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Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the marketing and production, with a view to marketing, of plant reproductive material, and repealing Council Directives 66/401/EEC, 66/402/EEC, 68/193/EC, 1998/56/EC, 1999/105/EC, 2002/53/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90/EC

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

Plant reproductive material (PRM) is a fundamental input for the productivity, the diversity, and the health and quality of agriculture and food production. 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 plan reproductive material certification process or integration of general principles concerning official controls embedded in Regulation (EC) No 882/2004 on official controls are needed.

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2. RESULTS OF CONSULTATIONS WITH THE INTERESTED PARTIES AND IMPACT ASSESSMENTS

The impact assessment of this proposal builds on the results of the evaluation of the European Union legislation on the marketing of seed and plant propagating material (hereafter plant reproductive material, PRM) that was carried out in 2007/2008 by the Food Chain Evaluation Consortium (FCEC), on the results of a study on variety registration conducted by the same consortium in the first half of 2010. It is furthermore based on a broad survey of all interested parties, in particular the competent authorities in the Member States, private sector representatives at EU and at national level, relevant international standard setting bodies, non-governmental organisations and the Community Plant Variety Office (CPVO). A number of Commission Horizontal Working Party meetings covering all the plant species were held in 2009-2011. In May 2011, four task forces created by the Hungarian presidency worked on specific topics. In addition, the Commission consulted the working group 'Seeds and Propagating Material' of the Advisory Group on the Food Chain, Animal and Plant Health on several occasions from 2009 – 2011. On 18 March 2009 an open conference "Ensuring Seed Availability in the 21st Century" was organised to present and discuss the evaluation results with different stakeholders. Finally, a web-based stakeholder survey using an "Interactive Policy Making" (IPM) questionnaire to collect comments on an "Options and Analysis" paper was organised from 19 April to 30 May 2011. It yielded more than 257 responses from a very wide range of stakeholder groups.

The main objective of the consultations was to seek views on the provisions and application of existing legislation and the needs for change. Overall, stakeholders were satisfied with the principles underlying the existing Directives, but supported the Commission's intention to revise the legislation. Room for improvement was in particular identified pertaining to legal simplification, cost reductions and efficiency gains, increased flexibility for operators, the level of harmonisation among Member States and the role of niche and emerging markets. Maintaining the general principles of the current legislation – especially the procedures for the registration of varieties and the pre-marketing certification of seed lots – was strongly supported by a majority of stakeholders.

The Impact Assessment identified the following main axes along which the system has to change in order to be fit for the changing economic, environmental, social, scientific circumstances: (i) Simplification of the basic legal acts (from 12 Directives to one Regulation), (ii) Cost recovery and improvement of the effectiveness and efficiency of the system, (iii) Horizontal coordination with recent, already adopted EU policies. Various ways – increased flexibility, deregulation or centralisation – are explored for improving the efficiency of the system, while maintaining the assurances for high quality PRM, competitiveness and addressing new challenges such as biodiversity. Based on these 3 axes, 5 policy options were identified, where legal simplification and cost recovery are constant for all options. In the various options, issues concerning SMEs and micro-enterprises have been addressed throughout, especially in order to ensure access for these enterprises to public services for the execution of certain tasks they cannot perform themselves and to support and further develop their flexibility to gain improved access to the PRM market. Specific attention is given to trade-offs between transferring operational work and maintenance of quality of PRM.

The impact assessment concludes that no single option succeeds in achieving the objectives of the review in an efficient, effective and coherent manner and suggests, in line with stakeholder opinion, a preferred option which combines elements from option 2, 4 and 5. The proposal thus creates an environment providing legal security for operators and consumers,

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guaranteeing high quality of PRM and securing competitive advantage on the internal and the world markets. This combination aims at striking a balance between flexibility for operators (option 2 and 4) and biodiversity (option 4) and the necessary rigor in health and quality requirement (elements of option 2 and 5) for the fair functioning of the market and for maintaining the quality and health of the products. This is combined with elements allowing minor crops or crops with particular uses low-burden access to specific or small market segments, but with coupled minimum obligations ensuring traceability, health and information to the consumer so that a level playing for all operators is established.

3. LEGAL ELEMENTS OF THE PROPOSAL

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 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

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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 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-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, 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 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

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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 (CVPO). 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 by the CPVO will be introduced with the aim to ensure the quality and harmonisation of the variety registration process in the Union.

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. This description can be based on an old official description of the variety, description

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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.

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. 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.

3.7. Union competence, subsidiarity and legal form

The PRM legislative framework is based on the Treaty on the Functioning of the European Union (TFEU) Article 43 implementing the Common Agricultural Policy (CAP). The objectives of that policy are to increase agricultural productivity, to ensure a fair standard of living for the agricultural community, to stabilise markets, to assure the availability of supplies and to ensure that supplies reach consumers at reasonable prices. The Lisbon Treaty qualifies agriculture as shared competence between the EU and its Member States. It is obvious, however, that to a very large extent all fields of agricultural activity as well as ancillary activities upstream and downstream, have been regulated at the EU level. This means that legislation is predominantly a role for the institutions of the European Union.

The proposal takes the form of a Regulation of the European Parliament and of the Council. Other means would not be appropriate because of the objectives of the measure can be achieved most efficiently by fully harmonized requirements throughout the Union, ensuring free movement of PRM.

4. BUDGETARY IMPLICATION

The financial appropriations for implementing the Regulation up to 31 December 2020 are being presented in the Regulation on Union expenditures for food and feed, animal health and welfare, plant health and plant reproductive material.

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5. OPTIONAL ELEMENTS

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THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 43(2) thereof,

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the European Economic and Social Committee[1],

Having regard to the opinion of the Committee of the Regions[2],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) The following Directives set out rules for the production and marketing of seeds and propagating material of agricultural crops, vegetables, vine, fruit plants, forest reproductive material and ornamental plants:

(a) Council Directive 66/401/EEC of 14 June 1966 on the marketing of fodder plant seed[3];

(b) Council Directive 66/402/EEC on the marketing of cereal seed[4];

(c) Council Directive 68/193/EEC of 9 April 1968 on the marketing of material for the vegetative propagation of the vine[5];

(d) Council Directive 98/56/EC of 20 July 1998 on the marketing of propagating material of ornamental plants[6];

(e) Council Directive 1999/105/EC of 22 December 1999 on the marketing of forest reproductive material[7];

(f) Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species[8];

1 OJ C , , p. .
2 OJ C , , p. .
3 OJ L 125, 11.7.1966, p. 2298
4 OJ L 125, 11.7.1966, p. 2309
5 OJ L 93, 17.4.1968, p. 15
6 OJ L 226, 13.8.1998, p. 16
7 OJ L 11, 15.1.2000, p.17

(g) Council Directive 2002/54/EC of 13 June 2002 on the marketing of beet seed[9];

(h) Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed[10];

(i) Council Directive 2002/56/EC of 13 June 2002 on the marketing of seed potatoes[11];

(j) Council Directive 2002/57/EC of 13 June 2002 on the marketing of seed of oil and fibre plants[12];

(k) Council Directive 2008/72/EC of 15 July 2008 on the marketing of vegetable propagating and planting material, other than seed[13];

(l) Council Directive 2008/90/EC of 29 September 2008 on the marketing of fruit propagating material and fruit plants intended for fruit production[14].

(2) These Directives have been substantially amended several times to adapt to the developments of the sectors that they cover,

(3) All above Directives cover plant reproductive material, either in the form of seeds or other types of plant propagation material, which may be used for the production and/or reproduction of plants. All those types of plant reproductive material are subject to common principles with regards to their production or marketing in the Union. Those principles concerns registration of varieties and clones, certification of material, and inspection of lots before marketing to ensure their identity, health and quality,

(4) Evolution in the areas of agriculture, horticulture, forestry, plant breeding and marketing of plant reproductive material has shown that the legislation needs to be simplified and further adapted to the developments of the sector. This Regulation should therefore only cover common provisions for all types of plant reproductive material, irrespective of their genera or species. Specific provisions and requirements for particular types of plant reproductive material should be adopted under implementing or delegated acts to introduce flexibility that is needed to follow scientific and technical developments,

(5) The basic objectives of the above Directives, namely productivity, health and quality of plant reproductive material, remain of outmost importance for agriculture, horticulture, food and feed security and the economy in general. Moreover the legislation needs to correspond to the needs of society that have emerged over the recent years. This concerns in particular consumers' expectations, adaptability of production to a diversity of agricultural, horticultural and environmental conditions and various uses, sustainability of production, challenges of climate change and protection of agro-biodiversity,

(6) It is therefore necessary to harmonise the legislation on plant reproductive material. In this view, the above Directives should be replaced by a single Regulation on the production with a view to marketing, and to the marketing, of plant reproductive material within the Union. This Regulation should also cover plant reproductive

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8 OJ L 193, 20.7.2002, p.1
9 OJ L 193, 20.7.2002, p.12
10 OJ L 193, 20.7.2002, p.33
11 OJ L 193, 20.7.2002, p.60
12 OJ L 193, 20.7.2002, p. 74
13 OJ L 205, 1.8.2008, p. 28
14 OJ L 267, 8.10.2008, p. 8

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material of agricultural raw materials intended for industrial purposes, as this material represents a major part of several sectors and should fulfil certain standards concerning its quality,

(7) However, and in order to adapt to the needs of producers and the requirements of flexibility, this Regulation should not apply on reproductive material intended solely for testing and scientific purposes, intended for breeding purposes and for conservation in gene banks or related networks,

(8) Other Union rules concerning plant health, cultivation of genetically modified organisms (GMOs), wild flora and packaging and packaging waste should also apply for the production and marketing of plant reproductive material. Therefore this Regulation should apply without prejudice to [new Regulation on plant health], Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC[15], Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed [16], Regulation (EC) No 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein [17] and Directive 94/62/EC of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein[18],

(9) It is necessary to set common definitions, principles, requirements and procedures so as to form a clear framework and a common basis for Union and national measures governing the marketing of plant reproductive material. To take into account the specific nature of reproductive material intended for forest purposes specific definitions and procedures SHOULD continue to apply,

(10) In order to ensure transparency and more effective controls with regards to production and marketing of plant reproductive material, the concerned operators should be registered in the public registers established by the Member States pursuant to Regulation [plant health], to ensure coherent and systematic controls in all areas of production and marketing and plant reproductive material. However it would be neither feasible nor proportionate to register operators trading with small quantities of plant reproductive material intended solely to non-professional final users,

(11) Basic obligations should be introduced for operators active in the production and marketing of plant reproductive material area to clarify their responsibilities. These concern the identification of critical control points in the production process, ensuring separation of lots, keeping of records, facilitation of controls and maintenance of plant reproductive material,

(12) Experience has shown that the credibility and quality of marketed reproductive material can be jeopardised where it is impossible to trace reproductive material which does not comply with the quality and health standards set out by the legislation. It is therefore necessary to establish a comprehensive system of traceability so that targeted and accurate withdrawals can be undertaken or information given to consumers or competent authorities. The operators should therefore ensure that the plant reproductive material remains traceable at all stages of production and marketing. For

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this reason, rules should be established concerning the keeping of the necessary information and records with regards to transfers from and to professional users. On the basis of the principle of proportionality, information concerning the supply of the material to non-professional final users should be excepted from that obligation,

(13) Certain genera and species of plant reproductive material, other than forest reproductive material and other than the material solely intended for ornamental uses, should be subject to enhanced requirements concerning their production and marketing. This applies in particular to genera or species of plants which are produced and marketed in at least two Member States, and they represent a significant area or value of production or are produced and marketed by a significant number of operators. These genera and species should, in their majority, be the same as the genera and species regulated by the above Directives. They should be inserted in a specific list (listed genera and species) which should be amended in accordance with the developments of the sector and on the basis of the criteria referred above,

(14) Plant reproductive material, other than forest reproductive material, not belonging to the listed genera and species should also be subject to certain basic requirements with regards to their health status, marketing with 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 it is intended solely for ornamental uses. In the latter case, and in order to inform the user, the label should indicate that the material is intended for ornamental use,

(15) Plant reproductive material, other than forest reproductive material, belonging to the listed genera and species should be only produced or marketed if it belongs to one of the following marketing categories: pre-basic, basic, certified and standard material. This is to ensure transparency and informed choices with its users,

(16) Plant reproductive material, other than forest reproductive material, belonging to certain listed genera or species should only be marketed as basic or certified material in view of the increased quality requirements expected by its users. The Commission should therefore determine the respective genera or species where there is a long production chain for ensuring traceability and/or stricter controls which are proportionate to ensure the health and quality of plant reproductive material and food security in the longer term,

(17) In order to ensure the identity and quality of the material, as well as informed choices for its users, plant reproductive material belonging to listed genera and species should only belong to varieties registered in national variety registers or the Union variety register. Plant reproductive material belonging to those varieties should be marketed throughout the Union once registered in the national register,

(18) In order to ensure the maximum possible purity of the material and the homogeinity of production lots, plant reproductive material of listed genera/species should be kept in separate lots. The operator should keep records including data about composition of the origin of its individual components,

(19) Harmonised rules should be adopted for the labelling of plant reproductive material of listed genera/species to ensure appropriate identification of the material. In the case of pre-basic, basic and certified material, the label should be produced and affixed by the competent authorities, or by the operators under the official supervision of the competent authorities. Labels on standard material should be produced or affixed by the operator, and should be accompanied by a document produced by the operator. In

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view of the specific nature of and expectations for different listed genera or species, harmonised rules should be established concerning the requirements for plant reproductive material belonging to those genera or species Detailed requirements should to be laid down, where applicable, for specific uses of genera and species, different marketing categories, types of variety and their possible subdivision to grades,

(20) Those rules should also include requirements concerning the certification of that material and post-certification tests. Therefore, detailed rules should be laid down for the inspection and examination process including, where applicable, field inspection, sampling and testing of plant reproductive material,

(21) As regards the thresholds for the presence of quality organisms listed in new PH Regulation the rules should include the detailed inspection and examination requirements to ensure the application of one single certification process for plant reproductive material. Where applicable, the official label should be combined with the plant passport in a single document,

(22) Harmonised rules should be adopted concerning the import of plant reproductive material of listed genera or species into the Union. Those rules should be determined on the basis of implementing acts determining whether plant reproductive material of specific genera or species produced in a third country affords the same assurances as regard its complies with requirements equivalent with those of this Regulation,

(23) Exports of plant reproductive material of listed genera or species to third countries should comply with the laws, regulations, standards, codes of practice and other legal and administrative procedures in force in the importing countries. If no agreement on this is established, exported plant reproductive material should comply with rules laid down in this Regulation,

(24) Basic requirements should be set out for plant reproductive material, other than forest reproductive material, not belonging to the listed species. Those requirements should concern minimum quality standards, labelling and marketing with reference to varieties,

(25) Harmonised rules should be established for the registration of varieties. Those rules should apply for varieties of listed species where the production and marketing of material is only allowed if that material belongs to a registered variety. However those rules should also apply to varieties of non-listed species, where no such requirement exists. That would be necessary to ensure that all varieties have access to registration if subject to common rules and conditions,

(26) Experience so far has shown that several breeders choose to apply for the registration of their varieties in only one or few national registers. However, several other breeders are more interested in marketing their varieties in the entire Union market, or in the bigger part of it. It should be therefore appropriate to offer the breeders the option of registering their varieties either in a national variety register or in a Union variety register. This task should be given to the Community Plant Variety Office (Office), which is currently in charge of granting plant variety rights, thus the Office would cover all aspect of plant varieties. However it should be ensured that in both cases the variety is marketed throughout the Union without further restrictions,

(27) Each Member State should therefore establish a single national register of the varieties of listed genera and species. Those national variety registers should be public to ensure

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their widest possible accessibility and usefulness. Harmonised rules should be adopted concerning the information to be included in them,

(28) Basic requirements should be set out for the registration of varieties in the national variety registers. In order to ensure their identity, quality and appropriateness for their intended purpose, varieties should be proven to be distinct, uniform and stable, they should bear a suitable unique denomination, they should have an official description and their material should be always available,

(29) The official description should be produced by a competent authority or any other official body on the basis of the results of a technical examination covering a sufficient number of characteristics for the variety to be described as regards distinctness, uniformity and stability,

(30) In addition to the above basic requirements, varieties belonging to species with particular importance for sustainable development in the Union should be proven of supplementary characteristics such as satisfactory value for cultivation and/or use,

(31) Several varieties have been marketed before the entry into force of this Regulation without an official description or according to the current requirements. These varieties could be of particular significance, mainly for conservation purposes in situ and for the protection of agriculture/horticulture biodiversity. Therefore they should be also included in the national variety registers on the basis of an officially recognised description,

(32) It should be a description, including the denomination, which has not been produced or verified by any competent authority or any other official body, and at the time of first marketing has been recognised as acceptable by a competent authority or any other official body in compliance with the relevant rules of the Member State or recognised as produced by a scientific/academic body. Finally, this description should be supported by the results of previous official inspections, unofficial examinations or knowledge gained from practical experience during cultivation,

(33) Pursuant to the provisions of Regulation (EC) No 2100/1994 on Community plant variety rights, varieties are proven to be distinct, uniform and stable in accordance with the procedures equivalent to the ones of this Regulation. Therefore if a variety has been granted a Community plant variety right, that variety should be deemed to be distinct, uniform and stable and have suitable denomination for the purposes of this Regulation too,

(34) In order to ensure adaptation to specific conditions, Member States should be allowed, by derogation to the provisions of this Regulation, to authorise operators to market, for test or trial purposes only, plant reproductive material of listed genera or species belonging to non-registered varieties. Quantitative restriction and appropriate control mechanism should be laid down to ensure the appropriate use of this possibility to gain additional practical information on the varieties,

(35) Member States should be allowed to adopt more stringent standards in certain cases on the basis of harmonised procedures,

(36) The possibility should be granted that, under certain conditions, plant reproductive material of particular genera or species may be marketed as basic material or certified material in case the applicable germination requirements are not yet fully ascertained. Those conditions may concern labeling and the availability of a provisional analytical report concerning germination,

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(37) Competent authorities should have the possibility to authorise operators to market in the Member State concerned specific quantities for tests and trials on farms or other production premises, for a specified period of time only, of plant reproductive material belonging to a variety not registered in a national variety register or the Union variety register. That authorisation should only be granted if that material belongs to a variety for which an application has been submitted for registration in those registers,

(38) It must be ensured that procedures for emergency measures are in place, in case reproductive material, belonging to particular genera, species, varieties or categories, is likely to present a risk to human, animal and plant health, and the environment,

(39) During periods in which there are difficulties in obtaining supplies of plant reproductive material, it should be allowed on the basis of harmonised procedures and for a limited time period to allow the supplies of material of listed genera or species which belongs to non-registered varieties or fulfils lower requirements that the requirements adopted for its category,

(40) It is desirable to organise temporary experiments for the purpose of seeking improved alternatives to certain provisions set out in this Regulation,

(41) Where appropriate, the Union legislation should be aligned with international standards and apply internationally accepted methods for sampling and testing including laboratory analysis of the material,

(42) Harmonised rules should be established concerning the procedures for the registration of varieties in the national variety registers. These rules should concern the submission and content of applications, formal and technical examinations, and reports of the examinations,

(43) The Office 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 Office to check a denomination, before the respective variety is registered in a national variety register,

(44) Harmonised rules should be established concerning the contents and conditions of a decision on the registration in a national variety register,

(45) It would be appropriate that varieties already accepted in the national catalogues, lists or registers of varieties pursuant to Directives 2002/53/EC, 2002/55/EC, Directive 68/193 and Directive 2008/90/EC are registered directly in the national variety registers without any further proceedings,

(46) Harmonised rules should be established concerning the deletion of varieties from the national variety registers and the maintenance of varieties. The maximum period of validity of the registration of a variety should be 30 years, with the possibility of renewal for further periods of 30 years. A Union variety register should be created on the basis of the notifications from Member States to ensure transparency and up-to-date and accurate information on the varieties which are marketed throughout the Union. Therefore, the Member States should notify immediately, within 5 working days, the registered varieties and any other changes in their national variety register to the Office,

(47) This register should further include, in a different part, all varieties that are directly registered at the Union level,

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(48) The Office should be responsible for the registration of varieties in the Union variety register, and for the administration of this register, in view of its technical expertise to best perform this task,

(49) Harmonised rules should be adopted for the registration in the Union variety register. These rules should concern 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 the purposes of coherence and consistency, those rules should be, where applicable, similar to the ones for the registration in the national variety registers,

(50) The decisions of the Office concerning registration of varieties in the Union variety register should be subject to a transparent appeal procedure. Therefore harmonised rules should be adopted concerning that procedure and the rights and obligations of the involved parties,

(51) The competent authorities and the Office should charge fees for the processing of applications, the formal and technical examinations, and each year of the duration of the registration. Therefore harmonised rules for those fees should be set out in this Regulation. That fee should be reduced in the case of varieties serving the conservation in situ and the sustainable use of genetic resources,

(52) In order to protect the commercial interests and intellectual property of several operators, exchanges of files under the procedures of this Regulation should remain confidential. Moreover, and where necessary, the results of the examination and the description of the genealogical components should be treated as confidential, if the breeder so requests,

(53) Forests cover a large area of the Union and fulfil a multifunctional role based on their social, economic, environmental, ecological and cultural functions. There is therefore a need for specific approaches and actions for the different types of forests, recognising the wide range of conditions of the forests in the Union. Both the restocking of these forests and new afforestation require a sustainable forest management in relation to the Forestry Strategy for the European Union as set out in the Council Resolution of 15 December 1998[19][20],

(54) Forest reproductive material of tree species and artificial hybrids which are important for forestry purposes should be genetically suited to the various site conditions and of high quality. The conservation and enhancement of biodiversity of the forests including the genetic diversity of the trees is essential to sustainable forest management,

(55) Research on forestry has shown that, if forests are to be of increased value including the aspects of stability, adaptation, resistance, productivity and diversity, it is necessary to use reproductive material which is genetically and phenotypically suited to the site and of high quality; forestry seeds should meet, where appropriate, certain quality standards,

(56) Harmonised rules should be set out concerning the specific requirements for forest reproductive material as regards approval of basic material, categories of marketing,

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marketing in lots, labelling, small packages and derogations from certain marketing provisions,

(57) It is desirable to make possible a Union financial contribution for the support of certain policy areas concerning the production and marketing of plant reproductive material. That contribution should be allocated for training of control staff, supply of information tools, development of policy and support of certification reference centres,

(58) As a new task on variety registration is given to the Office, the Regulation on Community Plant Variety Rights needs to be amended accordingly to include variety registration in its mission and to update the tasks of the Office,

HAVE ADOPTED THIS REGULATION:

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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

1. This Regulation shall not apply to plant reproductive material:

   (a) intended solely for testing or scientific purposes;

   (b) intended solely for selection purposes;

   (c) intended solely for, and maintained in, gene banks and networks of conservation of genetic resources associated with gene banks.

2. Plant reproductive material shall be subject to no restrictions concerning its production, with a view to marketing, and marketing, 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.

Article 3
Definitions

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

(1) 'plant' means a plant as defined in accordance with Article [2(1) of new Plant Health Regulation];

(2) 'plant reproductive material' means plant(s) capable of, and intended for, producing or reproducing entire plants;

(3) ‘marketing’ 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 marketing;

(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 of those tree species, and artificial hybrids thereof, which are important and intended solely for forestry purposes in all or part of the Union;

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(8) 'final user' means any person carrying out activities for purposes which are outside its business or profession and which receives for its own use small quantities of plant reproductive material;

(9) '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];

(10) 'official control' means official control defined in accordance with [Article 2(2)(a) of revised Regulation 882].

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PART II
OPERATORS

Article 4
Registers of operators

1. Operators shall be registered in the registers referred to in Article 52 of Regulation [Plant health Regulation] in accordance with the provisions of Article 53 of that Regulation.

2. Paragraph 1 shall not apply to operators exclusively marketing small quantities of plant reproductive material to final users.

Article 5
Responsibilities of operators

1. Operators shall ensure that plant reproductive material produced and marketed under their control is of good quality.

2. The operators 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.

3. For the purpose of facilitating the official controls of the certification referred to in Articles 20 and 106, 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 6
Traceability

1. Operators shall ensure that plant reproductive material is traceable at all stages of production and marketing.

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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 final users, 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.

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PART III
PLANT REPRODUCTIVE MATERIAL OTHER THAN FOREST REPRODUCTIVE MATERIAL

TITLE I
GENERAL PROVISIONS

Article 7
Scope

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

Article 8
Definitions

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

   (1) 'official description' means a description produced by a competent authority, covering the characteristics for the variety assessed for distinctness, uniformity and stability;

   (2) 'officially recognised description' means a description, which is recognised by a competent authority for fulfilling the following criteria:

      (a) describes the specific characteristics of the plants which are representative of the variety concerned, and make that variety identifiable; and

      (b) has not been produced on the basis of a technical examination by any competent authority; and

      (c) (i) at the time when material of that variety was marketed, that description 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; and/or

      (ii) 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.

   (3) 'clone' means the vegetative genetically uniform progeny of a single plant;

Article 9
Genera and species of Annex I

1. Genera and species shall be included in Annex I if they are produced and/or marketed in at least two Member States, and comply with one or more of the following criteria:

   (a) they represent a significant area of production;

   (b) they represent significant value of production;

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(c) they are produced or marketed by a significant number of operators in the Union.

2. The Commission shall be empowered to adopt delegated acts, in accordance with Article 124, amending Annex I on the basis of the criteria referred to in paragraph 1.

TITLE II
PRODUCTION AND MARKETING OF PLANT REPRODUCTIVE MATERIAL BELONGING TO GENERA AND SPECIES LISTED IN ANNEX I

CHAPTER I
SCOPE, CATEGORIES AND REQUIREMENTS

Article 10
Scope

This Title shall apply to the production and marketing of plant reproductive material belonging to genera and species included in Annex I [with the exception of plant reproductive material intended for ornamental uses only].

Article 11
Categories of plant reproductive material

Plant reproductive material shall only be produced, with a view to be marketed, and marketed, under one of the following categories:

(a) pre-basic material, which is at the first step of production and intended for the production of other categories of plant reproductive material;

(b) basic 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, which has been produced either directly or in a known number of generations from pre-basic or basic material;

(d) standard material, which is material other than pre-basic, basic or certified material.

Article 12
Production and marketing of pre-basic, basic and certified material

Plant reproductive material shall be produced and marketed as pre-basic, basic or certified material only if:

(a) it complies with the specific requirements adopted pursuant to Article 14 for the category concerned;

(b) it complies with the provisions on registration of variety or clones, where applicable, set out in Article 15;

(c) it complies with the requirements on lot composition and identification set out in Article 17;

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(d) it complies with the requirements on packaging set out in Article 18 and, in the case of small packages, it complies with the conditions adopted pursuant to Article 19;

(e) it bears an official label pursuant to Article 20 and the operator concerned is authorised to produce that label pursuant to Article 21.

Article 13

Production and marketing of standard material

Plant reproductive material shall be produced and marketed as standard material only if:

(a) it complies with the specific requirements adopted pursuant to Article 14;

(b) it complies with the provisions on registration of varieties or clones, where applicable, set out in Article 15;

(c) it complies with the requirements on lot composition and identification set out in Article 17;

(d) it complies with the requirements on packaging set out in Article 18 and, in the case of small packages, it complies with the conditions adopted pursuant to Article 19;

(e) it bears an operator's label pursuant to Article 22.

Article 14

Production and marketing as pre-basic, basic, certified and standard material

1. Plant reproductive material of certain genera or species shall only be produced or marketed under the categories of pre-basic, basic or certified material, if following conditions apply:

   (a) the production and marketing of standard material of those genera or species is not likely to fulfil the requirements of traceability and varietal identity due to the long chain of production and the enhanced plant health requirements of the genera or species concerned;

   (b) the costs and the certification activities linked to the production and marketing of pre-basic, basic and certified material are proportionate to the purpose of ensuring quality and health of the genera or species concerned; and

   (c) the genera or species concerned are important to ensure agricultural productivity and food and feed security for the Union.

2. Plant reproductive material of certain genera or species shall be produced or marketed under any of the categories referred to in Article 11, if following conditions apply:

   (a) the production and marketing of this material under all categories referred to in Article 11 is likely to fulfil the requirements for traceability and identity;

   (b) the production and marketing of any category would not compromise the expectations of operators and consumers with regards to health and quality of the plant reproductive material concerned;

   (c) the genera or species concerned are not critical in ensuring agricultural productivity and food and feed security for the Union.

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3. The Commission shall identify, by means of implementing acts, the genera or species referred to in paragraphs 1 and 2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 125(3).

Those implementing acts shall set out specific provisions for the production and marketing, of each category, of the plant reproductive material belonging to the genera or species concerned, within the scope set out in Annex II.

Those provisions shall concern, where applicable, the specific uses of the genera, species or types of material concerned, number of generations for each category, types of variety including intraspecific or interspecific hybrids, or subdivision of categories into grades satisfying different conditions. Those provisions may set out that particular grades may only be produced in particular areas, or that 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.

Those requirements 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].

4. The Commission shall be empowered to adopt delegated acts, in accordance Article 124, amending Annex II. Those amendments shall take into account the technical and scientific developments.

Article 15
Registration of varieties or clones

1. Plant reproductive material may be produced and marketed 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 42 or in Part A of the Union variety register referred to in Article 43.

2. Paragraph 1 shall not apply to rootstocks, which may be produced and marketed in the Union without belonging to a variety registered pursuant to those provisions.

3. The Commission shall be empowered to adopt delegated acts, in accordance with Article 124, setting out that particular genera or species may be produced and marketed without belonging to a variety registered pursuant to paragraph 1. Those delegated acts may set out that certain of those genera or species may be produced and marketed with reference to populations of plants if they comply with particular criteria set out by those acts.

Article 16
Marketing of clones

1. The Commission shall be empowered to adopt delegated acts, in accordance with Article 124, determining the genera or species whose plant reproductive material may be marketed in clones, and the conditions under which that marketing shall take place.

2. Plant reproductive material shall only be allowed to be marketed in clones if determined so by the delegated acts referred to in paragraph 1.

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Article 17

Lot composition and identification

1. Plant reproductive material shall be kept in separate lots, as soon as those lots are created.

2. Lots of plant reproductive material of different origins may be merged into a new lot. In that case, and if they are put together during processing, packaging, storage, transport or at delivery, the operator shall keep records including data about the origin of the individual components of that lot.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 124, setting out requirements concerning size, composition and identification of lots for particular genera or species.

Article 18

Packages, containers and bundles

1. Plant reproductive material shall be marketed as individual plants, or in packages, containers or bundles.

2. In the case of marketing in packages and containers, those 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. In the case of marketing in bundles, those 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 124, setting out that particular genera or species shall only be marketed 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 marketing requirements of the concerned genera or species.

Article 19

Small packages

The Commission shall be empowered to adopt delegated acts, in accordance with Article 124, setting out specific conditions for the marketing of plant reproductive material in small packages. Those acts shall describe 'small packages' for particular species, taking into account the characteristics of those species and their marketing. Those acts 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.

Article 20

Certification and official label of pre-basic, basic or certified material

1. In the case of pre-basic, basic or certified material, the operator shall certify that that material complies with the requirements adopted pursuant to Article 14(3). That certification shall take place through the production of a label (hereinafter 'official

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label') and under the official supervision of the competent authority. The official labels shall be produced and affixed by the competent authorities, if requested so by the operators.

In the case where the official labels are produced by the operators, the competent authorities shall carry out, for the purpose of official supervision, 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 adopted pursuant to Article 14(3). That proportion shall be based on the potential risk of non-compliance with those requirements.

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 adopted pursuant to Article 14(3).

2. Where applicable, the implementing act referred to in Article 14(3) shall also establish certification schemes under which the certification referred to in paragraph 1 shall take place for particular genera or species, in accordance with the criteria set out in Annex II.

Those certification schemes may set out conditions concerning certification examinations, including field inspection, sampling and testing to be carried out by the operator and the competent authorities.

Where applicable, those certification schemes shall include the examination requirements and the requirements for the production of plants for planting adopted pursuant to Article [67(3) of Plant Health Regulation].

The requirements for sampling and analysis referred to in point (a) shall take into account international standards, insofar as such standards exist.

3. 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.

4. Plant reproductive material which has been harvested in one Member State after field approval, but has not yet been finally certified as pre-basic, basic or certified material pursuant to paragraphs 1 to 3, may still be marketed if it identified as such and complies with specific conditions concerning its packaging and labelling. The Member State of production and the Member State of final certification shall exchange the relevant information. 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. The Commission shall be empowered to adopt delegated acts, in accordance with Article 125, setting out those conditions for particular genera or species to be marketed as not finally certified seed.

5. The Commission shall be empowered to adopt delegated acts, in accordance with Article 124, setting out the conditions under which plant reproductive material of particular genera or species may be marketed as basic material or certified material in case the applicable germination requirements adopted pursuant to Article 14(3) are not yet fully ascertained. Those conditions may concern labelling and the availability of a provisional analytical report concerning germination.

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Article 21

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

1. Operators may carry out the certification and produce the official label referred to in Article 21 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 market with the requirements adopted pursuant to Article 14(3);

   (b) the operators have in place systems and provisions to ensure the fulfilment of traceability provisions set out in Article 6.

   The Commission shall be empowered to adopt delegated acts, in accordance with Article 124, setting out further requirements under which operators shall be allowed to carry out certification under official supervision of the competent authority as referred to in Article 20(1). Those delegated acts may set out requirements concerning:

   (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.

   Those delegated acts may also set out requirements concerning monitoring and supervision to be carried out by the competent authorities for the purpose of allowing the operator concerned to carry out that certification.

2. Operators shall be supervised by the competent authorities through the conduct of regular audits, at least once per year.

3. Competent authorities shall withdraw the authorisation referred to in paragraph 1 if they conclude that the one or more of the requirements referred to in paragraph 1 are no longer fulfilled.

4. Competent authorities shall without delay withdraw, or modify as appropriate, the authorisation referred to in paragraph 1 if the operator concerned no longer complies with the conditions set out in paragraph 1, and does not apply the corrective measures referred to in paragraph 3 within the requested period of time.

Article 22

Production of an operator's label for standard material

1. In the case of standard material, the operators shall produce a label (hereinafter 'operator's label').

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.

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3. The operator's label shall only be produced if the operator has concluded that the standard material concerned complies with the requirements adopted pursuant to Article 14(3).

Article 23
Content and form of 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 [60 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 124, setting out requirements concerning:

   (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 intentioned use of the material, where applicable;

   (d) specific indications for last germination, where applicable.

5. The Commission shall be empowered to adopt delegated acts, in accordance with Article 124, 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.

CHAPTER II
TESTS

Article 24
Post certification tests

1. Following the certification referred to in Article 21 is carried out, the competent authorities may carry out tests of the plant reproductive material to confirm that it complies with the requirements adopted pursuant to Article 16(3) (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.

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4. In case it is concluded, on the basis of the post certification tests, that the plant reproductive material has not been produced or marketed in compliance with the requirements of Article 16(3), the competent authorities shall ensure that the concerned operator takes the necessary corrective actions to ensure that either the material concerned complies with the above requirements or it is withdrawn from the market.

5. The Commission shall be empowered to adopt delegated acts, in accordance with Article 124, setting out detailed requirements for the post certification tests of plant reproductive material belonging to particular genera or species.

Those 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.

Where, under the technical examination referred to in Article 63, examination of the genealogical components is necessary, the results of the examination and the description of the genealogical components shall be treated as confidential, if the applicant or his representative so requests.

Article 25

Non-compliance of operators with the specific requirements for categories

1. If it is repeatedly found, during the post certification tests referred to in Article 24, that an operator produces or markets plant reproductive material which does not comply with the requirements referred to in Article 14(3), the competent authorities shall ensure that the operator concerned is wholly or partially prohibited, for a specified period, to produce and 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.

2. Any measures taken under paragraph 1 shall be withdrawn as soon as it has been established with adequate certainty that the plant reproductive material of the operator concerned complies with the requirements referred to in Article 14(3).

CHAPTER III
MIXTURES

Article 26

Mixtures of species or varieties

1. The Commission shall be empowered to adopt delegated acts, in accordance with Article 124, setting out rules for the marketing 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 rules may set out, where appropriate, requirements for use, source areas, authorisation, packaging and labelling of those mixtures, and shall make reference to the particular genera or species on which they apply.

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2. Mixtures of genera or species shall not be marketed unless they comply with the rules of the acts referred to in paragraph 1.

CHAPTER IV
DEROGATIONS

Article 27

Plant reproductive material of varieties whose registration is pending

1. By way of derogation from Article 15(1), competent authorities may authorise operators to market in the Member State concerned specific quantities for tests and trials on farms or other production premises, for a specified period of time only, of plant reproductive material belonging to a variety not registered in a national variety register or the Union variety register pursuant to Articles 40 and 41. That authorisation may only be granted if that material belongs to a variety for which an application has been submitted, pursuant to Article 56, for registration in a national variety register or pursuant to Article 76 in the Union variety register.

2. The authorisations referred to in paragraph 1 may only be granted if the operators submit a request with the following information to the competent authorities of the Member States where the respective tests and trials are to take place:

   (a) a description of the envisaged tests and trials;

   (b) the objectives pursued by those trials;

   (b) the name(s) of the locations in which those tests and trials are to be carried out;

   (c) a provisional description of the variety;

   (d) the person responsible for the maintenance of the variety, where applicable;

   (e) the conditions for the maintenance of the variety;

   (f) information about the authority under which the application for the registration of the variety is pending;

   (g) the period of time of the requested authorisation;

   (h) the quantities of the material to be marketed.

3. 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").

   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 2 during the preceding year.

4. The Commission shall be empowered to adopt delegated acts, in accordance with Article 124, setting out rules on labelling of packages and on authorised quantities for specific genera or species to be marketed pursuant to paragraphs 1 and 2 of this Article.

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Article 28

More stringent requirements

1. The Commission may authorise Member States, by means of implementing acts, to adopt more stringent measures than the ones adopted pursuant to Article 14(3), for the production and marketing of particular genera, species or categories of plant reproductive material. Those implementing acts referred to in paragraph 1 shall be adopted in accordance with the examination procedure referred to in Article 125(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 unsuitability of the existing measures 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 29

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 marketing 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 125(3).

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 125(4).

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 marketing 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 125(3). The Member State may maintain its national interim emergency measures until the implementing acts mentioned in this paragraph have been adopted.

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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 30

Derogations in the case of temporary difficulties in supply

1. By way of derogation from Article 17, 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 marketing 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 marketed per genera or species. Those implementing acts shall be adopted in accordance with the examination procedure referred to in accordance with Article 125(3).

   Those authorisations shall be granted on the basis of a request submitted by the Member State concerned and justifying the reasons for granting those authorisations.

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 marketing of plant reproductive material complying with requirements lower that the ones adopted pursuant to Article 14(3). Those implementing acts may set out the maximum quantities allowed to be marketed per genera or species. Those implementing acts shall be adopted in accordance with the examination procedure referred to in accordance with Article 125(3).

   Those authorisations shall be granted on the basis of a request submitted by the Member State concerned and justifying the reasons for granting those authorisations.

   In the case where those requirements concern the reduction of the germination rate of seed by less than 5%, the competent authority of the Member State concerned may authorise the marketing of seed with that reduced germination without the adoption of the above implementing acts. In that case, the competent authorities shall grant such an authorisation after the applicant submits a justification with the reasons for granting such authorisations. In that case, the label shall indicate the actual lower germination rate.

3. The label of the plant reproductive material marketed pursuant to paragraphs 1 and 2 shall be brown. It shall respectively state that the reproductive material in question is standard material, belongs to a non-registered variety or complies with lower certification requirements.

Article 31

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 125(3).

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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

Article 32
Imports on the basis of Union 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 affords the same assurances that it fulfils requirements equivalent with those of paragraph 2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 125(3).

2. For the purposes of the decision referred to in paragraph 1, the Commission shall consider whether:

   (a) the official examinations of varieties carried out in the third country afford the same assurances as those provided for in Article 61 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 72; 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 of that material, afford the same assurances as those adopted pursuant to Articles 16 and 21 for the relevant species.

3. For the purpose of adopting the implementing acts 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].

   When adopting the implementing acts 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.

4. 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';

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(b) a statement that the plant reproductive material has been produced, sampled and tested in accordance with current international methods and rules;

(c) date of official closing;

(d) country of production;

(e) declared net or gross weight or declared number of plant reproductive material.

This information may be given either on an official document or/and on an additional official label which shall give the name of the service and the country or for standard material on the operator label.

5. Plant reproductive material may be imported into the Union only in accordance with a decision taken pursuant to paragraph 1.

6. 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 paragraph 2.

Article 33

Council decisions on equivalence

Where Council decisions have adopted prior to the entry into force of this Regulation on the equivalence, as referred to in Article 32, of plant propagating material produced in third countries, the Commission shall consider that the conditions for plant 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 plant reproductive material from third countries on the pre-existing basis.

In case it is assessed that the third country no longer complies with the requirements of Article 32(2), the Commission may decide, by means of implementing acts, that paragraph 1 shall no longer apply for the third country concerned. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 125(3).

Article 34

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 plant reproductive material takes place in accordance with the relevant rules for production and marketing of that material in the Union.

2. However, if requested by the authorities of the importing country, or established by the laws, regulations, standards, codes of practice and other legal and administrative procedures in force in the importing country, export and re-export of plant reproductive material may take place in accordance with those provisions.

3. Where the provisions of a bilateral agreement concluded between the Union and a third country are applicable, plant reproductive material exported from the Union to that third country shall comply with the said provisions.

TITLE III
PRODUCTION AND MARKETING OF PLANT REPRODUCTIVE MATERIAL BELONGING TO GENERA OR

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SPECIES OTHER THAN THOSE LISTED IN ANNEX I [OR INTENDED FOR ORNAMENTAL USES ONLY]

Article 35
Scope

This Title shall apply to plant reproductive material belonging to genera and species other than the ones listed in Annex I, [and to plant reproductive material intended for ornamental uses only].

Article 36
Basic requirements

1. Plant reproductive material belonging to genera and species referred to in Article 35 shall be marketed 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 good germination capacity;
   (d) if marketed 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 35 shall be marketed 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 37
Labelling

1. Plant reproductive material referred to in Article 35, when marketed, 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, or the clones where appropriate, if the plant reproductive material is respectively marketed with reference to a variety or a clone;
   (c) the name and address of the operator;
   (d) the reference number of the lot given by the operator;
   (e) the net or gross weight, or, where applicable, declared number of seeds, rootstocks or other units of reproductive material;
   (f) the indication 'EU quality';
   (g) the date of the issuance of the label;

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(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".

Where reproductive material is placed on the market with a reference to genera or species rather than a variety referred to in point (b), the operator shall indicate the species or group of species in such a way as to avoid confusion with any varietal denomination.

2. 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.

3. 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 20 and 22.

4. 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 38

Marketing with reference to varieties

1. Plant reproductive material referred to in Article 37, may be marketed with reference to a variety 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 or in Part A of the Union variety register pursuant to Articles 42 and 43;

(c) the variety is entered on a list kept 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 to ensure that the denomination concerned is the same in all Member States. 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 50.

Article 39

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

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equivalent guarantees in all respects to plant reproductive material produced in the Union pursuant to the requirements of Articles 36 to 38.

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 40

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 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 125(3).

Article 41

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"). That register shall consist of a Part A and of a Part B.

   Part A shall include all varieties, other than varieties referred to in Article 42, registered in accordance with the procedure referred to in Articles 76 to 81.

   Part B shall include all varieties registered in the national variety registers referred to in Article 42, on the basis of information notified by the Member States to the Office in accordance with Article 55(2).

2. The Commission shall adopt, by means of implementing acts, the format of the Union variety register, on the basis of consultation with the Office. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 125(3).

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CHAPTER II
REQUIREMENTS FOR REGISTRATION IN THE NATIONAL AND UNION VARIETY REGISTERS

Article 42
General provision

Varieties shall be registered in the national variety registers, or in Part A of the Union variety register, if they comply with the requirements set out in the provisions of this Chapter.

Article 43
Requirements for varieties

Varieties shall be registered only if they comply with the following conditions:

(a) they have an official description proving that they are distinct, uniform and stable in accordance with Articles 46 to 48, or they have an officially recognised description;

(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 referred to in Article 45;

(c) they bear a suitable denomination accepted pursuant to Article 52;

(d) a sample of sufficient quality of the material is made available to the competent authority;

(e) 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.

Article 44
No registration with officially recognised description

Varieties may not be registered on the basis of an officially recognised description if one or more of the following conditions apply:

(a) they are already included in the national variety register concerned, or Part A of the Union variety register, on the basis of an official description;

(b) they have been deleted from the registers referred to in point (a) in accordance with Articles 72 or 82, during the last two years;

(c) they are protected by a Union plant variety right as provided for in Council Regulation (EC) No 2100/94, or by a national plant variety right, or an application for such a right is pending.

Article 45
Satisfactory value for cultivation and/or use

1. For the purpose of Article 43(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 qualities, taken as a whole, offer, at least as far as production in any region is concerned, a clear improvement either for cultivation or as regards the uses which can be made of the

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crops or the products derived there from. Where other important characteristics are present, individual less important characteristics may be disregarded for the purposes of registration.

This paragraph shall not apply to:

(a) varieties with officially recognised description only;

(b) varieties used only as components for the creation of other varieties.

2. The Commission shall be empowered to adopt delegated acts, in accordance with Article 124, determining the genera and species, and the particular uses of those genera or species, whose varieties must be of satisfactory value and/or use in order to be registered in a national variety register. Those acts may further set out that the requirements of paragraphs 1 and 2 shall also apply for the registration of particular genera or species in the Union variety register.

3. The Commission shall be empowered to adopt delegated acts, in accordance with Article 124, 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.

Article 46
Distinctness

1. For the purposes of Article 43(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 in the Union on the date of application determined pursuant to Article 60.

2. The existence of another variety shall be deemed to be commonly known, if on the date of application determined pursuant to Article 60 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 pursuant to Article 40 or Union variety register pursuant to Article 41 has been filed.

Article 47
Uniformity

For the purposes of Article 43(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

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in the examination for distinctness, as well as any others used for the official description of the variety.

Article 48
Stability

For the purposes of Article 43(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 49
Granted plant variety rights

If a variety has been granted a plant variety right pursuant to Article 62 of Regulation (EC) No 2100/1994, or pursuant to national rules, that variety shall be deemed to be distinct, uniform and stable and has a suitable denomination for the purposes of Article 43(a) and (b).

Article 50
Denomination of varieties

1. In order to be suitable for the purpose of Article 43(c), the denomination of a variety shall be identical to that under which the variety is registered by the operators and competent authorities in the other Member States. This provision shall not apply if:
   (a) this denomination 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 name in connection with the variety in question.
2. For the purposes of Article 43(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 marketing 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 policy;

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(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.

3. The Commission shall be empowered to adopt delegated acts, in accordance with Article 124, 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 in the meaning of paragraph 1(a);

(e) specific criteria concerning the evaluation of the denomination concerned;

(f) specific prohibitions of particular types of denominations;

(g) criteria for the use of synonyms; and

(h) the use of a denomination in the form of a code.

4. The provisions concerning the use of variety denomination of Article 17 of Regulation (EC) No 2100/1994 and the limitation of the use of variety denominations of Article 18 of Regulation (EC) No 2100/1994 shall also apply for the purposes of this Regulation.

Article 51

Requirements for clones

1. A clone of a variety shall be included in the national variety register only if it complies with the following requirements:

(a) its varietal identify has been confirmed; 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 delegated acts, in accordance with Article 124, setting out specific requirements for the genetic selection of the clones of varieties of particular genera or species.

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CHAPTER III
REGISTRATION OF VARIETIES IN THE NATIONAL VARIETY REGISTERS

SECTION I
NATIONAL VARIETY REGISTERS

Article 52
Content of the national variety register

1. The national variety register shall include:
   (a) varieties;
   (b) rootstocks and other parts of plants of other genera or species, or their hybrids, if material of one of the listed genera or species, or their hybrids, is grafted on them; and
   (c) clones of varieties registered pursuant to the requirements of Article 51.
2. The Commission shall be empowered to adopt delegated acts, in accordance with Article 124, setting out that only the clones of particular genera or species may be registered in a national variety register.

Article 53
Data concerning varieties

1. With regards to varieties, the national 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, where applicable for varieties placed on the market before the entry into force of this Regulation, its synonyms where appropriate pursuant to Art. 50(3)(g);
   (c) the date of the registration of the variety or, where applicable, of the renewal of the registration;
   (d) end of validity of registration;
   (e) where applicable, indication of existing officially recognised description as referred to in Article 43(a);
   (f) where applicable, indication that the variety contains or consists of a genetically modified organism;
   (g) where applicable, indication that the variety is a component variety of another registered variety;
   (h) the name of the of the operator responsible for the maintenance of a variety, pursuant to Article 73;
   (i) specific information relating to the results of the technical examination of the variety in accordance with Article 61, where applicable, including content of undesirable substances.

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2. Notwithstanding point (h) of paragraph 2, 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 54
Documentation

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 Article 65. Where applicable, the file shall only contain the officially recognised description of the variety referred to in Article 46, and the documents supporting this description.

Article 55
Information

1. Each Member State shall inform the other Member States, the Office and the Commission about the site or any other document where its national variety register is published.

2. 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 80, the person responsible for the maintenance of the variety, the deletion of a variety pursuant to Article 72 and the new denomination after registration pursuant to Article 68.

3. The Commission may adopt, by means of implementing acts, modalities concerning the submission of the notifications referred to in paragraph 2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 125(3).

4. 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.

5. 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 61;

   (c) the varieties for which an application for registration is pending.

6. 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 52. This provision shall not apply where the information must be treated as confidential under Article 63.

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SECTION 2
REGISTRATION PROCEDURE

Article 56
Submission of applications

Any person may submit to the competent authority an application for registration of a variety in a national variety register in writing or, where provided so by national rules, in an electronic form.

Article 57
Content of applications

1. The applications for registration of a variety in the 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, the joint applicants, [and the credentials of any procedural representative];
   (d) a proposed denomination;
   (e) the details 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 with an officially recognised description, a file containing that description and any document or publication supporting it;
   (k) in the case an application concerning varieties granted a plant variety right as referred to in Article 51, the proof that the variety is protected by that right;
   (l) the contact details of the applicant.
2. The Office shall adopt additional items, to the ones referred to in paragraph 1, to be included in that 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.

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Article 58

Implementing acts concerning the form of application

The Commission may adopt, by means of implementing acts, the format of the application referred to in Article 56 to be contained therein. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 125(3).

Article 59

Formal examination

1. The competent authority shall register each application it receives for registration in the national variety register and shall examine whether:

   (a) the application complies with the provisions of Article 57;

   (b) where applicable, the conditions laid down in the rules adopted pursuant to Article 58;

   (c) the fees due pursuant to Article 73(1)(a) concerning the conduct of formal examination have been paid within the time limit specified by the competent authority.

2. If the application does not comply with one or some of the conditions laid down in Article 57 or, where applicable, with any conditions laid down in an act adopted pursuant to Article 58, the competent authority shall give the applicant the possibility to make its application compliant within due time.

Article 60

Date of application

The date of application for registration in a national variety register shall be the date on which a valid application was submitted to the competent authority.

Article 61

Technical examination of the variety

1. Where, as a result of the formal examination, the application is found to comply with the conditions laid down in Article 59(1), the competent authority shall carry out a technical examination of the application and the respective material for the purpose of establishing an official description referred to in Article 43(a).

   That technical examination shall examine compliance with the requirements for distinctiveness, uniformity and stability of the variety, as laid down in Articles 46 to 48, the suitability of the denomination, in accordance with Article 50, and, where applicable, the additional requirements for value for cultivation and/or use, as laid down in Article 45.

2. The competent authority may carry out those technical examinations only if its premises, which are dedicated to this purpose, and the organisation of those examinations have been audited and approved by the Office. On the basis of that audit, the Office may 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.

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The Commission shall be empowered to adopt delegated acts, in accordance with Article 124, 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 45 concerning the satisfactory value for cultivation and use of certain species.

Unless those delegated acts are adopted, this paragraph shall not apply for the conduct of examinations concerning value for cultivation and use.

3. The technical examination referred to in paragraph 1 shall be carried out by the applicant, if the applicant requests so. In that case, the applicant shall carry out the technical examination only in premises of its choice, which are dedicated to this purpose, and the organisation of those examinations have been audited and authorised by the competent authority. In that case, the competent authority shall [sign] [produce] the official description. That authorisation shall only be granted, and maintained, if the premises and organisation of examinations comply with the respective requirements of the Office.

4. For the purpose of application of paragraphs 2 and 3, the Office may adopt criteria concerning:

(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 paragraph 1;

(c) the necessary equipment, including laboratories for the obligatory disease resistance characteristics;

(d) record of activities;

(e) variety reference collection to assess the distinctness and storage management of the reference collection;

(f) quality management system;

(g) visit of technical facilities for each group of species.

5. In case an official description of the variety, produced by the Office or another competent authority, is already available, the competent authority shall decide that the technical examination referred to in paragraph 1 is not necessary.

Article 62

Specific requirements for the technical examination

1. The Office may set out, through technical protocols, specific requirements for the technical examinations referred to in Article 61(1) concerning varieties of particular genera or species. Those requirements shall concern, where applicable, the conduct of growing trials and laboratory tests.

2. Technical examinations shall be carried out in accordance with the requirements adopted by the Office under paragraph 1. If no such requirements have been adopted, the 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.

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Article 63
Confidentiality

Where, under the technical examination referred to in Article 63, examination of the genealogical components is necessary, the results of the examination and the description of the genealogical components shall be treated as confidential, if the applicant or his representative so requests.

Article 64
Examination of the denomination

1. After the formal examination referred to in Article 59, 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 50.

Article 65
Examination reports and official description

1. Following the technical examination referred to in Article 63, the competent authority shall produce a provisional examination report and, where it considers that the conditions laid down in Articles 48 to 50 are complied with, a provisional official description of the variety on the basis of that report.

   The examination reports may refer to findings of other examination reports of other competent authorities or the Union concerning the variety in question.

2. The competent authority shall communicate the provisional examination report and the provisional official description of the variety to the applicant. The competent authority shall give the applicant an opportunity to comment thereon, before it makes the examination report and official description final.

3. 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 68 shall be considered to be part of the technical examination referred to in Article 63.

4. Competent authorities shall make available the examination reports to all other competent authorities, the Commission and the Office upon their request.

   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 or, where applicable, the officially recognised description of the variety.

5. By way of derogation to paragraphs 1 to 4, and for the purpose of registration in a national variety register, a variety shall be deemed to have an official description if that description has been produced by another competent authority or the Office.

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Article 66

Decision on registration

1. If on the basis of the procedure referred to in Articles 56, 59, 61, 64 and 65 it is concluded that the variety complies with the requirements set out in Article 43, 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 43 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 59(2);

   (c) where applicable, the applicant has not complied with a rule pursuant to an act adopted under Article 60, or a request of the competent authority to comply with that rule within a time limit laid down;

   (d) the respective variety may pose a risk for human, animal and plant health and the environment.

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 61.

Article 67

Already registered varieties

By way of derogation from Articles 59 to 68, 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 68

New denomination after registration

Where, after the registration of a variety, it is established that its denomination within the meaning of 50 was not suitable at the time of the registration of the variety, the applicant shall submit a new application for denomination conforming with Article 50. 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.

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SECTION 3
VALIDITY, RENEWAL AND DELETION

Article 69
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 70
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 2 and 3.

   That renewal shall only be granted if the variety continues complying with the requirements of Article 43 and provided that material of that variety is still available and maintained.

   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.

2. 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 paragraph 1 are fulfilled.

3. 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. This paragraph shall apply only once the competent authority concludes that a person is responsible to maintain the variety in accordance with the provisions of Article 71.

Article 71
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.

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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. In case the person responsible for the maintenance does not comply with the provisions of this Article, the competent authority shall provide the opportunity to that person to take corrective action.

Article 72
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 authorities concludes, on the basis of any new evidence, that the conditions for registration at the time of registration, as set out in Article 43, 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 73(1)(d)];

   (d) the applicant or the person responsible for the maintenance the variety, referred to in Article 73(1), so requests, unless maintenance of the variety is assured by another person; or

   (e) 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;

   (f) if it is proven that the variety is no longer maintained pursuant to Article 71;

   (g) where it is established pursuant to Article 68 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.

   This paragraph shall also apply on varieties already registered in the registers, catalogues and lists of the Directives referred to in Article 69.

2. 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 made available on the market until 30 June of the third year following the deletion from the register.

3. By way of derogation from paragraph 1, points (b) and (d), the competent authority may keep the variety in the national variety register in one of the following cases:

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(a) if the conditions referred to in Article 72(3) concerning the renewal of registration are applicable; or

(b) if requested so by another person interested in the production and marketing 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.

This paragraph 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 4
FEES

Article 73
Registration fees

1. The competent authorities shall charge fees to recover the necessary costs for the following actions:

(a) the formal examination referred to in Article 61;

(b) the arrangement for and the technical examination and the audits referred to in Article 63, if carried out by them;

(c) the examination of the variety denomination referred to in Article 66;

[(d) the inclusion of the variety in the national variety register for each year of the duration of the registration;]

2. The acts set out 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. The Commission shall be empowered to adopt delegated acts, in accordance with the procedure referred to in Article 124, setting out the amount of specific costs to be covered under points (a) to (d) of paragraph 1. That amount may be reduced in the case of varieties with officially recognised description only, and which serve the purpose of conservation of genetic resources, genetic diversity and sustainable production.

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CHAPTER IV
REGISTRATION OF VARIETIES IN THE UNION VARIETY REGISTER

SECTION 1
CONTENT OF THE UNION VARIETY REGISTER

Article 74
Content of the Union variety register

1. The provisions of Articles 52 and 53 shall apply accordingly for the content of Part A of the Union variety register.

2. The provisions of Article 52 and 53 shall apply accordingly for the content of Part B of the Union variety register, which shall indicate the respective data as they are included in the respective national variety registers. In addition, that Part shall include:

   (a) the Member State and the competent authority of registration in the national variety register; and

   (b) a hyperlink to the respective item of the national variety register(s).

Article 75
Information

1. The Office shall notify the competent authorities and the Commission of the information required to access the Union variety register.

2. The Office shall immediately notify the competent authorities and the Commission of the adoption of the decision to register in the Union variety register referred to in Article 80 and the deletion of a variety referred to in Article 72.

3. By 31 March of each year, the Office shall notify the other competent authorities and the Commission:

   (a) the varieties as included in Part A of the Union variety register during the preceding year; and

   (b) any other amendments to Part A of the Union variety register respective made during the preceding year.

4. 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 official or officially recognised description of the registered varieties;

   (b) the results of technical examinations referred to in Article 61;

   (c) any other information available in respect of registered or deleted varieties;

   (d) the list of varieties for which applications for registration are pending.

5. The Office shall take appropriate measures to make available information contained in the files referred to in Article 54. This provision shall not apply where the information must be treated as confidential under Article 63.

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SECTION 2
REGISTRATION PROCEDURE

Article 76

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

1. Articles 56 to 60, and 62 to 65 shall apply accordingly for the submission, content, form, formal examination, date of applications, confidentiality and for the documentation of files, concerning the registration of a variety 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 77

Technical examination of the variety

1. Where, as a result of the formal examination, the application is found to be compliant with the conditions laid down in Article 61(1), the Office shall carry out a technical examination of the application and the respective material for the purpose of establishing an official description referred to in Article 45(a).

   That technical examination shall examine compliance with the requirements for distinctiveness, uniformity and stability of the variety, as laid down in Articles 48 to 50, the suitability of the denomination, in accordance with Article 52, and, where applicable, the additional requirements for value for cultivation and/or use, as laid down in Article 47.

2. The Office may carry out those technical examinations only in premises, which are dedicated to this purpose, and where the organisation of those examinations have been audited and approved by the Office. On the basis of that audit, the Office may recommend to the owners of the premises corrective actions concerning the premises and the organisation of examinations. If the applicant requests so, the Office shall carry out those examinations in specific premises under the condition that they comply with the requirements of this paragraph.

   The Commission shall be empowered to adopt delegated acts, in accordance with Article 124, setting out the conditions under which this paragraph shall apply for the audit by the Office of premises and of organisations for examinations to confirm compliance with the requirements referred to in Article 45 concerning the satisfactory value for cultivation and use of certain species.

   Unless those delegated acts are adopted, this paragraph shall not apply for the conduct of examinations concerning value for cultivation and use.

3. The technical examination referred to in paragraph 1 shall be carried out by the applicant, if the applicant requests so. In that case, the applicant shall carry out the technical examination only in premises of its choice, which are dedicated to this purpose, and the organisation of those examinations have been audited and authorised by the Office. In that case, the Office shall sign the official description. That authorisation shall only be granted, and maintained, if the premises and organisation of examinations comply with the respective protocols of the Office, if available.

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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.

5. Article 63(5) shall also apply for the purposes of this Article.

Article 78
Examination of the denomination

1. After the formal examination referred to in Article 61(1), 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 50.

Article 79
Examination reports and official description in Part A of the Union variety register

1. Article 65 shall apply accordingly for the examination reports and the official description of the varieties, concerning the registration of a variety 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 80
Decision on registration

1. If on the basis of the procedure referred to in Articles 76 to 79 it is concluded that the variety complies with the requirements set out in Article 45, 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 45 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 61(2);

   (c) where applicable, the applicant has not complied with a rule pursuant to an act adopted pursuant to Article 59(2), or a request of the competent authority to comply with that rule within a time limit laid down;

   (d) the respective variety may pose a risk for human, animal and plant health and the environment.

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 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 63.

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Article 81

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

Where, after the registration of a variety, it is established that its denomination within the meaning of 50 was not suitable at the time of the registration of the variety, the applicant shall submit a new application for denomination conforming with Article 50. The Office shall decide on that application on the basis of any new information. The Office may permit the previous denomination to be used temporarily.

SECTION 3
VALIDITY, RENEWAL AND DELETION

Article 82

Period of validity and renewal of registration

1. The provisions of Articles 69, 70 and 72 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 83

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.

SECTION 4
FEES

Article 84

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 76;

      (ii) the arrangement for and the technical examination and the audits referred to in Article 77;

      (iii) the examination of the variety denomination referred to in Article 79;

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(iv) the decision on the variety registration referred to in Article 80;

[(iv) 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 85, including the decision;

2. The acts 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 63, 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 124, setting out the amount of the fees referred to in paragraph 1. This amount may be reduced in the case of varieties which serve public interest, varieties with officially recognised description only, and in the case of applicants who are producers of small quantities only.

Those acts shall be adopted in consultation with the Office. 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.

SECTION 5
APPEALS

Article 85

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 81, the amendment of a denomination pursuant to 82, and the fees pursuant to Article 84. 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 86

Persons entitled to appeal and to be parties to appeal proceedings

Any person may appeal, subject to Article 85, 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

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direct and individual concern to the former. The parties to proceedings may, and the Office shall, be party to the appeal proceedings.

Article 87
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 88
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 85(2), second sentence, and remit the appeal to the Board of Appeal.

Article 89
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 90
Decision on appeal

The Board of Appeal shall decide on the appeal on the basis of the examination carried out pursuant to Article 89. 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 91
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.

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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 92

Delegated acts on miscellaneous conditions governing proceedings

The Commission shall be empowered to adopt delegated acts, in accordance with Article 124, 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.

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PART IV
PRODUCTION AND MARKETING OF FOREST REPRODUCTIVE MATERIAL

TITLE I
GENERAL PROVISIONS

Article 93
Scope

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

Article 94
Definitions

For the purposes of this Part, the following definitions shall apply for forest reproductive material:

(1) 'basic material' means any of the following:

(i) Seed Source: Trees within a delimited area from which seed is collected;

(ii) Stand: A delineated population of trees possessing sufficient uniformity in composition;

(iii) Seed Orchard: 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;

(iv) Parents of Family: 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);

(v) Clone: Group of individuals (ramets) derived originally from a single individual (ortet) by vegetative propagation, including by cuttings, micropropagation, grafts, layers or divisions;

(vi) Clonal Mixture: A mixture of identified clones in defined proportions.

(2) 'Autochthonous stand' or 'autochthonous seed source' means: An autochthonous stand or seed source is one which normally has been continuously regenerated by natural regeneration or one may be regenerated artificially from reproductive material collected in the same stand or seed source or autochthonous stands or seed sources within the close proximity;

(3) 'Indigenous stand' or 'indigenous seed source': An indigenous stand or seed source is an autochthonous stand or seed source or is a stand or seed source raised artificially from seed, the origin of which is situated in the same region of provenance;

(4) 'origin' means:

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(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.

The origin of a stand or seed source may be unknown.

(5) 'provenance' means the place in which any stand of trees is growing;

(6) '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;

(7) 'production' means all stages in the generation of the seed unit, the conversion from seed unit to seed and the raising of planting stock from seed and parts of plants;

(8) ‘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;

(9) ‘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;

(10) ‘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;

(11) ‘tested’ means reproductive material derived from basic material consisting of stands, seed orchards, parents of families, clones or clonal mixtures of superior quality;

(12) Seed unit: cones, infructescenses, fruits and seeds intended for the production of planting stock;

(13) parts of plants: 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;

(14) planting stock: plants raised from seed units, from parts of plants, or from plants from natural regeneration.

TITLE II
BASIC MATERIAL

Article 95
Approval of basic material

1. Only approved basic material shall be used for the production of forest reproductive material with a view to marketing.

2. Basic 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, and shall be given a reference identifying the basic material as such (hereinafter: 'unit of approval'). Each unit of approval shall be identified by a unique reference to the register referred to in Article 98(1).

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3. The competent authorities shall approve, for a period of ten years, in all or part of their territory, basic material for the production of tested reproductive material where, from the provisional results of the genetic evaluation or comparative tests referred to in Annex VII, it can be assumed that the basic material will, when tests have been completed, satisfy the requirements for approval under this Regulation.

4. The approval shall be withdrawn if those requirements are no longer met.

Article 96

Post approval inspections

After approval, the basic 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 97

Demarcation of regions of provenance

1. In the case of basic 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 98

Register and national list of approved basic material

1. Member States shall draw up a national register of the basic 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, keep, update and publish 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 material. The following details shall be provided:

   (a) botanical name;

   (b) category;

   (c) purpose;

   (d) type of basic 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 one 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;

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(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/ nonindigenous basic material, the origin shall be stated if known;

(j) in the case of material of the ‘tested’ category, whether it is genetically modified.

For the categories ‘source-identified’ and ‘selected’, a summary of basic material based on regions of provenance is permitted.

3. The Commission shall adopt, by means of implementing acts, the form in which such national lists shall be drawn up. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 125(3).

Article 99

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 98(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 98 and indicate the area of utilisation and any authorisations or restrictions under Article 120.

3. The Commission shall adopt, by means of implementing acts, the formats 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 125(3).

TITLE III
PRODUCTION AND MARKETING OF MATERIAL DERIVED FROM BASIC MATERIAL

Article 100

Requirements for production and marketing of forest reproductive material

Forest reproductive material may be marketed if:

(a) basic material approved pursuant to Article 95 is used for its production;

(b) it complies with the specific requirements for the category concerned pursuant to Article 101;

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(c) it complies with the specific requirements for certain forms of forest reproductive material set out in Article 102;

(d) where it consists of parts of plants or planting stock, it complies with international standards pursuant to Article 103;

(e) it complies with the provisions of Article 105;

(f) it has a master certificate issued in accordance with Article 106 or, in the case of mixtures, it complies with the provisions referred to in Article 109;

(g) it is produced in lots in accordance with Article 107, complies with the provisions referred to in Article 108, and is accompanied by an operator's label or document pursuant to Article 110;

(h) where it consists of seed units, it is sealed pursuant to Article 114.

Article 101

Specific requirements for 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 102

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 103

Specific requirements for certain parts of plants and planting stock

The Commission shall be empowered to adopt delegated acts, in accordance with Article 124, setting out specific requirements for the marketing of specific parts of plants and planting stock. Those requirements shall take into account the applicable international standards.

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Article 104

Specific requirements to conserve genetic resources

1. Member States may adopt measures departing from the requirements of Article 95 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 marketing 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 105

Marketing of registered forest reproductive material

Forest reproductive material shall be marketed as such in accordance with the provisions of this Part only if derived from approved basic material registered in a national register pursuant to Article 98(1).

Article 106

Master certificate

1. After harvesting, a master certificate showing the unique reference of the register referred to in Article 98 (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.

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 109(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 107

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;

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(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 cuttings, whether undercuts, transplants or containerised;

(k) whether it is genetically modified.

Article 108

Subsequent vegetative propagation of certain units of approval

Subsequent vegetative propagation of forest reproductive material belonging to the 'selected', 'qualified' and 'tested' categories may take place. In such cases the material shall be kept separate and identified as such.

Article 109

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 107(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 110

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 may include, or be supplemented by, another document produced by the operator containing further information concerning the forest reproductive material (hereinafter: 'operator's document'). The operator's label shall contain, in addition to the information required under Article 107 and 109, the following information:

   (a) master certificate number(s) issued under Article 106 or reference to the other document available according to Article 106(3);

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(b) name of operator;

(c) quantity supplied;

(d) in the case of forest reproductive material of the ‘tested’ category whose basic material is approved under Article 95(3), 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’.

Article 111

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 110(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 110 2(b) and (d) shall be stated by the operator as soon as possible.

Article 112

Exception for small quantities

In the case of small quantities of seed, the requirements as laid down in Article 110 (2)(b) and (d) do not apply. The Commission shall be empowered to adopt delegated acts, in accordance with the Article 124, setting out the quantities and conditions for the application of this Article.

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Article 113

Exception and condition for Populus spp.

In the case of *Populus* spp., parts of plants shall only be marketed 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 114

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 115

Amendment of Annexes IV to XI

The Commission shall be empowered to adopt delegated acts, in accordance with Article 124, 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 116

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 marketing as does forest reproductive material produced within the Union and complying with the provisions set out in Article 100 of this Regulation. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 125(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 subparagraph 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 117

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 118, 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.

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Article 118

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 marketing of that material in the Union.

2. However, if requested by the authorities of the importing country, or established by the laws, regulations, standards, codes of practice and other legal and administrative procedures in force in the importing country, export and re-export of forest reproductive material may take place in accordance with those provisions.

3. Where the provisions of a bilateral agreement concluded between the Union and a third country are applicable, forest reproductive material exported from the Union to that third country shall comply with the said provisions.

TITLE V
Derogations

Article 119

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 adopted pursuant to Article 95, 101 and 102 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 125(3).

2. The implementing acts referred to paragraph 1 may authorise a Member State to prohibit the marketing 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 marketing 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.

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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 120
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 marketing, for a period to be set by those acts, of forest reproductive material of one or more species which satisfies less stringent requirements then those prescribed in Articles 95, 101 and 102.

2. The label accompanying forest reproductive material marketed pursuant to paragraph 1 shall state that the material in question satisfies less stringent requirements.

Article 121
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 125(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 122
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 marketing of the plant reproductive

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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 125(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 126(4).

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 marketing 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 125(3). The Member State may maintain its national interim emergency measures until the implementing acts mentioned 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 123
Fees

1. Competent authorities shall charge fees for the following acts:

   (a) registration of approved basic material pursuant to Article 100; and

   (b) issuance of a master certificate pursuant to Article 106(1) and (2).

2. The acts 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 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 124, 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 serve public interest and in the case of applicants who are producers of small quantities only.

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PART IV
PROCEDURAL PROVISIONS

Article 124
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 11(2), 17(4), 19(3), 20(4), 21, 23(1), 25(4), 25(5), 26(5), 28(1), 28(3), 29(1), 30(4), 47(2), 47(3), 52(3), 60(2), 63(2), 75(3), 79(2), 86(4), 94, 101(3), 105, 114, 117, 123(2) and 128(3) 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 11(2), 17(4), 19(3), 20(4), 21, 23(1), 25(4), 25(5), 26(5), 28(1), 28(3), 29(1), 30(4), 47(2), 47(3), 52(3), 60(2), 63(2), 75(3), 79(2), 86(4), 94, 101(3), 105, 114, 117, 123(2) and 128(3) 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 11(2), 17(4), 19(3), 20(4), 21, 23(1), 25(4), 25(5), 26(5), 28(1), 28(3), 29(1), 30(4), 47(2), 47(3), 52(3), 60(2), 63(2), 75(3), 79(2), 86(4), 94, 101(3), 105, 114, 117, 123(2) and 128(3) 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 125
Committee procedure

1. The Commission shall be assisted by the Standing Committee on the Food Chain, Animal Health and Plant Health established by Article 58 of Regulation (EC) No 178/2002 of the European Parliament and of the Council.[21] 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.

[21] OJ L 31, 1.2.2002, p. 1.

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4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof shall apply.

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PART V
FINAL PROVISIONS

Article 126
Amendment of Regulation (EC) No 2100/94

Regulation (EC) No 2100/94 is amended as follows:

1. the following sentence is added to Article 4:

   'The Office shall also manage and support the Union variety register, established in accordance with Article 43 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].

2. The following paragraph is added to Article 4:

3. The Office shall carry out the following tasks:

   (a) to offer recommendations on variety denominations, where requested so pursuant to Article [38 of PRM Regulation];

   (b) to promote and coordinate development of uniform technical examination of varieties, carried out pursuant to [Article 61 and 77 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 [Articles 61 and 77 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 [32 of PRM Regulation];

   (e) to participate and offer training in its area of mission; (g) to provide technical support to the Commission in the areas within its mission;

   (f) to commission studies necessary for the accomplishment of its mission; (i) to search for, collect, collate, analyse and summarise technical data in the fields within its mission;

   (h) to ensure that the public and interested parties receive rapid, reliable, objective and comprehensible information in the fields within its mission;

   (i) 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.';

Article 127
Penalties

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.

The Member States shall notify thee provisions 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.

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Article 128
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 124, setting out that one or more of the acts referred to in Annex IV 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 129
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 [date x]

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament *For the Council*
The President *The President*

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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.

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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.

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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.

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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 13.

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

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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.

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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.

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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 identify 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.

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(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.

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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; [needed for certified seed]

(i) in the case of seeds, declared or gross net weight of pure seeds;

(j) a bar code, comprising all above items;

(k) place of production.

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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.

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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-authochthonous/ 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 should 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 should be low.

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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 should 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

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(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.

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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 fo 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:

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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,

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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 should 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 should 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 compensates 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.

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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

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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.

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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

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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,

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they have injuries other than pruning cuts,

they have multiple stems,

they have excessive stem curvature.

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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.

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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

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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)** ……..

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:

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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) …….**

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 ☐

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

4. **Type of basic material**
   Seed orchard ☐
   Parents of family(ies) ☐

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:	Name of Responsible Officer:

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	Date:	Signature:

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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) ……**

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 ☐

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

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

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:** .....
    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:**

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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
21. 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

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22. 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

[This list remains under the review of DG SANCO; to be completed in consultation with the Legal Service during the inter-service consultation]

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ANNEX XIII
CORRELATION TABLE

[to be completed during the inter-service consultation]

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