

Draft on plant reproductive materials

Plant reproductive material (PRM) is a fundamental input for the productivity, the diversity, and the health and quality of agriculture and food production. Forests cover a large area of the Union and fulfil a multifunctional role based on their social, economic, environmental, ecological and cultural functions. The current EU legislation on the marketing of PRM is based on two main pillars, namely the registration of varieties/material and the certification of individual PRM lots of plant species as identified in the Directives ('EU listed species').

The draft proposal consolidates and updates the legislation on marketing of plant reproductive material by repealing and replacing the following 12 Directives: Council Directive 66/401/EEC on the marketing of fodder plant seed, Council Directive 66/402/EEC on the marketing of cereal seed, Council Directive 2002/53/EC on the common catalogue of varieties of agricultural plant species, Council Directive 2002/54/EC on the marketing of beet seed, Council Directive 2002/55/EC on the marketing of vegetable seed, Council Directive 2002/56/EC on the marketing of seed potatoes, Council Directive 2002/57/EC on the marketing of seed of oil and fibre plants, Council Directive 68/193/EC on the marketing of material for the vegetative propagation of the vine, Council Directive 1998/56/EC on the marketing of propagating material of ornamental plants, Council Directive 92/33/EEC on the marketing of vegetable propagating and planting material, other than seed, Council Directive 2008/90/EC on the marketing of fruit plant propagating material and fruit plants intended for fruit production and Council Directive 1999/105/EC of 22 December 1999 on the marketing of forest reproductive material.

The majority of Council Directives for the marketing of PRM have first been adopted between 1966 and 1971 and some Directives are more recent. The old Directives have been updated both frequently and substantially, creating the need for clarity and transparency. As a consequence of this history, the Directives are quite diverse in the technical backgrounds they are based on, but also in their approaches, ranging from official controls on products to official supervision of processes. In particular, the product control is very demanding for competent authorities.

Furthermore, the complexity and fragmentation of the existing legislation is likely to perpetuate existing uncertainties and discrepancies in its implementation between the Member States. This creates an uneven playing field for operators on the single market. The need to harmonise implementation and to reduce cost and administrative burdens, but also the technical progress in plant breeding, the rapid evolution of the European and global PRM market and of agriculture and stronger support for innovation make their update and modernisation necessary. The aim of conservation of agro-biodiversity in situ should be further strengthened. In addition, the weak horizontal coordination with other EU legislation, policies and strategies is an obstacle to their more efficient implementation (sustainable agriculture and forestry, biodiversity protection, climate change, bio-economy). In the past years, agricultural policy in the EU has come to be seen as strategically important for food security and safety, the nutritional value of food, the environment, biodiversity and climate change. "Sustainable intensification" of food crop production in which yields are increased without adverse environmental impact and without the cultivation of more land has become a central concern. PRM legislation is critically important for reaching this aim.

Coherence and synergies with the Plant Health Law concerning the plant health checks which are part of the plant reproductive material certification process or integration of general principles concerning official controls embedded in Regulation (EC) No 882/2004 on official controls are needed.

The aim of the proposal is to replace the existing 12 Directives by one single proposed Regulation.

3.1. Part I – Scope and definitions

The scope of the proposed Regulation covers all types of plant reproductive material. The largest part of it covers though the species currently covered by the 12 Directives (so called 'listed species'). However, to clarify and harmonise the existing approaches in the Member States on the other species, i.e. plant species not listed and thus not covered by the current Directives, also these species will be subject to some very basic rules on identity and fitness for purpose as is currently the case for ornamentals. The ornamentals would also be included under these new rules of non-listed species.

In order to adapt to the needs of producers and the requirements of flexibility, the Regulation continues not to apply to plant reproductive material intended for testing and scientific purposes and intended for breeding purposes. In addition, it should not apply to material intended to or maintained in gene banks, and networks of conservation of genetic resources or organisations associated with gene banks as well as material exchanged in kinds between two persons.

As regards definitions, the main change is the introduction of a common term to cover all the plant reproductive material, either in the form of seeds or other types of plant propagating material, is created. Plant reproductive material is defined to mean plants or parts of plant capable and intended for producing or reproducing entire plants. All those types of plant reproductive material are subject to common principles with regards to their production with a view to marketing and marketing.

3.2. Part II – Operators

Operators are defined by a single definition and shall be registered to ease the control activities. This register shall be combined with the register established under [Plant Health Regulation]. Basic obligations will be introduced for operators concerning the identification of the plant reproductive material they are producing or marketing, keeping of records, facilitation of controls and maintenance of the material. The traceability of any plant reproductive material is ensured by the obligation for the operators to have information one step before and one step after their commercial activities.

3.3. Part III – Plant reproductive material other than forest reproductive material

In general, the basic approach on registration of varieties/material and certification/inspection of lots before marketing would be kept. However, more flexibility would be given to the operators so that they may decide to carry out the necessary testing for variety registration or inspections, sampling and analysis of plant reproductive material for certification under the official supervision of the competent authorities. In addition, secondary acts will be adopted setting out the specific requirements for the production and marketing of particular species and their

categories (pre-basic, basic, certified and standard material). This is important to increase flexibility for changes due to technical and scientific developments.

The marketing requirements for plant reproductive material may be summarised as follows:

- it belongs to a variety or clone registered in accordance the provisions of this Regulation;
- it complies with the specific requirements adopted for the marketing category concerned per genera and species;
- it bears an official label for pre-basic, basic and certified material, or an operator's label in case of standard material;
- it complies with the requirements on traceability, lot size, lot composition and identification;
- it complies with the requirements on labelling, packaging or on small packages;
- production and marketing of plant reproductive material belonging to listed genera and species.

Certain genera and species of plant reproductive material, which are listed in the current Directives, should continue to be subject to enhanced requirements concerning their production and marketing. However, there is a need to set criteria to decide on these plant species. Genera or species of plants which are produced and made available on the market in at least two Member States, and represent a significant area and value of production or are produced and made available on the market by a significant number of operators should be included in the list.

Plant reproductive material should only be produced and placed on the market as pre-basic, basic, certified or standard material, in order to ensure transparency and informed choices with its users. Specific requirements should be adopted per genera and species for each of those categories. The requirements on identity, purity, health and other quality requirements, labelling, lots, packaging including small packages, post-certification control tests, comparative tests and trial and mixtures will continue to be applied. The existing permanent derogations on limited marketing for testing on farm of not-yet registered varieties and, authorisation of more stringent national requirements should be maintained. This also concerns the important temporary derogations on emergency measures, temporary difficulties in supply and temporary experiments.

The EU equivalence system is maintained as a basic condition for imports from third countries. However, exports are included in the scope of the Regulation. Exports should take place in line with legislation, standards, code of practice or any other legal or administrative procedure in place in the importing third country. Where a bilateral or multilateral agreement between the Union and the third country exists, the exports from the Union shall comply with the agreement.

- Production and making available on the market of plant reproductive material belonging to non-listed genera or species, or intended for ornamental uses

Plant reproductive material not belonging to the listed genera and species shall also be subject to a few basic requirements with regards to their health status, fitness for purpose, appropriate reference to varieties, where applicable, and

identification of the respective material. The same should apply to material belonging to the listed genera and species in case they are intended for ornamental uses only.

– Registration of varieties in national and Union Variety registers

The varieties, in order to be marketed throughout the Union, shall be included in a national register or in the Union register via direct application procedure to the Community Plant Variety Office (CPVO: in legal text 'office'). CPVO will keep the updated information on all plant varieties that can be marketed in the Union, including the varieties registered in national registers (Union plant variety database).

For new improved varieties the basic requirement of DUS (distinct, uniform and stable) will be kept. In addition, by secondary act it can be decided for which plant species additional requirements on value for cultivation and use (VCU) can be laid down. In particular, rules on a sustainable value for cultivation will be laid down and harmonised in the EU by adopting specific requirements concerning resistance to specific harmful organisms, reduced need for input of resources, decreased content of undesirable substances or increased adaptation to divergent agro-climatic environment. This is an important tool to guide the breeding process to a more sustainable direction.

If a variety has been granted a Union Plant Variety Right pursuant to Regulation (EC) No 2100/1994, or pursuant to national rules, that variety shall be deemed to be distinct, uniform and stable and to have a suitable denomination for the purposes of variety registration under this Regulation.

The basic principle of the use of a single denomination throughout the Union for one variety is kept. In certain specific cases synonyms will be allowed. The CPVO is best placed to have an overview of applicable denominations of varieties throughout the Union. Therefore, and in order to ensure coherence regarding the assignment of denominations throughout the Union, the competent authorities should consult with this CPVO to check a denomination, before the respective variety is registered in a national variety register.

The Regulation lays down the detailed requirement for the variety registration procedure concerning conditions for registration, submission and content of applications, formal and technical examinations, examination reports, decisions on registration, period of validity and its renewal, revocation/deletion of registration and maintenance of varieties. For coherence reasons the same rules shall also apply to direct variety applications to the CPVO and the Union variety register.

Specific provisions are set out on the registration in the Union variety register and with regards to the possibility for the applicant to launch an appeal against a CPVO decision. Such provisions are not laid down for the registration in the national variety registers, because they are subject to national administrative procedures.

A new obligation for each national variety examination centre to be audited and approved by the CPVO will be introduced with the aim to ensure the quality and harmonisation of the variety registration process in the Union. The examination centre of the operators will be audited and approved by the national competent authorities.

The competent authorities and the CPVO should charge fees for the processing of applications, the formal and technical examinations, and the maintenance of the

varieties for each year for the duration of the registration. Therefore, harmonised rules for those fees should be set out in this Regulation. The principle of cost recovery shall prevail.

Concerning old varieties, such as conservation varieties (landraces, populations) or amateur varieties, less stringent requirements will be laid down. The varieties will continue to be registered, however, on the basis of an 'officially recognised description' which shall be recognised – but not produced – by the competent authorities. For that description no DUS testing is obligatory. It shall describe the specific characteristics of the plants and parts of plants which are representative for the variety concerned and make the variety identifiable, including the region of origin. This description can be based on an old official description of the variety, description produced at the time by a scientific, academic body or organisation. The accuracy of its content could be supported by previous official inspections, unofficial examinations or knowledge gained from practical experience during cultivation, reproduction and use. The current quantitative restrictions are abolished. The users are informed about the material by a label indicating that this variety is identified by an officially recognised description and the region of origin.

3.4. Part IV – Production and marketing of forest reproductive material

The EU legislation sets a specific approach including specific terminology on forest reproductive material. Therefore, for this area a separate chapter is laid down whereby the current basic approach is kept. The requirements for forest reproductive material concern approval of basic material, inclusion in national and Union registers, master certificate, marketing categories, lots, mixtures, labelling, packaging and import setting the condition of EU equivalence. In addition, the following derogatory rules need to be set: authorisation of more stringent national requirements, prohibition to make available to end user specified forest reproductive material, temporary difficulties in supply and temporary experiments.

3.5. Part VI – Procedural provisions

Rules for delegated acts and the committee procedure are laid down.

3.6. Part VII – Transitional and final provisions

The necessary rules on penalties are laid down as well the possibility to consult EFSA. [is it in,] The Regulation (EC) NO 2100/94 on Community Variety Rights is amended as regards the role of CPVO. This concerns the extension of the mission of the CPVO to the area of variety registration, in particular the management of Union plant variety register and the registration of plant varieties via direct application procedure the CPVO. In addition, a number of tasks are attributed to the CPVO within its new mission on offering recommendations on variety denominations, harmonisation of technical examination of varieties, audits of technical examination centres, advisory tasks, training and technical support.

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REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

On the production with a view to placing on the market, and placing on the market, of plant reproductive material and repealing Directive 66/401/EEC, Directive 66/402/EEC, Directive 68/193/EEC, Directive 98/56/EC, Directive 1999/105/EC, Directive 2002/53/EC, Directive 2002/54/EC, Directive 2002/55/EC, Directive 2002/56/EC, Directive 2002/57/EC, Directive 2008/72/EC and Directive 2008/90/EC

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,
HAVE ADOPTED THIS REGULATION:

PART I

GENERAL PROVISIONS

Article 1 ***Subject matter***

This Regulation lays down rules for the production, with a view to marketing, and to the marketing of plant reproductive material.

Article 2 ***Scope***

This Regulation shall not apply to plant reproductive material:

- (a) intended solely for testing or scientific purposes;
- (b) intended solely for selection purposes; or
- (c) intended solely for, and maintained in, gene banks and networks of conservation of genetic resources associated with gene banks;
- (d) exchanged in kind between persons other than operators.

Article 3 ***Definitions***

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

- (1) 'plant' means a plant as defined in Article [2(1) of new Plant Health Regulation];
- (2) 'plant reproductive material' means plant(s) capable of, and intended for, producing entire plants;
- (3) 'placing on the market' means the holding for the purpose of sale within the Union, including offering for sale or any other form of transfer, and the sale, distribution, entry into the Union and other forms of transfer, whether free of charge or not;
- (4) 'operator' means any natural or legal person carrying out professionally at least one of the following activities with regard to plant reproductive material: reproducing, producing, breeding, maintaining, providing services, preserving, including storing, and placing on the market;
- (5) 'competent authority' means a competent authority as defined in accordance with [Article 2(2)(b) of Reg 882];
- (6) 'genetically modified organism' means a genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC;
- (7) 'forest reproductive material' means plant reproductive material intended for forestry purposes;
- (8) 'lot' means a number of a unit of plant reproductive material, identifiable by its homogeneity of composition and origin, which may also be part of a consignment as defined in accordance with [Article of 2(2)(s) of revised Regulation 882];
- (9) 'official control' means official control defined in [Article 2(2)(a) of revised Regulation 882].

Article 4
Free circulation

Plant reproductive material shall be subject to no restrictions concerning its production, with a view to placing on the market, and placing on the market, other than those laid down in this Regulation and in [Plant Health Regulation], Directive 2001/18/EC, Regulation (EC) No 1829/2003, Regulation (EC) No 338/97 and Directive 94/62/EC.

PART II OPERATORS

Article 5 ***Registers of operators***

1. Operators shall be registered in the registers referred to in Article [52] of Plant health Regulation in accordance with the provisions of Article [53] of that Regulation.
2. Paragraph 1 shall not apply to operators exclusively placing on the market plant reproductive material in retail.

Article 6 ***General responsibilities of operators***

Operators shall ensure that plant reproductive material produced and placed on the market under their control fulfil the requirements of this Regulation.

Article 7 ***Specific responsibilities of operators producing plant reproductive material***

1. Operators producing plant reproductive material shall:
 - (a) be available personally, or designate a particular person, to liaise with the competent authorities for the purpose of facilitating the official controls;
 - (b) identify and monitor the critical points of the production process which may influence the quality of the plant reproductive material;
 - (c) keep records of the monitoring of those critical points, which shall be available for examination when requested by the persons carrying out the official controls;
 - (d) ensure that, during production, lots of plant reproductive material remain separately identifiable;
 - (e) keep updated information of the premises and other locations used for the production of plant reproductive material;
 - (f) make sure that persons carrying out official controls have access to the premises of production, including premises and fields of third contracting parties, and to the records of the monitoring and all related documents;
 - (g) take measures, where appropriate, for the maintenance of the plant reproductive material.
2. For the purpose of facilitating the official controls of the certification referred to in Articles 20(4) and 125, the operators shall inform the respective competent authorities in due time about the intention to produce plant reproductive material, with indication of plant species and categories, and to collect material from approved basic material of forest reproductive material.

Article 8
Traceability

1. Operators shall ensure that plant reproductive material is traceable at all stages of production and placing on the market.
2. For the purpose of paragraph 1, operators shall keep information allowing them to identify the operators supplying them with plant reproductive material, as well as the respective material. On request, they shall make such information available to the competent authorities.
3. For the purpose of paragraph 1, operators shall keep information allowing them to identify the persons to whom they have supplied plant reproductive material, with the exception of operators exclusively placing on the market plant reproductive material in retail, as well as the respective material. On request they shall make such information available to the competent authorities.
4. Operators shall keep records of the plant reproductive material referred to in paragraphs 2 and 3 for at least three years since that material has been respectively supplied to or by them.

PART III

PLANT REPRODUCTIVE MATERIAL OTHER THAN FOREST REPRODUCTIVE MATERIAL

TITLE I

GENERAL PROVISIONS

Article 9

Scope

This Part shall apply to the production with a view to placing on the market, and placing on the market, of plant reproductive material other than forest reproductive material.

Article 10

Definitions

For the purposes of this Part, the following definitions shall apply:

- (1) 'variety' means a plant reproductive material within a single botanical taxon of the lowest known rank, which fulfils all of the following requirements:
 - (a) it is defined by the expression of the characteristics that results from a given genotype or combination of genotypes;
 - (b) it is distinguished from any other plant grouping by the expression of at least one of the said characteristics; and
 - (c) it is considered as a unit with regard to its suitability for being propagated unchanged;
- (2) 'official description' means a description produced by a competent authority, covering the characteristics of a variety concerning its distinctiveness, uniformity and stability;
- (3) 'officially recognised description' means a description of a variety placed on the market before the entry into force of this Regulation, which describes the specific characteristics, including the region of origin, of the plants that are representative of the variety concerned, and make that variety identifiable, and which is recognised by a competent authority for fulfilling the following criteria:
 - (a) at the time when material of that variety was placed on the market, it had been found by a competent authority in compliance with the relevant rules of the respective Member State or third country, or had been recognised by the competent authority as produced by a scientific, academic or technical body or organisation; or
 - (b) the accuracy of its content is supported by the results of previous official inspections, unofficial examinations or knowledge gained from practical experience during cultivation, reproduction and use.

TITLE II

PRODUCTION AND PLACING ON THE MARKET OF PLANT REPRODUCTIVE MATERIAL BELONGING TO GENERA AND SPECIES LISTED IN ANNEX I

CHAPTER I

SCOPE, CATEGORIES AND REQUIREMENTS

Article 11

Scope

1. This Title shall apply to the production and placing on the market of plant reproductive material belonging to genera and species which comply with one or more of the following criteria:
 - (a) they represent a significant area of production;
 - (b) they represent significant value of production;
 - (c) they are produced or placed on the market by a significant number of operators in the Union.
2. The genera and species referred to in paragraph 1 are listed in Annex I.
3. This Title shall also apply to rootstocks and other parts of plants of other genera or species, or their hybrids, hereinafter jointly referred to as "rootstocks", if material of one of the genera or species listed in Annex I, or their hybrids, is grafted on them.
4. The Commission shall be empowered to adopt delegated acts, in accordance with Article 143, amending Annex I.

Article 12

Definitions

For the purposes of this Title, the following definitions shall apply:

- (a) "pre-basic material" means plant reproductive material which is at the first step of production and is intended for the production of other categories of plant reproductive material;
- (b) "basic material" means plant reproductive material which has been produced either directly or in a known number of generations from pre-basic material, and is intended for the production of certified material;
- (c) "certified material" means plant reproductive material which has been produced either directly or in a known number of generations from pre-basic or basic material;
- (d) "standard material" means plant reproductive material other than pre-basic, basic or certified material;
- (e) "category" means pre-basic material, basic material, certified material or standard material;
- (f) 'major genera or species' means genera or species meeting one or both of the following conditions:

- (i) the production and placing on the market of plant reproductive material belonging to those genera or species as pre-basic, basic and certified material entail costs and certification activities which are proportionate to the purpose of ensuring quality and health of that material;
- (ii) the production and placing on the market of plant reproductive material belonging to those genera or species as standard material are not likely to fulfil the requirements of traceability and varietal identity due to the long chain of production and enhanced plant health requirements;
- (g) 'non-major' general or species" means genera or species listed in Annex I, other than the ones referred to in point (f) of this Article.

Article 13

Identification of major and non-major genera or species

The Commission shall identify, by means of implementing acts, major and non-major genera or species. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 144(3).

Article 14

Categories of plant reproductive material

1. Plant reproductive material belonging to major general or species may only be produced, with a view to be placed on the market, and placed on the market, under one of the following categories:
 - (a) pre-basic material,
 - (b) basic material,
 - (c) certified material.
2. Plant reproductive material belonging to non-major general or species may only be produced, with a view to be placed on the market, and placed on the market, under one of the following categories:
 - (a) pre-basic material,
 - (b) basic material,
 - (c) certified material,
 - (d) standard material.

Article 15

Production and placing on the market of pre-basic, basic and certified material

Plant reproductive material produced and placed on the market as pre-basic, basic or certified material shall:

- (a) comply with the specific requirements adopted pursuant to Article 17 for the category concerned;
- (b) bear an official label pursuant to Article 21 and 23;
- (c) in the case of clones, comply with the specific conditions set out in Article 24;

- (d) comply with the provisions on registration of variety or clones, where applicable, set out in Article 25;
- (d) comply with the requirements on lot composition and identification set out in Article 26;
- (e) comply with the requirements on packaging set out in Article 27; and
- (f) in the case of small packages, comply with the specific conditions adopted pursuant to Article 28.

Article 16

Production and placing on the market of standard material

Plant reproductive material produced and placed on the market as standard material shall:

- (a) comply with the specific requirements adopted pursuant to Article 17 for standard material;
- (b) bear an operator's label pursuant to Article 22 and 23;
- (c) in the case of clones, comply with the specific conditions adopted pursuant to Article 24;
- (d) comply with the provisions on registration of varieties or clones, where applicable, set out in Article 25;
- (e) comply with the requirements on lot composition and identification set out in Article 26;
- (f) comply with the requirements on packaging set out in Article 27; and
- (g) in the case of small packages, comply with the specific conditions adopted pursuant to Article 28.

Article 17

Specific requirements for the production and placing on the market of plant reproductive material

1. Plant reproductive material shall be produced and placed on the market in accordance with requirements suited to the specific characteristics of the genera or species to which it belongs.
2. The Commission may identify, by means of implementing acts, the requirements referred to in paragraph 1, for the production and placing on the market of specific genera or species of plant reproductive material. Those requirements shall be adopted per category, within the scope set out in Annex II. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 144(3).
3. The requirements referred to in paragraph 2 shall, where applicable, concern:
 - (a) the specific uses of the genera, species or types of plant reproductive material concerned;
 - (b) the number of generations for each category;
 - (c) the types of variety including intraspecific or interspecific hybrids; and/or
 - (d) the subdivision of categories into grades satisfying different conditions.

4. The requirements referred to in paragraph 1 may set out that:
 - (a) particular grades may only be produced in particular areas; or
 - (b) the production of plant reproductive material shall take place separately from the production of material belonging to the same genera or species for food or feed purposes to ensure purity, quality and/or health of the material concerned.
5. The requirements referred to in paragraph 1 shall be without prejudice to the requirements, and where appropriate the thresholds, for the presence of quality organisms listed in accordance with Article [35 of Plant Health Regulation].
6. The Commission shall be empowered to adopt delegated acts, in accordance with Article 143, for the purpose of amending Annex II. Those amendments shall take into account the technical and scientific developments.

Article 18

Official label for pre-basic, basic or certified material

1. Pre-basic, basic or certified material shall be certified through a label (hereinafter 'official label'). That label shall certify that the material complies with the requirements identified pursuant to Article 17.
2. The official labels shall be produced and affixed by:
 - (a) the operator, under the official supervision of the competent authority; or
 - (b) the competent authority, if requested so by the operator.
3. In the case where the official labels are produced by the competent authorities, the competent authorities shall carry out all necessary field inspections, sampling and testing to confirm compliance with the requirements identified pursuant to Article 17.
4. The official label shall be produced with reference to a lot, and shall be affixed on the outside of packages, containers and bundles. If a lot is split into more lots, a new official label shall be issued for each lot. If several lots are merged into a new lot, a new official label shall be issued for that new lot.

Article 19

Supervision by the competent authorities

1. For the purposes of the official supervision by the competent authorities referred to in Article 18(2)(a), competent authorities shall carry out inspection, sampling and testing on a proportion of the crops in the fields and on the lots of plant reproductive material, to confirm compliance of that material with the requirements identified pursuant to Article 17(2). That proportion shall be based on the potential risk of non-compliance with those requirements.
2. Operators shall be supervised by the competent authorities through the conduct of regular audits, at least once per year.
3. The Commission shall be empowered to adopt delegated acts, in accordance with Article 143, setting out requirements concerning the official supervision referred to in Article 18(2). Those requirements shall concern one or more of the following:
 - (a) a minimum proportion as referred to in paragraph 1 for particular genera or species;

- (b) monitoring activities to be carried out by the competent authorities;
- (c) qualification, training and activities of inspectors used by the operators;
- (d) conditions for laboratories to be used by the operators.

Article 20
Certification schemes

1. The Commission may, by means of implementing acts, establish certification schemes under which the certification referred to in Article 18(1) shall take place for particular genera or species. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 144(3).
2. The schemes referred to in paragraph 1 shall be established in accordance with the criteria set out in Annex II. Those schemes shall set out requirements concerning field inspection, sampling and testing to be carried out by the operator and the competent authorities. Those requirements shall take into account international standards, insofar as such standards exist.

Where applicable, those schemes shall include the examination requirements and the requirements for the production of plants for planting adopted pursuant to Article [68(3) of Plant Health Regulation].

Article 21
Authorisation of operators to carry out certification and produce and affix official labels

1. Operators may carry out the certification referred to in Article 18(1) and produce the label as referred to in Article 18(2)(a), only if they are authorised for this purpose by the competent authorities. That authorisation shall be granted only if the following requirements are fulfilled:
 - (a) the operators provide assurances concerning compliance of the species that they produce and place on the market with the requirements identified pursuant to Article 17(2);
 - (b) the operators have in place systems and provisions to ensure the fulfilment of traceability provisions set out in Article 8.
2. The Commission shall be empowered to adopt delegated acts, in accordance with Article 143(3), setting out further requirements under which operators shall be allowed to carry out the certification referred to in Article 18(1). Those requirements may concern:
 - (a) minimum qualifications and training for the operators concerned;
 - (b) conduct of examinations;
 - (c) authorisation of staff and laboratories involved in the certification;
 - (d) suitability of premises and availability of particular equipment;
 - (e) authorisation requirements for laboratories, and their personnel, which carry out the testing of plant reproductive material concerned.
3. In case competent authorities conclude that the operators concerned do not fulfil one or more of the requirements referred to in paragraphs 1 or 2, they shall request the

operators to take corrective actions within a specified period of time to comply with those requirements.

Competent authorities shall without delay withdraw, or modify as appropriate, the authorisation referred to in paragraph 1, if the operator does not apply those corrective measures within that specified period of time.

Article 22

Production of operator's label for standard material

1. In the case of standard material, the operator shall indicate through a label (hereinafter 'operator's label') that the material complies with the requirements identified pursuant to Article 17(2).

The operator shall produce and affix the operator's label only after it ensures through inspections that the plant reproductive material complies with those requirements.

2. The operator's label shall be produced with reference to a lot, and shall be affixed on the outside of individual plants, packages, containers and bundles. If a lot is split into more lots, a new operator's label shall be issued for each lot. If several lots are merged into a new lot, a new operator's label shall be issued for that new lot.

Article 23

Content and form of the official label and operators' label

1. The official label and the operators' label shall contain the items listed in Annex III. It shall be written in one of the official Union languages. It shall be legible, indelible, printed in one side and easily visible.
2. In case the issuance of a plant passport is required pursuant to Article [61 of Plant health Regulation], that plant passport shall be combined with the official label in a single label.
3. Each label shall have a distinct colour per category and type of plant reproductive material.
4. The Commission shall be empowered to adopt delegated acts, in accordance with Article 143, setting out requirements concerning, where applicable, one or more of the following cases:
 - (a) the colours and shape of the label for specific categories and types of plant reproductive material;
 - (b) specific indications for generations of pre-basic, basic, certified and standard material;
 - (c) specific indications for the intended use of the material;
 - (d) specific indications for last germination.
5. The Commission shall be empowered to adopt delegated acts, in accordance with Article 14, setting out the cases in which, by way of derogation to Annex III, the botanical name of the genera, instead of the species, may be included in the official or the operator's label.
6. This Article shall apply without prejudice to Article 49(4) of Regulation (EC) No 1107/2009 concerning the label and documents accompanying treated seeds in the meaning of that Regulation.

Article 24

Placing on the market of clones

1. The Commission shall be empowered to adopt delegated acts, in accordance with Article 144, determining one or both of the following:
 - (a) the genera or species, the plant reproductive material of which may be produced and placed on the market in clones, and the definition of clone for those genera or species; and
 - (b) the conditions under which clones referred to in point (a) may be produced and placed on the market.
2. Clones may not be produced or placed on the market, if they do not comply with the provisions of the delegated acts adopted pursuant to paragraph 1.

Article 25

Plant reproductive material belonging to registered varieties or clones

1. Plant reproductive material may be produced and placed on the market throughout the Union only from the date on which the variety, or, where applicable the clone, to which it belongs has been included in the national variety register referred to in Article 49 or in Part A of the Union variety register referred to in Article 50.

This paragraph shall not apply to rootstocks, which do not fulfil the conditions of a variety.
2. Plant reproductive material belonging to varieties with officially recognised description only, shall only be produced in the region(s) of origin of that variety.
3. The Commission shall be empowered to adopt delegated acts, in accordance with Article 143, setting out that particular genera or species may be produced and placed on the market without belonging to a variety registered pursuant to paragraph 1.

Article 26

Lot composition and identification

1. Plant reproductive material shall be kept in separate lots, as soon as those lots are created.
2. During processing, packaging, storage, transport or at delivery, lots of plant reproductive material of different origins may be merged into a new lot. In that case the operator shall keep records including data about the origin of the individual components of the new lot.
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 143, setting out requirements concerning size, composition and identification of lots for particular genera or species.

Article 27

Packages, containers and bundles

1. Plant reproductive material shall be placed on the market as individual plants, or in packages, containers or bundles.

2. Packages and containers shall be closed in such a way that they cannot be opened without damaging the closure and, in the case of packaging, without the packaging showing signs of tampering.
3. Bundles shall be tied up in such a way that the material forming parts of the bundles cannot be separated without damaging the tie or ties.
4. The Commission shall be empowered to adopt delegated acts in accordance with Article 143, setting out that particular genera or species shall only be placed on the market in packages or containers. Those delegated acts may also set out rules about the closure, including, where appropriate, the sealing, of packages, containers or bundles of particular genera or species. Those rules shall take into account the characteristics and requirements for placing on the market of the concerned genera or species.

Article 28

Small packages

1. The Commission shall be empowered to adopt delegated acts, in accordance with Article 143, setting out specific conditions for the placing on the market of particular genera or species in small packages.
2. The delegated acts referred to in paragraph 1 shall define the concept of 'small packages' for particular species, taking into account the characteristics of those species and their placing on the market. They shall also set out the colour, content and methods of labelling, requirements concerning checking of the material, and requirements concerning the closure of those packages.

CHAPTER II TESTS

Article 29

Post certification tests

1. After the certification referred to in Article 18(1), the competent authorities may carry out tests of the plant reproductive material to confirm that it complies with the requirements identified pursuant to Article 17(2) and the certification schemes adopted pursuant to Article 20(1) (hereinafter: 'post certification tests').
2. Competent authorities shall design and plan the post certification tests on the basis of a risk analysis concerning possible non-compliance of the respective plant reproductive material with those requirements.
3. The post certification tests shall be carried out through samples taken by the competent authority.
4. The Commission shall be empowered to adopt delegated acts, in accordance with Article 143, setting out detailed requirements for the post certification tests of plant reproductive material belonging to particular genera or species. Those delegated acts may set out that, by way of derogation to paragraph 1, post certification tests for particular genera or species shall be obligatory, if the effective control of the production of those genera or species by the operators during the certification has limitations due to the characteristics of those genera or species.

Article 30

Non-compliance of operators with the specific requirements for categories

1. In case it is concluded, on the basis of the post certification tests, that the plant reproductive material has not been produced or placed on the market in compliance with the requirements identified pursuant to Article 17(2), or that its certification has not complied with the scheme referred to in Article 20(1), the competent authorities shall ensure that the operator concerned takes the necessary corrective actions to ensure that either the material concerned complies with the above requirements or it is withdrawn from the market.
2. If it is repeatedly found, during the post certification tests referred to in Article 29, that an operator produces or places on the market plant reproductive material which does not comply with the requirements referred to in Article 17(2), or the certification of which does not comply with the scheme referred to in Article 20(1), the competent authorities shall ensure that the operator concerned is wholly or partially prohibited, for a specified period, to produce and place on the market such material. That period may be prolonged if, at its expiration, the competent authorities conclude that the operator has failed to ensure compliance with those requirements.
3. Any measures taken under paragraph 2 shall be withdrawn as soon as, where applicable, it has been established with adequate certainty that the plant reproductive material of the operator concerned complies with the requirements referred to in Article 17(2) or the certification scheme referred to in Article 20(1).

CHAPTER III MIXTURES

Article 31

Mixtures of species or varieties

1. The Commission shall be empowered to adopt delegated acts, in accordance with Article 143, setting out rules for the placing on the market of:
 - (a) mixtures of plant reproductive material belonging to different species, or different varieties of genera or species, listed in Annex I;
 - (b) mixtures of plant reproductive material belonging to species listed in Annex I with plant reproductive material belonging to species not listed in Annex I.

Those delegated acts referred to in paragraph 1 may set out, where appropriate, requirements for the use, source areas, authorisation, packaging and labelling of those mixtures, and shall make reference to the particular genera or species on which they apply.

2. Mixtures of genera or species shall not be placed on the market unless they comply with the rules and requirements referred to in paragraph.

CHAPTER IV DEROGATIONS

Article 32

Plant reproductive material which is not finally certified

1. Plant reproductive material which has been harvested in one Member State, after a field inspection carried out by the competent authority and confirming compliance of that material with the respective requirements identified pursuant to Article 17(2) concerning production of that material, but has not yet been finally certified as pre-basic, basic or certified material pursuant to Article 18(1), may still be placed on the market if:
 - (a) it is identified as not finally certified material pursuant to Article 18(1); and
 - (b) it complies with the specific requirements referred to in paragraph 3.

That material may only be placed on the market within the premises of the same operator, or only once from one operator to another without being further transferred to any other operator.

2. In the case of paragraph 1, the operator shall inform in advance the competent authority concerned of its intention to place on the market such a material.

The Member State where the plant reproductive material has been harvested (hereinafter: 'Member State of production') and the Member State where the plant reproductive material is certified pursuant to Article 18(1) (hereinafter: 'Member State of certification') shall exchange the relevant information concerning the placing on the market of that material.

On request, the Member State of production shall supply all relevant production data to the certifying Member State. The certifying Member State shall supply information on the quantities certified to the Member State of production.

3. The Commission shall be empowered to adopt delegated acts, in accordance with Article 143, setting out specific packaging and labelling requirements for plant reproductive material referred to in paragraph 1.

Article 33

Plant reproductive material not certified as complying with applicable germination requirements

The Commission shall be empowered to adopt delegated acts, in accordance with Article 143, setting out the conditions under which plant reproductive material of particular genera or species may be temporarily placed on the market as basic material or certified material, in case the applicable germination requirements identified pursuant to Article 17(2) for basic material or certified material are not yet fully ascertained. Those conditions may concern labelling, the duration of the temporary period for placing on the market and the availability of a provisional analytical report concerning germination.

Article 34

Plant reproductive material of varieties whose registration is pending

1. By way of derogation from Article 25, competent authorities may authorise operators, for a specified period of time only, to place on the market specific

quantities for tests and trials, on farms or other production premises, of plant reproductive material belonging to a variety not registered in a national variety register pursuant to Article 49 or the Union variety register pursuant to Article 50.

2. The authorisation referred to in paragraph 1 may only be granted if that material belongs to a variety for which an application has been submitted, pursuant to Article 63 for registration in a national variety register or pursuant to Article 88 for registration in the Union variety register.
3. In order to obtain the authorisation referred to in paragraph 1, the operator shall submit to the competent authorities of the Member States where the relevant tests and trials are to take place, a request with the following information:
 - (a) a description of the envisaged tests and trials;
 - (b) the objectives pursued by those trials;
 - (c) the name(s) of the locations in which those tests and trials are to be carried out;
 - (d) a provisional denomination of the variety;
 - (e) the person responsible for the maintenance of the variety, where applicable;
 - (f) the conditions for the maintenance of the variety;
 - (g) information about the authority under which the application for the registration of the variety is pending;
 - (h) the period of time of the requested authorisation;
 - (i) the quantities of the material to be placed on the market.
4. Following the authorisation referred to in paragraph 1, Member States shall inform accordingly the other Member States, the Commission and the Community Plant Varieties Office (hereinafter: "the Office").
5. By 31 March of each year, the Office shall report to the Commission and the other Member States concerning the authorisations granted pursuant to paragraph 1 and the information submitted pursuant to paragraph 3 during the preceding year.
6. The Commission shall be empowered to adopt delegated acts, in accordance with Article 143, setting out rules on labelling of packages and on authorised quantities for specific genera or species to be placed on the market pursuant to paragraphs 1, 2 and 3 of this Article.

Article 35

More stringent requirements

1. The Commission may authorise Member States, by means of implementing acts, to adopt more stringent measures than the ones identified pursuant to Article 17(2), for the production and placing on the market of particular genera, species or categories of plant reproductive material. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 144(3).
2. In order to obtain the authorisation referred to in paragraph 1, Member States shall submit to the Commission a request about the measures they intend to adopt, indicating:
 - (a) the draft provisions of the requested measure;

- (b) the objectives of the requested measure;
- (c) a justification on the need for the adoption of such requirements, and an explanation on why less stringent requirements would not suffice to achieve the same objectives; and
- (d) whether the requested measure would be permanent or for a specified period.

Article 36

Emergency measures

1. Where it is evident that plant reproductive material is likely to constitute a serious risk to human, animal and plant health and environment, and that such risk cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned, the Commission on its own initiative or at the request of a Member State, shall without delay, by means of implementing acts, take any appropriate interim emergency measures, including measures restricting or prohibiting the placing on the market of the plant reproductive material concerned, depending on the gravity of the situation. Those measures shall be adopted in accordance with the examination procedure referred to in Article 144.
2. On duly justified imperative grounds of urgency to contain and/or address a serious risk to human health, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 144.
3. 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, the Member State concerned may adopt any appropriate interim emergency measures, restricting or prohibiting the placing on the market of the plant reproductive material concerned, depending on the gravity of the situation, within its territory. It shall immediately inform the other Member States and the Commission thereof, giving the grounds for its decision. The Commission shall adopt implementing acts aiming at extending, amending or abrogating the national interim emergency measures. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 144. The Member State may maintain its national interim emergency measures until the implementing acts referred to in in this paragraph have been adopted.
4. This Article shall apply without prejudice to any measures adopted pursuant to Article 23(2) of Directive 2001/18/EC or Article 34 of Regulation (EC) No 1829/2003 prohibiting or restricting the cultivation of GMOs.

Article 37

Derogations in the case of temporary difficulties in supply

1. By way of derogation from Article 25, and in order to remove temporary difficulties in the general supply of plant reproductive material that may occur in the Union due to unforeseeable and extraordinary circumstances, the Commission may, by means of implementing acts, authorise Member States to permit, for a maximum period of one year, the production and placing on the market of plant reproductive material belonging to a variety not included in a national variety register or in the Union register. Those implementing acts may set out the maximum quantities allowed to be placed on the market per genera or species.

2. In order to remove temporary difficulties in the general supply of plant reproductive material that may occur in the Union due to unforeseeable and extraordinary circumstances, the Commission may, by means of implementing acts, authorise Member States to permit, for a maximum period of one year, the placing on the market of plant reproductive material complying with requirements lower than the ones identified pursuant to Article 17(2). Those implementing acts may set out the maximum quantities allowed to be placed on the market per genera or species.
3. The implementing acts referred to in paragraphs 1 and 2 shall be adopted in accordance with the examination procedure referred to in accordance with Article 144(3).
4. The authorisations referred to in paragraphs 1 and 2 shall be granted on the basis of a request submitted by the Member State concerned and justifying the reasons for granting those authorisations.
5. The label of the plant reproductive material placed on the market pursuant to paragraphs 1 and 2 shall be brown. It shall respectively state that the reproductive material in question belongs to a non-registered variety or complies with lower certification requirements.

Article 38

Reduced germination rate

1. In order to remove temporary difficulties in the general supply of plant reproductive material that may occur in a Member State due to unforeseeable and extraordinary circumstances, the competent authority of the Member State concerned may authorise the placing on the market of seed with a reduced germination rate, provided that such rate is reduced by less than 5% compared to the germination rate identified pursuant to Article 17(2).
2. The authorisation referred to in paragraphs 1 shall be granted on the basis of a request submitted by the operator concerned and stating the reasons for granting those authorisations.
3. The label of the seed referred to in paragraph 1 shall indicate the actual lower germination rate.
4. In the case where the germination rate referred to in paragraph 1 is reduced by 5% or more compared to the germination rate identified pursuant to Article 17(2), the seed concerned may only be placed on the market for a specified period of time if requested so by a Member State and authorised so by the Commission. The Commission shall be empowered, in accordance with Article 143, to adopt the following requirements for the placing on the market of such seed:
 - (a) procedures and conditions for the submission of a respective request by a Member State, including the content of the application;
 - (b) a procedure and conditions for the response of other Member States, which may either offer available seeds or object to the placing on the market of seeds with reduced germination rate;
 - (c) conditions under which the seeds may be placed on the market with reduced germination rate, after the procedures of points (a) and (b) are followed;
 - (d) provisions concerning the labelling of those seeds;

- (e) a decision to be taken by the Commission concerning the placing on the market of such seeds, or a decision setting out that the seeds concerned do not fulfil the requirements of that delegated act;
- (f) conditions under which operators may request authorisation to place on the market such material in advance; and
- (g) co-ordinating tasks of the requesting Member State.

Article 39

Temporary experiments

1. The Commission may decide, by means of implementing acts, the organisation of temporary experiments to identify improved alternatives to any measures set out in, or adopted under, this Part. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 144(3).
2. The implementing acts referred to in paragraph 1 shall specify the genera or species concerned, the conditions of the experiment per genera or species concerned, the duration of the experiments, and the monitoring and reporting obligations of the participating Member States. They shall take into account the evolution of techniques for reproduction, production and control of the concerned material. The duration of an experiment shall not exceed seven growing cycles of the plant reproductive material concerned.

CHAPTER V

IMPORTS FROM AND EXPORTS TO THIRD COUNTRIES

SECTION 1

IMPORTS

Article 40

Imports on the basis of Union equivalence

Plant reproductive material may be imported from third countries only if it fulfils equivalent requirements as determined by a decision taken pursuant to Article 41.

Article 41

Commission decision on equivalence

1. The Commission may decide, by means of implementing acts, whether plant reproductive material of specific genera or species produced in a third country fulfils requirements equivalent with those applicable to plant reproductive material produced in the Union. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 144(3).
2. When adopting the decisions referred to in paragraph 1, the Commission shall consider whether:
 - (a) the official examinations, or examinations of varieties carried out by operators in accordance with the rules of the third countries concerned, afford the same assurances as the technical examination referred to in Article 68 concerning the distinctness, stability and uniformity of the variety concerned;

- (b) the checks on practices for the maintenance of the varieties carried out in the third country afford the same assurances as those provided for in Article 82; and
 - (c) the requirements in the third country concerning production of plant reproductive material and the related field inspections, lot sampling and analysis, and the certification procedures, and, in the case of standard material, the inspection by the operator, of that material, afford the same assurances as those adopted pursuant to Articles 17(2) and 19(3) for the relevant species.
3. For the purpose of adopting the decisions referred to in paragraph 1, the Commission may apply the provisions of Article [47 of revised Reg. 882] concerning the assessment of information on third countries' control systems, and may request from the third country the information, data and evidence set out in Art. [48a of revised Reg. 882].
4. When adopting the decisions referred to in paragraph 1, account shall be taken of information that the third countries concerned have provided and, where necessary, of the results of Commission controls carried out in accordance with Article [45 of revised Reg. 882]. Import conditions may apply to a single third country, to regions of a third country, or to a group of third countries.

Article 42

Accompanying documents

1. Plant reproductive material imported from third countries shall be accompanied by the following information:
- (a) an indication that the plant reproductive material concerned 'meets EU rules and standards';
 - (b) a statement that the plant reproductive material has been produced, sampled and tested in accordance with current international methods and rules, where those standards are applicable;
 - (c) date of official closing, in case of placing on the market in containers, packages or bundles;
 - (d) country of production;
 - (e) declared net or gross weight or declared number of plant reproductive material.
2. The information referred to in paragraph 1 may be given either on an official document or/and on an additional official label which shall indicate the name of the service and the country or, for standard material, on the operator's label.

SECTION 2 EXPORTS

Article 43

Exports from the Union

1. The operators and the Member States shall take the appropriate measures to ensure that export and re-export from the Union to a third country of plant reproductive material takes place in accordance with the relevant rules for production and placing on the market of that material in the Union.

2. Where the provisions of a bilateral or multilateral agreement concluded between the Union and/or one or more Member States and one or more third country(ies) are applicable, plant reproductive material exported from the Union to that third country shall comply with those provisions.
3. In absence of an agreement referred to in paragraph 2, and if requested by the authorities of the importing country, or if established by the respective legal provisions of the importing country, plant reproductive material exported from the Union to that third country shall comply with those provisions.

In the absence of those legal provisions, export or re-export of plant reproductive material may take place in accordance with the provisions of a bilateral agreement concluded between the operators concerned, with regards to the quality of that material.
4. In the cases as referred to in paragraphs 2 and 3, the operators shall make sure that such material is identified as such and kept sufficiently isolated.

TITLE III

PRODUCTION AND PLACING ON THE MARKET OF PLANT REPRODUCTIVE MATERIAL BELONGING TO GENERA OR SPECIES OTHER THAN THOSE LISTED IN ANNEX I

Article 44

Scope

This Title shall apply to plant reproductive material belonging to genera and species other than the ones listed in Annex I.

Article 45

Basic requirements

1. Plant reproductive material belonging to genera and species referred to in Article 44 shall be placed on the market in accordance with the following requirements:
 - (a) it shall be visually free from any defects likely to impair its usefulness for the purposes it is intended;
 - (b) it shall have good vigour and appropriate dimensions;
 - (c) in the case of seeds, it shall have satisfactory germination capacity;
 - (d) if placed on the market with reference to a variety, it shall have sufficient varietal identity and purity;
 - (e) it shall at least on visual inspection, be substantially free from any harmful organisms impairing quality, or any signs or symptoms thereof, which reduce its usefulness.
2. Plant reproductive material referred to in Article 44 shall be placed on the market in lots. In case lots of plant reproductive material of different origins merge into a new lot and are put together during packaging, storage, transport or at delivery, the operator shall keep records including data about composition and the origin of its individual components.

Article 46

Labelling

1. Plant reproductive material referred to in Article 44, when placed on the market, shall be accompanied by a label, including the following information:
 - (a) the species, indicated with the botanical name and in roman characters;
 - (b) the denomination of the variety, if the plant reproductive material is respectively marketed with reference to a variety;
 - (c) the name and address of the operator;
 - (d) the reference number of the lot given by the operator;
 - (e) declared number of seeds, rootstocks or other units of reproductive material, and, where applicable, the net or gross weight;
 - (f) the indication 'EU quality';
 - (g) the date of the issuance of the label;
 - (h) in the case of import from third countries, indication of the country of harvesting.
 - (i) the place of production;
 - (j) in the case of genera or species listed in Annex I, indication "for ornamental uses only";
 - (k) where applicable, indication that the respective plant reproductive material belongs to a clone or rootstock, and the denomination of the variety to which that clone or rootstock may belong to.
2. Where reproductive material is placed on the market with a reference to genera or species rather than a variety, the operator shall indicate the species or group of species in such a way as to avoid confusion with any varietal denomination.
3. The label shall be clearly and indelibly marked, produced and affixed by the operator on the outside of the package, the container or the bundle of plant reproductive material. The label shall be printed in at least one of the official languages of the Union.
4. The colour and any other characteristics of the label shall be substantially distinct to the colour and the respective characteristics of the official and the operators' labels referred to in Articles 18 and 22.
5. This Article shall apply without prejudice to Article 49(4) of Regulation (EC) No 1107/2009 concerning the label and documents accompanying treated seeds in the meaning of that Regulation.

Article 47

Placing on the market with reference to varieties

1. Plant reproductive shall be placed on the market with reference to a variety only in one or more of the following cases:
 - (a) the variety is legally protected by a plant variety right in accordance with the provisions of Regulation (EC) No 2100/94 or in accordance with national provisions;

- (b) the variety is registered in a national variety register as referred to in Article 49 or in Part A of the Union variety register as referred to in Article 50;
 - (c) the variety is entered on a list run by an operator with a description and denomination, and drawn up in accordance with accepted international guidelines, where these are applicable;
 - (d) the variety has been entered in any other public or private list with an officially recognised description.
2. Each variety shall bear the same denomination in all Member States. The operator may request the advice of the Office concerning the suitability of the denomination pursuant to the provisions of Article 61. The Office shall submit to the competent authority a recommendation on the suitability of the variety denomination proposed by the applicant, taking into account the requirements set out in Article 61.

Article 48

Import conditions

1. Plant reproductive material may not be imported from third countries unless the importing operator ensures prior to import that the material to be imported affords equivalent guarantees in all respects to plant reproductive material produced and placed on the market in the Union pursuant to the requirements of Articles 45, 46 and 47.
2. The importer shall notify the competent authorities of plant reproductive material pursuant to paragraph 1, and shall keep documentary evidence of its contract with the operator in the third country.

TITLE IV

REGISTRATION OF VARIETIES IN NATIONAL AND UNION VARIETY REGISTERS

CHAPTER I

ESTABLISHMENT OF NATIONAL AND UNION VARIETY REGISTERS

Article 49

Establishment of national variety registers

1. Each Member State shall establish, publish and update a single national register of varieties of plant reproductive material (hereinafter "national variety register").
2. The national variety registers shall include varieties and clones.
3. The Commission may adopt, by means of implementing acts, the format of the national variety registers. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 144(3).

Article 50
Establishment of Union variety register

1. The Office shall establish, publish and update a single register of varieties of plant reproductive material (hereinafter "Union variety register").
2. The Union variety register shall consist of the following two parts:
 - (a) a Part A, including varieties, rootstocks and clones directly registered at Union level and
 - (b) a Part B, including varieties, rootstocks and clones registered at national level and notified by the Member States to the Office.
3. The Commission shall adopt, by means of implementing acts, the format of the Union variety register. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 144(3).

CHAPTER II
CONTENT OF THE NATIONAL AND UNION VARIETY
REGISTERS

Article 51
Data concerning varieties

1. For varieties, the national and Union variety registers shall include at least:
 - (a) the name of the genus or species to which the variety belongs;
 - (b) the denomination of the variety and, for varieties placed on the market before the entry into force of this Regulation, where applicable its synonyms;
 - (c) the name, and where applicable the available reference number, of the applicant;
 - (d) the date of the registration of the variety or, where applicable, of the renewal of the registration;
 - (e) the end of validity of registration;
 - (f) where applicable, the indication that the variety is registered with an officially recognised description, including an indication of the region of origin of that variety;
 - (g) where applicable, the indication that the variety contains or consists of a genetically modified organism;
 - (h) where applicable, the indication that the variety is a component variety of another registered variety;
 - (i) the name of the operator responsible for the maintenance of a variety;
 - (j) specific information relating to the results of the technical examination as referred to in Article 72, including, where this has been subject to that examination, the content of undesirable substances as referred to in Article 68(2)(b);
 - (k) where applicable, indication that the variety is only produced and placed on the market in rootstocks.

2. Notwithstanding point (i) of paragraph 1, the names of the operators need not be indicated in the register when several operators are responsible for the maintenance of a variety. In that case, the national variety registers shall indicate the competent authority holding the list of names of operators responsible for the maintenance of the variety.

Article 52

Data concerning clones

For clones, the national and Union variety registers shall include at least:

- (a) the name of the genus or species, and the variety, to which the clone belongs;
- (b) the denomination of the variety to which the clone belongs and, for varieties placed on the market before the entry into force of this Regulation, where applicable its synonyms;
- (c) the date of the registration of the clone or, where applicable, of the renewal of the registration;
- (d) the end of validity of registration;
- (e) where applicable, the indication of an existing officially recognised description of the variety to which the clone belongs, including the region of origin of that variety;
- (f) where applicable, the indication that the clone contains or consists of a genetically modified organism.

Article 53

Additional Data to be included in Part B of the Union variety register

In addition to the data required pursuant to Articles 51 and 52, Part B of the Union variety register shall include:

- (a) the Member State and the competent authority of registration in the national variety register; and
- (b) a reference to the respective item of the national variety register(s).

CHAPTER III

REQUIREMENTS FOR REGISTRATION IN THE NATIONAL AND UNION VARIETY REGISTERS

SECTION 1

VARIETIES

Article 54

Requirements for varieties

1. Varieties may be registered in the national or Union variety registers only if they comply with the following requirements:
- (a) they have an official description proving that they are distinct, uniform and stable in accordance with Articles 57, 58 and 59;

- (b) in case they belong to genera or species with particular importance for sustainable development of agriculture in the Union, they have a satisfactory value for cultivation, and/or use in accordance with the provisions of Article 56;
 - (c) they bear a suitable denomination accepted pursuant to Article 61;
 - (d) in case of varieties which are genetically modified, the genetically modified organism of which those varieties consist is authorised for cultivation pursuant to Directive 2001/18/EC or Regulation (EC) 1829/2003;
 - (e) the respective variety shall not pose a risk for human, animal and plant health and the environment.
2. In addition to paragraph 1, point (c), the provisions set out in Articles 17 and 18 of Regulation (EC) No 2100/1994 concerning the use of variety denominations shall apply for the purposes of this Regulation.

Article 55

Registration concerning varieties with officially recognised description

1. In the case of national variety registers, and by way of derogation to Article 54(1)(a), varieties may also be registered in those registers if they only have an officially recognised description.
2. In the case of a registration of a variety with officially recognised description pursuant to paragraph 1, the region or regions in which the variety has historically been grown and to which it is naturally adapted, hereinafter ‘region(s) of origin’, shall be identified. The officially recognised description shall be based, where available, on information from plant genetic resource authorities or from organisations recognised for that purpose by the Member States.
3. Paragraph 1 shall not apply, and varieties may only be registered in the national variety register with an official description, if one or more of the following conditions apply:
 - (a) the variety concerned is already included in the national variety register concerned or in another national variety register, or in Part A of the Union variety register, on the basis of an official description;
 - (b) the variety concerned has been deleted from the registers referred to in point (a) in accordance with Articles 83 and 96, during the last two years;
 - (c) the variety concerned is protected by a Union plant variety right as provided for in [Article 62 of] Council Regulation (EC) No 2100/94, or by a national plant variety right, or an application for such a right is pending.

Article 56

Satisfactory value for cultivation and/or use

1. For the purpose of Article 54(b), a variety shall be deemed to have a satisfactory value for cultivation and/or use if, compared to other varieties registered in any national variety register or in the Union variety register, its characteristics, taken as a whole, offer, at least as far as production in any region is concerned, a clear improvement either for cultivation or for the uses which can be made of the crops or the products derived there from.

2. The requirement of a satisfactory value for cultivation or uses, as referred to in Article 54(b), shall not apply to:
 - (a) varieties with officially recognised description only;
 - (b) varieties used only as components for the creation of other varieties.
3. The Commission shall be empowered to adopt delegated acts, in accordance with Article 143, setting out that the varieties, with regards to all or particular uses, of certain genera and species may only be registered in a national variety register if they are of satisfactory value and/or use.
4. The Commission shall be empowered to adopt delegated acts, in accordance with Article 143, specifying requirements for the satisfactory value for cultivation and/or use of the varieties of particular genera, species or groups of species, concerning resistance to specific harmful organisms, reduced need for input of resources, decreased content of undesirable substances or increased adaptation to divergent agro-climatic environment. Those requirements shall take into account, where applicable, the available protocols.
5. Without prejudice to the requirements adopted pursuant to paragraph 4, Member States may set out requirements for the satisfactory value for cultivation and use of the varieties belonging to the genera and species set out in the delegated acts referred to in paragraph 3. Those requirements shall only be applicable for the registration of a variety in the respective national variety register.

Article 57 ***Distinctness***

1. For the purposes of Article 54(a), a variety shall be deemed to be distinct, if it is clearly distinguishable, by reference to the expression of the characteristics that result(s) from a particular genotype or combination of genotypes, from any other variety whose existence is commonly known on the date of application determined pursuant to Article 66.
2. The existence of another variety, as referred to in paragraph 1, shall be deemed to be commonly known, if on the date of application determined pursuant to Article 66 one of the following conditions apply:
 - (a) it was the object of a plant variety right in the Union;
 - (b) it has entered in a register or catalogue, in the Union or any Member State, in accordance with Article 3 of Directive 2002/53/EC, Article 3(2) of Directive 2002/55, Article 7(4) of Directive 2008/90/EC and Article 5 of Directive 68/193/EEC;
 - (c) an application for the granting of a plant variety right in respect of that variety in the Union, or for entering that variety in a national variety register as referred to Article 49 or in the Union variety register as referred to in Article 50, has been filed;
 - (d) the official description of the variety has been produced in the Union, and that technical examination has been conducted pursuant to the provisions of Article 68;
 - (e) [*SANCO reservation: to also include varieties notified to Commission (AGRI) under legislation for subsidies – to check with DG AGRI*].

Article 58

Uniformity

For the purposes of Article 54(a), a variety shall be deemed to be uniform if, subject to the variation that may be expected from the particular features of its propagation and type of variety, it is sufficiently uniform in the expression of those characteristics which are included in the examination for distinctness, as well as any others used for the official description of the variety.

Article 59

Stability

For the purposes of Article 54(a), a variety shall be deemed to be stable if 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.

Article 60

Granted plant variety rights

If a variety has been granted a plant variety right pursuant to Article 62 of Regulation (EC) No 2100/1994, that variety shall be deemed to be distinct, uniform and stable and to have a suitable denomination for the purposes of Article 54(a) and (c).

Article 61

Denomination of varieties

1. In order to be suitable for the purpose of Article 54(c), the denomination of a variety shall be identical to that under which the variety is registered in the other national variety registers and the Union variety register.
2. Paragraph 2 shall not apply if:
 - (a) the denomination in question is likely to mislead or cause confusion concerning the variety in question in one or more Member States; or
 - (b) the rights of third parties impede the free use of that denomination in connection with the variety in question.
3. For the purposes of Article 54(c), the denomination of a variety shall not be deemed suitable if:
 - (a) its use in the territory of the Union is precluded by the prior right of a third party;
 - (b) it may commonly cause its users difficulties as regards recognition or reproduction;
 - (c) it is identical or may be confused with a variety denomination under which another variety of the same or of a closely related species is entered in an official register of plant varieties or under which material of another variety has been made available in a Member State or in a Member of the International Union for the Protection of New Varieties of Plants, unless the other variety no longer remains in existence and its denomination has acquired no special significance;

- (d) it is identical or may be confused with other designations which are commonly used for the placing on the market of goods or which have to be kept free under other legislation;
 - (e) it is liable to give offence in one of the Member States or is contrary to public order;
 - (f) it is liable to mislead or to cause confusion concerning the characteristics, the value or the identity of the variety, or the identity of the breeder or any other party to proceedings.
4. The Commission shall be empowered to adopt delegated acts, in accordance with Article 143, setting out specific rules concerning the suitability of denominations of varieties. Those rules shall concern:
- (a) the relation of denomination to trade marks;
 - (b) geographical indications or designations of origin for agricultural products;
 - (c) written consents of holders of prior rights to remove impediments to the suitability of a denomination;
 - (d) specific criteria to determine whether a denomination is misleading or confusing as referred to in paragraph 2(a);
 - (e) specific criteria concerning the assessment of the suitability of the denomination concerned;
 - (f) criteria for the use of synonyms; and
 - (g) the use of a denomination in the form of a code.

SECTION 2 CLONES

Article 62

Requirements for clones

1. A clone shall be included in the national variety register, or in the Union variety register, only if it complies with the following requirements:
 - (a) it belongs to a variety registered pursuant to Article 77; and
 - (b) it has been subject to sanitary selection, and, where applicable, complies with the requirements adopted pursuant to Article 37(2) of [Plant Health Regulation].
2. The Commission shall be empowered to adopt, in accordance with Article 143, delegated acts setting out one or both of the following:
 - (a) that paragraph 1 shall only apply to the clones of particular genera or species;
 - (b) specific requirements for the genetic selection of the clones of varieties of particular genera or species.
3. Clones shall only be registered in a national variety register, or the Union variety register, in accordance with the provisions and requirements of the delegated acts referred to in paragraph 2.

CHAPTER IV NATIONAL VARIETY REGISTER PROCEDURES

SECTION 1 REGISTRATION PROCEDURE

Article 63

Submission of applications

Any person may submit to the competent authority an application for registration of a variety. That application shall be submitted in writing, including in an electronic form where applicable.

Article 64

Content of applications

1. The applications for registration of a variety in a national variety register shall contain the following items:
 - (a) a request for registration;
 - (b) identification of the botanical taxon to which the variety belongs;
 - (c) name and address of the applicant, or, where appropriate, of the joint applicants, and the credentials of any procedural representative;
 - (d) a provisional denomination;
 - (e) name and address of the person responsible for maintenance of the variety;
 - (f) a description of the main characteristics of the variety and, if available, a completed technical questionnaire;
 - (g) the geographic origin of the variety;
 - (h) information on whether the variety is registered, or is known to the applicant that an application for registration in another national variety register or the Union variety register is pending;
 - (i) in the case of a variety containing a genetically modified organism, evidence that the genetically modified organism in question is authorised for cultivation pursuant to Directive 2001/18/EC or Regulation (EC) No 1829/2003;
 - (j) in the case of an application on the basis of an officially recognised description, a file containing that description and any document or publication supporting it;
 - (k) in the case of a pending application concerning varieties granted a plant variety right as referred to in Article 60, the proof that the variety is protected by that right;
 - (l) the contact details of the applicant.

The application shall be accompanied by the submission of a sample of sufficient quality of the variety.

2. The Commission may, by means of implementing acts, determine additional items to be included in the application, taking into account the technical questionnaires

indicated in the protocols and test guidelines of the Office and/or the International Union for the Protection of New Varieties of Plants (hereinafter: "UPOV") or national protocols. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 144(3).

Article 65

Application format

The Commission shall adopt, by means of implementing acts, the format of the application referred to in Article 63 to be contained therein. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 144(3).

Article 66

Date of application

The date of application for registration shall be the date on which an application fulfilling the requirements of Article 64 was submitted to the competent authority.

Article 67

Formal examination

1. The competent authority shall register each application for registration in the national variety register it receives and shall examine whether:
 - (a) the application complies with the requirements laid down in Article 64;
 - (b) the application complies with format laid down pursuant to Article 65;
 - (c) the fees due pursuant to Article 87(1)(a) concerning the conduct of the formal examination have been paid within the time limit specified by the competent authority.
2. If the application does not comply with the requirements laid down in Article 64 or, where applicable, with the format laid down pursuant to Article 65, the competent authority shall give the applicant the possibility to make its application compliant within due time.

Article 68

Technical examination

1. Where, as a result of the formal examination, the application is found to comply with the requirements referred to in Article 64, and where applicable Article 65, a technical examination of the plant reproductive material provided shall be carried out for the purpose of establishing an official description.
2. The technical examination referred to in paragraph 1 shall verify compliance with:
 - (a) the requirements for distinctiveness, uniformity and stability of the variety, as laid down in Articles 57 to 59; and
 - (b) where applicable, the additional requirements for value for cultivation and/or use, as laid down in Article 56(5).

It shall also concern the potential content of undesirable substances.

3. The technical examination referred to in paragraph 1 shall be carried out:
 - (a) by the competent authorities; or
 - (b) by the applicant, if the applicant requests so.
4. In case an official description of the variety, produced by the Office or a competent authority, is already available, the competent authority shall decide that the technical examination referred to in paragraph 1 is not necessary.

Article 69

Technical examination by the competent authorities and audits by the Office

1. The competent authority may carry out the technical examination referred to in Article 68 only if its premises, which are dedicated to this purpose, and the organisation of those examinations have been audited and approved by the Office. That audit shall concern the suitability of those premises and organisations to comply with the requirements concerning the technical examination on distinctiveness, suitability, stability and value for cultivation and/or use of the variety, as referred to in Article 68(2(a)).
2. Further to the authorisation referred to in paragraph 1, the Office may carry out additional audits and, where applicable, recommend to the competent authorities corrective actions concerning the premises and the organisation of examinations. The competent authorities shall ensure that those premises comply with the recommendations of the Office.

In case the Office concludes that the competent authorities concerned repeatedly do not comply with its recommendations, it may revoke or modify the approval referred to in paragraph 1.
3. The Commission shall be empowered to adopt delegated acts, in accordance with Article 143, setting out conditions for the audit by the Office of premises and of organisations for examinations to confirm compliance with the requirements referred to in Article 56, concerning the satisfactory value for cultivation and use of certain species. After the adoption of those delegated acts, paragraph 1 shall also apply for the technical examination concerning the additional requirements for value for cultivation and/or use, as laid down in Article 56(5).

Article 70

Technical examination by the applicant

1. The applicant may carry out the technical examination referred to in Article 68 only if its premises, which are dedicated to this purpose, and the organisation of those examinations have been audited and approved by the competent authority. That audit shall concern the suitability of those premises and organisations to comply with the requirements concerning the technical examination on distinctiveness, suitability, stability and value for cultivation and/or use of the variety, as referred to in Article 68(2(a) and (b)).
2. Further to the authorisation referred to in paragraph 1, the competent authority may carry out additional audits and, where applicable, recommend to the applicant corrective actions concerning the premises and the organisation of examinations. The applicant shall ensure that those premises comply with the recommendations of the competent authority.

In case the competent authority concludes that the applicant concerned repeatedly does not comply with its recommendations, it may revoke or modify the approval referred to in paragraph 1.

Article 71

General requirements for the technical examination

The Commission may, by means of implementing acts, identify requirements for the technical examination referred to in Article 68, as regards:

- (a) the scope of the audit with regard to specific genera and species;
- (b) interviews of staff of competent authority concerning the technical examination referred to in Article 68;
- (c) the necessary equipment, including laboratories for the obligatory disease resistance characteristics;
- (d) record of activities;
- (e) the establishment of variety reference collection to assess the distinctness and storage management of the reference collection;
- (f) the establishment of quality management system;
- (g) visit of technical facilities for each group of species.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 144(3).

Article 72

Specific requirements for the technical examination

1. The Commission may, by means of implementing acts, set out specific requirements for the technical examination referred to in Article 68 concerning varieties of particular genera or species. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 144(3). The requirements of those implementing acts shall concern, where applicable, the conduct of growing trials and laboratory tests.
2. If no requirements have been adopted pursuant to paragraph 1, the respective technical examinations shall take place in accordance the available protocols and guidelines adopted by the Office before the entry into force of this Regulation, or adopted by UPOV, or, in their absence, adopted by national protocols.

Article 73

Confidentiality

Where, in the framework of the technical examination referred to in Article 68, an examination of the genealogical components is necessary, the results of that examination and the description of the genealogical components shall be treated as confidential, if the applicant or his representative so requests.

Article 74

Provisional official description

1. Following the technical examination referred to in Article 68, the competent authority shall produce a provisional examination report and, where it considers that the conditions laid down in Articles 57 to 59 are complied with, a provisional official description of the variety on the basis of that report.
2. The examination reports may refer to findings of other examination reports of other competent authorities or the Office concerning the variety in question.
3. The competent authority shall communicate the provisional examination report and the provisional official description of the variety to the applicant.
4. Where the competent authority does not consider the examination report to constitute a sufficient basis for a decision on the registration of the variety, it shall provide a complementary examination of its own motion, after consultation of the applicant, or on request of the applicant. For the purposes of assessment of the results, any complementary examination carried out until a decision is taken pursuant to Article 77 shall be considered to be part of the technical examination referred to in Article 68.

Article 75

Final official description

1. After having given the applicant an opportunity to comment on the provisional examination report official description, the competent authority shall establish a final examination report and official description.
2. Competent authorities shall make available the examination reports to all other competent authorities, the Commission and the Office upon their request.
3. Competent authorities shall make available the examination reports to third parties upon request, subject to the national or Union provisions on data protection and applicable rules on confidentiality. Upon request, competent authorities shall make available to any person the official description of the variety.

Article 76

Examination of the denomination

1. After the formal examination referred to in Article 67, and before a variety is registered in a national variety register, the competent authority shall consult the Office on the denomination of the variety proposed by the applicant.
2. The Office shall submit to the competent authority a recommendation on the suitability of the variety denomination proposed by the applicant, taking into account the requirements set out in Article 61. The competent shall inform the applicant on that recommendation.

Article 77

Decision on registration

1. If on the basis of the procedure set out in Articles 63 to 76 it is concluded that the variety complies with the requirements set out in Article 54, the competent authority shall adopt a decision to register the variety in the national variety register.

2. The competent authority shall adopt a decision refusing registration in the national variety register if, and as soon as, it establishes that:
 - (a) the requirements set out in Article 54 have not been fulfilled;
 - (b) the applicant has not remedied any deficiencies which it was given an opportunity to correct within due time pursuant to Article 67(2);
 - (c) where applicable, the applicant has not complied with a rule pursuant to an act adopted under Article 70, or a request of the competent authority to comply with that rule within a time limit laid down.
3. The competent authority shall communicate to the applicant a copy of the decision referred to in paragraphs 1 and 2. In case of a decision refusing the registration of a variety, the competent authority shall explain in its decision the reasons justifying the refusal and shall make available to the applicant the results of the technical examinations referred to in Article 68.

Article 78

Already registered varieties

By way of derogation from Articles 63 to 77, the competent authorities shall register in their respective national variety registers all varieties officially accepted or registered, before the entry into force of this Regulation, in the catalogues, lists or registers established pursuant to Article 3 of Directive 2002/53/EC, Article 3(2) of Directive 2002/55/EC, Article 7(4) of Directive 2008/90/EC and Article 5 of Directive 68/193/EC and all clones of varieties registered pursuant to Article 5 of Directive 68/193/EC and Article 7(4) of Directive 2008/90/EC.

Article 79

New denomination after registration

Where, after the registration of a variety, it is established by the competent authority that at the time of the registration the denomination of the variety was not suitable within the meaning of Article 61, the applicant shall submit an application for a new denomination. The competent authority shall decide on that application on the basis of any new information and upon consultation with the Office. The competent authorities may permit the previous denomination to be used temporarily.

SECTION 2

VALIDITY, RENEWAL AND DELETION

Article 80

Period of validity

1. The period of validity of the registration of a variety in a national variety register shall be 30 years.
2. In the case of varieties consisting of or containing genetically modified organisms, the validity of the registration shall be limited to the period for which the genetically modified organism of which the variety consists is authorised for cultivation pursuant to Directive 2001/18/EC or Regulation (EC) No 1829/2003.

Article 81
Renewal of registration

1. The registration of a variety in a national variety register may be renewed for further periods of 30 years, pursuant to paragraphs 4 and 5.
2. That renewal shall only be granted if the variety continues complying with the requirements of Article 57 and provided that material of that variety is still available and maintained.
3. In the case of a variety consisting of or containing genetically modified organisms, the renewal shall be, in addition, subject to the condition that the respective genetically modified organism continues to be authorised for cultivation pursuant to Directive 2001/18/EC or Regulation (EC) No 1829/2003. The renewal period shall be limited to the period of authorisation of the genetically modified organism concerned.
4. Any person intending to renew the registration of a variety shall submit an application for renewal of the registration of the variety in writing, or, where provided so by national rules, in an electronic form. That application shall be accompanied by evidence showing that the conditions set out in paragraphs 2 and 3 are fulfilled.
5. A competent authority may renew the registration of a variety, for which no application for renewal has been submitted, where it considers, that renewal serves to preserve genetic diversity and sustainable production.
6. Paragraph 5 shall apply only once the competent authority concludes that a person is responsible to maintain the variety in accordance with the provisions of Article 82.

Article 82
Maintenance of varieties

1. Varieties registered in a national variety register shall be maintained, in accordance with accepted practices, by the applicant, or any other person in mutual agreement with the applicant notified to the competent authority.
2. The persons referred to in paragraph 1 shall keep records concerning the maintenance of the respective variety. It shall at all times be possible for the competent authority to check the maintenance of the variety from those records. Those records shall also cover the production of all generations prior to basic material.
3. The competent authority may request from the persons referred to in paragraph 1 samples of the respective varieties. Such samples shall if necessary be taken by the competent authority.
4. Where maintenance takes place in a Member State other than that in which the variety has been registered, the competent authorities of the two member States concerned shall assist each other as regards the checks relating to maintenance.
5. Varieties with officially recognised description only, shall only be maintained in their region(s) of origin.
6. In case the competent authority finds that the person responsible for the maintenance does not comply with the provisions of this Article, it shall provide the opportunity to that person to take corrective action.

Article 83

Deletion from national variety registers

1. The competent authority shall adopt a decision deleting from the national variety register a variety, in one or more of the following cases:
 - (a) the competent authority concludes, on the basis of any new evidence, that the requirements for registration, as set out in Article 54, are no longer fulfilled;
 - (b) a request to delete the variety from the national variety register is submitted by the applicant of the registration of that variety;
 - [(c) the applicant does not pay the annual fee pursuant to Article 87(1)(d)];
 - (d) the applicant or the person responsible for the maintenance the variety, referred to in Article 82(1), so requests, unless maintenance of the variety is assured by another person;
 - (e) if it is proven that the variety is no longer maintained pursuant to Article 82;
 - (f) it is proven that, at the time of the application, false or fraudulent data were supplied concerning the facts on the basis of which registration was decided;
 - (g) where it is established pursuant to Article 61 that a denomination was not suitable at the time of the registration of the variety, the applicant does not propose another suitable denomination;
 - (h) after the expiration of the validity of the period referred to in Article 69(1), the applicant has not submitted an application for renewal and the competent authority does not consider that a renewal serves to preserve genetic diversity and sustainable production.
2. Paragraph 1 shall also apply to varieties already registered in the registers, catalogues and lists of the Directives referred to in Article 78.
3. On request by the applicant, the competent authority may allow the variety deleted from the national variety register in accordance to paragraph 1(b) to continue to be placed on the market until 30 June of the third year following the deletion from the register.
4. The competent authority may keep the variety in the national variety register in one of the following cases:
 - (a) if the conditions referred to in Article 81(3) concerning the renewal of registration are applicable; or
 - (b) if requested so by another person interested in the production and placing on the market of plant reproductive material of this variety. That request may be submitted at any time before, or within six months after, the deletion of the variety from this register.
5. Paragraph 4 shall apply only once the competent authority concludes that a person is responsible to maintain the variety in accordance with the provisions of Article 73.

SECTION 3 REGISTRATION OF CLONES

Article 84

Applications

1. Any person may submit to the competent authority an application for registration of a clone in a national variety register in writing or, where provided so by national rules, in an electronic form.
2. The applications for registration of a clone in the national variety register shall contain the following items:
 - (a) a request for registration;
 - (b) identification of the botanical taxon, and where applicable variety, to which the clone belongs;
 - (c) name and address of the applicant, or, where appropriate, the joint applicants, [and the credentials of any procedural representative];
 - (d) a provisional denomination;
 - (e) the details of the person responsible for maintenance of the clone, where applicable;
 - (f) a description of the main characteristics of the clone and, if available, a completed technical questionnaire;
 - (g) the geographic origin of the clone;
 - (h) information on whether the clone is registered, or is known to the applicant that an application for registration in another national variety register or the Union variety register is pending;
 - (i) in the case of a clone containing a genetically modified organism, evidence that the genetically modified organism in question is authorised for cultivation pursuant to Directive 2001/18/EC or Regulation (EC) No 1829/2003;
 - (j) the contact details of the applicant.

The application shall be accompanied by the submission of a sample of sufficient quality of the clone.
3. The date of application for registration shall be the date on which an application fulfilling the requirements of Article 64 was submitted to the competent authority.

Article 85

Formal and technical examination of the application for registration of clones

1. The competent authority shall register each application it receives for registration of a clone in the national variety register and shall examine whether:
 - (a) the application complies with the requirements laid down in Article 84(2); and
 - (b) the fees due pursuant to Article 87(1)(a) concerning the conduct of the formal examination have been paid within the time limit specified by the competent authority.

2. If the application does not comply with the requirements laid down in Article 84(2), the competent authority shall give the applicant the possibility to make its application compliant within due time.
3. A technical examination shall be carried out to confirm compliance of the clone with the requirements referred to in Article 62. The provisions of Articles 70 and 71 shall apply accordingly for the technical examination of clones.

Article 86

Denomination, decision, renewal, maintenance, period of validity and deletion concerning clones

Articles 61, 76, 77, 78, 79, 80, 81, 82 and 83 shall apply accordingly to the denomination of clones, decision on registration of clones, already registered clones, new denominations of clones, period of validity and renewal of registration of clones, maintenance of clones and deletion of clones from the national variety register. Any reference in those Articles to varieties shall be construed as reference to clones.

SECTION 4 REGISTRATION FEES

Article 87

Registration fees

1. The competent authorities shall charge fees to recover the necessary costs incurred for the following actions:
 - (a) the formal examination referred to in Article 67;
 - (b) the technical examination referred to in Article 68 and the audits referred to in Article 70(2);
 - (c) the examination of the variety denomination referred to in Article 76;
 - (d) the processing of the decision referred to in Article 77, and an appeal lodged pursuant to national rules against that decision;
 - (e) the inclusion of the variety in the national variety register for each year of the duration of the registration;
 - (f) the formal examination, technical examination, examination of variety denomination and processing of the decision concerning the registration of clones, as set out in Articles 85 and 86.
2. The action referred to in paragraph 1 shall only be carried out on demand. The demand shall be deemed not to have been made, if the payment of the fees has not been effected within one month from the date on which the competent authority requested payment of the fees and indicated in that request the consequences of the failure to pay.
3. If certain information provided by the applicant for registration of a variety in the Union variety register, can only be verified by a specific technical examination which goes beyond the framework established pursuant to Article 68, the fees for the technical examination may be increased, after having heard the person liable to pay the fees, up to the amount of the expenditure actually incurred.

4. The Commission shall be empowered to adopt delegated acts, in accordance with the procedure referred to in Article 143, setting out the amount of specific cost items to be covered pursuant to paragraph 1(a-d). That amount may be reduced in the case of varieties with officially recognised description only.
5. Fees provided for pursuant to paragraph 1 shall not directly or indirectly be refunded, unless unduly collected. However, Member States may:
 - (a) refund fully or partly fees provided for in paragraph 1 collected from enterprises employing fewer than 10 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 2 million;
 - (b) exempt enterprises referred to in point (a) from the payment of the fees provided for in paragraph 1 provided that:
 - (i) all costs incurred by the competent authorities, including those related to the activities of the enterprises referred to in point (a), are calculated in accordance with [Articles 43 and 44 of revised Reg 882/2004]; and
 - (i) the loss of revenue for the competent authorities which is the result of the exemption is compensated by the transfer to the competent authorities of an amount equivalent to the loss.
6. Union legislation applicable to State aid shall apply to the measures referred to in paragraph 5.

CHAPTER V

PROCEDURES CONCERNING PART A OF THE UNION VARIETY REGISTER

SECTION 1

REGISTRATION PROCEDURE

Article 88

Applications and examination of applications for registration in Part A of the Union variety register

1. For the registration of a variety in Part A of the Union variety register, the following Articles shall apply accordingly:
 - (a) Article 63, on the submission of applications;
 - (b) Article 64, on the content of applications;
 - (c) Article 65, on the application format;
 - (d) Article 66, on the date of application;
 - (e) Article 67, on the formal examination;
 - (f) Article 73, on confidentiality.
2. References in those Articles to the competent authority shall be construed, for the purpose of paragraph 1, as references to the Office.

Article 89

Technical examination

1. Where, as a result of the formal examination, the application is found to be compliant with the conditions laid down in Article 88(1)(e), a technical examination of the plant reproductive material shall be carried out for the purpose of establishing an official description.
2. That technical examination shall examine compliance with:
 - (a) the requirements for distinctiveness, uniformity and stability of the variety, as laid down in Articles 57 to 59; and
 - (b) where applicable, the additional requirements for value for cultivation and/or use, as laid down in Article 56(5).

It shall also concern the potential content of undesirable substances.
3. The technical examination referred to in paragraph 1 shall be carried out:
 - (a) by the Office, or another person delegated by the Office; or
 - (b) by the applicant, if the applicant requests so.
4. In case an official description of the variety, produced by the Office or another competent authority, is already available, the Office shall decide that the technical examination referred to in paragraph 1 is not necessary.

Article 90

Technical examination by the Office

1. The Office, or a person delegated by the Office, may carry out the technical examinations referred to in Article 89, only in premises which are dedicated to this purpose, and where the organisation of those examinations has been audited and approved by the Office.

If the applicant requests so, the Office, or a person delegated by the Office, shall carry out those examinations in specific premises, provided that they have been audited and approved pursuant to this paragraph.
2. Further to the authorisation referred to in paragraph 1, the Office may carry out additional audits and, where applicable, recommend to the applicant corrective actions concerning the premises and the organisation of examinations. The applicant shall ensure that those premises comply with the recommendations of the Office.

In case the Office concludes that the applicant concerned repeatedly does not comply with its recommendations, it may revoke or modify the approval referred to in paragraph 1.

Article 91

Technical examination by the applicant

The provisions of Article 70 shall apply accordingly for the technical examinations by the applicant for the purpose of registration of a variety in the Union variety register. References in that Article to the competent authority shall be construed, for the purpose of this Article, as reference to the Office.

Article 92

Examination of the denomination

1. After the formal examination referred to in Article 88(1)(e), and before a variety is registered in the Union variety register, the Office shall examine the denomination of the variety proposed by the applicant.
2. The Office shall decide on the suitability of the variety denomination proposed by the applicant, taking into account the requirements set out in Article 61.

Article 93

Examination reports and official description in Part A of the Union variety register

1. Articles 74 and 75 shall apply accordingly for the examination reports and the official description of the varieties, for the purpose of registration in Part A of the Union variety register.
2. References in those Articles to the competent authority shall be construed, for the purpose of this Article, as references to the Office.

Article 94

Decision on registration

1. If on the basis of the procedure set out in Articles 88 to 93 it is concluded that the variety complies with the requirements set out in Article 54, the Office shall adopt a decision to register the variety in Part A of the Union variety register.
2. The Office shall adopt a decision refusing registration in the national variety register if, and as soon as, it establishes that:
 - (a) the requirements set out in Article 54 have not been fulfilled;
 - (b) the applicant has not remedied any deficiencies which it was given an opportunity to correct within the notified time limit pursuant to Article 67(2);
 - (c) where applicable, the applicant has not complied with a rule pursuant to an act adopted pursuant to Article 91, or a request of the competent authority to comply with that rule within a time limit laid down.
3. The Office shall communicate to the applicant a copy of the decision referred to in paragraphs 1 and 2. In case of a decision refusing the registration of a variety, the Office shall explain in its decision the reasons justifying the refusal and shall make available to the applicant the results of the technical examination referred to in Article 91.

Article 95

New denomination after registration in part A of the Union variety register

The provisions of Article 79 shall apply accordingly for the technical examinations by the applicant for the purpose of registration of a variety in the Union variety register. References in that Article to the competent authority shall be construed, for the purpose of this Article, as reference to the Office.

SECTION 2

VALIDITY, RENEWAL AND DELETION

Article 96

Validity, renewal and deletion

1. The provisions of Articles 80, 81 and 83 shall apply accordingly for the period of validity of registration, renewal of registration and deletion of varieties from Part A of the Union variety register.
2. References in those Articles to the competent authority shall be construed, for the purpose of this Article, as references to the Office.

Article 97

Maintenance of varieties

1. Varieties registered in Part A of the Union variety register shall be maintained, in accordance with accepted practices, by the applicant, or any other person in mutual agreement with the applicant and notified to the Office.
2. The persons referred to in paragraph 1 shall keep records concerning the maintenance of the respective variety. It shall at all times be possible for the Office to check the maintenance of the variety from those records. Those records shall also cover the production of all generations prior to basic material.
3. The Office may request samples from the persons referred to in paragraph 1. Such samples may if necessary be taken by the Office.
4. The Office shall co-operate with the Member State(s) in which the maintenance of the variety takes place, as regards the checks relating to maintenance.
5. Varieties with officially recognised description only shall be maintained in their region(s) of origin.

SECTION 3

FEES

Article 98

Registration Fees

1. The Office shall charge fees to the necessary costs for the following actions:
 - (a) the processing of applications for registration of a variety in Part A of the Union variety register, including:
 - (i) the formal examination referred to in Article 88(1)(e);
 - (ii) the technical examination referred to in Article 89 and the audits referred to in Article 91;
 - (iii) the examination of the variety denomination referred to in Article 92;
 - (iv) the decision on the variety registration referred to in Article 94;
 - (v) the inclusion of the variety in the Union variety register referred for each year of the duration of the registration;] and

- (b) the processing of an appeal lodged pursuant to Article 99, including the decision.
- 2. The actions set out in paragraph 1 shall only be carried out on demand. If fees due in respect of those are not paid, the demand shall be deemed not to have been filled if the acts necessary for the payment of the fees have not been effected within one month of the date on which the Office requested payment of fees and indicated in so doing these consequences of failure to pay.
- 3. If certain information provided by the applicant for registration of a variety in the Union variety register, can only be verified by a specific technical examination which goes beyond the framework established pursuant to Article 68, the fees for the technical examination may be increased, after having heard the person liable to pay the fees, up to the amount of the expenditure actually incurred.
- 4. The Commission shall be empowered to adopt delegated acts, in accordance with the procedure referred to in Article 143, setting out the amount of the fees referred to in paragraph 1. This amount may be reduced in the case of applicants who are producers of small quantities only. The level at which the fees are set shall reflect the principle of sound financial management to allow the Office to maintain a balanced budget.
- 5. Fees provided for pursuant to paragraph 1 shall not directly or indirectly be refunded, unless unduly collected. However, Member States may:
 - (a) refund fully or partly fees provided for in paragraph 1 collected from enterprises employing fewer than 10 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 2 million;
 - (b) exempt enterprises referred to in point (a) from the payment of the fees provided for in paragraph 1 provided that:
 - (i) all costs incurred by the competent authorities, including those related to the activities of the enterprises referred to in point (a), are calculated in accordance with [Articles 43 and 44 of revised Reg 882/2004]; and
 - (ii) the loss of revenue for the competent authorities which is the result of the exemption is compensated by the transfer to the competent authorities of an amount equivalent to the loss.
- 6. Union legislation applicable to State aid shall apply to the measures referred to in paragraph 5.

SECTION 4

APPEALS

Article 99

Decisions subject to appeal

- 1. An appeal shall lie from decisions of the Office which have been taken concerning the registration of varieties pursuant to Article 94, the amendment of a denomination pursuant to 95, and the fees pursuant to Article 98. It shall be examined by the Board of Appeal of the Office referred to in Article 46 of Regulation (EC) No 2100/1994 (hereinafter 'the Board of Appeal').

2. An appeal lodged pursuant to paragraph 1 shall have suspensory effect. The Office may, however, if it considers that circumstances so require, order that the contested decision shall not be suspended.
3. An appeal against a decision which does not terminate proceedings as regards one of the parties may only be made in conjunction with an appeal against the final decision, unless the decision provides for separate appeal.

Article 100

Persons entitled to appeal and to be parties to appeal proceedings

Any person may appeal against a decision, addressed to that person, or against a decision which, although in the form of a decision addressed to another person, is of direct and individual concern to the former. The parties to proceedings may, and the Office shall, be party to the appeal proceedings.

Article 101

Time limit and form

Notice of appeal shall be filed in writing at the Office within two months of the service of the decision where addressed to the appealing person, or, in the absence thereof, within two months of the publication of the decision, and a written statement setting out the grounds of appeal shall be filed within four months after the aforesaid service or publication.

Article 102

Interlocutory revision

1. If the Office considers the appeal to be admissible and well founded, it shall rectify the decision. This shall not apply where the appellant is opposed by another party to the appeal proceedings.
2. If the decision is not rectified within one month after receipt of the statement of grounds, for the appeal, the Office shall forthwith decide whether it will take an action pursuant to Article 99(2), second sentence, and remit the appeal to the Board of Appeal.

Article 103

Examination of appeals

1. If the appeal is admissible, the Board of Appeal shall examine whether the appeal is well-founded.
2. When examining the appeal, the Board of Appeal shall as often as necessary invite the parties to the appeal proceedings to file observations on notifications issued by itself or on communications from the other parties to the appeal proceedings within specified time limits. Parties to the appeal proceedings shall be entitled to make oral representations.

Article 104

Decision on appeal

The Board of Appeal shall decide on the appeal on the basis of the examination carried out pursuant to Article 103. The Board of Appeal may exercise any power which lies within the competence of the Office, or it may remit the case to the competent body of the Office for

further action. The latter one shall, in so far as the facts are the same, be bound by the *ratio decidendi* of the Board of Appeal.

Article 105

Actions against decisions of the Boards of Appeal

1. Actions may be brought before the Court of Justice against decisions of the Boards of Appeal on appeals.
2. The action may be brought on grounds of lack of competence, infringement of an essential procedural requirement, infringement of the Treaty, of this Regulation or of any rule of law relating to their application, or misuse of power.
3. The Court of Justice shall have jurisdiction to annul or to alter the contested decision.
4. The action shall be open to any party to appeal proceedings which has been unsuccessful, in whole or in part, in its submissions.
5. The action shall be brought before the Court of Justice within two months of the date of service of the decision of the Board of Appeal.
6. The Office shall be required to take the necessary measures to comply with the judgment of the Court of Justice.

Article 106

Delegated acts on miscellaneous conditions governing proceedings

The Commission shall be empowered to adopt delegated acts, in accordance with Article 143, setting out provisions concerning statement of grounds on which decisions are based, examination of the facts by the Office on its own motion, oral proceedings, taking of evidence, service of decisions and summonses by the Office, restoration of applicant's rights in case it fails to respect time limits, application of general principles of procedural law and procedural representative.

CHAPTER VI PROCEDURES CONCERNING PART B OF THE UNION VARIETY REGISTER

Article 107

Registration procedure

1. Each competent authority shall notify within 5 working days the Office of the application for the registration of a variety, the adoption of the decision referred to in Article 77, the person responsible for the maintenance of the variety, the deletion of a variety pursuant to Article 83 and the new denomination after registration pursuant to Article 79.
2. The Commission may adopt, by means of implementing acts, modalities concerning the submission of the notifications referred to in paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 144(3).

CHAPTER VII INFORMATION

Article 108

Documentation on the national variety registers and on the Union variety register

1. The competent authority shall keep a file on each variety registered in the national variety register, containing the official description, the examination report and any complementary report issued pursuant to Articles 78 and 79. Where applicable, the file shall only contain the officially recognised description of the variety, and the documents supporting that description.
2. The Office shall keep a file on each variety registered in the Union variety register, containing the official description, the examination report and any complementary report issued pursuant to Articles 94. Where applicable, the file shall only contain the officially recognised description of the variety, and the documents supporting that description.

Article 109

Information on the national variety registers

1. Each Member State shall inform the other Member States, the Office and the Commission the information required to access its national variety register.
2. By 31 March of each year, each competent authority shall notify to the other competent authorities, the Office and the Commission any amendments of the respective national variety registers which took place during the preceding year.
3. Each competent authority shall, on request, make available to another competent authority, the Office or the Commission:
 - (a) the examination reports, official description or officially recognised description of varieties registered in the respective national variety register;
 - (b) the results of technical examinations referred to in Article 68;
 - (c) the list of varieties for which an application for registration is pending;
 - (d) any other information available in respect of registered or deleted varieties.
4. The competent authority shall take appropriate measures to make available to any person requesting access to information contained in the files referred to in Article 51. This provision shall not apply where the information must be treated as confidential under Article 73.

Article 110

Information on the Union variety register

1. The Office shall notify the competent authorities and the Commission of the information required to access the Union variety register.
2. By 31 March of each year, the Office shall notify the other competent authorities and the Commission any other amendments to Part A of the Union variety register respectively made during the preceding year.

3. The Office shall, on request, and with regards to Part A of the Union variety register, make available to a competent authority or the Commission:
 - (a) the examination reports or official description of the registered varieties;
 - (b) the results of technical examinations referred to in Article 89;
 - (c) the list of varieties for which applications for registration are pending;
 - (d) any other information available in respect of registered or deleted varieties.
4. The Office shall take appropriate measures to make available information contained in the files referred to in Article 109. This provision shall not apply where the information must be treated as confidential under Article 73.

PART IV

PRODUCTION AND PLACING ON THE MARKET OF FOREST REPRODUCTIVE MATERIAL

TITLE I

GENERAL PROVISIONS

Article 111

Scope

This Part shall apply to the production with a view to placing on the market, and placing on the market, of forest reproductive material.

Article 112

Definitions

1. For the purposes of this Part, the following definitions shall apply:
 - (a) 'basic forest material' means seed source, stand, seed orchard, parents of family, clone or clonal mixture;
 - (b) "seed source" means trees within a delimited area from which seed is collected;
 - (c) "stand" means a delineated population of trees possessing sufficient uniformity in composition;
 - (d) "seed orchard" means a plantation of selected clones or families which is isolated or managed so as to avoid or reduce pollination from outside sources, and managed to produce frequent, abundant and easily harvested crops of seed;
 - (e) "parents of family" means trees used to obtain progeny by controlled or open pollination of one identified parent used as a female, with the pollen of one parent (full-sibling) or a number of identified or unidentified parents (half sibling);
 - (f) "clone" means group of individuals (ramets) derived originally from a single individual (ortet) by vegetative propagation, including by cuttings, micropropagation, grafts, layers or divisions;
 - (g) "clonal mixture" means a mixture of identified clones in defined proportions;
 - (h) "Autochthonous stand" or 'autochthonous seed source' means a stand or seed source which:
 - (i) has been continuously regenerated by natural regeneration; or
 - (ii) has been regenerated artificially from reproductive material collected in the same stand or seed source ; or
 - (iii) has been regenerated artificially from reproductive material collected in autochthonous stands or seed sources within the close proximity;
 - (i) 'Indigenous stand' or 'indigenous seed source' means:
 - (i) an autochthonous stand or seed source or

- (ii) a stand or seed source raised artificially from seed, the origin of which is situated in the same region of provenance;
- (j) 'origin' means:
 - (i) for an autochthonous stand or seed source – the place in which the trees are growing;
 - (ii) for a non-autochthonous stand or seed source – the place from which the seed or plants were originally introduced;
- (k) 'provenance' means the place in which any stand of trees is growing;
- (l) 'region of provenance' means, for a species or sub-species, the area or group of areas subject to sufficiently uniform ecological conditions in which stands or seed sources showing similar phenotypic or genetic characters are found, and is delimited, where appropriate, by altitudinal boundaries;
- (m) "category" means source-identified, selected, qualified or tested reproductive material; (n) 'source-identified': means reproductive material derived from forest basic material which may be either a seed source or stand located within a single region of provenance;
- (n) 'selected' : means reproductive material derived from forest basic material consisting of a stand located within a single region of provenance and which has been phenotypically selected at the population level;
- (o) 'qualified': means reproductive material derived from forest basic material consisting of seed orchards, parents of families, clones or clonal mixtures, the components of which have been phenotypically selected at the individual level;
- (p) 'tested': means reproductive material derived from basic material consisting of stands, seed orchards, parents of families, clones or clonal mixtures of superior quality;
- (r) "planting stock" means plants raised from seed units, from parts of plants, or from plants from natural regeneration(s);
- (q) "Seed unit" means cones, infructescences, fruits and seeds intended for the production of planting stock;
- (r) "parts of plants" means stem cuttings, leaf cuttings and root cuttings, explants or embryos for micropropagation, buds, layers, roots, scions, sets and any parts of a plant intended for the production of planting stock;
- (s) 'area of utilisation' means the area where the forest reproductive material is used for a specified purpose.

TITLE II

BASIC FOREST MATERIAL

Article 113

Approval of basic material

1. Basic forest material shall be approved by the competent authority if it meets the requirements set out in Annexes IV, V, VI or VII for each category. Each approved basic forest material (hereinafter: 'unit of approval') shall be identified by a unique reference to the register referred to in Article 117(1).

2. The approval shall be withdrawn, if the requirements referred to in paragraph 1 are no longer met.

Article 114

Provisional approval of basic forest material intended for the production of tested material

1. Notwithstanding Article 113(2), the competent authorities may provisionally approve basic material for the production of tested reproductive material even if the comparative tests provided for in Annex VII have not been completed, provided that it can be assumed that the basic material will, when tests have been completed, satisfy the requirements for approval.
2. The assumption that the basic material will satisfy the requirements for approval, as referred to in paragraph 1, shall be based on the provisional results of the genetic evaluation or comparative tests referred to in Annex VII.
3. The provisional approval referred to in paragraph 1 shall be issued for a period of ten years and may cover all or part of the territory of the Member State concerned.

Article 115

Post approval inspections

After approval, the basic forest material for the production of forest reproductive material under the selected, qualified and tested categories shall be re-inspected by the competent authority at regular intervals.

Article 116

Demarcation of regions of provenance

1. In the case of basic forest material intended for the production of reproductive material of the 'source-identified' and 'selected' categories, the Member States shall, for the relevant species, demarcate the regions of provenance.
2. Member States shall draw up and publish maps showing the demarcations of the regions of provenance. Those maps shall be communicated to the Commission and other Member States.

Article 117

Register and national list of approved basic material

1. Member States shall establish a national register of the basic forest material of the various species approved on its territory including full details of each unit of approval together with its unique register reference.
2. Each Member State shall draw up, publish and update a summary of the national register in the form of a national list. The national list shall be presented in a common form for each basic forest material. The following details shall be provided:
 - (a) botanical name;
 - (b) category;
 - (c) purpose;
 - (d) type of basic forest material;

- (e) register reference to the unit of approval or, where appropriate, summary thereof or identity code for region of provenance;
 - (f) location: a short name, if appropriate, and any of the following sets of particulars:
 - (i) for the 'source-identified' category, region of provenance and the latitudinal and longitudinal range;
 - (ii) for the 'selected' category, region of provenance and the geographical position defined by latitude and longitude or the latitudinal and longitudinal range;
 - (iii) for the 'qualified' category, the exact geographical position(s) where the basic material is maintained;
 - (iv) for the 'tested' category, the exact geographical position(s) where the basic material is maintained;
 - (g) altitude or altitudinal range;
 - (h) area: the size of a seed source(s), stand(s) or seed orchard(s);
 - (i) origin: it shall be stated whether the basic material is autochthonous/indigenous, non autochthonous/non-indigenous or if the origin is unknown. For non-autochthonous/non-indigenous basic material, the origin shall be stated if known;
 - (j) in the case of material of the 'tested' category, whether it is genetically modified.
3. For the categories 'source-identified' and 'selected', a summary of basic material based on regions of provenance is permitted.
 4. The Commission shall adopt, by means of implementing acts, the form in which such national lists shall be established. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 144(3).

Article 118

Union List of Approved Basic Material for the Production of Forest Reproductive Material

1. Member States shall notify to the Office and the other Member States the national lists referred to in Article 117(2) and any of its updates within 5 working days.
2. On the basis of the national lists notified by each Member State, the Office shall draw up, keep, update and publish a register entitled 'Union List of Approved Basic Material for the Production of Forest Reproductive Material'.

That Union list shall reflect the details contained in the national lists referred to in Article 117 and indicate the area of utilisation and any authorisations or restrictions under Article 138.
3. The Commission shall adopt, by means of implementing acts, the format of the notification referred to in paragraph 1 and of the register referred to in paragraph 2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 144(3).

TITLE III

PRODUCTION AND PLACING ON THE MARKET OF MATERIAL DERIVED FROM BASIC FOREST MATERIAL

Article 119

Requirements for production and placing on the market of forest reproductive material

1. Forest reproductive material may be placed on the market if:
 - (a) basic forest material approved pursuant to Articles 113 and 114 is used for its production;
 - (b) where it is of the species or artificial hybrids listed in Annex VIII, it complies with the specific requirements for the category concerned pursuant to Article 120;
 - (c) where it is of the species or artificial hybrids listed in Annex VIII, it complies with the specific requirements for certain forms of forest reproductive material set out in Article 120;
 - (d) where it consists of parts of plants or planting stock, it complies with standards pursuant to Article 122;
 - (e) it complies with the provisions of Article 124;
 - (f) it has a master certificate issued in accordance with Article 125 or, in the case of mixtures, it complies with the provisions referred to in Article 128;
 - (g) it is produced in lots in accordance with Article 126, complies with the provisions referred to in Article 128 and is accompanied by an operator's label or document pursuant to Article 129;
 - (h) where it consists of seed units, it is sealed pursuant to Article 133.
2. Subsequent vegetative propagation of forest reproductive material belonging to the 'selected', 'qualified' and 'tested' categories may take place.

Article 120

Specific requirements for certain species and artificial hybrids

1. Material of the species listed in Annex VIII shall only be marketed provided it is of the categories 'source-identified', 'selected', 'qualified' or 'tested' and meets the requirements of Annexes IV, V, VI and VII respectively.
2. Material of the artificial hybrids listed in Annex VIII shall only be marketed provided it is of the 'selected', 'qualified' or 'tested' categories and meets the requirements of Annexes V, VI and VII respectively.
3. Material of the species and artificial hybrids listed in Annex VIII which are vegetatively reproduced shall only be marketed provided it is of the 'selected', 'qualified' or 'tested' categories and meets the requirements of Annexes V, VI and VII respectively. In the case of reproductive material of the 'selected' category, it may only be marketed if it has been mass propagated from seeds.
4. Material of the species and artificial hybrids listed in Annex VIII, which consists wholly or partly of genetically modified organisms, shall only be marketed provided it is of the 'tested' category and meets the requirements of Annex VII.

5. The categories under which reproductive material from the different types of basic material may be marketed are as set out in the table in Annex IX.

Article 121

Specific requirements for certain forms of forest reproductive material

Forest reproductive material of the species and artificial hybrids listed in Annex VIII shall only be marketed provided it meets the relevant requirements in Annex X.

Article 122

Specific requirements for certain parts of plants and planting stock

The Commission shall be empowered to adopt delegated acts, in accordance with Article 143, setting out specific requirements for the placing on the market of specific parts of plants and planting stock. Those requirements shall take into account the applicable international standards.

Article 123

Specific requirements to conserve genetic resources

1. Member States may adopt measures departing from the requirements of Article 119 in the interest of conserving plant genetic resources used in forestry. In doing so, they shall take account of developments in relation to the conservation in situ and the sustainable use of plant genetic resources through growing and placing on the market of forestry reproductive material of origin which are naturally adapted to the local and regional conditions and threatened by genetic erosion.
2. Member States shall notify to the Commission and the other Member States the measures adopted pursuant to paragraph 1, and a justification concerning the interest of conserving plant genetic resources as referred to in that paragraph.

Article 124

Placing on the market of registered forest reproductive material

Forest reproductive material shall be placed on the market as such in accordance with the provisions of this Part only if derived from approved basic forest material registered in a national register pursuant to Article 117(1).

Article 125

Master certificate

1. After harvesting, a master certificate showing the unique reference of the register referred to in Article 117(1) shall be issued by the competent authority for all forest reproductive material derived from approved basic material, giving the relevant information set out in Annex XI and confirming the compliance of that material with the provisions of this Part.
2. For subsequent vegetative propagation in accordance with Article 108, a new master certificate shall be issued.
3. Where mixing takes place in accordance with Article 128 (1), (2), (3) or (5), the register references of the components of the mixtures shall be identifiable, and a new master certificate, or other document identifying the previous master certificates of the material composing the mixture shall be issued.

Article 126

Production of forest reproductive material in lots

Forest reproductive material shall, during all stages of production, be kept separated by reference to individual units of approval. Each lot of forest reproductive material shall be identified by the following:

- (a) master certificate code and number;
- (b) botanical name;
- (c) category;
- (d) purpose;
- (e) type of basic material;
- (f) unique register reference or identity code for region of provenance;
- (g) region of provenance, where appropriate;
- (h) if appropriate, whether the origin of the material is autochthonous or indigenous, non-autochthonous or nonindigenous, or unknown;
- (i) in the case of seed units, the year of ripening;
- (j) age and type of planting stock of seedlings or of cuttings, whether undercuts, transplants or containerised;
- (k) whether it is genetically modified.

Article 127

Subsequent vegetative propagation of certain units of approval

In the case of subsequent vegetative propagation as referred to in Article 119(2), the material shall be kept separate and identified as such.

Article 128

Provisions concerning mixture of material

1. Mixtures of forest reproductive material shall take place only in accordance with the provisions of this Article.
2. Within a single region of provenance, mixing of reproductive material derived from two or more units of approval within the 'source-identified' category or within the 'selected' category may take place.
3. When mixing of forest reproductive material within a single region of provenance, from seed sources and stands in the 'source-identified' category takes place, the new combined lot shall be certified as 'reproductive material derived from a seed source'.
4. When mixing of forest reproductive material derived from nonautochthonous or non-indigenous basic material with that from basic material of unknown origin takes place, the new combined lot shall be certified as being 'of unknown origin'.
5. When mixing takes place in accordance with paragraphs 1, 2 or 3, the identity code for the region of provenance may be substituted for the register reference as in Article 126(f).
6. Mixing of reproductive material derived from a single unit of approval from different years of ripening may take place. When mixing takes place in accordance with this

paragraph, the actual years of ripening and proportion of material from each year shall be recorded.

Article 129

Labelling

1. Forest reproductive material shall be marketed in lots which are accompanied by a label produced by the operator (hereinafter 'operator's label').. The operator's label shall contain, in addition to the information required under Article 125 and 126, the following information:
 - (a) master certificate number(s) issued under Article 125 or reference to the other document available according to Article 125(3);
 - (b) name of operator;
 - (c) quantity supplied;
 - (d) in the case of forest reproductive material of the 'tested' category whose basic forest material is provisionally approved under Article 114, the words 'provisionally approved';
 - (e) whether the material has been vegetatively propagated.
2. In the case of seeds, the operator's label, or the operator's document, referred to in paragraph 1 shall also include the following additional information, assessed, as far as possible, by internationally accepted techniques:
 - (a) purity: the percentage by weight of pure seed, other seed and inert matter of the product marketed as a seed lot;
 - (b) the germination percentage of the pure seed, or, where germination percentage is impossible or impractical to assess, the viability percentage assessed by reference to a specified method;
 - (c) the weight of 1 000 pure seeds;
 - (d) the number of germinable seeds per kilogram of product marketed as seed, or, where the number of germinable seeds is impossible or impractical to assess, the number of viable seeds per kilogram.
3. The colour of the operator's label or document shall be yellow in the case of 'source-identified' reproductive material, green in the case of 'selected' reproductive material, pink in the case of 'qualified' reproductive material and blue in the case of 'tested' reproductive material.
4. Where an operator handles both plant reproductive material intended for forestry purposes and plant reproductive material which is shown to be intended for purposes other than forestry, the latter shall be accompanied by a label or other document bearing the following statement: 'Not for forestry purposes'.
5. The Commission shall be empowered to adopt delegated acts, in accordance with Article 143, setting out the conditions under which the operator's label may include, or be supplemented by, another document produced by the operator. Those delegated acts may determine the information items to be included in that document.

Article 130

Exception to make seed rapidly available

In order to make seed of the current seasons crop rapidly available, notwithstanding the fact that the examination in respect of germination indicated in Article 129(2)(b) has not been concluded, forest reproductive material may be marketed as far as to the first buyer. The respect of the conditions as laid down in Article 129(2)(b) and (d) shall be stated by the operator as soon as possible.

Article 131

Exception for small quantities

In the case of small quantities of seed, the requirements as laid down in Article 129(2)(b) and (d) do not apply. The Commission shall be empowered to adopt delegated acts, in accordance with the Article 143, setting out the quantities and requirements for the application of this Article.

Article 132

Provision concerning *Populus* spp.

In the case of *Populus* spp., parts of plants shall only be placed on the market if the Union classification number according to point 2(b) of Annex X, Part C is given on the operator's label or document.

Article 133

Packaging of seed units

Seed units shall be marketed only in sealed packages. The sealing device shall be such that when the package is opened, it will become unserviceable.

Article 134

Amendment of Annexes IV to XI

The Commission shall be empowered to adopt delegated acts, in accordance with Article 143 amending Annexes IV to XI. Those amendments shall be made in the light of the development of scientific or technical knowledge.

TITLE IV IMPORTS FROM AND EXPORTS TO THIRD COUNTRIES

Article 135

Forest reproductive material from third countries

1. The Commission shall determine, by means of implementing acts, whether forest reproductive material produced in a third country affords the same assurances as regards the approval of its basic material and the measures taken for its production with a view to placing on the market as does forest reproductive material produced within the Union and complying with the provisions set out in Article 119 of this Regulation. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 144(3).
2. Those implementing acts shall determine the species, type of basic material and categories of forest reproductive material, together with its region of provenance,

which may be permitted to be placed on the market under paragraph 1 within the Union.

3. The decision referred to in paragraph 1 may be amended or repealed in case it is assessed that the third country no longer complies with the requirements of that paragraph.

Article 136

Council decisions on equivalence

Where Council decisions adopted prior to the entry into force of this Regulation on the equivalence, as referred to in Article 135 of forest propagating material produced in third countries, the Commission shall consider that the conditions for forest reproductive material of those genera or species produced in the concerned third countries are equivalent to those laid down in the Union legislation and shall authorise the import of forest reproductive material from third countries on the pre-existing basis.

Article 137

Export from the Union

1. The operators and the Member States shall take the appropriate measures to ensure that export and re-export from the Union to a third country of forest reproductive material takes place in accordance with the relevant rules for production and placing on the market of that material in the Union.
2. Where the provisions of a bilateral or multilateral agreement concluded between the Union and/or one or more Member States and one or more third country(ies) are applicable, forest reproductive material exported from the Union to that third country shall comply with those provisions.
3. In absence of an agreement referred to in paragraph 2 and if requested by the authorities of the importing country, or if established by the respective legal provisions of the importing country, forest reproductive material exported from the Union to that third country shall comply with those provisions.

In the absence of those laws, export or re-export of forest reproductive material may take place in accordance with the provisions of a bilateral agreement concluded between the operators concerned, with regards to the quality of that material.

4. In the cases as referred to in paragraphs 2 and 3, the operators shall make sure that such material is identified as such and kept sufficiently isolated.

TITLE V DEROGATIONS AND FEES

Article 138

More stringent requirements and restrictions

1. The Commission may authorise Member States, by means of implementing acts, to adopt more stringent requirements than the requirements referred to in Articles 119 to 122 concerning the approval of basic material and the production of forest reproductive material in their own territory. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 144(3).

2. The implementing acts referred to paragraph 1 may authorise a Member State to prohibit the placing on the market with a view to seeding or planting in all or part of its territory of specified forest reproductive material. That prohibition may be restricted to placing on the market to the end users only.

That authorisation shall be granted only where there is reason to believe:

- (a) that the use of the relevant forest reproductive material would, on account of its phenotypic or genetic characteristics, have an adverse effect on forestry, environment, genetic resources or biodiversity in all or part of that Member State on the basis of:
 - (i) evidence relating to the region of provenance or the origin of the material; or
 - (ii) results of trials or scientific research carried out in appropriate locations, either within or outside the Union.
 - (b) on the basis of known results of trials, scientific research, or the results obtained from forestry practice concerning survival and development of planting stock in relation to morphological and physiological characteristics, that the use of the said forest reproductive material would have an adverse effect on forestry, environment, genetic resources or biodiversity in all or part of that Member State.
3. In order to obtain the authorisation referred to in paragraph 1, Member States shall submit to the Commission a request about the measures they intend to adopt, indicating:
 - (a) the draft provisions of the requested measure;
 - (b) the objectives of the requested measure;
 - (c) a justification on the unsuitability of the existing requirements and their potential adverse effects on the production, the environment and/or plant genetic diversity in all or part of the Member State concerned;
 - (d) an explanation why a measure with existing stringent requirements would not suffice to achieve the same objectives; and
 - (e) whether the requested measure would be permanent or for a specified period.

Article 139

Temporary difficulties in supply

1. In the case temporary difficulties in the general supply to the end user of forest reproductive material, due to extraordinary circumstances, that occur in one or more Member States and cannot be overcome within the Union, Member States may approve the placing on the market, for a period to be set by those acts, of forest reproductive material of one or more species which satisfies less stringent requirements than those prescribed in Articles 119 to 122.
2. The label accompanying forest reproductive material marketed pursuant to paragraph 1 shall state that the material in question satisfies less stringent requirements.

Article 140
Emergency measures

1. Where it is evident that forest reproductive material is likely to constitute a serious risk to human, animal and plant health and the environment, and that such risk cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned, the Commission on its own initiative or at the request of a Member State, shall without delay take any appropriate interim emergency measures, including measures restricting or prohibiting the placing on the market of the plant reproductive material concerned, depending on the gravity of the situation. Those measures shall be adopted by means of implementing acts in accordance with the examination procedure referred to in Article 144(3).
2. On duly justified imperative grounds of extreme urgency to contain and/or address a serious risk to human health, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 144(3).
3. 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, the Member State concerned may adopt any appropriate interim emergency measures, restricting or prohibiting the placing on the market of the plant reproductive material concerned, depending on the gravity of the situation, within its territory. It shall immediately inform the other Member States and the Commission thereof, giving the grounds for its decision. The Commission shall adopt implementing acts aiming at extending, amending or abrogating the national interim emergency measures. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 143(3). The Member State may maintain its national interim emergency measures until the implementing acts referred to in this paragraph have been adopted.
4. This Article shall apply without prejudice to any measures adopted pursuant to Article 23(2) of Directive 2001/18/EC or Article 34 of Regulation (EC) No 1829/2003 prohibiting or restricting the cultivation of GMOs.

Article 141
Temporary experiments

1. The Commission may decide, by means of implementing acts, the organisation of temporary experiments to identify improved alternatives to any provisions set out in, or adopted under, this Part. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 144(3).
2. The implementing acts referred to in paragraph 1 shall identify the genera or species concerned, the conditions of the experiment per genera or species concerned, the duration of the experiments, and the monitoring and reporting obligations of the participating Member States. They shall take into account the evolution of techniques for reproduction, production and control of the concerned material. The duration of an experiment shall not exceed seven growing cycles of the plant reproductive material concerned.

Article 142

Fees

1. Competent authorities shall charge fees for the following actions:
 - (a) registration of approved basic material pursuant to Article 117; and
 - (b) issuance of a master certificate pursuant to Article 125(1 and 2).
2. The actions referred to in paragraph 1 shall only be carried out on demand. If fees due in respect of those are not paid, the demand shall be deemed not to have been filled if the acts necessary for the payment of the fees have not been effected within one month of the date on which the competent authority requested payment of fees and indicated in so doing these consequences of failure to pay.
3. The Commission shall be empowered to adopt delegated acts, in accordance with the procedure referred to in Article 143, setting out the amount of the fees referred to in paragraph 1. This amount may be reduced in the case of forest reproductive material which serves conservation of genetic resources.
4. Fees provided for pursuant to paragraph 1 shall not directly or indirectly be refunded, unless unduly collected. However, Member States may:
 - (a) refund fully or partly fees provided for in paragraph 1 collected from enterprises employing fewer than 10 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 2 million;
 - (b) exempt enterprises referred to in point (a) from the payment of the fees provided for in paragraph 1 provided that:
 - (i) all costs incurred by the competent authorities, including those related to the activities of the enterprises referred to in point (a), are calculated in accordance with [Articles 43 and 44 of revised Reg 882/2004]; and
 - (i) the loss of revenue for the competent authorities which is the result of the exemption is compensated by the transfer to the competent authorities of an amount equivalent to the loss.
5. Union legislation applicable to State aid shall apply to the measures referred to in paragraph 4.

PART V

PROCEDURAL PROVISIONS

Article 143 **Delegated acts**

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The delegation of power referred to in Articles [*reservation SANCO: numbers to be inserted after finalisation of the text*] shall be conferred on the Commission for an indeterminate period of time from [*date of entry into force of this Regulation*].
3. The delegation of power referred to in Articles [*reservation SANCO: numbers to be inserted after finalisation of the text*] [*the references marked yellow to be renumbered*] may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
5. A delegated act adopted pursuant to Articles [*reservation SANCO: numbers to be inserted after finalisation of the text*] [*the references marked yellow are not renumbered*] shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or the Council.

Article 144 **Committee procedure**

1. The Commission shall be assisted by the Standing Committee on the Plants, Animals, Food and Feed established by Article 58 of Regulation (EC) No 178/2002 of the European Parliament and of the Council.¹ This committee shall be a committee within the meaning of Regulation (EC) No 182/2011.
2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.
3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.
4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof shall apply.

¹ OJ L 31, 1.2.2002, p. 1.

PART VI

FINAL PROVISIONS

Article 145 ***Amendment of Regulation (EC) No 2100/94***

In Article 4 of Regulation (EC) No 2100/94 Article 4 is replaced by the following:

Article 4 *Union Office*

1. For purposes of the implementation of this Regulation, a Union Plant Variety Office, hereinafter referred to as 'the Office', is hereby established.
2. The Office shall carry out the following tasks:
 - (a) to offer recommendations on variety denominations, where requested so pursuant to Article 76 [of PRM Regulation];
 - (b) to promote and coordinate development of uniform technical examination of varieties, carried out pursuant to Articles 68, 71 and 72 [of PRM Regulation];
 - (c) to carry out audits of bodies, including their premises and organisation of work, carrying out technical examinations, as referred to in Article 69 [of PRM Regulation];
 - (d) to assist and participate in evaluating Union equivalence with third countries concerning the distinctness, uniformity and stability of varieties in accordance with Article 41 [of PRM Regulation];
 - (e) to participate and offer training in its area of mission;
 - (f) to provide technical support to the Commission in the areas within its mission;
 - (g) to commission studies necessary for the accomplishment of its mission;
 - (h) to search for, collect, collate, analyse and summarise technical data in the fields within its mission;
 - (i) to ensure that the public and interested parties receive rapid, reliable, objective and comprehensible information in the fields within its mission;
 - (j) to provide technical assistance, when requested to do so by the Commission, with a view to improving cooperation between the Union, applicant countries, international organisations and third countries, in the fields within its mission.'.
3. The Office shall also manage and support the Union variety register, established in accordance with Article 50 of [PRM Regulation]. It shall implement and apply the procedure for the registration of varieties in the Union varieties register in accordance with [the provisions of PRM Regulation]'.

Article 146

Penalties

1. The Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive.
2. The Member States shall notify the provisions referred to in paragraph 1 to the Commission within one year after the entry into force of this Regulation and shall notify without delay any subsequent amendments of those provisions.

Article 147

Repeals

1. The acts referred to in Annex [...] are hereby repealed.
2. References to the repealed acts shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex XIII.
3. The Commission shall be empowered to adopt delegated acts, in accordance with Article 143, setting out that one or more of the acts referred to in Annex XII shall be repealed at a specific date after the date from which this Regulation shall apply. In case of conflict between the provisions of those acts and the provisions of this Regulation, the provisions of this Regulation shall prevail.

Article 148

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 36 months after the entry into force of this Regulation.

...

ANNEX I

GENERA AND SPECIES AS REFERRED TO IN ARTICLE 10

x Festulolium Asch. et Graebn.

x Triticosecale Wittm. ex A. Camus

Abies alba Mill.

Abies cephalonica Loud.

Abies grandis Lindl.

Abies pinsapo Boiss.

Acer platanoides L.

Acer pseudoplatanus L.

Agrostis canina L.

Agrostis capillaris L.

Agrostis gigantea Roth.

Agrostis stolonifera L.

Allium cepa L.

Allium fistulosum L.

Allium porrum L.

Allium sativum L.

Allium schoenoprasum L.

Alnus glutinosa Gaertn.

Alnus incana Moench.

Alopecurus pratensis L.

Anthriscus cerefolium (L.) Hoffm.

Apium graveolens L.

Arachis hypogea L.

Arrhenatherum elatius (L.) P. Beauv. ex J. Presl et C. Presl.

Asparagus officinalis L.

Avena nuda L.

Avena sativa L. (including *A. byzantina* K. Koch)

Avena strigosa Schreb.

Beta vulgaris L.

Beta vulgaris L.

Betula pendula Roth.

Betula pubescens Ehrh.

Brassica juncea (L.) Czern.

Brassica napus L.(partim)
Brassica napus L.var. *napobrassica* (L.)Rchb.
Brassica nigra (L.)W.D.J. Koch
Brassica oleracea L.
Brassica oleracea L.convar. *acephala* (DC.) Alef. var. *medullosa* Thell. + var. *viridis* L.
Brassica rapa L.
Brassica rapa L.var. *silvestris* (Lam.) Briggs
Bromus catharticus Vahl
Bromus sitchensis Trin.
Cannabis sativa L.
Capsicum annuum L.
Carpinus betulus L.
Carthamus tinctorius L.
Carum carvi L.
Castanea sativa Mill.
Castanea sativa Mill.
Cedrus atlantica Carr.
Cedrus libani A. Richard
Cichorium endivia L.
Cichorium intybus L.
Citrullus lanatus (Thunb.) Matsum. et Nakai
Citrus L.
Corylus avellana L.
Cucumis melo L.
Cucumis sativus L.
Cucurbita Maxima Duchesne
Cucurbita pepo L
Cydonia oblonga Mill.
Cynara cardunculus L
Cynodon dactylon (L.)Pers.
Dactylis glomerata L.
Daucus carota L.
Fagus sylvatica L.
Festuca arundinacea Schreber
Festuca filiformis Pourr.

Festuca ovina L.
Festuca pratensis Huds.
Festuca rubra L.
Festuca trachyphylla (Hack.) Krajina
Ficus carica L.
Foeniculum vulgare Mill.
Fortunella Swingle
Fragaria L.
Fraxinus angustifolia Vahl.
Fraxinus excelsior L.
Galega orientalis Lam.
Glycine max (L.)Merrill
Gossypium spp.
Hedysarum coronarium L.
Helianthus annuus L.
Hordeum vulgare L.
Juglans regia L.
Lactuca sativa L.
Larix decidua Mill.
Larix kaempferi Carr.
Larix sibirica Ledeb.
Larix x eurolepis Henry
Linum usitatissimum L.
Lolium × *boucheanum* Kunth
Lolium multiflorum Lam.
Lolium perenne L.
Lotus corniculatus L.
Lupinus albus L.
Lupinus angustifolius L.
Lupinus luteus L.
Lycopersicon esculentum Mill.
Malus Mill.
Medicago × *varia* T. Martyn
Medicago lupulina L.
Medicago sativa L.

Olea europaea L.
Onobrychis viciifolia Scop.
Oryza sativa L.
Papaver somniferum L.
Petroselinum crispum (Mill.) Nyman ex A. W. Hill
Phacelia tanacetifolia Benth.
Phalaris aquatica L.
Phalaris canariensis L.
Phaseolus coccineus L.
Phaseolus vulgaris L.
Phleum nodosum L.
Phleum pratense L.
Picea abies Karst.
Picea sitchensis Carr.
Pinus brutia Ten.
Pinus canariensis C. Smith
Pinus cembra L.
Pinus contorta Loud.
Pinus halepensis Mill.
Pinus leucodermis Antoine
Pinus nigra Arnold
Pinus pinaster Ait.
Pinus pinea L.
Pinus radiata D. Don
Pinus sylvestris L.
Pistacia vera L.
Pisum sativum L. (partim)
Pisum sativum L. (Partim)
Poa annua L.
Poa nemoralis L.
Poa palustris L.
Poa pratensis L.
Poa trivialis L.
Poncirus Raf.
Populus spp. and artificial hybrids between those species

Prunus amygdalus Batsch
Prunus armeniaca L.
Prunus avium (L.) L.
Prunus avium L.
Prunus cerasus L.
Prunus domestica L.
Prunus persica (L.) Batsch
Prunus salicina Lindley
Pseudotsuga menziesii Franco
Pyrus L.
Quercus cerris L.
Quercus ilex L.
Quercus petraea Liebl.
Quercus pubescens Willd.
Quercus robur L.
Quercus rubra L.
Quercus suber L.
Raphanus sativus L.
Raphanus sativus L. var. *oleiformis* Pers.
Rheum rhabarbarum L.
Ribes L.
Robinia pseudoacacia L.
Rubus L.
Scorzonera hispanica L.
Secale cereale L.
Sinapis alba L.
Solanum melongena L.
Solanum tuberosum L.
Sorghum bicolor (L.) Moench
Sorghum bicolor (L.) Moench × *Sorghum sudanense* (Piper) Stapf.
Sorghum sudanense (Piper) Stapf
Spinacia oleracea L.
Tilia cordata Mill.
Tilia platyphyllos Scop.
Trifolium alexandrinum L.

Trifolium hybridum L.
Trifolium incarnatum L.
Trifolium pratense L.
Trifolium repens L.
Trifolium resupinatum L.
Trigonella foenum-graecum L.
Trisetum flavescens (L.)P. Beauv.
Triticum aestivum L.
Triticum durum Desf.
Triticum spelta L.
Vaccinium L.
Valerianella locusta (L.)Laterr.
Vicia faba L.(Partim)
Vicia faba L.(partim)
Vicia pannonica Crantz
Vicia sativa L.
Vicia villosa Roth.
Vitis L.
Zea mays L.
Zea mays L.

ANNEX II

PRINCIPLES FOR THE ADOPTION OF REQUIREMENTS FOR PRE-BASIC, BASIC, CERTIFIED AND STANDARD MATERIAL

1. REQUIREMENTS FOR ALL STAGES OF PRODUCTION.

The quality and inspection requirements for plant reproductive material, as referred to in Article 17, shall concern three stages of their production: (a) before sowing or planting; (b) during cultivation; and (c) after harvesting.

(a) Before sowing or planting:

Where applicable, the requirements shall set out provisions concerning:

- (i) sowing and/or planting according to category and types of the concerned plant (e.g. lines or hybrids) to ensure appropriate levels of pollination;
- (ii) previous cropping, and also duration between cropping period with the same species, to avoid impurities and ensure appropriate levels of plant health;
- (iii) minimum distance from neighbouring pollen sources of the same species and/or the same varieties, and isolation rules according to botanical characteristics and breeding techniques, to ensure protection from any undesirable foreign pollination;
- (iv) cleaning of agricultural machines to ensure absence of weed or other species which are difficult to distinguish at seed level in laboratory tests;
- (v) quality of soil or substrates, to avoid presence of harmful organisms or their vectors;
- (vi) inspections concerning the presence of harmful organisms as listed in an implementing act adopted in accordance with Article [35(2) of new PH Regulation].

(b) During cultivation:

Where applicable, the requirements shall set out provisions concerning:

- (i) inspection of varietal identity and purity, including thresholds for off-types according to mode of reproduction and male/female types per category of material, to ensure varietal identity and purity;
- (ii) treatment and/or elimination of off-types to ensure varietal identity and purity;
- (iii) thresholds for the presence of other plant species in the material concerned, according to category;
- (iv) the production/reproduction system of hybrids, inbred lines or any other varietal types, to ensure efficient production;
- (v) inspections concerning the presence of harmful organisms as listed in an implementing act adopted in accordance with [Article 35(2) of new PH Regulation] to ensure plant health and the usefulness of the material;

- (vi) conditions for harvesting per category of material, including whether the material would be harvested in bulk or as individual plants to ensure the identity and purity of the harvested material.
- (c) After harvesting:
- In order to ensure quality, purity, hygiene, health, preservation, economic value and usefulness of the material, the requirements shall set out, where applicable, provisions concerning:
- (i) minimum germination;
 - (ii) maximum content of hard seed;
 - (iii) minimum analytical purity;
 - (iv) maximum moisture content;
 - (v) maximum content of plant reproductive material of other genera or species (total number, list of single specific species and thresholds, maximum content of seeds or other species in the sample of the weight specified);
 - (vi) vigour, dimension, grading of plant reproductive material;
 - (vii) examinations of harmful organisms as listed in an implementing act adopted in accordance with Article 67(3) of [new PH Regulation];
 - (viii) pomological characteristics;
 - (ix) lot and sample weights, including provisions concerning maximum weight of a lot in kilograms or number of units of plant reproductive material, minimum weight of a sample to be drawn from a lot and specific sample weight for determining content of certain weeds, to ensure representative sampling for the analysis of the material;
 - (x) presence of earth or extraneous matter technical impurities;
 - (xi) specific defects, damages;
 - (xii) methods of maintenance of the identity of the variety and, where applicable, of the clone;
 - (xiii) testing methods and procedures, and sampling, to ensure the credibility of the certification procedure.

2. ROOTSTOCKS AND OTHER PARTS OF PLANTS.

The requirements referred to in Article 17 may set out special conditions for rootstocks and other specific parts of plants of genera and species of non listed species, or their hybrids, when reproductive material of the listed genera and species is grafted onto them.

3. RECORD KEEPING.

The requirements referred to in Article 17, where applicable, shall set out provisions concerning records to be kept by the operators.

ANNEX III

ITEMS TO BE INCLUDED IN THE OFFICIAL LABEL AND OPERATOR'S LABEL

- (a) the indication "EU rules and standards";
- (b) the competent authority and Member State where the operator is registered, or their initials;
- (c) in the case of imported material from a third country, the name of the country of origin or its initials;
- (d) the registration number of the operator, as registered pursuant to [Article 52 of the plant health Regulation];
- (e) reference number of lot;
- (f) month and year of labelling;
- (g) species, indicated at least under its botanical name and in roman characters, and, if applicable, variety also in roman characters;
- (h) the category, where appropriate first or second generation;
- (i) declared number of seeds, rootstocks or other units of reproductive material, and, where applicable, the net or gross weight;
- (j) a bar code or an equivalent system, comprising all above items;
- (k) place of production;
- (l) where applicable, indication that the plant reproductive material belongs to a variety with officially recognised description only, and indication of the region of origin of that variety;
- (m) where applicable, indication that the respective plant reproductive material is a clone or rootstock.

ANNEX IV

MINIMUM REQUIREMENTS FOR THE APPROVAL OF BASIC MATERIAL INTENDED FOR THE PRODUCTION OF REPRODUCTIVE MATERIAL TO BE CERTIFIED AS ‘SOURCE-IDENTIFIED’

1. The basic material shall be as seed source or stand located within a single Region of Provenance. It shall be at the discretion of the Member State in each individual case as to whether a formal inspection is required except that, a formal inspection must be made where the material is destined for a specific forestry purpose.
2. The seed source or stand shall meet criteria set by the Member States.
3. The Region of Provenance and the location and the altitude or altitudinal range of the place(s) where the reproductive material is collected must be stated. It must be stated whether the basic material is:
 - (a) autochthonous or non-autochthonous or the origin is unknown or
 - (b) indigenous or non-indigenous or the origin is unknown. In the case of non-autochthonous or non-indigenous basic material the origin must be stated if known.

ANNEX V

MINIMUM REQUIREMENTS FOR THE APPROVAL OF BASIC MATERIAL INTENDED FOR THE PRODUCTION OF REPRODUCTIVE MATERIAL TO BE CERTIFIED AS 'SELECTED'

General: The stand will be judged with respect to the specific stated purpose for which the reproductive material will be intended and due weight shall be given to requirements 1-10, depending on the specific purpose. The criteria for selection shall be determined by the Member State and the purpose shall be indicated in the National Register.

1. **Origin:** It must be determined either by historical evidence or other appropriate means whether the stand is autochthonous/indigenous, non-autochthonous/non-indigenous or the origin is unknown and for non-autochthonous/ non-indigenous basic material the origin must be stated if known.
2. **Isolation:** Stands must be situated at a sufficient distance from poor stands of the same species or from stands of a related species or variety which can form hybrids with the species in question. Particular attention shall be paid to this requirement when the stands surrounding autochthonous/indigenous stands are non-autochthonous/nonindigenous or of unknown origin.
3. **Effective Size of the Population:** Stands must consist of one or more groups of trees well distributed and sufficiently numerous to ensure adequate inter-pollination. To avoid the unfavourable effects of inbreeding, selected stands shall consist of a sufficient number and density of individuals on a given area.
4. **Age and Development:** Stands must consist of trees of such an age or stage of development that the criteria given for the selection can be clearly judged.
5. **Uniformity:** Stands must show a normal degree of individual variation in morphological characters. When necessary, inferior trees shall be removed.
6. **Adaptedness:** Adaptation to the ecological conditions prevailing in the Region of Provenance must be evident.
7. **Health and Resistance:** Trees in stands must in general be free from attacks by damaging organisms and show resistance to the adverse climatic and site conditions, except for damage by pollution, in the place where they are growing.
8. **Volume production:** For the approval of selected stands volume production of wood must normally be superior to the accepted mean under similar ecological and management conditions.
9. **Wood Quality:** The quality of the wood shall be taken into account and, in some cases, it may be an essential criterion.
10. **Form or Growth Habit:** Trees in stands must show particularly good morphological features, especially straightness and circularity of stem, favourable branching habit, small size of branches and good natural pruning. In addition, the proportion of forked trees and those showing spiral grain must be low.

ANNEX VI

MINIMUM REQUIREMENTS FOR THE APPROVAL OF BASIC MATERIAL INTENDED FOR THE PRODUCTION OF REPRODUCTIVE MATERIAL TO BE CERTIFIED AS 'QUALIFIED'

1. Seed Orchards

- (a) The type, objective, crossing design and field layout, components, isolation and location and any changes of these must be approved and registered with the official body;
- (b) The component clones or families shall be selected for their outstanding characters and special consideration shall be given to the requirements 4, 6, 7, 8, 9 and 10 of Annex III;
- (c) The component clones or families shall be planted or shall have been planted according to a plan which has been approved by the official body and established in such a way that each component can be identified;
- (d) Thinning carried out in seed orchards shall be described together with the selection criteria used for such thinnings and registered with the official body;
- (e) The seed orchards shall be managed and seed harvested in such a way that the objectives of the orchards are attained. In the case of a seed orchard intended for the production of an artificial hybrid, the percentage of hybrids in the reproductive material must be determined by a verification test.

2. Parents of Family(ies)

- (a) The parents shall be selected for their outstanding characters and special consideration will be given to the requirements 4, 6, 7, 8, 9 and 10 of Annex III, or selected for their combining ability;
- (b) The objective, crossing design and pollination system, components, isolation and location and any significant changes of these must be approved and registered with the official body;
- (c) The identity, number and proportion of the parents in a mixture must be approved and registered with the official body;
- (d) In the case of parents intended for the production of an artificial hybrid, the percentage of hybrids in the reproductive material must be determined by a verification test.

3. Clones

- (a) Clones shall be identifiable by distinctive characters which have been approved and registered with the official body;
- (b) The value of individual clones shall be established by experience or have been demonstrated by sufficiently prolonged experimentation;
- (c) Ortets used for the production of clones shall be selected for their outstanding characters and special consideration shall be given to the requirements 4, 6, 7, 8, 9 and 10 of Annex III;
- (d) Approval shall be restricted by the Member State to a maximum number of years or a maximum number of ramets produced.

4. Clonal Mixtures

- (a) Clonal mixture shall meet the requirements in points 3(a), 3(b) and 3(c);
- (b) the identity, number and proportion of the component clones of a mixture, and the selection method and foundation stock must be approved and registered with the official body. Each mixture must contain sufficient genetic diversity;
- (c) Approval shall be restricted by the Member State to a maximum number of years or a maximum number of ramets produced.

ANNEX VII

MINIMUM REQUIREMENTS FOR THE APPROVAL OF BASIC MATERIAL INTENDED FOR THE PRODUCTION OF REPRODUCTIVE MATERIAL TO BE CERTIFIED AS 'TESTED'

1. REQUIREMENTS FOR ALL TESTS

(a) General

The basic material must satisfy the appropriate requirements in Annex III or IV.

Tests set up for the approval of basic material are to be prepared, laid out, conducted and their results interpreted in accordance with internationally recognised procedures. For comparative tests, the reproductive material under test must be compared with one or preferably several approved or pre-chosen standards.

(b) Characters to be examined

- (i) Tests must be designed to assess specified characters and these must be indicated for each test;
- (ii) Weight shall be given to adaptation, growth, biotic and abiotic factors of importance. In addition, other characters, considered important in view of the intended specific purpose, shall be evaluated in relation to the ecological conditions of the region in which the test is carried out.

(c) Documentation

Records must describe the test sites, including location, climate, soil, past use, establishment, management and any damage due to abiotic/biotic factors, and be available to the official body. Age of the material and results at the time of the evaluation must be recorded with the official body.

(d) Setting up the tests

- (i) Each sample of reproductive material shall be raised, planted and managed in an identical way as far as the types of plant material permit;
- (ii) Each experiment must be established in a valid statistical design with a sufficient number of trees in order that the individual characteristics of each component under examination can be evaluated.

(e) Analysis and validity of results

- (i) The data from experiments must be analysed using internationally recognised statistical methods and the results presented for each character examined;
- (ii) The methodology used for the test and the detailed results obtained shall be made freely available;
- (iii) A statement of the suggested region of probable adaptation within the country in which the test was carried out and characteristics which might limit its usefulness must also be given;

- (iv) If during tests it is proved that the reproductive material does not possess at least the characteristics:
 - of the basic material or
 - of similar resistance of the basic material to harmful organisms of economic importance,then such reproductive material shall be eliminated.

2. REQUIREMENTS FOR GENETIC EVALUATION OF COMPONENTS OF BASIC MATERIAL

- (a) The components of the following basic material may be genetically evaluated: seed orchards, parents of family(ies), clones and clonal mixtures.
- (b) Documentation

The following additional documentation is required for approval of the basic material:

 - (i) The identity, origin and pedigree of the evaluated components;
 - (ii) The crossing design used to produce the reproductive material used in the evaluation tests.
- (c) Test procedures

The following requirements must be met:

 - (i) The genetic value of each component must be estimated in two or more evaluation test-sites, at least one of which must be in an environment relevant to the suggested use of the reproductive material;
 - (ii) The estimated superiority of the reproductive material to be marketed shall be calculated on the basis of these genetic values and the specific crossing design;
 - (iii) Evaluation tests and genetic calculations must be approved by the official body.
- (d) Interpretation
 - (i) The estimated superiority of the reproductive material shall be calculated against a reference population for a character or set of characters;
 - (ii) It shall be stated whether the estimated genetic value of the reproductive material is inferior to the reference population for any important character.

3. REQUIREMENTS FOR COMPARATIVE TESTING OF REPRODUCTIVE MATERIAL

- (a) Sampling of the reproductive material
 - (i) The sample of the reproductive material for comparative testing must be truly representative of the reproductive material derived from the basic material to be approved;
 - (ii) Sexually produced reproductive material for comparative testing shall be:

- harvested in years of good flowering and good fruit/seed production; artificial pollination may be utilised,
- harvested by methods that ensure that the samples obtained are representative.

(b) Standards

- (i) The performance of standards used for comparative purposes in the tests shall if possible have been known over a sufficiently long period in the region in which the test is to be carried out. The standards represent, in principle, material that has been shown useful for forestry at the time that the test starts, and in ecological conditions for which it is proposed to certify the material. They shall come as far as possible from stands selected according to the criteria in Annex III or from basic material officially approved for production of tested material;
- (ii) For comparative testing of artificial hybrids, both parent species must, if possible, be included among the standards;
- (iii) Whenever possible several standards are to be used. When necessary and justified, standards may be replaced by the most suitable of the material under test or the mean of the components of the test;
- (iv) The same standards will be used in all tests over as wide a range of site conditions as possible.

(c) Interpretation

- (i) A statistically significant superiority as compared with the standards must be demonstrated for at least one important character;
- (ii) It will be clearly reported if there are any characters of economic or environmental importance which show significantly inferior results to the standards and their effects must be compensated for by favourable characters.

4. **CONDITIONAL APPROVAL**

Preliminary assessment of young trials may be the basis for conditional approval. Claims of superiority based on an early assessment must be re-examined at a maximum interval of ten years.

5. **EARLY TESTS**

Nursery, greenhouse and laboratory tests may be accepted by the official body for conditional approval or for final approval if it can be shown that there is a close correlation between the measured trait and the characters which would normally be assessed in foreststage tests. Other characters to be tested must meet the requirements set out in paragraph 3.

ANNEX VIII

LIST OF TREE SPECIES AND ARTIFICIAL HYBRIDS

Abies alba Mill.
Abies cephalonica Loud.
Abies grandis Lindl.
Abies pinsapo Boiss.
Acer platanoides L.
Acer pseudoplatanus L.
Alnus glutinosa Gaertn.
Alnus incana Moench.
Betula pendula Roth.
Betula pubescens Ehrh.
Carpinus betulus L.
Castanea sativa Mill.
Cedrus atlantica Carr.
Cedrus libani A. Richard
Fagus sylvatica L.
Fraxinus angustifolia Vahl.
Fraxinus excelsior L.
Larix decidua Mill.
Larix x eurolepis Henry
Larix kaempferi Carr.
Larix sibirica Ledeb.
Picea abies Karst.
Picea sitchensis Carr.
Pinus brutia Ten.
Pinus canariensis C. Smith
Pinus cembra L.
Pinus contorta Loud.
Pinus halepensis Mill.
Pinus leucodermis Antoine
Pinus nigra Arnold
Pinus pinaster Ait.
Pinus pinea L.
Pinus radiata D. Don

Pinus sylvestris L.
Populus spp. and artificial hybrids between those species
Prunus avium L.
Pseudotsuga menziesii Franco
Quercus cerris L.
Quercus ilex L.
Quercus petraea Liebl.
Quercus pubescens Willd.
Quercus robur L.
Quercus rubra L.
Quercus suber L.
Robinia pseudoacacia L.
Tilia cordata Mill.
Tilia platyphyllos Scop.

ANNEX IX

**CATEGORIES UNDER WHICH REPRODUCTIVE MATERIAL FROM THE
DIFFERENT TYPES OF BASIC MATERIAL MAY BE MARKETED**

Type of basic material	Category of forest reproductive material (Label colour if colours label or document used)			
	Source identified (Yellow)	Selected (Green)	Qualified (Pink)	Tested (Blue)
Seed Source	x			
Stand	x	x		x
Seed Orchard			x	x
Parents of Family(ies)			x	x
Clone			x	x
Clonal Mixture			x	x

ANNEX X

PART A

Requirements to be met by fruit and seed lots of the species listed in Annex VIII

1. Fruit and seed lots of the species listed in Annex VIII may not be marketed unless the fruit or seed lot reaches a minimum species purity level of 99 %.
2. Notwithstanding the provisions of paragraph 1, in the case of closely related species in Annex VIII, excluding artificial hybrids, the species purity of the fruit or seed lot if it does not reach 99 % shall be stated.

PART B

Requirements to be met by parts of plants of the species and artificial hybrids listed in Annex VIII

Parts of plants of the species and artificial hybrids listed in Annex VIII shall be of fair marketable quality. Fair marketable quality shall be determined by reference to general characteristics, health and appropriate size. In the case of *Populus* spp. it may be stated that the additional requirements set out in Part C are met.

PART C

Requirements for external quality standards for *Populus* spp. propagated by stem cuttings or sets

1. Stem cuttings
 - a. Stem cuttings shall not be considered to be of fair marketable quality if any of the following defects exist:
 - i. their wood is more than two years old;
 - ii. they have less than two well formed buds;
 - iii. they are affected by necroses or show damage by harmful organisms;
 - iv. they show signs of desiccation, overheating, mould or decay.
 - b. Minimum dimensions for stem cuttings
 - minimum length: 20 cm,
 - minimum top diameter:

Class EC 1: 8 mm
Class EC 2: 10 mm.
2. Sets
 - a. Sets shall not be considered to be of fair marketable quality if any of the following defects exist:
 - their wood is more than three years old,
 - they have less than five well formed buds,
 - they are affected by necroses or show damage by harmful organisms,
 - they show signs of desiccation, overheating, mould or decay,
 - they have injuries other than pruning cuts,

- they have multiple stems,
- they have excessive stem curvature.

b. Size classes for sets

Class	Minimum diameter at mid-length (mm)	Minimum height (m)
Non-Mediterranean regions		
N1	6	1,50
N2	15	3,00
Mediterranean regions		
S1	25	3,00
S2	30	4,00

PART D

Requirements to be met by planting stock of the species and artificial hybrids listed in Annex VIII

The planting stock shall be of fair marketable quality. Fair marketable quality shall be determined by reference to general characteristics, health, vitality and physiological quality.

PART E

Requirements to be met by planting stock to be marketed to the end-user in regions having a Mediterranean climate

Planting stock shall not be marketed unless 95 % of each lot is of fair marketable quality.

1. Planting stock shall not be considered to be of fair marketable quality if any of the following deficits exist:
 - (a) injuries other than pruning cuts or injuries due to damage when lifting;
 - (b) lack of buds with the potential to form a leading shoot;
 - (c) multiple stems;
 - (d) deformed root system;
 - (e) signs of desiccation, overheating, mould, decay or other harmful organisms;
 - (f) the plants are not well balanced.

2. Size of the plants

Species	Maximum age (years)	Minimum height (cm)	Maximum height (cm)	Minimum root collar diameter (mm)
Pinus halepensis	1	8	25	2
	2	12	40	3
Pinus leucodermis	1	8	25	2
	2	10	35	3
Pinus nigra	1	8	15	2
	2	10	20	3
Pinus pinaster	1	7	30	2
	2	15	45	3
Pinus pinea	1	10	30	3
	2	15	40	4
Quercus ilex	1	8	30	2
	2	15	50	3
Quercus suber	1	13	60	3

3. Size of the container, where used

Species	Minimum volume of the container (cm ³)
Pinus pinaster	120
Other species	200

ANNEX XI

PART A

MODEL MASTER CERTIFICATE OF IDENTITY FOR REPRODUCTIVE MATERIAL DERIVED FROM SEED SOURCES AND STANDS

(Certificate must contain all the information outlined below, and in the exact format)

ISSUED IN ACCORDANCE WITH REGULATION XXXX/XXXX

MEMBER STATE:	CERTIFICATE No EC:/(MEMBER STATE CODE)/(No)
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It is certified that the forest reproductive material described below has been produced:

in accordance with the EC Directive ☐
under transitional arrangements ☐

1. **Botanical name:**

2. Nature of reproductive material	
Seed unit	☐
Part of plants	☐
Planting stock	☐

3. Category of reproductive material	
Source-identified	☐
Selected	☐
Tested	☐

4. Type of basic material	
Seed source	☐
Stand	☐

5. **Purpose:**

6. **Country register reference or identity of basic material in National register:**
..... / Mixture:

7. Autochthonous ☐ Non-autochthonous ☐ Unknown ☐
Indigenous ☐ Non-indigenous ☐

8. **Origin of basic material (for non-autochthonous/non-indigenous material, if known):**

9. **Country and Region of provenance of basic material:**
Provenance (Short title, if appropriate):

10. **Altitude or altitudinal range of site of basic material:**

11. **Year in which seeds ripened:**

12. **Quantity of reproductive material:**

13. Is the material covered by this certificate the result of a subdivision of a larger lot covered by a previous EC Certificate?	Yes ☐	No ☐
Previous certificate number:	Quantity in initial lot:	

14. Length of time in nursery:

15. **Has there been subsequent vegetative propagation of material derived from seed?** Yes ☐ No ☐
Method of propagation Number of cycles of propagation

16. **Other relevant information:**

17. Name and address of supplier

Name and Address of Official Body:

Stamp of Official Body:
Date:

Name of Responsible Officer:
Signature:

PART B
MODEL MASTER CERTIFICATE OF IDENTITY FOR REPRODUCTIVE
MATERIAL DERIVED FROM SEED ORCHARDS OR PARENTS OF FAMILY(IES)

(Certificate must contain all the information outlined below, and in the exact format)

ISSUED IN ACCORDANCE WITH REGULATION XXXX/XXXX

MEMBER STATE:	CERTIFICATE No EC:/(MEMBER STATE CODE)/(No)
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It is certified that the forest reproductive material described below has been produced:

in accordance with the EC Directive ☐
under transitional arrangements ☐

1. (a) **Botanical name:**
(b) **Name of basic material (as mentioned in the catalogue):**

2. **Nature of reproductive material**

Seed unit	☐
Part of plants	☐
Planting stock	☐

4. **Type of basic material**

Seed orchard	☐
Parents of family(ies)	☐

3. **Category of reproductive material**

Qualified	☐
Tested	☐

5. **Purpose:**

6. **Country register reference or identity of basic material in National register:**

7. (If appropriate) Autochthonous ☐ Non-autochthonous ☐ Unknown ☐
 Indigenous ☐ Non-indigenous ☐

8. **Origin of basic material (for non-autochthonous/non-indigenous material, if known):**

9. **Country and Region of provenance or location of basic material:**
Provenance (Short title):

10. **Seed derived from:**

open pollination	☐
supplemental pollination	☐
controlled pollination	☐

11. **Year in which seeds ripened:**

12. **Quantity of reproductive material:**

13. **Is the material covered by this certificate the result of a subdivision of a larger lot covered by a previous EC Certificate?** Yes ☐ No ☐

Previous certificate number: Quantity in initial lot:

14. **Length of time in nursery:**

15. **Number of components represented:**

Families:

Clones:

16. **Altitude or altitudinal range of site of basic material:**

17. **Has genetic modification been used in the production of the basic material?** Yes ☐ No ☐

18. **For reproductive material derived from parents of family(ies)**

Crossing design Range of percentage composition of component families:

19. **Has there been subsequent vegetative propagation of material derived from seed?** Yes ☐ No ☐

Method of propagation Number of cycles of propagation:

20. **Other relevant information:**

21. **Name and address of supplier**

Name and Address of Official Body:

Stamp of Official Body:

Date:

Name of Responsible Officer:

Signature:

PART C
MODEL MASTER CERTIFICATE OF IDENTITY FOR REPRODUCTIVE
MATERIAL DERIVED FROM CLONES AND CLONAL MIXTURES

(Certificate must contain all the information outlined below, and in the exact format)

ISSUED IN ACCORDANCE WITH REGULATION XXXX/XXXX

MEMBER STATE:	CERTIFICATE No EC:/(MEMBER STATE CODE)/(No)
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It is certified that the forest reproductive material described below has been produced:

in accordance with the EC Directive ☐
under transitional arrangements ☐

1. **a) Botanical name:**

b) Name of clone or clonal mixture:

2. **Nature of reproductive material**
Part of plants ☐
Planting stock ☐

4. **Type of basic material**
Clones ☐
Clonal mixture ☐

3. **Category of reproductive material**
Qualified ☐
Tested ☐

5. **Purpose:**

6. **Country register reference or identity of basic material in National register:**

7. (If appropriate) Autochthonous ☐ Non-autochthonous ☐ Unknown ☐
 Indigenous ☐ Non-indigenous ☐

8. **Origin of basic material (for non-autochthonous/non-indigenous material, if known):**

9. **Country and Region of provenance or location of basic material:**

 Provenance (Short title):

10. **Has genetic modification been used in the production of the basic material?** Yes ☐ No ☐

11. **a) Method of propagation:**

11. **b) Number of cycles of propagation:**

12. **Quantity of reproductive material:**

13. **Is the material covered by this certificate the result of a subdivision of a larger lot covered by a previous EC Certificate?** Yes ☐ No ☐
Previous certificate number: Quantity in initial lot:

14. **Length of time in nursery:**

15. **For clonal mixtures:**
Number of clones in mixture: Range of percentage composition of component clones:

16. **Other relevant information:**

17. **Name and address of supplier**

Name and Address of Official Body:

Stamp of Official Body:

Date:

Name of Responsible Officer:

Signature:

ANNEX XII

REPEALED ACTS AS REFERRED TO IN ARTICLE 129

1. Directive 66/401/EEC
2. Directive 66/402/EEC
3. Directive 68/193/EEC
4. Directive 98/56/EC
5. Directive 1999/105/EC
6. Directive 2002/53/EC
7. Directive 2002/54/EC
8. Directive 2002/55/EC
9. Directive 2002/56/EC
10. Directive 2002/57/EC
11. Directive 2008/72/EC
12. Directive 2008/90/EC
13. Commission Decision 80/755/EEC of 17 July 1980 authorizing the indelible printing of prescribed information on packages of cereal seed.
14. Commission Directive 93/49/EEC of 23 June 1993 setting out the schedule indicating the conditions to be met by ornamental plant propagating material and ornamental plants pursuant to Council Directive 91/682/EEC.
15. Commission Directive 1999/66/EC of 28 June 1999 setting out requirements as to the label or other document made out by the supplier pursuant to Council Directive 98/56/EC.
16. Commission Directive 1999/68/EC of 28 June 1999 setting out additional provisions for lists of varieties of ornamental plants as kept by suppliers under Council Directive 98/56/EC.
17. Commission Decision 2006/10/EC of 10 January 2006 concerning the provisional prohibition in Greece of the marketing of seeds of maize hybrids with the genetic modification MON 810 inscribed in the common catalogue of varieties of agricultural plant species, pursuant to Directive 2002/53/EC.
18. Commission Decision 97/125/EC of 24 January 1997 authorizing the indelible printing of prescribed information on packages of seed of oil and fibre plants and amending Decision 87/309/EEC authorizing the indelible printing of prescribed information on packages of certain fodder plant species.
19. Commission Decision 2004/266/EC of 17 March 2004 authorising the indelible printing of prescribed information on packages of seed of fodder plant.
20. Commission Directive 2008/62/EC of 20 June 2008 providing for certain derogations for acceptance of agricultural landraces and varieties which are naturally adapted to the local and regional conditions and threatened by genetic erosion and for marketing of seed and seed potatoes of those landraces and varieties.

21. Commission Directive 2009/145/EC of 26 November 2009 providing for certain derogations, for acceptance of vegetable landraces and varieties which have been traditionally grown in particular localities and regions and are threatened by genetic erosion and of vegetable varieties with no intrinsic value for commercial crop production but developed for growing under particular conditions and for marketing of seed of those landraces and varieties.

ANNEX XIII

CORRELATION TABLE

[to be completed...]