subsp. <i>aestivum</i>	1	
<i>Triticum aestivum</i> L. subsp. <i>spelta</i> (L.) Thell.	1	

1	2	3
Intended use of PRM belonging to the genera and species	Genera or species may be produced and marketed only as category: pre-basic, basic or certified PRM in accordance with Article 6a*	Genera or species may be produced and marketed as commercial seed in accordance with Article 32a
<i>Triticum dicoccum</i> <i>turgidum</i> L. subsp. <i>dicoccum</i> (Shrank ex Schübl.) Thell.	+	+
<i>Triticum monococcum</i> L.	+	+
<i>Triticum</i> <i>turgidum</i> L. subsp. <i>durum</i> (Desf.) van Slageren	1	
{ <i>Vicia benghalensis</i> L.}	1	1
<i>Vicia ervilia</i> (L.) Willd.	+	
<i>Vicia faba</i> L. var. <i>minuta</i> (hort. Ex Alef.) Mansf. partim	1	+
<i>Vicia narbonensis</i> L.	+	
<i>Vicia pannonica</i> Crantz	1	1
<i>Vicia sativa</i> L.	1	+
<i>Vicia villosa</i> Roth	1	+
<i>x-Festulolium</i> Asch. & Graebn.	1	+

1	2	3
Intended use of PRM belonging to the genera and species	Genera or species may be produced and marketed only as category: pre-basic, basic or certified PRM in accordance with Article 6a*	Genera or species may be produced and marketed as commercial seed in accordance with Article 32a
<i>x-Triticosecale</i> Wittm. ex A. Camus	1	
<i>Zea mays</i> L. (partim)	1	
Potatoe		
<i>Solanum tuberosum</i> L.	1	
Vegetable plants		
<i>Abelmoschus esculentus</i> Mönch (L.) Moench		
<i>Allium cepa</i> L.		
<i>Allium fistulosum</i> L.		
<i>Allium porrum</i> L.		
<i>Allium sativum</i> L.		
<i>Allium schoenoprasum</i> L.		

1	2	3
Intended use of PRM belonging to the genera and species	Genera or species may be produced and marketed only as category: pre-basic, basic or certified PRM in accordance with Article 6a*	Genera or species may be produced and marketed as commercial seed in accordance with Article 32a
<i>Anthriscus cerefolium</i> (L.) Hoffm.		
<i>Apium graveolens</i> L.		
<i>Asparagus officinalis</i> L.		
<i>Beta vulgaris</i> L. (partim)		
<i>Brassica napus</i> L. var. <i>napobrassica</i> (L.) Rchb.		
<i>Brassica oleracea</i> L. (partim)		
<i>Brassica oleracea</i> L. var. <i>capitata</i> fo. <i>alba</i> subfo. <i>Conica</i>		
<i>Brassica rapa</i> L. partim		
<i>Brassica rapa</i> L. subsp. <i>chinensis</i> (L.) Hanelt		
<i>Capsicum annuum</i> L.		
<i>Cicer arietinum</i> L.		

1	2	3
Intended use of PRM belonging to the genera and species	Genera or species may be produced and marketed only as category: pre-basic, basic or certified PRM in accordance with Article 6a*	Genera or species may be produced and marketed as commercial seed in accordance with Article 32a
<i>Cichorium endivia</i> L.		
<i>Cichorium intybus</i> L.		
<i>Citrullus lanatus</i> (Thunb.) Matsum. et Nakai		
<i>Coriandrum sativum</i> L.		
<i>Cucumis melo</i> L.		
<i>Cucumis sativus</i> L.		
<i>Cucurbita maxima</i> Duchesne		
<i>Cucurbita moschata</i> Duchesne		
<i>Cucurbita pepo</i> L.		
<i>Cynara cardunculus</i> L.		
<i>Daucus carota</i> L.		

1	2	3
Intended use of PRM belonging to the genera and species	Genera or species may be produced and marketed only as category: pre-basic, basic or certified PRM in accordance with Article 6a*	Genera or species may be produced and marketed as commercial seed in accordance with Article 32a
<i>Diplotaxis tenuifolia</i> (L.) DC.		
<i>Eruca vesicaria</i> (L.) Cav. subsp. <i>sativa</i> (Mill.) Thell. (L.) Cav.		
<i>Foeniculum vulgare</i> Mill.		
<i>Glycine max</i> (L.) Merr. partim		
<i>Ipomoea batatas</i> (L.) Lam.		
<i>Lactuca sativa</i> L.		
<i>Lens culinaris</i> Medik.		
<i>Pastinaca sativa</i> L.		
<i>Petroselinum crispum</i> (Mill.) Nyman ex A. W. Hill		
<i>Phaseolus coccineus</i> L.		
<i>Phaseolus vulgaris</i> L.		

1	2	3
Intended use of PRM belonging to the genera and species	Genera or species may be produced and marketed only as category: pre-basic, basic or certified PRM in accordance with Article 6a*	Genera or species may be produced and marketed as commercial seed in accordance with Article 32a
<i>Pisum sativum</i> L. partim		
<i>Raphanus sativus</i> L. P partim		
<i>Rheum rhabarbarum</i> L.		
<i>Scorzonera hispanica</i> L.		
<i>Solanum lycopersicum</i> L.		
<i>Solanum melongena</i> L.		
<i>Spinacia oleracea</i> L.		
<i>Valerianella locusta</i> (L.) Laterr.		
<i>Vicia faba</i> L. var. major Harz partim		
<i>Vigna unguiculata</i> (L.) Walp.		
<i>Zea mays</i> L. partim		

1	2	3
Intended use of PRM belonging to the genera and species	Genera or species may be produced and marketed only as category: pre-basic, basic or certified PRM in accordance with Article 6a*	Genera or species may be produced and marketed as commercial seed in accordance with Article 32a
Fruit plants		
<i>Actinidia</i> Lindl.		
<i>Amelanchier alnifolia</i> (Nutt.)		
<i>Aronia melanocarpa</i> (Michx.) Elliott		
<i>Aronia mitschurinii</i> A.K. Skvortsov & Maitulina		
<i>Castanea sativa</i> Mill.		
<i>Ceratonia siliqua</i> L.		
<i>Citrus</i> L.		
<i>Cornus mas</i> L.		
<i>Corylus avellana</i> L.		
<i>Cydonia oblonga</i> Mill.		

1	2	3
Intended use of PRM belonging to the genera and species	Genera or species may be produced and marketed only as category: pre-basic, basic or certified PRM in accordance with Article 6a*	Genera or species may be produced and marketed as commercial seed in accordance with Article 32a
<i>Diospyros kaki</i> L. f.		
<i>Ficus carica</i> L.		
<i>Fortunella</i> Swingle		
<i>Fragaria</i> L.		
<i>Hippophae rhamnoides</i> L.		
<i>Juglans regia</i> L.		
<i>Lonicera caerulea</i> var. <i>kamtschatica</i> Sevast.		
<i>Malus</i> Mill.		
<i>Mespilus germanica</i> L.		
<i>Olea europaea</i> L.		
<i>Persea americana</i> Mill.		

1	2	3
Intended use of PRM belonging to the genera and species	Genera or species may be produced and marketed only as category: pre-basic, basic or certified PRM in accordance with Article 6a*	Genera or species may be produced and marketed as commercial seed in accordance with Article 32a
<i>Pistacia</i> L.		
<i>Prunus armeniaca</i> L.		
<i>Prunus avium</i> (L.) L.		
<i>Prunus cerasus</i> L.		
<i>Prunus domestica</i> L.		
<i>Prunus dulcis</i> <u>(Mill.)</u> D.A. Webb		
<i>Prunus persica</i> (L.) Batsch		
<i>Prunus salicina</i> Lindl.		
<i>Punica granatum</i> L.		
<i>Pyrus</i> L.		
<i>Ribes</i> L.		

1	2	3
Intended use of PRM belonging to the genera and species	Genera or species may be produced and marketed only as category: pre-basic, basic or certified PRM in accordance with Article 6a*	Genera or species may be produced and marketed as commercial seed in accordance with Article 32a
<i>Rubus</i> L.		
<i>Sambucus nigra</i> L.		
<i>Selenicereus undatus</i> (<u>Haw.</u>) D. R. Hunt		
<i>Vaccinium</i> L.		
Hop and Vine		
[<i>Humulus lupulus</i> L.]		
<i>Vitis</i> L.**		

* Except for PRM of conservation varieties as referred to in Article 26

** Vine rootstocks may be produced and marketed only as pre-basic, basic or certified material in accordance with Article 6a

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

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Section 1 — General requirements:

- PART A seeds of agricultural and vegetable species, and true potato seed
- PART Aa seed of fruit plant species, and vine and true seed potatoes
- PART B material of ~~agricultural, vegetable and~~ fruit plant species; and vine,
including selected clones and polyclonal PRM
- PART Ba seed potatoes and other material of potatoes

Section 2 — Specific requirements:

- PART C ~~material of selected clones and polyclonal selection~~
- PART D [...]
- 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, AND
TRUE POTATO SEED

1. **Requirements for the production of pre-basic, basic and certified seeds of agricultural and vegetable species, and true potato seed**

A. Sowing or planting:

- (a) The variety **and identity** of the seed sown, including where applicable mother plants, shall be **determined** ~~identified through an official label or a label issued by the~~ **competent authority or** by the professional operator, and shall be recorded to ensure its traceability. ~~The label, or the records on the mother plant, shall be retained by the professional operator until the issuance of the official label of the marketed seed.~~
- (b) The previous cropping of the field shall **not have been in** incompatible with the production of seed of the species, variety and category of the crop, and the field shall be sufficiently free from such plants, which may have remained from previous cropping (volunteers).
- (c) The **seed or** mother plants ~~or seed,~~ **where applicable,** shall be planted and/or sown ~~in~~ in a way, ~~which~~ **that** assures **ensures**:
 - (i) sufficient distance from pollen sources of the same **genus,** species and/or different varieties, from any undesirable foreign pollination, ~~so as to avoid cross pollination with other crops, where applicable;~~ and
 - (ii) ~~an appropriate source and level of pollination to ensure the subsequent reproduction, where applicable.~~
- (d) ~~The quality of soil, substrates, mother plants and the immediate environment shall be inspected to avoid presence of pests or their vectors.~~
- (e) [...]
- (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, to ensure the fulfillment of the requirements applicable only for the PRM concerned.~~
- (g) Where applicable, **plants derived from** *in vitro* propagation may also be used for the reproduction of seeds.

B. Field cultivation:

(a) **The field crop shall have sufficient varietal identity and varietal purity.**

It shall be ensured that plants of other species, other varieties, or 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, or significant defects likely to impair the quality of the seeds.~~

(c) [...]

~~(d) The mother plants shall be cultivated, in all stages of development in such a way 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 **or part of it** shall be rejected for seed production, **or, if possible, shall be used for the production of seed belonging to a lower category or generation,** unless the undesirable seeds can be mechanically separated at a later stage.

C. Harvesting and post-harvesting:

- (a) The seed shall be harvested **in a way that** ~~in bulk or as individual plants, as appropriate, to ensure~~ its identity, purity and traceability.
- (b) A sample of seed shall be taken **officially or under official supervision** from each lot. The sample size and the sampling intensity, equipment and method shall be appropriate for the species concerned ~~and in accordance with the applicable international standards.~~
- (c) ~~All~~ **The** seed samples shall be subjected to **official** laboratory testing, **or laboratory testing under official supervision** to ensure the fulfilment of the quality requirements for the respective species. Laboratory testing shall be carried out in accordance with methods, equipment and growing media appropriate for the species concerned, ~~and in accordance with the applicable international standards. Testing shall include, where appropriate, retesting of germination rate after a certain period appropriate to the species concerned.~~
- ~~(d) The seed lots belonging to the pre-basic, basic, or certified category that will be used for the production of further seed generations, and 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 to verify the compliance with:~~
 - ~~(i) their varietal identity; and~~
 - ~~(ii) the standards of the minimum varietal purity;~~
 - (iii) [...]

2. **Requirements for the marketing of pre-basic, basic and certified seeds of agricultural and vegetable species, and true potato seed**

The seed shall fulfil ~~all of~~ the following quality requirements, depending on the characteristics of each genus or species and the category concerned:

- (a) have a minimum **sufficient** germination **[that shall be regularly confirmed through retesting];**

- (b) have a maximum **allowed** content of hard seed ~~to allow an appropriate number of plant per square metre;~~
- (c) have a minimum **sufficient analytical** purity ~~to secure the highest level of varietal identity, **and, where applicable, have a maximum allowed presence of soil or extraneous matter;**~~
- (d) have ~~an~~ maximum **appropriate** moisture content ~~to ensure the preservation of the material during processing, storage and making available on the market;~~
- (e) have a maximum **allowed** content of seeds of other genera or species ~~to ensure the lowest presence of undesirable plants in the lot;~~
- (f) [...]
- ~~(g) have a maximum presence of soil or extraneous matter and technical impurities; and~~
- (h) be **practically** free from specific **significant** defects and damages ~~to ensure the quality and health of the material.~~

PART Aa

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

1. Requirements for the production of pre-basic, basic and certified seed of fruit plant species; ~~and vine and true seed potatoes~~
 - A. Sowing or planting:
 - (aa) ~~The variety~~ **and identity** of the seed sown, including where applicable mother plants, shall be **determined** ~~identified through an official label or a label issued~~ **by the competent authority or** by the professional operator, and shall be recorded to ensure its **their** 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 **genus**, species, **and/or different varieties**, 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.~~
- (c) **Where applicable, plants derived from *in vitro* propagation may be used for the production of seed.**

B. Field cultivation:

- (a) ~~During all stages of cultivation, PRM shall be kept separate from each other.~~
- (b) ~~PRM satisfying the requirements of a given category shall not be mixed with 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 **mother** plants shall be disposed of at all stages of cultivation in order to ensure trueness to the identity of the variety, or for plants not belonging to a variety, to ensure the trueness to the identity of the species to which they belong, their sufficient purity and efficient production.
- (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 to enable the production of seeds and to permit their identification and verification of compliance with the official description or the officially recognised description of their variety. ~~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~~ **the** 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 **officially or under official supervision** at their relevant growth stage(s), at the relevant frequency and with the relevant methods as appropriate for the genera or species concerned **to verify the respective requirements.**

C. Harvesting and post-harvesting:

- (ga) **The seed shall be harvested in a way that ensures its identity, purity and traceability.**
- (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 species, and 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 a variety or, in the case of seed not belonging to a variety, to a species;~~

- (b) have minimum **sufficient** germination; ~~and~~
- (c) be practically free from significant 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, VEGETABLE AND] FRUIT PLANT SPECIES, AND VINE, INCLUDING SELECTED CLONES AND POLYCLONAL PRM

1. Requirements for the production of pre-basic, basic and certified material of [agricultural, vegetable and] fruit plant species, and vine, including selected clones and polyclonal PRM
 - A. Sowing or planting:
 - (a) The **variety and** identity of the material, ~~including, where applicable, mother plants or seed sown, shall be determined through an official label or a label issued~~ **by the competent authority or** by the professional operator, and **shall be** recorded ~~by the professional operator to ensure its~~ **their** traceability. ~~The label of the material after the marketing of that material, or the records on the mother plant, shall be kept by the professional operator for at least five years.~~
 - (b) The material, **mother plants or seed** shall be planted **or sown** in a way that:
 - (i) ensures ~~freedom from infection through~~ **from** and any possible sources **its viability and quality** throughout the production process;
 - (ii) ~~there is sufficient distance from other plants of the same genera, or species, determined on the basis of botanical characteristics and breeding techniques of each species, and as appropriate for the category of the material, to ensure protection from any undesirable foreign pollination and to avoid cross pollination with other crops; and~~

~~(iii) planting densities are adequate to allow plants or crops to be observed adequately.~~

~~(e) The production of material shall take place separately from the cultivation of material belonging to the same genera or species not intended for PRM production.~~

(d) Where applicable, plants derived from *in vitro* propagation may be used for the production of material.

B. Field cultivation:

(aa) The field crop shall have sufficient varietal identity and varietal purity.

~~(a) During all stages of cultivation, PRM of different categories shall be kept separate from each other.~~

~~(b) PRM satisfying the requirements for a given category shall not be mixed with material of other categories.~~

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

~~(d) Mother plants shall be treated or excluded as a source of PRM in case of positive test results or visual symptoms of pests or significant defects likely to impair the quality of the material.~~

(e) Mother plants **and material** shall be cultivated, in all stages of development, in such a way to enable the production of **PRM-material**, and to permit their identification and verification of compliance with the official description or the officially recognised description of their variety, **selected clone or polyclonal PRM**. ~~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 material** not belonging to a variety, ~~that~~ **the** verification of compliance with the official description ~~or the officially recognised description~~ shall concern the species to which those mother plants **and material** belong.

- (f) Mother plants **and material** shall be inspected **officially or under official supervision** at their relevant growth stage(s), at the relevant frequency and with the relevant methods, ~~including biomolecular techniques,~~ as appropriate for the genera or species concerned **to verify the respective requirements.**

€ Ba. Harvesting and post-harvesting:

(fa) The material shall be harvested in a way that ensures its identity, purity and traceability.

- (g) The sample to be drawn **officially or under official supervision** from a lot shall have the appropriate minimum size for determining the fulfilment of the quality requirements for the respective genera or species. The intensity, equipment and method of sampling shall be appropriate for the genera or species concerned ~~and in accordance with the applicable international standards.~~
- (h) **Official** ~~Testing~~ **or testing under official supervision** shall be carried out in accordance with the methods, equipment and growing media appropriate for the genera or species concerned, ~~and in accordance with the applicable international standards,~~ to ensure that the quality requirements have been fulfilled.

C. [...]

2. Requirements for the marketing of pre-basic, basic and certified material of ~~{agricultural, vegetable and}~~ fruit plant species, and vine, including selected clones and polyclonal PRM

The material shall fulfil ~~all of~~ the following requirements, depending on the characteristics of each genus or species, and the category concerned:

- (a) have minimum **sufficient** vigour and, where applicable, specific grading, ~~to ensure the appropriateness of the material and sufficient homogeneity of the lot for planting; and~~
- (b) be practically free from significant defects **and damages** ~~likely to impair the quality of the material.~~

In the case of polyclonal PRM, the mixture composition of genotypes constituting the polyclonal PRM shall be made before the final packaging of that PRM and shall include identical proportions of material from all genotypes that constitute the polyclonal PRM.

PART Ba

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

1. Requirements for the production of pre-basic, basic and certified seed potatoes and other material of potatoes
 - A. Sowing or planting:
 - (a) The variety and identity of the material, ~~including, where applicable, mother tubers or seed sown,~~ shall be determined ~~through an official label or a label issued by the~~ competent authority or the professional operator, and shall be 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 is maintained in facilities that ensures freedom from infection through aerial vectors and~~ from any other possible sources its viability and quality throughout the production process;~~and~~
 - (ii) [...]
 - (iii) ~~planting densities are adequate to allow plants to be observed individually.~~
 - (c) ~~Where appropriate, the cultivation of the seed potatoes shall take place separately from the cultivation of seed potatoes not intended for PRM production.~~
 - (d) Where applicable, plants derived from *in vitro* propagation may be used for the production of seed potatoes or other material of potatoes.

B. Field cultivation:

(aa) The field crop shall have sufficient varietal identity and varietal purity.

- ~~(a) During all stages of cultivation, 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 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 or significant defects likely to impair the quality of the material.~~
- (e) ~~Mother p~~Plants shall be cultivated, in all stages of development, in such a way to enable the production of PRM, and to permit their identification and verification of compliance with the official description ~~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 p~~Plants shall be inspected **officially or under official supervision** at their relevant growth stage(s), at the relevant frequency and with the relevant methods, ~~including biomolecular techniques.~~
- ~~(g) The sample to be drawn from a lot shall have the appropriate minimum size for determining the fulfilment of the quality requirements. The intensity, equipment and method of sampling shall be appropriate 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, 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 shall be harvested ~~in bulk, to~~ **in a way that** ensures its **their** 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 determining the fulfilment of the quality requirements** ~~in accordance with the applicable international standards.~~ **The sample may be also taken from the field.**
- (c) ~~All~~ **The** tubers samples shall be subjected to **official** laboratory testing **or laboratory testing under official supervision and visual inspection**, to ensure the fulfilment of the quality ~~and phytosanitary~~ requirements. Laboratory testing shall be carried out in accordance with methods, equipment and growing media appropriate for potato, ~~and in accordance with the applicable international standards.~~
- ~~(d) The lots belonging to the pre-basic, basic or certified category, shall be subject to risk-based pre- and post-control plot testing by the competent authority, to verify the compliance with:~~
 - ~~(i) their varietal identity; and~~
 - ~~(ii) the standards of the minimum varietal purity.~~
 - (iii) [...]
 - (iv) [...]

2. **Requirements for the marketing of pre-basic, basic and certified seed potatoes and other material of potatoes**

The ~~material~~ **seed potatoes** shall fulfil ~~all of the~~ following requirements, depending **on** the category concerned:

- (a) have ~~minimum germination rate,~~ **sufficient vigour**, defined dimension, and specific grading, ~~to ensure the appropriateness of the tubers and sufficient homogeneity of the lot for planting; and~~

- (b) be practically free from significant defects and damages likely to impair the quality of the material.

SECTION 2

SPECIFIC REQUIREMENTS

PART C

REQUIREMENTS FOR THE PRODUCTION AND MARKETING OF SELECTED CLONES AND POLYCLONAL SELECTION

1. Requirements for the production of pre-basic, basic and certified selected clones and polyclonal selections

A. Planting:

- (a) The identity of the selected clone or polyclonal selection 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 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, 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 planting densities are adequate to allow each plant to be observed individually.
- (i) [...]
- (ii) [...]
- (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.

B. Field cultivation:

- (a) During all stages of cultivation, PRM shall be kept separate from each other.

- ~~(b) PRM 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 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) [...]

- (j) ~~In the case of polyclonal selections, the mixture of genotypes constituting the polyclonal selections shall be made before the final packaging of that PRM and shall include identical proportions of all genotypes that constitute the polyclonal selections.~~

2. [...]

PART D

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

[...]

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 by the competent authority or by the professional operator through a label or records and shall be 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) [...]

~~[(c) Material that has been taken from *in vivo* material shall be sterilised.]~~

B. *In vitro* production

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

- ~~(b) During all stages of cultivation, PRM 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)~~ **The material** shall be cultivated, in all stages of development, in such a way to permit ~~their~~ **its** identification and verification of compliance with the official description or the officially recognised description of their variety. Where the official description **or officially recognised description** cannot be used because of the particular growing stage of the plant, biomolecular techniques **or a number sample of clones material planted in vivo**, may be used. In the case of ~~clone(s)~~ **material** not belonging to a variety, that **the** verification of compliance ~~with the official description or the officially recognised description~~ shall concern the species to which ~~those~~ ~~clone(s)~~ **that material** belongs.
- (f) ~~Clone(s)~~ **The material** shall be inspected ~~at their relevant growth stage(s), at the relevant frequency and with the relevant methods,~~ as appropriate, for the genera or species concerned **to verify the respective requirements**.
- ~~(g) The sample to be drawn from a lot shall have the appropriate minimum size for determining the fulfilment of the quality requirements for the respective genera or species. The intensity, equipment and method of sampling shall be appropriate for the genera or species concerned and in accordance with the applicable international standards.~~
- ~~(h) Testing shall be carried out in accordance with the methods, equipment and growing media appropriate for the genera or species concerned, and in accordance with the applicable international standards, to ensure that the quality requirements have been fulfilled.~~

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

The *in vitro* ~~or in vivo~~ 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~~ **sufficient** vigour, and, **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 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

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SECTION 1

GENERAL REQUIREMENTS

PART A

REQUIREMENTS FOR THE PRODUCTION AND MARKETING OF STANDARD SEED
OF AGRICULTURAL AND VEGETABLE SPECIES, AND TRUE POTATO SEED

1. Requirements for the production of standard seed of agricultural and vegetable species, and true potato seed

A. Sowing or planting:

- (a) The variety **and identity** of the seed sown, including where applicable, mother plants, shall be determined **and recorded** to ensure its traceability. ~~The label of the seed, 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~~ **or mother plants, where applicable,** shall be planted and/or sown~~ed~~ in a way that ~~there is~~ **ensures**:
 - (i) sufficient distance from pollen sources of the same **genus**, species and/or ~~the~~ different varieties, ~~in accordance with isolation rules determined on the basis of botanical characteristics for each species and breeding techniques, to ensure protection~~ from any undesirable foreign pollination, ~~and~~ to avoid cross pollination with other crops, where applicable; ~~and~~
 - (ii) ~~an appropriate source and level of pollination to ensure the subsequent reproduction, where applicable.~~
- (d) ~~The quality of soil, substrates, mother plants and the immediate environment shall be inspected to avoid presence of pests or their vectors.~~
- (e) [...]
- (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, to ensure health of the material concerned.~~
- (g) Where applicable, **plants derived from** *in vitro* propagation may also be used for the reproduction of seeds.

B. Field ~~production~~ **cultivation**:

(a) **The field crop shall have sufficient varietal identity and varietal purity.**

It shall be ensured that ~~off-types~~ **plants of other species, other varieties, or plants that are obviously differing from the variety in one or more characteristics from the variety description ('off-type')**, in the field, are absent. Where this is not possible due to the characteristics of the species concerned, they shall be present up to the lowest possible level.

In the case of presence of off-types or other plant species, ~~or varieties~~, during the cultivation stage, ~~or during seed processing~~, appropriate treatment and/or elimination shall be applied ~~to ensure varietal identity and purity of the seed, and to avoid the presence of any undesirable species.~~

~~(b) The plants shall be treated or excluded as a source of PRM in case of positive test results or visual symptoms of pests or significant defects likely to impair the quality of the seed.~~

(c) [...]

~~(d) The mother plants shall be cultivated, in all stages of development, in such a way to permit their identification and verification of compliance with the official description 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 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 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 **a way that** ~~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.~~
- (e) ~~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) [...]
 - (iv) [...]

2. **Requirements for the marketing of standard seed of agricultural and vegetable species, and true potato seed**

The seed shall fulfil ~~all of~~ the following quality requirements, depending on the characteristics of each genus or species:

- (a) have ~~at least a minimum~~ **sufficient** germination ~~{that shall be regularly confirmed through retesting};~~
- (b) have ~~at most a maximum~~ **allowed** content of hard seed, ~~to allow an appropriate number of plants per square metre;~~
- (c) have ~~at least a minimum~~ **sufficient analytical** purity, ~~to secure the appropriate level of varietal identity~~ **and, where applicable, have a maximum allowed presence of soil or extraneous matter;**
- (d) have ~~at most a maximum~~ **an appropriate** moisture content, ~~to ensure the preservation of the material during processing, storage and making available on the market;~~
- (e) have ~~at most a maximum~~ **allowed** content of seeds of other genera or species, ~~to ensure the lowest presence of undesirable plants in the lot;~~
- (f) [...]

- (g) ~~have a maximum presence of soil or extraneous matter, to prevent fraudulent practices and technical impurities; and~~
- (h) be **practically** free from specific **significant** defects and damage ~~to ensure the quality and health of the material.~~

PART Aa

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

1. Requirements for the production of standard seed of fruit plant species, **and vine, and true seed potatoes from conservation varieties**
- A. Sowing or planting:
 - (aa) **The variety and identity of mother plants shall be determined checked and recorded to ensure its traceability.**
 - (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 **genus**, or species, **and/or different varieties**, 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.~~
 - (c) **Where applicable, plants derived from *in vitro* propagation may be used for the production of seed.**

B. Field cultivation:

- ~~(a) During all stages of cultivation, PRM shall be kept separate from each other.~~
- ~~(b) 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 **mother** plants shall be disposed of at all stages of cultivation in order to ensure trueness to the identity of the variety, or for plants not belonging to a variety, to ensure the trueness to the identity of the species to which they belong, their sufficient purity and efficient production.
- (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 seed**.
- (f) Mother plants shall be cultivated, in all stages of development, in such a way to permit their identification and verification of compliance with the official description or the officially recognised description of their variety. ~~Where the official description 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~~ **the** 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 **Mother plants and pollinator plants** shall be inspected **checked** at their relevant growth stage(s), at the relevant frequency ~~and with the relevant methods~~, as appropriate, for the **genera or** species concerned to verify the respective requirements. ~~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) [...]

(h) [...]

(i) [...]

C. Harvesting and post-harvesting:

(a) The seed shall be harvested in a way that ensures its identity, purity and traceability.

(b) A sample of seed shall be taken from each lot and tested to ensure the fulfilment of the quality requirements for the respective genera or species.

2. Requirements for the marketing of standard seed of fruit plant species, and vine, ~~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 **sufficient germination;**

(c) be practically free from significant defects and damages ~~to ensure the quality of the seeds.~~

PART B

REQUIREMENTS FOR THE PRODUCTION AND MARKETING OF STANDARD MATERIAL OF [AGRICULTURAL,] VEGETABLE AND FRUIT PLANT SPECIES AND VINE, INCLUDING POLYCLONAL PRM

1. Requirements for the production of standard material of [agricultural,] vegetable and fruit plant species, and vine, including polyclonal PRM

A. Sowing or planting:

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

their traceability. ~~The label of the material after the marketing of that material, or the records on the mother plant, shall be kept by the professional operator.~~

(b) [...]

(b) The material, mother plants or seed shall be planted or sown in a way that ensures freedom from infection from any possible source its viability and quality throughout the production process.

(i) [...]

~~(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.~~

~~(e) 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.~~

(d) Where applicable, plants derived from *in vitro* propagation may be used for the production of material.

B. Field cultivation:

(aa) The field crop shall have sufficient varietal identity and varietal purity.

~~(a) During all stages of cultivation, PRM shall be kept separate from each other.~~

(b) [...]

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

- (d) ~~Mother plants shall be treated or excluded as a source of PRM in case of positive test results or visual symptoms of pests or significant defects likely to impair the quality of the PRM.~~
- (e) Mother plants **and material** shall be cultivated, in all stages of development, in such a way to **enable the production of material, and to** permit their identification and verification of compliance with the official description or the officially recognised description of their variety, **or polyclonal PRM**. ~~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 material** not belonging to a variety, ~~that~~ **the** verification of compliance with the official description or the officially recognised description shall concern the species to which those mother **and material** plants belong.
- (ea) All crops **Mother plants and material** in the field shall be inspected **checked** at their relevant growth stage(s), at the relevant frequency ~~and with the relevant methods~~, as appropriate, for the **genera or** species concerned to verify the respective requirements. ~~The methods for inspections shall be such to ensure the reliability of the observations.~~
- (f) [...]
- (g) [...]
- (h) [...]
- C. [...]

C. Harvesting and post-harvesting:

The material shall be harvested in a way that ensures its identity, purity and traceability.

2. Requirements for the marketing of standard material of [agricultural,] vegetable and fruit plant species and vine, including polyclonal PRM

The material shall fulfil ~~all of~~ the following requirements, depending on the characteristics of each genus or species, ~~and the category~~ concerned:

- (a) have minimum **sufficient** vigour 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 significant defects **and damages** ~~likely to impair the quality of the material.~~

~~In the case of polyclonal PRM, the mixture composition of genotypes constituting the polyclonal PRM shall be made before the final packaging of that PRM and shall include identical proportions of material from all genotypes that constitute the polyclonal selection.~~

PART Ba

REQUIREMENTS FOR THE PRODUCTION AND MARKETING OF STANDARD SEED POTATOES OF CONSERVATION VARIETIES AND OTHER MATERIAL OF POTATOES

~~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 and other material of potatoes~~

A. Sowing or planting:

- (a) The **variety and** identity of the material, ~~including, where applicable, mother tubers 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 ~~planting densities are adequate to allow plants to be observed individually.~~
- (i) [...]

ensures freedom from infection from any possible source its viability and quality throughout the production process.

(ii) [...]

(iii) [...]

~~(e) Where appropriate, the cultivation of the seed potatoes shall take place separately from the cultivation of seed potatoes not intended for PRM production.~~

(d) Where applicable, plants derived from *in vitro* propagation may be used for the production of seed potatoes or other material of potatoes.

B. Field cultivation:

(aa) The field crop shall have sufficient varietal identity and varietal purity.

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

~~(b) 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 shall be treated or excluded as a source of PRM in case of positive test results or visual symptoms of pests or significant defects likely to impair its quality.~~

(e) ~~Mother p~~**Plants** shall be cultivated, in all stages of development to permit their identification and verification of compliance with the official description or the officially recognised description of their variety. ~~Where the official description cannot be used because of the particular growing stage of the plant, biomolecular techniques may be used.~~

(f) ~~Mother p~~**Plants** shall be ~~inspected~~ **checked** at their relevant growth stage(s), at the relevant frequency.

~~(g) The sample to be drawn from a lot shall have the appropriate minimum size for determining the fulfilment of the quality requirements. The intensity, equipment and method of sampling shall be appropriate and in accordance with the applicable international standards.~~

~~(h) Testing shall be carried out in accordance with the methods, equipment and growing media appropriate, 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 shall be harvested in ~~bulk to~~ **a way that** ensures ~~its~~ **their** 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 and in accordance with the applicable international standards.~~ **The sample may be also taken from the field.**
- (c) ~~All~~ **The** tubers samples shall be subjected to laboratory testing **and visual inspection**, to ensure the fulfilment of the quality and phytosanitary requirements. ~~Laboratory testing shall be carried out in accordance with methods, equipment and growing media appropriate for potato, and in accordance with the applicable international standards.~~
- (d) ~~The lots belonging to the standard category shall be subject to risk-based official 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.~~

2. **Requirements for the marketing of standard seed potatoes of conservation varieties and other material of potatoes**

The material **seed potatoes** shall fulfil all of the following requirements:

- (a) have ~~minimum~~ **sufficient** vigour, defined dimension ~~for the specific variety, and specific grading, to ensure the appropriateness of the tubers and sufficient homogeneity of the lot for planting;~~
- (b) be practically free from significant defects **and damages** ~~likely to impair the quality of the seed potatoes.~~

SECTION 2

SPECIFIC REQUIREMENTS

PART C

REQUIREMENTS FOR THE PRODUCTION AND MARKETING OF SELECTED CLONES AND POLYCLONAL SELECTIONS

1. Requirements for the production of standard PRM of selected clones and polyclonal selections

A. Planting:

(a) The identity of the selected clone or polyclonal selections 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 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.

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 to permit their identification and verification of compliance with the official description or the officially recognised description of their variety. Where the official description or officially recognised description cannot be used because of the particular growing stage of the plant, biomolecular techniques 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) [...]~~
- ~~(g) [...]~~
- ~~(h) [...]~~
- ~~(i) [...]~~
- ~~(j) In the case of polyclonal selections, 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.~~

2. [...]

PART D
REQUIREMENTS 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

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 **shall be** recorded to ensure its traceability. The label of the material shall be kept.
 - ~~[(b) Material that has been sampled **taken** from *in vivo* material shall be sanitised **sterilised.**]~~
 - B. *In vitro* production
 - (a) The ~~clone(s)~~ **material** that originate from the material referred to under point A.(a) shall be produced by *in vitro* 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)~~ **The material** shall be cultivated, in all stages of development, in such a way to enable the production of PRM, and permitting their **its** identification and verification of compliance with the official description or the officially recognised description of their variety. Where the official description or officially recognised description cannot be used because of the particular growing stage of the plant, biomolecular techniques **or a number sample of clones material planted *in vivo*** may be used. In the case of ~~clone(s)~~ **material** not belonging to a variety, ~~that~~ **the** verification of compliance ~~with the official description or the officially recognised description~~ shall concern the species to which ~~those clone(s)~~ **that material** belongs.
- (ea) ~~All clones~~ **The material** in the field shall be inspected **checked** at their relevant growth stage(s), at the relevant frequency and with the relevant methods, as appropriate, for the **genera or** species concerned to verify the respective requirements. ~~The methods for inspections shall be such to ensure the reliability of the observations.~~
- (f) [...]
- (g) [...]
- (h) [...]

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~~ **sufficient** vigour, defined dimension, and, where applicable, specific grading, ~~to ensure the appropriateness of the material and sufficient homogeneity of the lot for planting;~~
- (c) be practically free from ~~specific~~ **significant** defects and damages.

ANNEX 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 or polyclonal **selections** 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 polyclonal selections;~~
 - ~~(iv) the maintainer of the selected clone or polyclonal selections;~~
 - ~~(v) reference to the description of the main characteristics of the variety to which the selected clone or polyclonal selections belongs;~~
 - ~~(vi) description of the main VSCU characteristics of the selected clone or polyclonal selections;~~
 - ~~(vii) the estimated genetic gain of the selected clone or polyclonal selections in relation to the overall performance of the relevant variety;~~
 - ~~(viii) information on whether the selected clone or polyclonal selections is already registered in a register of another Member State.~~
- (b) ~~The selected clone or polyclonal selections shall fulfil the following requirements as appropriate for the type of material concerned in order to be registered:~~
- ~~(i) the polyclonal selections 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. That design shall be based on methods prescribed by the International Organisation of Vine and Wine;~~
 - ~~(ii) The polyclonal selections shall be composed of 7 to 20 distinct genotypes;~~

~~(iii) the trueness of the selected clone or each genotype of the polyclonal selections 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 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 (e) 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).~~

ANNEX VI

**REQUIREMENTS FOR PRODUCTION AND MARKETING OF PRM OF
HETEROGENEOUS MATERIAL AS REFERRED TO IN ARTICLE 27(2)**

A. — Notification of heterogeneous material

~~PRM of heterogeneous material as referred to in Article 27 (2) may be marketed following a notification of the heterogeneous material by the professional operator to the competent authorities, made by means of a dossier containing:~~

- ~~a) — the contact details of the applicant;~~
- ~~b) — the species and denomination of the heterogeneous material;~~
- ~~c) — the description of the heterogeneous material as referred in point B~~
- ~~d) — a declaration by the applicant concerning the truth of the elements in points (a), (b) and (c);~~
- ~~e) — a representative sample~~

~~The notification shall be sent by registered letter or by any other means of communication accepted by the competent authorities with confirmation of receipt requested. Three months after the date shown on the return receipt provided that no additional information was requested or that non formal refusal for reasons of incompleteness of the notification was communicated to the supplier, the competent authority shall be deemed to have acknowledged the notification and its content, and the heterogeneous material shall be included in the heterogeneous material register.~~

B. — Description of the heterogeneous material

~~1. — The description of heterogeneous material shall include all of the following elements:~~

- ~~(a) — a description of its characteristics, including:~~
 - ~~(i) — the phenotypic characterisation of the key characters which are common to the material, together with the description of the heterogeneity of the material, by characterising the phenotypic diversity observable between individual reproductive units;~~

~~(ii) — documentation of its relevant characteristics, including agronomic aspects such as yield, yield stability, suitability for low input systems, performance, resistance to abiotic stress, disease resistance, quality parameters, taste or colour;~~

~~(iii) — any available results from tests concerning the characteristics referred to in point (ii);~~

~~(b) — a description of the type of technique used for the breeding or production method of the heterogeneous material;~~

~~(c) — a description of the parental material used to breed or produce the heterogeneous material and own production control programme used by the operator concerned with a reference to the practices as referred to in point B.2.(a) and, if applicable, in point B.2.(c);~~

~~(d) — a description of the on farm management and selection practices with a reference to point B.2.(b) and, if applicable, of the parental material with a reference to point B.2.(c);~~

~~(e) — a reference to the country of breeding or production, with information on the year of production and description of the pedo-climatic conditions.~~

~~2. — The heterogeneous material may be generated by one of the following techniques:~~

~~(a) — crossing of several different types of parental material, using crossing protocols to produce diverse heterogeneous material by bulking of the progeny, repeatedly re-sowing and exposing the stock to natural and/or human selection, provided that this material shows a high level of genetic diversity;~~

~~(b) — on farm management practices, including selection, establishing or maintaining material, which is characterized by a high level of genetic diversity;~~

~~(c) — any other technique used for breeding or production of heterogeneous material, taking into account particular features of propagation.~~

~~C. — Requirements concerning the identity of PRM lots of heterogeneous material~~

~~PRM of heterogeneous material shall be identifiable on the basis of all of the following elements:~~

- ~~(a) — the initial material and the production scheme used in the crossing for creation of the heterogeneous material, as provided for in point B.2.(a) or, if applicable, in point B.2.(c), or the history of the material and the on-farm management practices, including whether the selection has occurred naturally and/or through human intervention, in the cases of points B.2.(b) and point B.2.(c);~~
- ~~(b) — the country of breeding or production; and~~
- ~~(c) — characterisation of the common key characters and of the phenotypic heterogeneity of the material.~~

~~D. — Requirements concerning the sanitary quality, analytical purity and germination of PRM of heterogeneous material~~

- ~~1. — PRM of heterogeneous material shall comply with the requirements for the analytical purity and germination requirements for seed and the quality requirements for other material of the lowest category for the respective species.~~

~~The plants shall be treated or excluded as a source of PRM, in case of defects or positive test results or visual symptoms of pests in accordance with Regulation (EU) 2016/2031.~~

- ~~2. — By way of derogation from point D.1, professional operators may place on the market PRM of heterogeneous material which does not satisfy the conditions with respect to germination, provided that the operator indicates the germination rate of the PRM concerned on the label or directly on the package.~~

~~E. — Requirements for packaging and labelling of PRM of heterogeneous material~~

- ~~1. — PRM of heterogeneous material shall be contained in small packages and in maximum quantities as defined in point H. However, they may be contained in other packages or containers, only if these are closed in such a manner that they cannot be opened without leaving evidence of tampering on the package or container.~~
- ~~2. — The professional operators shall affix on packages or containers of PRM of heterogeneous material a label in at least one of the official languages of the Union.~~

~~That label shall:~~

- ~~(i) be legible, printed or written on one side, newly issued and easily visible;~~
- ~~(ii) include the information set out in point G of this Annex, except where that information is printed or written directly on the package or the container; and~~
- ~~(iii) be yellow, with a green diagonal cross.~~

~~3. In the case of small, transparent packages, the label may be placed inside the package provided it is clearly legible.~~

~~4. By way of derogation from points E.1 and E.2, PRM of heterogeneous material contained in closed and labelled packages and containers may be sold to final users in unmarked and unsealed packages up to the maximum quantities provided for in point H, if on request, the purchaser is informed in writing at the time of delivery, about the species, the denomination of the heterogeneous material and the reference number of the lot.~~

~~F. Maintenance of heterogeneous material~~

~~1. Where maintenance is possible, the professional operator who has notified the heterogeneous material to the competent authorities, shall preserve the main characteristics of the material at the time of its notification, by maintaining it as long as it remains on the market.~~

~~2. That maintenance shall be undertaken in accordance with accepted practices adapted to the maintenance of such heterogeneous material. The professional operator responsible for the maintenance shall keep records of duration and content of maintenance.~~

~~3. At all times, the competent authorities shall have access to all records kept by the professional operator responsible for the material, in order to check its maintenance. The professional operator shall keep those records for 5 years after the moment the heterogeneous material is not marketed anymore.~~

~~G. Content of the label of the packages~~

~~PRM of heterogeneous material shall be marketed in packages bearing a label containing the following elements:~~

- ~~(1) the denomination of the heterogeneous material, together with the phrase ‘heterogeneous material’;~~

- (2) — the indication ‘EU rules and standards’;
- (3) — the name and address of the professional operator responsible for affixing the label, or its registration code;
- (4) — country of production;
- (5) — lot reference number given by the professional operator responsible for affixing the labels;
- (6) — month and year of closing, following the term: ‘closed’;
- (7) — species, indicated at least under its botanical name, which may be given in abridged form and without the authors’ names;
- (8) — declared net or gross weight, or declared number of PRM, except for small packages;
- (9) — where weight is indicated and pelleting substances or other solid additives are used, the nature of the additive and also the approximate ratio between the weight of pure seeds and the total weight; and
- (10) — the germination rate, if applicable.

H. — Maximum quantities of PRM of heterogeneous material in small packages

Species	Maximum net mass (kg)
Fodder plants	10
Beet	10
Cereals	30
Oil and fiber plants	10
Potato	30
Vegetable:	-
Legumes	5
Onions, chervil, asparagus, spinach beet or chard, red beet or beetroot, turnips, water melon, gourd, marrows, carrots, radishes, scorzonera or black salsify, spinach, corn salad or lamb’s lettuce	0,5
All other vegetable species	0,1