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From: Presidency
To: Delegations

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

With a view to the informal videoconference of the members of the Working Party on Genetic Resources and Innovation in Agriculture (Seeds, propagating and planting material) of 19 and 20 December 2023, Delegations will find attached a Presidency text on the above proposal. The revised text tries to accommodate the comments provided by delegations on the articles discussed so far (1-22). Deletions are marked in strikethrough and additions in bold and underline.

CHAPTER I GENERAL PROVISIONS

Article 1

Subject matter

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

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

Article 2

Scope and objectives

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

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

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

2. The objectives of this Regulation are the following:
- (a) to ensure quality and diversity of choice ~~for~~of PRM, and its availability ~~for professional operators and final users~~;
 - (b) to ensure a equal conditions for the competition of the professional operators across the Union and the functioning of the internal market in PRM;
 - (c) to support innovation and competitiveness of the PRM sector in the Union;
 - (d) to contribute to conservation and sustainable use of plant genetic resources and agrobiodiversity;
 - (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 to the developments of technical and scientific knowledge, and the economic data concerning production and marketing of genera and species, by adding genera and species to or removing them from ~~the list~~ that Annex.

The delegated act referred to in the first subparagraph shall add genera or species to the list in Annex I if they fulfil at least two of the following elements:

- (a) represent a significant area of production of PRM and a significant value of marketed PRM in the Union
- (b) are of substantial importance for security of food and feed production in the Union, compared to other genera and species not listed in that Annex; and
- (c) are marketed in at least two Member States.

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

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

4. This Regulation does not apply to:

- (a) propagating material of ornamental plants as defined in Article 2 of Directive 98/56/EC **and PRM of genera or species from the list in Annex I exclusively used for ornamental purposes;**
- (b) forest reproductive material as defined in Article 3 of Regulation (EU) .../... of the European Parliament and of the Council¹ **and FRM of the species and artificial hybrids listed in Annex I of that Regulation;**
- (c) PRM ~~produced~~ **[intended** for export to third countries];
- (d) PRM ~~sold or~~ transferred in any way, whether free of charge or not, between final users for their own private use and outside their commercial activities;
- (e) PRM used solely for **sampling**, ~~official~~-testing, **official** inspections, exhibitions or **research for** scientific purposes;
- (f) **PRM not aimed at commercial exploitation of the variety, such as the supply of seed to providers of services for processing or packaging, provided the provider of services does not acquire title to seed thus supplied. The supply of seed under certain conditions to providers of services for the production of certain agricultural raw materials, intended for industrial purposes, or seed propagation for that purpose, shall not be regarded as marketing, provided the provider of services does not acquire title to either the seed thus supplied or the product of the harvest. The supplier of seed shall provide the Competent Authority with a copy of the relevant parts of the contract made with the provider of services and this shall include the standards and conditions currently met by the seed provide.**

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.

Article 3

Definitions

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

- (1) ‘plant reproductive material’ (‘PRM’) means plants as defined in Article 2(1) of Regulation (EU) 2016/2031, capable of, and intended for, producing **or reproducing** entire plants;
- (2) ‘professional operator’ means any ~~natural or legal~~ person, **other than a competent authority**, involved professionally in one or more of the following activities in the Union concerning PRM:
 - (a) production **with a view to marketing [breeding]**;
 - (b) marketing;
 - (c) maintenance of varieties **registered in accordance with article 47 (1) (a) (i)**;
 - ~~(d) provision of services for identity and quality;~~
 - (e) ~~preservation,~~ **laboratory analysis, field inspections,** storage, drying, processing, treating, packaging, sealing, labelling, sampling or testing;
- (3) ‘marketing’ means the following actions ~~conducted by a professional operator~~ **in relation to PRM**: sale, holding, transfer for free, or offering for sale **including online** or any other way of transferring or distribution within, or import into, the Union, **with the exception of those listed in article 2 (4)(e)**;
- (4) ‘variety’ means a variety as defined in Article 5(2) of Regulation (EC) No 2100/94;
- (5) ‘clone’ means an individual plant progeny, ~~originally~~ derived from another single plant by vegetative reproduction, remaining genetically identical to that plant;
- (6) ‘selected clone’ means a clone that has been selected and chosen for some special intravarietal phenotypic traits and its phytosanitary status that give the selected clone a better performance, is true to the description of the variety to which it belongs and, in the case of selected clones not belonging to a variety, it is true to the description of the species to which it belongs. **It is applicable to [vine and fruit] species in which this intra-variatal variability has been able to occur;**

- (7) ~~‘polyclonal plant reproductive material selections’ means a group of several distinct individual plant progenies derived from different genotypes, each of which is true to the description of the variety to which it belongs~~ **vine propagating material obtained from a selection, made through quantitative genetics tools, of a group of at least 7 genotypes from the same experimental set of a specific ancient variety, containing most of its intra-varietal diversity;**
- (8) ~~‘multiclonal mixture’ means a mixture of selected clones, all belonging to the same variety or species, as appropriate, whereby each of them has been obtained through independent selection;~~
- (9) ‘competent 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~~ **used to describe** a conservation variety, ~~which has been recognised by a competent authority, includes the specific characteristics of the variety, and has been obtained by other means than the examination of its distinctness, uniformity and stability;~~ **[The officially recognised description shall be recognised by the competent authority as a sufficiently complete description to ensure the identification and distinctness of these conservation varieties];**
- (12) ‘variety maintenance’ means the actions taken for ~~controlling~~ **ensuring** varietal purity and identity with the aim to ensure that **the expression of the characteristics which are included in the examination for distinctness as well as any others used for the variety description, remain unchanged after repeated propagation or, in the case of a particular cycle of propagation, at the end of each such cycle** a variety remains in accordance with its description over subsequent cycles of reproduction;
- (13) ‘seeds’ means seeds in the botanical sense;
- (14) ‘pre-basic seed’ means seed that **[has been produced under the responsibility of the maintainer according to accepted practices for the maintenance of the variety, [mainly]from breeder’s seed]**, belongs to a ~~generations~~ preceding the generation of the basic seed, is intended for the production and certification of **pre-basic**, basic or certified seed, and has been found by means of official certification, or certification under official supervision, to satisfy the respective conditions laid down in Part A of Annex II;

- (15) ‘basic seed’ means seed that has been produced **[under the responsibility of the maintainer according to accepted practices for the maintenance of the variety]**, from pre-basic seed or preceding generations of basic seed, is intended for the production of further generations of basic seed or certified seed, and which has been found by means of official certification, or certification under official supervision, to satisfy the respective conditions laid down in Part A of Annex II;
- (16) ‘certified seed’ means seed that has been produced from pre-basic, basic or preceding generations of certified seed, and which has been found by means of official certification, or certification under official supervision, to satisfy the respective conditions laid down in Part A of Annex II;
- (17) ‘standard seed’ means seed, other than pre-basic, basic or certified seed, ~~that is not intended for further multiplication,~~ and satisfies the respective conditions laid down in Part A of Annex III;
- (17a) [‘Commercial Seed’] means...**
- (17b) [‘Mother Plant’] means a identified plant intended for propagation.**
- (17c) [‘Pre-basic mother plant’] means a mother plant intended for the production of pre-basic material or lower categories.**
- (17d) [‘Basic mother plant’] means a mother plant intended for the production of basic material or lower categories.**
- (17e) [‘Certified mother plant’] means a mother plant intended for the production of certified material or lower categories.**
- (17f) [‘Standard mother plant’] means a mother plant intended for the production of standard material.**
- (17g) [‘multiplication’] means vegetative production of mother plants in order to obtain a sufficient number of mother plants in the same category;**
- (17h) [‘renewal of a mother plant’] means replacing a mother plant by a plant vegetatively produced from it;**
- (18) ‘pre-basic material’ means PRM, other than seeds, that **has been produced, under the responsibility of the maintainer according to the accepted practices for the maintenance of the identity of the variety and of the clone and for its phytosanitary status,** belongs to a 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 ~~Part B of~~ Annex II;

- (19) ‘basic material’ means PRM, other than seed, that has been produced, **[under the responsibility of the maintainer according to the accepted practices for the maintenance of the identity of the variety and of the clone and for its phytosanitary status]**, from pre-basic material or preceding generations of basic material, is intended for the production and certification of further generations of basic material or certified material, and has been found by means of official certification or certification under official supervision to satisfy the respective conditions laid down in ~~Part B~~ of Annex II;
- (20) ‘certified material’ means PRM, other than seed, that has been produced from pre-basic, basic or preceding generations of certified material **or seed, [if intended to be used for the production of rootstocks, by certified seeds from basic or certified material of rootstocks]**, and has been found by means of official certification or certification under official supervision to satisfy the respective conditions laid down in ~~Part B~~ of Annex II; **[In case it corresponds to vine, it shall not be produced from preceding generations of certified material]**;
- (21) ‘standard material’ means PRM other than seed, and other than pre-basic, basic or certified material, that ~~is not intended for further multiplication, and~~ satisfies the respective conditions laid down in ~~Part B~~ of Annex III;
- (22) ‘official certification’ means official attestation by the competent authority of the compliance of pre-basic, basic or certified seed or material with the respective requirements of this Regulation, where all relevant inspections on site, sampling and testing including where appropriate control plot testing have been carried out by that authority, ~~and if it has concluded that the seed or material concerned meets those requirements;~~
- (23) ‘certification under official supervision’ means attestation by a specifically authorised professional operator that pre-basic, basic or certified seed or material complies with the applicable requirements, and where at least one or more of the relevant inspections, sampling, testing or label printing **and affixing** have been carried out by that professional operator, under the official supervision of the competent authority, ~~and if it has concluded that the seed or material concerned meets those requirements;~~
- (24) ‘category’ of PRM means a group or an individual unit of PRM that qualifies as pre-basic, basic, certified or standard seed or material and is identifiable by complying with specific identity and quality requirements;
- (25) ‘genetically modified organism’ means a genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC of the European Parliament and of the Council ⁽²⁾, excluding organisms obtained through the techniques of genetic modification listed in Annex I B to Directive 2001/18/EC;

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).

- (25a) **‘NGT plant’ as defined in article 3 (3) of Regulation (EU) (...)**
- (26) ‘lot’ means a unit of PRM, identifiable by its homogeneity of composition and origin **or origins, in the case of seed mixtures;**
- (27) [**‘organic heterogeneous material’ as defined in article 3(18) of Regulation (EU) 2018/848, produced in accordance with Regulation (EU) 2018/848, intended only for further use in organic production**] means a plant grouping within a single botanical taxon of the lowest known rank which:
- (a) presents common phenotypic characteristics;
 - (b) is characterised by a high level of genetic and phenotypic diversity between individual reproductive units, so that that plant grouping is represented by the material as a whole, and not by a small number of units;
 - (c) is not a variety; and
 - (d) is not a mixture of varieties;]
- (28) [~~‘final user’ means any person acquiring, transferring and using PRM acting for purposes which are outside that person’s person’s~~ **professional activities, [who acquires PRM for personal use]**professional activities];
- (29) ‘conservation variety’ means a variety that is:
- (a) traditionally grown or [~~locally newly bred~~] under specific local conditions in the Union, and adapted to those conditions; and
 - (b) [~~characterised by a high level of genetic and phenotypical diversity between individual reproductive units,~~ **except in the case of vegetative propagated material;**]
- (30) [**‘quality pests’ means pests fulfilling all of the following:**]
- (a) they are not Union quarantine pests, protected zone quarantine pests, or regulated non-quarantine pests (‘RNQPs’) within the meaning of Regulation (EU) 2016/2031, nor pests subject to the measures adopted pursuant to Article 30(1) of that Regulation;
 - (b) they occur during PRM production or storage [**post harvesting activities**]; and
 - (c) their presence has an unacceptable ~~adverse~~ impact on the quality of the PRM, and an unacceptable economic impact as regards the use of that PRM in the Union;
- (31) ‘practically free from **quality pests**’ means [~~completely free from quality pests~~], or a situation where the presence of quality pests on the respective PRM is so low that those pests do not affect adversely the quality of that PRM;

- (32) ‘seed potatoes’ means tubers **(including minitubers) and potato micropropagative material of cultivated tuber-forming of *Solanum tuberosum* L., used for planting** ~~used for the reproduction of other potatoes;~~
- (33) [‘farmer’ means farmer as defined in Article 3(1) of Regulation (EU) 2021/2115 of the European Parliament and of the Council ³];]
- (34) ‘off-type’ means, ~~in relation with seed or other plants,~~ a **plant that can be clearly distinguished from the** ~~not corresponding to the description of the variety or species to which it is supposed to belong pursuant to this Regulation~~ **in the expression of any characteristic included in its variety description, taking into consideration the particular features of its propagation;**
- (35) ~~‘hybrid variety’ means a variety produced as a result from the crossbreeding of two or more other varieties.~~

Article 4

Compliance with Regulation (EU) 2016/2031

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

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

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

³ Regulation (EU) 2021/2115 of the European Parliament and of the Council of 2 December 2021 establishing rules on support for strategic plans to be drawn up by Member States under the common agricultural policy (CAP Strategic Plans) and financed by the European Agricultural Guarantee Fund (EAGF) and by the European Agricultural Fund for Rural Development (EAFRD) and repealing Regulations (EU) No 1305/2013 and (EU) No 1307/2013 (OJ L 435, 6.12.2021, p. 1).

SECTION 1

General requirements for the production and marketing of PRM

Article 5

Belonging to a registered variety

Only PRM belonging to a variety registered in a national variety register **and in the Union Variety Register** referred to in Article 44 **and 45,** may be produced and marketed within the Union, except the following cases:

- (a) [as rootstocks, if produced and marketed with a reference, contained in an appropriate labelling, to the species to which they belong;
- (b) as **organic**]heterogeneous material in accordance with Article 27.
- (c) [as PRM marketed to final users in accordance with Article 28;]
- (d) as PRM [produced and]–marketed **to and between gene banks, organisations, and networks** ~~for the purposes of conservation of genetic resources~~ in accordance with Article 29;
- (e) [as seed exchanged in kind between farmers in accordance with Article 30;]
- (f) as breeder's seed, in accordance with Article 31;
- (g) as PRM of not yet registered varieties in accordance with Article 32;
- (h) in the event of supply difficulties of PRM in accordance with Article 33;
- (i) [as PRM of parent lines for the production of hybrid varieties];**
- (j) as PRM marketed as preservation mixtures in accordance with Article 22.**

Article 6

Belonging to certain categories of PRM

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

- (a) pre-basic material or seed;
- (b) basic material or seed;
- (c) certified material or seed;
- (d) standard material or seed.

Where a reference is made in this Regulation to ~~lower or higher~~ categories concerning ~~identity and quality~~ of PRM, that determination shall be based on the ranking the order of points (a) - (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 (a) - (d) in the following cases:

- (a) marketing of PRM of **[organic]** heterogeneous material in accordance with Article 27;
- (b) marketing to a final user in accordance ~~to~~ **with** Article 28;
- (c) marketing to and between **gene banks, organizations and** ~~conservation~~ networks as referred to in Article 29;
- (d) **[as seed exchanged in kind between farmers in accordance with Article 30;]**
- (e) **[breeder's PRM seed as referred to in Article 31;]**
- (f) [Commercial seed].**

SECTION 2

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

Article 7

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

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

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

3. [The Commission is empowered to adopt delegated acts in accordance with Article 75, in order to amend Annex II. Those amendments shall adapt **Annex II** to the developments of international technical and scientific standards and may concern the requirements for the following:]
- (a) sowing and planting, and production in the field, of pre-basic, basic and certified seed;
 - (b) harvesting and post-harvesting of pre-basic, basic and certified seed;
 - (c) marketing of **pre-basic, basic and certified** seeds;
 - (d) ~~[sowing and planting, and production in the field,]~~ **previous cropping and isolation distances** 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) pre-basic, basic and certified material of clones, selected clones, multiclonal mixtures and polyclonal 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 ~~may~~**shall** adopt implementing acts specifying the production and marketing requirements referred to in Part A ~~and Part B~~**to E** of Annex II for certain genera, species or categories of PRM, and, where appropriate, for certain grades, classes, generations or other sub-divisions of the category concerned. Those requirements ~~shall~~**may** concern one or more of the following elements

- (a) specific uses of the genera, species or the types of the PRM concerned;
- (b) production methods of PRM, including sexual and asexual reproduction and in vitro propagation;
- (c) conditions for sowing or planting;
- (ca) **previous cropping and isolation distances**;
- (d) **[open field or in greenhouse** cultivation];
- (e) **[harvesting and post-harvesting]**;
- ~~(e)~~**(ea)** germination rates, purity and content of other PRM, moisture, vigour, presence of earth or extraneous matter;
- ~~(e)~~**(eb)** certification methods of PRM, including the application of bio-molecular or other technical methods, as well as their approval and use, and the listing of approved methods in the Union;
- ~~(e)~~**(ec)** the conditions for rootstocks and other parts of plants of genera or species other than those listed in Annex I, or their hybrids, if propagating material of the genus or species listed in Annex I or their hybrids is grafted onto them;
- ~~(e)~~**(ed)** conditions for the production of seeds from fruit plants, **from seed potatoes** or vine;
- (f) conditions for the production of fruit plants, vine or seed potatoes from seeds.

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

Article 8

Requirements for the production and marketing of standard seed and material

1. Standard seed may only be produced and marketed within the Union, if all the following conditions are fulfilled:
 - (a) [it is practically free from quality pests;]
 - (b) it is produced and marketed:
 - (i) under the responsibility of the professional operator;
 - (ii) in accordance with the requirements set out in Part A of Annex III, and its compliance with those requirements is attested by the operator's label referred to in Article 16.
2. Standard material may only be produced and marketed within the Union, if all the following conditions are fulfilled:
 - (a) it is practically free from quality pests;
 - (b) it is produced and marketed:
 - (i) under the responsibility of the professional operator;
 - (ii) in accordance with the requirements set out in Part **B, C, D and E** of Annex III, and its compliance with those requirements is attested by the operator's label referred to in Article 16.
3. [Once a year, professional operators shall submit to the competent authority a declaration concerning the quantities per species of standard seed and material they produced **for the purpose of its marketing in the Union.**]

4. The Commission is empowered to adopt delegated acts, in accordance with Article 75, in order to amend Annex III, to adapt the requirements referred to in paragraphs 1 and 2 to the scientific and technical developments and to the applicable international standards. Those amendments shall concern the following:
- (a) [requirements for sowing and planting, and production in the field **or greenhouse,** **previous cropping and isolation distances** of standard seeds;
 - (b) [requirements for harvesting and post-harvesting of standard seeds];
 - (c) requirements for marketing of standard seeds;
 - (d) requirements for sowing and planting, and production in the field, of standard material;
 - (e) requirements for harvesting and post-harvesting of standard material;
 - (f) requirements for the marketing of standard material;
 - (g) requirements for clones, selected clones, ~~multiclonal mixtures~~ and polyclonal PRM of standard material;
 - (h) requirements for the production of standard material produced by in vitro propagation;
 - (i) requirements for the marketing of standard material produced by in vitro propagation.

5. The Commission ~~shall~~ ~~may~~ adopt implementing acts specifying the production and marketing requirements referred to in Part A ~~and Part B to E~~ of Annex III for certain genera or species of standard seed or material. Those requirements shall concern one or more of the following elements:
- (a) specific 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) **previous cropping and isolation distances** [conditions for sowing or planting;
 - (d) field **or greenhouse** cultivation;
 - (e) harvesting and post-harvesting;]
 - (f) germination rates, purity and content of other PRM, moisture, vigour, presence of earth or extraneous matter;
 - (g) the application of bio-molecular or other technical methods, as well as their approval and use, and the listing of approved methods in the Union;
 - (h) the conditions for rootstocks and other parts of plants of genera or species other than those listed in Annex I, or their hybrids, if propagating material of the genus or species listed in Annex I or their hybrids is grafted onto them;
 - (i) conditions for the production of seeds from fruit plants or vine;
 - (j) conditions for the production of fruit plants, vine or seed potatoes from seeds.

Those implementing acts shall be adopted in accordance with the examination procedure set out in Article 76(2), in order to adapt to the developments of the relevant international technical and scientific standards.

Article 9

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

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

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

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

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

SECTION 3

Authorisation of professional operators and official supervision of the competent authorities

Article 10

Authorisation of professional operators to carry out certification under official supervision

1. ~~A professional operator may, upon application, be authorised by the competent authority to perform all or certain activities required for certification of PRM under official supervision of the competent authority for pre-basic, basic and certified material or seeds, and to issue an official label for them.~~ **Member States may decide that professional operators, upon application to the competent authority, are authorised to perform certain activities required for certification of PRM under official supervision of the competent authority for pre-basic, basic and certified material or seeds, and to print an official label for them.**

~~In order to be granted such authorisation and depending on the activities to be authorised for, the professional operator shall~~ **Where a Member State provides for operators to make such requests, the professional operator shall, in order to be granted such authorisation and depending on the activities to be authorised for:**

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

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

Article 11

Withdrawal or modification of the authorisation of a professional operator

Where an authorised professional operator no longer fulfils the requirements set out in Article 10(1), the competent authority shall request that operator to take corrective actions within a specified period of time.

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

Article 12

Official supervision by the competent authorities

1. For the purposes of the certification **activities** under official supervision, the competent authorities shall, ~~at least once per year,~~ conduct audits **regular evaluations** to ensure that the professional operator fulfils the requirements referred to in Article 10(1). **The frequency of the evaluations shall be based on the performance of the professional operator concerned.**

They **competent authorities** shall also organise training and examinations of the personnel carrying out field inspections, sampling and testing provided for in this Regulation. **Delegations should be carried out in accordance with articles 28 to 33 of OCR.**

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 **of each professional operator** in order to confirm compliance of that material with the requirements referred to in Article 7.

That portion shall be determined on the basis of the assessment of the potential risk of non-compliance of the PRM with those requirements. **In the case of seeds, it will cover at least 5% according to the second subparagraph.**

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

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

- (a) the risk criteria as referred to in paragraph **1 and 2** ~~and minimum portion of the crops and the lots of PRM, to be subject to inspections, sampling and testing, as referred to in paragraph 2;~~
- (b) ~~monitoring activities to be carried out by the competent authorities;~~
- (c) use of ~~particular accreditation schemes~~ **quality control systems** by the professional operator, and the possibility for the competent authorities to reduce the inspections, sampling and testing, and monitoring activities referred to in this Article due to the use of those ~~schemes~~ **quality control systems**.

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

SECTION 4

HANDLING REQUIREMENTS

Article 13

Lots

1. PRM shall be **produced and** marketed in lots. The content of ~~the varieties and species of~~ each lot shall be sufficiently homogeneous ~~regarding~~ and identifiable by **its unique reference number ensuring traceability**. ~~its users as distinct from other lots of PRM~~
2. During processing, packaging, storage, or at delivery, lots of PRM may be merged into a new lot only if they belong to the same variety ~~and harvest year~~.

Where lots consisting of different certification categories are merged, the new lot shall belong to the category of the component of the lowest category. ~~[The merging operation may only be undertaken in a facility and by persons authorised by the competent authority for this specific purpose].~~

3. During processing, packaging, storage, or at delivery, lots of PRM may be split into two or more lots. **If a lot of the same variety is split into two or more lots, a new official label or operator's label, as applicable, shall be issued for each lot.**
4. In cases of merging or splitting of the lots of PRM, as referred to in paragraphs 2 and 3, the professional operator shall keep records concerning the origin **and quantities of the original lots and** ~~of~~ the new lots.

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

Article 14

Packages, bundles and containers

1. PRM shall be marketed in ~~fastened~~ packages, bundles or containers, bearing a sealing device and marking. In the case of PRM other than seeds, it may also be marketed in the form of individual plants.
2. The packages, bundles and containers referred to in paragraph 1 shall be ~~fastened~~ **sealed** in such a way, that they cannot be opened without destroying that ~~fastening~~ **seal** or leaving traces demonstrating that the package, bundle or container has been opened. ~~the~~ The effectiveness of the ~~fastening~~ **sealing** device shall be ensured, either by incorporating the labels provided for in Articles 15 and 16 in the device or by use of a seal. Packages and containers shall be exempted from this requirement if the ~~fastening~~ **sealing** cannot be reused.
3. In the case of pre-basic, basic or certified **PRM seed and material**, those packages, bundles and containers shall be ~~fastened~~ **sealed** by the competent authority, or by the professional operator under the official supervision of the competent authority. Those packages and containers shall not be ~~refastened~~ **resealed** unless this is done by the competent authority or by the professional operator under the official supervision of the competent authority. If a package, bundle or a container is ~~refastened~~ **resealed**, the date of **production**, ~~refastening~~ **resealing** and the details of the responsible competent authority shall be stated on the label referred to in Article 15.
4. ~~Lots of pre-basic, basic or certified PRM may be repackaged, re-labelled, and re-sealed.~~ **In the case of lots of pre-basic, basic or certified seeds and material, it shall be done only by the competent authority** ~~under official control or under the official supervision of the competent authority.~~
5. [By way of derogation from paragraph 1, seeds may be marketed from a professional operator directly to a farmer in bulk.

That professional operator shall be ~~authorized~~ **approved** for that purpose by the competent authority. It shall ~~inform~~ **keep records** ~~the competent authority in advance~~ of such activity and of the lot from which such seed comes. **Those records shall be made available to the competent authority on request.**

Where seed is loaded directly into the farmer's machinery or trailer, the professional operator and the farmer concerned shall ensure traceability of that seed by issuing and retaining documents indicating the species and variety, quantity, the time of transfer and lot identification.]

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

SECTION 5

LABELLING REQUIREMENTS

Article 15

Official label

1. Pre-basic, basic and certified materials and seeds shall be identified, and their compliance with this Regulation shall be attested, through an official label, issued ~~after the conclusion~~ by the competent authority **confirming** that the requirements referred to in Article 7 have been fulfilled. **Seed lots shall be sealed and labelled before sampling.**
2. The official label shall be issued by the competent authority and bear a serial number, given by the competent authority. **That label shall ensure the unique identification and traceability of the respective lot.**

It shall be printed by:

- (a) ~~the competent authority, if so requested by the professional operator, or if the professional operator is not authorised to carry out certification under official supervision, by the competent authority in accordance with Article 10;~~ or
 - (b) the professional operator, **or a third party contracted with the professional operator,** under the official supervision of the competent authority, ~~where~~ **when** the professional operator is authorised to carry out **such printing** ~~certification under official supervision in accordance with Article 10.~~
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 **or by a third party contracted with the professional operator,** under the official supervision of the competent authority, ~~or by the person acting under the responsibility of the professional operator.~~
 4. The official label shall be newly issued. Adhesive official labels may be used, if so **approved** ~~authorised~~ by the competent authority where there is no risk that they can be re-used.

4a. The official label may be issued in electronic format (electronic official label).

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

- (a) ~~the digital recording of all actions taken by the professional operators and the competent authorities in order to issue the official label~~ **the recording and collection of digital data on the certification activities carried out by professional operators and competent authorities in order to issue the electronic labels;**
- (b) the establishment of a centralised platform that connects the Member States and the Commission to facilitate the processing of, access to, and use of ~~those records~~ **the information collected;**
- (c) the technical arrangements for the issuance of electronic official labels **and their format and content of those labels.**

Only ~~Following the adoption of such delegated act, the official label may also be issued in an electronic form (‘an electronic official label’)~~ **may be issued.**

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

Article 16

Operator’s label

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

2. That label shall attest that the PRM referred to in paragraph 1 ~~standard material or standard seed~~ complies with the relevant production and marketing requirements, referred to in this Regulation, Article 8, on the basis of inspections, sampling and testing carried out by the professional operator. **In particular, it shall be used for:**
- (a) **Standard material or standard seeds as referred to in Article 8,**
 - (b) **Mixtures referred to in Article 21, if they include standard material;**
 - (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 gene banks, organizations and networks referred to in Article 29;**
 - (h) **PRM of not yet registered varieties referred to in Article 32;**
 - (i) **PRM authorised in cases of temporary difficulties in the supply referred to in Article 33, if it contains PRM which does not fulfill the requirements for pre-basic, basic or certified material;**
 - (j) **seeds with a provisional authorization for marketing referred to in Article 34;**
 - (k) **seeds which are not finally certified referred to in Article 35;**
 - (l) **PRM imported from third countries referred to in Article 40 (2) if it includes standard material.**

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

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

Article 17

Content and nature of labels

1. The official label and the operator's label, shall be written in at least one of the official Union languages **which is also an official Union language in the Member State where the label is issued.**
2. The official label and the operator's label shall be legible, indelible, not modifiable if tampered with, printed on one side, **made of untearable material unless it is an adhesive label,** not having been used previously, and easily visible.

3. Any space of the official label or the operator's label apart from the elements mentioned in paragraph 4, may be used for additional information by the competent authority. Such information shall be presented in letters not larger than those used for the content of the official label or the operator's label as referred to in paragraph 4. That additional information shall be strictly factual, it shall not represent advertising material, and shall be related only to the production and marketing requirements or to labelling requirements for genetically modified organisms or category 1 NGT plants as defined in Article 3(7) of Regulation (EU) .../... (Office of Publications, please insert reference to NGT Regulation ...). . . **In the case of pre-basic, basic or certified material or seed of species and genera required to carry a plant passport in accordance with Regulation (EU) 2016/2031 , the plant passport shall be clearly included on the official label, in accordance with the models adopted pursuant to [Article... of that Regulation] laying down the format specifications for the plant passport for movements within the Union territory and the plant passport for introduction into and movements within a protected zone. Where applicable the operators label may make reference to the respective plant passport.**
4. The Commission shall, by means of implementing acts, specify the content, size, colour and form of the official **label** or operator's label, as applicable, in relation to the respective categories or types of PRM, ~~for:~~
- (a) ~~the official label referred to in Article 15(1);~~
 - (b) ~~the operator's label referred to in Article 16;~~
 - (c) ~~the label for mixtures referred to in Article 21(1);~~
 - (d) ~~the label for preservation mixtures referred to in Article 22(1);~~
 - (e) ~~the label for repackaged and relabelled seeds referred to in Article 23(5);~~
 - (f) ~~the label for PRM belonging to conservation varieties referred to in Article 26(2);~~
 - (g) ~~the label for PRM marketed to final users referred to in Article 28(1), point (a);~~
 - (h) ~~the label for the PRM marketed by certain gene banks, organisations and networks referred to in Article 29;~~
 - (i) ~~the label for breeder's material referred to in Article 31(2);~~
 - (j) ~~the label for PRM of not yet registered varieties referred to in Article 32(5);~~
 - (k) ~~the label for PRM authorised in cases of temporary difficulties in the supply referred to in Article 33(2); and~~
 - (l) ~~the label for seeds with a provisional authorisation for marketing referred to in Article 34(3);~~
 - (m) ~~the label for seeds which are not finally certified referred to in Article 35(3);~~
 - (n) ~~the label for PRM imported from third countries referred to in Article 40(1) and (2).~~

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

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

Article 18

Reference to lots

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

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

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

Article 19

Non-compliance of PRM with production and marketing requirements

In the case where official controls carried out during the **production and** marketing of PRM show that pre-basic, basic, certified seeds or material, or standard seeds or materials, have not been produced or marketed within the Union in compliance with the respective requirements referred to in Articles 7 or 8, or in the case where **during one of the random control plot testing referred to Article 24**~~the varietal identity and purity of the PRM were not confirmed in the control plot testing in accordance with Article 24~~, the competent authorities shall ensure that the professional operator concerned takes the necessary corrective actions concerning the PRM concerned and its premises and production methods, as appropriate. Those actions shall aim at achieving one or more of the following elements:

- (a) the PRM concerned complies with the respective requirements;
- (b) the PRM concerned is withdrawn from the market or is used as material other than PRM;
- (c) with the exception of standard seed or standard material, the PRM concerned is produced or marketed under a lower category, in accordance with the requirements applicable for that category;
- (d) the professional operator is sanctioned by additional means to the withdrawal or modification of the authorisation referred to in Article 11.

Article 20

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

1. PRM belonging to the genera or species as listed in Annex IV may only be produced and marketed as pre-basic, basic or certified seeds or material [and some species as commercial seeds].
2. The Commission is empowered to adopt a delegated act in accordance with Article 75 in order to amend Annex IV.

The delegated act referred to in the first subparagraph shall add a genus or a species to Annex IV, if both the following conditions are fulfilled:

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

That proportionality shall be based on an overall assessment of the following elements in combination: the importance of the respective genus or species for the Union food and feed security; the volume of its production in the Union; its demand by the professional operators and operators of the food/feed industry; the costs of the production of pre-basic, basic and certified PRM seed compared to the cost of production of other seed of the same genus or species; and the economic, phytosanitary and environmental benefits derived from the production and marketing of pre-basic, basic and certified seed compared to other seed of the same genus or species.

The delegated act referred to in the first subparagraph shall remove a genus or a species from Annex IV, if one of the conditions set out in the second subparagraph, point (b), points (i) and (ii), is no longer fulfilled.

SECTION 6

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

Article 21

Mixtures of seeds

1. Mixtures of certified seed or mixtures of standard seed of various genera or species listed in Part A **and B** of Annex I ~~and complying with the requirements of Articles 5 to 8,~~ as well as of different varieties of those genera or species, may be produced and marketed in the Union, if they fulfill the requirements of **Articles 5 to 8 and the requirements of** this Article. **These mixtures may also contain seed of genera or species not listed in Annex I [in accordance with (new) art. 26]this Article.**

The seeds included in those mixtures shall be accompanied by:

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

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

2. Mixtures of seeds referred to in paragraph 1 may only be produced by professional operators, which are authorised for that purpose by the competent authority. In order to receive an authorisation for the production of such mixtures, professional operators shall fulfil the following requirements:
 - (a) having installed suitable mixing equipment and appropriate procedures ensuring that the finished mixture is uniform and the stated ratio between the component varieties in each container can be achieved;
 - (b) having a person in charge who has direct responsibility for the mixing and packaging operation; and
 - (c) maintaining a register of seed mixtures and their intended use.
3. The mixing and packaging operation of the **certified** seeds referred to in paragraph 1, point (a), shall be carried out under the supervision of the competent authority.

The mixing operation shall be carried 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.

By way of derogation from Articles 5 to 8 and Article 21(1), Member States may allow the production and marketing of a mixture of seeds of various genera or species listed in Part A and Part B of Annex I, as well as a mixture of seeds of those genera or species with genera or species not listed in that Annex. When the mixture includes protected varieties, the denomination as well as the percentage should be mentioned in the label.

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

3a. Species likely to compete with native wild species, alter their genetic purity or ecological balances and species included in the Catalogue of Invasive Alien Species shall not be components of the mixtures.

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

- (a) the mixing equipment and procedure;
- ~~(b) maximum lot sizes for particular species and varieties.~~

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

Article 22

Preservation mixtures

1. By way of derogation from ~~Articles 5 to 8 and Article 21(1)~~, Member States may ~~authorise~~ **approve** the production and marketing of a mixture of seeds of various genera or species listed in Part A **and Part B** of Annex I, as well as ~~of different varieties of those genera or species, together with seeds of genera or species of other Parts of that Annex, or of genera or species not listed in that Annex,~~ if such a mixture fulfils all of the following conditions:

- (a) it contributes to the conservation of genetic resources, or the restoration of the natural environment; and
- (b) it is naturally associated with a particular ~~area~~ **region** (~~source area~~ **region of origin**) contributing to the conservation of genetic resources or the restoration of the natural environment;
- (c) it complies with the requirements of Annex V.

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

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

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

- (a) ~~authorisation~~ **approval** requirements for mixtures of seeds collected directly from a natural place belonging to a defined ~~source area~~ **region of origin**, for the conservation and restoration of the natural environment (directly harvested preservation mixtures);
- (b) ~~authorisation~~ **approval** requirements for crop-grown preservation mixtures;
- (c) use and content of certain species;
- (d) requirements on sealing and packaging;
- (e) requirements for the authorisation of the professional operators.

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

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.
