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Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

On the production and making available on the market of plant reproductive material (plant reproductive material law)

(Text with EEA relevance)

{SWD(2013) 162 final}
{SWD(2013) 163 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

Plant reproductive material is a fundamental input for the productivity, the diversity, and the health and quality of agriculture, horticulture and food and feed production and our environment. Forests cover a large area of the Union and fulfil multiple social, economic, environmental, ecological and cultural functions. The current EU legislation for making available on the market of plant reproductive material is based on two main pillars, namely the registration of varieties/material and the certification of individual plant reproductive material 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/EEC 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 making available on the market of plant reproductive material 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 professional operators on the single market. There is a need to harmonise implementation of the legislation, reduce cost and administrative burdens and support innovation. It is also important to adapt to the technical progress in plant breeding, and to the rapid evolution of the European and global market of plant reproductive material. All those needs make the update and modernisation of the legislative framework imperative. The aim of *in situ* conservation of agro-biodiversity 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. 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" and greening of food crop production, in which yields

are increased without adverse environmental impact and without the cultivation of more land, have become a central concern. Plant reproductive material legislation is critically important for reaching this aim. The EU Forest Strategy emphasises the importance of the multifunctional role of forest and its sustainable management.

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

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 EU legislation on the marketing of seed and plant propagating material (now plant reproductive material) 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 under 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 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 professional operators, the level of harmonisation among Member States, the role of niche and emerging markets and the conservation of agro-biodiversity and plant genetic resources. 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. In addition, concerning the EU legislation on forest reproductive material, the stakeholders requested to maintain the current approach.

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 and (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 plant reproductive material, 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 regarding 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 plant reproductive material market. Specific attention is given to trade-offs between transferring operational work and keeping of quality of plant reproductive material.

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 professional operators and consumers, guaranteeing high quality of plant reproductive material and securing competitive advantage on the internal and the world markets. This combination aims at striking a balance between flexibility for professional 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 plant reproductive material. 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 professional 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 – General provisions

The scope of the proposed Regulation covers all types of plant reproductive material. The largest part of it covers, though, the species currently regulated 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 (see Part III, Title III).

In order to take into account the needs of producers and the requirements of flexibility and proportionality, the Regulation will not to apply to plant reproductive material intended for testing and scientific purposes and intended for breeding (selection) purposes. In addition, it should not apply to material intended to or maintained in gene banks, organisations and networks of ex-situ and in-situ or on farm conservation of genetic resources following national strategies on conservation of genetic resources. Furthermore, plant reproductive material exchanged in kind between two persons other than professional operators is excluded from the scope of the Regulation.

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. Plant reproductive material is defined to mean plants or parts of plant capable of and intended for producing or reproducing entire plants. This includes also young plants. All those types of plant reproductive material are subject to common principles with regard to their production with a view to making available on the market and with regard to making them available on the market.

3.2. Part II – Professional operators

As under this Regulation the definition of operator does not include private persons, the term 'professional operator' is used. Professional 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 [title of the new Plant Health Regulation]. Basic obligations will be introduced for professional operators concerning the identification of the plant reproductive material they are producing or making available on the market, 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 professional 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

Title I General provisions

Definitions of variety and its maintenance, variety with official description or variety with officially recognised description, clone as well as of the different marketing categories are laid down.

Title II Production and making available on the market of listed species

In general, the basic approach on registration of varieties/material and certification/inspection of lots before making available on the market will be maintained. However, more flexibility will be given to the professional operators so that they may decide to carry out the necessary examination 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 making available on the market of particular species and their categories (pre-basic, basic, certified and standard material). This is important to increase flexibility for changes due to technical and scientific developments and at the same time respecting proportionality and sustainability in regulatory approach.

The requirements for making available on the market of plant reproductive material may be summarised as follows:

– it belongs to a variety or clone registered in accordance the provisions of this Regulation;

– it complies with the specific requirements adopted for the marketing category concerned per genera and species;

– it bears an official label for pre-basic, basic or certified material, or an operator's label in case of standard material;

– it complies with the handling requirements;

– it complies with the requirements for certification and identification.

The obligation of variety registration shall not apply to rootstocks which do not fulfil the conditions of a variety. In addition, in order to introduce flexibility for future technical and scientific developments, heterogeneous material, which does not fulfil the definition of a variety, could be exempted under certain conditions from the requirement that that material belongs to a registered variety. Furthermore, a specific derogation for niche market plant reproductive material is laid down.

Certain genera and species of plant reproductive material, which are listed in the current Directives, should continue to be subject to enhanced requirements relating to their production and making available on the market (listed species). However, there is a need to set criteria to decide on these plant species. Genera or species of plants which represent a significant area and value of production, are produced and made available on the market by a significant number of professional operators or they contain substances requiring specific rules to protect human, animal health or the environment should be included in the list.

Plant reproductive material should only be produced and made available on the market as pre-basic, basic, certified or standard material, in order to ensure transparency and informed choices for users. Detailed criteria need to be established to decide which genera and plant species shall not be made available on the market as standard material to ensure enhanced quality and health, identity and traceability of plant reproductive material as well as food and feed security. Specific requirements should be adopted per genera and species for each of those categories. The requirements on identity, purity, health and other quality requirements, labelling, lots, packaging including small packages, post-certification control tests, comparative tests and trial and mixtures will continue to be applied.

Derogations

The existing permanent derogations on making available on the market to a limited extent not-yet registered varieties for testing on farm and not finally certified material and authorisation of more stringent national requirements should be maintained. This should also concern the important temporary derogations on emergency measures, temporary difficulties in supply and temporary experiments.

Derogation on niche market plant reproductive material

In addition, proportionate and sustainable rules for small scale activities concerning plant reproductive material, which is adapted to local conditions, and made available on the market in small quantities, should be established. Such varieties should be exempted from the requirements on registration and making available on the market. This material is defined as niche market plant reproductive material. The exemption should concern e.g. farmer-breeders or gardener-breeders whether being professional operators or not. However, some basic rules on labelling and traceability of the material should be laid down. In order to prevent an abuse of the exemption the material should only be made available on the market in a defined size of packages.

Imports and exports

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

absence of the latter, an agreement conducted between the professional operators shall apply.

Title III Production and making available on the market of plant reproductive material belonging to non-listed genera or species

Plant reproductive material not belonging to the listed genera and species shall also be subject to a few basic requirements with regard to its health status, fitness for purpose, appropriate reference to varieties, where applicable, and identification of the respective material and imports.

Title IV Registration of varieties in national and Union registers

Variety registers

The varieties, in order to be made available on the market throughout the Union, shall be included in a national register or in the Union register via direct application procedure to the CVPO. CPVO will keep the updated information on all plant varieties that can be made available on the market 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 maintained. The uniformity examination should take into account the type of variety and type of reproduction. 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. The Member States shall adopt more detailed criteria for the VCU examination of these plant species as regards their yield, quality characteristics, resilience and suitability for low input production systems including organic production. Thus, given the specific characteristics required for organic farming, the methodology and requirements established for variety examination should take due account of the specific needs.

Rules on a sustainable value for cultivation will be laid down and harmonised in the EU by adopting specific requirements concerning resistance to specific pests, 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 should 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 made available 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 CPVO to check a denomination, before the respective variety is registered in a national variety register.

The Regulation establishes the detailed requirements for the variety registration procedure regarding 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, the same rules shall also apply to direct variety applications to the CPVO for registration in the Union variety register.

Specific provisions are set out on the registration in the Union variety register and with regard 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 examination centre of the professional operators will be audited and approved by the national competent authorities. In case of direct application to the CPVO it will audit and approve the examination centres it uses for variety examination.

The competent authorities and the CPVO should charge fees for the processing of applications, the formal and technical examinations including audits, variety denomination, 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 general principle of cost recovery shall prevail. However, the micro-enterprises shall be exempted from fees to fulfil the Commission's commitment to lower the burden on very small businesses, in line with its new policy on minimizing regulatory burden for SMEs and adapting EU regulation to the needs of micro-enterprises. Moreover, the fee for registration of varieties with officially recognised description and heterogeneous material shall be reduced in a manner to ensure that the fee does not constitute a barrier to the registration of the variety or material concerned.

Old traditional varieties

Concerning old varieties, such as conservation varieties (including landraces), or so called 'amateur varieties', less stringent requirements should continue to be laid down in view of promoting their on farm conservation and use as currently regulated under the Directives 2008/62/EC and 2009/145/EC. 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 DUS examination is no longer obligatory. The officially recognised description shall only describe the specific characteristics of the plants and parts of plants which are representative for the variety concerned and make the variety identifiable, including the region of origin. This description can be based on an old official description of the variety, description produced at the time by e.g. a scientific, academic body or organisation. The accuracy of its content could be supported by previous official inspections, unofficial examinations or knowledge gained from practical experience during cultivation, reproduction and use. The current quantitative restrictions are abolished. The users are informed about the material by a label indicating that this variety is identified by an officially recognised description and the region of origin. Plant reproductive material belonging to those varieties should only be made available on the market as standard material.

3.4. Part IV – Production and making available on the market of forest reproductive material

The EU legislation sets a specific approach including specific terminology on forest reproductive material. Therefore, for this area a separate part is laid down in which

the current basic approach is kept. The requirements for forest reproductive material concern approval of basic material, inclusion in national register and Union list, master certificate, marketing categories, lots, mixtures, labelling, packaging and establishment of the conditions of EU equivalence for imports. 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, rules concerning temporary difficulties in supply and rules concerning temporary experiments.

3.5. Part V – Procedural provisions

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

3.6. Part VI – Final provisions

The Regulation (EC) NO 2100/94 on Community Variety Rights is amended as regards the name and role of CPVO. The name of the agency is amended to follow the recommendations of the EU inter-institutional working group to 'European Agency on Plant Varieties' (EAPV). The mission of CPVO is extended to the area of variety registration, in particular the management of Union variety register and the registration of plant varieties via direct application procedure to the CPVO. In addition, a number of tasks are attributed to the CPVO within its new mission on offering recommendations on variety denominations, database on reference collections of varieties, harmonisation of technical examination of varieties, audits of technical examination centres, advisory tasks, training and technical support.

The necessary rules on penalties are laid down.

3.7. Part VII – Union competence, subsidiarity and legal form

The plant reproductive material 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. Requirements with regard to the sustainability of agriculture have been integrated through the successive revisions of the CAP. 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 the objectives of the measure can be achieved most efficiently by fully harmonised requirements throughout the Union, ensuring free movement of plant reproductive material.

4. BUDGETARY IMPLICATION

The financial appropriations for implementing the Regulation up to 31 December 2020 are being presented in the Regulation on laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material.

5. OPTIONAL ELEMENTS

2013/0137 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

On the production and making available on the market of plant reproductive material (plant reproductive material law)

(Text with EEA relevance)

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,

Having regard to the opinion of the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure[1],

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[2];

(b) Council Directive 66/402/EEC OF 14 June 1966 on the marketing of cereal seed[3];

(c) Council Directive 68/193/EEC of 9 April 1968 on the marketing of material for the vegetative propagation of the vine[4];

(d) Council Directive 98/56/EC of 20 July 1998 on the marketing of propagating material of ornamental plants[5];

(e) Council Directive 1999/105/EC of 22 December 1999 on the marketing of forest reproductive material[6];

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1 Position of the European Parliament of … and position of the Council at first reading of ... Position of the European Parliament of ... and decision of the Council of ....

2 OJ L 125, 11.7.1966, p. 2298.

3 OJ L 125, 11.7.1966, p. 2309.

4 OJ L 93, 17.4.1968, p. 15.

5 OJ L 226, 13.8.1998, p. 16.

6 OJ L 11, 15.1.2000, p. 17.

(f) Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species[7];

(g) Council Directive 2002/54/EC of 13 June 2002 on the marketing of beet seed[8];

(h) Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed[9];

(i) Council Directive 2002/56/EC of 13 June 2002 on the marketing of seed potatoes[10];

(j) Council Directive 2002/57/EC of 13 June 2002 on the marketing of seed of oil and fibre plants[11];

(k) Council Directive 2008/72/EC of 15 July 2008 on the marketing of vegetable propagating and planting material, other than seed[12];

(l) Council Directive 2008/90/EC of 29 September 2008 on the marketing of fruit propagating material and fruit plants intended for fruit production[13].

(2) The basic objective of the above Directives is sustainable agricultural, horticultural and forestry production. In order to ensure productivity, the health, quality and diversity of plant reproductive material is of outmost importance for agriculture, horticulture, food and feed security, and the economy in general. Moreover, to ensure sustainability, legislation should take account of the need to meet consumers' expectations, to ensure the adaptability of production to manifold agricultural, horticultural and environmental conditions, to face the challenges of climate change and to foster the protection of agro-biodiversity.

(3) Evolution in the areas of agriculture, horticulture, forestry, plant breeding and making available on the market of plant reproductive material has shown that the legislation needs to be simplified and further adapted to the developments of the sector. Therefore, the above Directives should be replaced by a single Regulation on the production, with a view to making available on the market, and the making available on the market, of plant reproductive material within the Union.

(4) Plant reproductive material, should be defined in a comprehensive manner, including all plants capable of, and intended for, producing (including reproducing at any further stage of production) entire plants. This Regulation should, therefore, cover seeds, as well as all other forms of plant at any growth stage, intended for and capable of producing entire plants.

(5) This Regulation should also cover plant reproductive material used for the production of agricultural raw materials intended for industrial purposes, since that material represents a major part of several sectors and should fulfil certain quality standards.

(6) In order to determine the scope of the several provisions of this Regulation it is necessary to define the concepts of “professional operator” and “making available on the market”. In particular, in view of the marketing developments of the sector, the

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

definition of 'making available on the market' should be as wide as possible to ensure all forms of transactions of plant reproductive material. That definition should include *inter alia* persons concluding sales through distance contracts (e.g. electronically) and persons who collect basic forest material.

(7) Given the needs of producers and the requirements for flexibility and proportionality, this Regulation should not apply to reproductive material intended solely for testing, scientific and breeding purposes, to gene banks, organisations and networks devoted to the exchange and conservation of genetic resources (including on-farm conservation), or to reproductive material exchanged in kind between persons other than professional operators.

(8) Directive 94/62/EC of 20 December 1994 on packaging and packaging waste[14], Regulation (EC) No 338/97/EC of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein[15], 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[16], Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed[17], Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC[18] and Regulation (EU) No …/… [*Office of publications, please add number of Regulation on protective measures against pests of plants*], should also apply for the production and making available on the market of plant reproductive material.

(9) In order to ensure transparency and more effective controls on the production and making available on the market of plant reproductive material, professional operators should be registered. However, in order to reduce the administrative burden for professional operators, by allowing them to register only once in a single register, it is appropriate that they register in the public registers established by the Member States pursuant to Regulation (EU) No …/… (*Office of Publication, please insert number of Regulation on protective measures against pests of plants*).

(10) Basic obligations should be introduced for professional operators active in the production and making available on the market of plant reproductive material area to ensure the proper application of this Regulation.

(11) Experience has shown that the reliability and quality of reproductive material made available on the market can be jeopardised where it is impossible to trace reproductive material not complying with applicable standards. It is therefore necessary to establish a comprehensive system of traceability allowing withdrawals to be undertaken or information to be given to consumers or competent authorities. For that reason, the keeping of the necessary information and records on transfers from and to professional users should be mandatory. On the basis of the principle of proportionality, that rule should not apply in case that supply is part of making available on the market in retail.

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14 OJ L 365, 31.12.1994, p. 10–23
15 OJ L 61, 3.3.1997, p. 1–69
16 OJ L 106, 17.4.2001, p. 1–39
17 OJ L 268, 18.10.2003, p. 1–23
18 OJ L 268, 18.10.2003, p. 24–28

(12) Certain genera and species of plant reproductive material should be subject to enhanced requirements concerning their production and making available on the market due to their increased economic, health or environmental importance. That importance should be determined through the area or value of production of those genera or species, the number of professional operators or the content of substances which present a potential risk for health or the environment. The majority of those genera and species is currently regulated by the above Directives. Those genera and species should be inserted in a specific list (hereinafter: 'listed genera and species').

(13) In order to ensure transparency and enable informed choices by consumers, plant reproductive material belonging to listed genera and species should only be produced or made available on the market under predefined categories. Those categories should reflect different quality levels and production stages and be named “pre-basic”, “basic”, “certified” and “standard”,

(14) In order to ensure the widest possible availability of plant reproductive material and choices by its users, professional operators should, in principle, be able to make available on the market plant reproductive material belonging to listed genera or species under any of the categories. However, in order to ensure food and feed security, and to achieve a high level of identity, quality and health of plant reproductive material, plant reproductive material should not be made available on the market as standard material if the certification costs are proportionate to those objectives.

(15) Plant reproductive material belonging to varieties with officially recognised description, as well as heterogeneous material and niche market material, should be subject to minimum requirements. Therefore, such material should in all cases be produced and made available on the market only as standard material.

(16) In order to allow for informed choices by users concerning its identity and characteristics, plant reproductive material belonging to listed genera and species should only be produced and made available on the market if it belongs to varieties registered in national variety registers or in the Union variety register.

(17) In order to facilitate adaptation to developments in plant breeding, and to possible new techniques, heterogeneous plant reproductive material, which does not fulfil the definition of a variety in the meaning of this Regulation, should be allowed to be produced or made available on the market, under certain conditions, without belonging to a registered variety, and even if it does not comply with the requirements concerning registration of varieties, namely distinctiveness, uniformity or stability, or the requirements concerning the satisfactory value for cultivation or those concerning the sustainable value for cultivation. The registration of such material should take into account its contribution to increase the genetic variability of agricultural crops, the genetic resource basis and biodiversity in the Union, as well as to the sustainability of agriculture and thus to the adaptation to climate change. The methodology for the registration should particularly take into account those specific characteristics and it should be based on the minimum possible burden for operators who wish to register such material. It would also be appropriate and proportionate to exempt from the same requirement rootstocks, as they have a significant commercial and practical value for the sectors where they are used, but they frequently do not fulfil the definition of a variety.

(18) Rules should be set out for the certification of plant reproductive material, as well as for the activities aiming at verifying the reliability of certification at the post-

certification stage, to ensure the fulfilment of the applicable quality requirements. Those rules should be adapted to the technical and scientific developments.

(19) The quality requirements and certification schemes should take into account international recommendations, such as the Seed Scheme Rules and Regulations of the Organisation for Economic Co-operation and Development (OECD), the seed potato standards of the United Nations Economic Commission for Europe (UNECE) and the rules on sampling and testing of the International seed testing association (ISTA).

(20) Given the thresholds established for the presence of quality pests by Regulation (EU) No …/… (*Office of Publication, please insert number of Regulation on protective measures against pests of plants*) on protective measures against pests of plants[19], it is appropriate to establish detailed inspection and examination procedures leading to a single certification as regards compliance with the requirements adopted pursuant to this Regulation and to Regulation (EU) No. .../… (*Office of Publication, please insert number of Regulation on protective measures against pests of plants*).

(21) In order to ensure the maximum possible purity of the material and the homogeneity of production, plant reproductive material belonging to listed genera or species should be kept in separate lots.

(22) In view of the diversity of plant reproductive material, professional operators should have the option to produce and make available on the market plant reproductive material in the form of individual plants, packages, containers or bundles.

(23) Rules should be adopted for the labelling of plant reproductive material of listed genera or species to ensure the appropriate identification of that material. In the case of material of the categories subject to certification, the label (hereinafter: 'official label') should be produced and affixed by authorised professional operators and under the official supervision of the competent authorities. However, and since certain professional operators may not have the resources to carry out the certification activities and issue official labels, it should be provided that official labels may be issued by competent authorities upon request of professional operators.

(24) For the preservation of the natural environment in the context of the conservation of genetic resources, it is desirable to allow the mixture of plant reproductive material belonging to listed genera or species with non-listed genera or species. Those mixtures should be permitted only if their composition is naturally linked to a certain region. In order to ensure transparency and better control concerning the quality of the mixtures concerned, the production and making available on the market of those mixtures should be subject to the authorisation by the competent authorities.

(25) Rules should be adopted for the import of plant reproductive material of listed genera or species into the Union, only allowing the import of plant reproductive material fulfilling the same production and quality requirements as for material produced and made available on the market in the Union.

(26) To ensure flexibility, and facilitate adaptation of the professional operators and the markets to specific circumstances, or in cases of temporary supply difficulties, it is appropriate to provide for certain derogations from the general rules of this Regulation. Those derogations should be granted under specific conditions to avoid

[19] (*Office of Publication, please insert OJ reference number of Regulation on protective measures against pest of plants*).

abuses and to ensure that the overall purposes of this Regulation are respected. They should concern plant reproductive material belonging to varieties, the registration of which is pending, plant reproductive material which is not finally certified or not certified as complying with applicable germination requirements. The possibility should also exist to adopt emergency measures to address risks for human, animal and plant health, and the environment.

(27) Plant reproductive material which is made available on the market only in limited quantities by small producers ("niche market plant reproductive material") should be exempted from the requirement of belonging to a registered variety. That derogation is necessary to prevent undue constraints to the making available on the market of plant reproductive material, which is of lesser commercial interest, but is important for the maintenance of genetic diversity. However, it should be ensured that that derogation is not regularly used by a wide range of professional operators and it is only used by professional operators which cannot afford the costs and administrative burden of variety registration. This is important to avoid abuses of that derogation and to ensure the application of the rules of this Regulation. Therefore, niche market material should only be made available on the market by professional operators employing a small number of persons and with a small annual turnover.

(28) It is desirable to organise temporary experiments for the purpose of seeking improved alternatives to any measures adopted for listed genera or species. In the organisation of those experiments the evolution of techniques relating to the production and control of plant reproductive material should be taken into account.

(29) Exported plant reproductive material of listed genera or species to third countries should comply with the rules on plant reproductive material produced and made available on the market in the Union, unless the material concerned is subject to bilateral or multilateral agreements or rules of third countries.

(30) Basic requirements should be set for plant reproductive material not belonging to listed genera or species, to ensure minimum quality and identification standards for their production and making available on the market.

(31) In order to ensure that all varieties have access to registration and are subject to common rules and conditions rules should be established for the registration of varieties and should apply to varieties of listed genera or species as well as to varieties of non-listed species.

(32) Experience so far has shown that some breeders are interested in making available on the market their varieties in the entire Union market, or in the bigger part of it. It is therefore appropriate to offer the breeders the option of registering their varieties either in a national variety register or in a Union variety register. The task of establishing , publishing and updating the Union variety register should be assigned to the European Agency on Plant Varieties (hereinafter: 'the Agency'), previously titled 'Community Plant Variety Office' as established pursuant to Article 4 of Regulation (EC) No 2100/1994 of the Council, which is currently in charge of granting plant variety rights. The activities of the Agency should thus cover all aspects of plant variety management.

(33) Varieties should, in principle, be registered on the basis of an official description produced by a competent authority or the Agency. However, in order to reduce the burden for the competent authorities and the Agency and ensure flexibility, it is

appropriate to provide for the possibility that the examinations necessary to produce the official description may also be carried out by the applicants.

(34) Further to the basic registration requirements, varieties belonging to species with particular importance for the development of agriculture and horticulture in the Union should be subject to the additional requirements ensuring satisfactory and sustainable value for cultivation or use.

(35) The requirements ensuring sustainable value for cultivation should be established at Union level in order to support sustainable development, direct plant breeding and meet breeders', producer and consumer demands concerning that type of development. The requirements ensuring satisfactory value for cultivation and use may be only developed by Member States according to their agro-climatic and agricultural conditions. Therefore, the respective varieties should only be registered in the national variety registers. The requirements ensuring satisfactory value for cultivation and use should concern yields and quality characteristics. When Member States develop and apply such requirements, they should consider the constraints characterising specific agricultural management practices. In particular, they should duly take into account the specific needs of organic farming as regards resilience and low input conditions.

(36) In the context of the Convention on Biological Diversity to which the Union is a party, the Union has committed to maintain the genetic diversity of cultivated plants, and of wild relatives, and to minimise genetic erosion. That commitment complements the objective of the Union to halt biodiversity loss by 2020. In that context, certain varieties should be allowed to be produced and made available on the market even if they do not comply with the requirements concerning distinctiveness, uniformity or stability, to ensure their conservation and sustainable use and thus contribute to the sustainability of agriculture and the adaptation to climate change. Therefore, those varieties should only be registered on the basis of an officially recognised description.

(37) However, the varieties registered on the basis of an officially recognised description should be produced in the region where they have been historically grown and adapted, to ensure their authenticity and their added value for the conservation of genetic diversity and the protection of the environment. Therefore, they should only be included in national variety registers. For the same reason, those varieties should have been available on the market and/or collected e.g. in gene banks before the entry into force of this Regulation, or, should have been deleted for more than five years from the national variety register or Union variety register, in case they have been registered there on the basis of a technical examination concerning their distinctness, uniformity and stability.

(38) Rules should be established concerning the procedures for the registration of varieties and clones in the national variety registers to ensure uniform conditions for all applications and a transparent framework for all interested parties.

(39) Certain varieties which are naturally adapted to the local and regional conditions and threatened by genetic erosion, or which have no intrinsic value for commercial crop production but have been developed for growing under particular conditions, are already accepted in national catalogues, lists or registers of varieties pursuant to Article 3 of Directive 2008/62/EC of the Commission 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[20], and pursuant to Article 3(1) of Directive 2009/145/EC of the Commission 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[21]. Those varieties have not been subject to complete technical examination concerning their distinctiveness, uniformity or stability. It is therefore appropriate that those varieties be registered directly in the national variety registers without any further proceedings as varieties with an officially recognised description.

(40) The Union variety register should also include all varieties that are registered in the national variety registers. In this way, it will be ensured that the Union variety register offers a transparent overview of all varieties registered in the Union.

(41) Rules should be adopted for the registration of varieties and clones in the Union variety register. For the purposes of consistency, those rules should be similar to the rules on registration in national variety registers.

(42) The competent national authorities and the Agency should charge fees for the processing of applications, the formal and technical examinations and for each year of the registration period. This would be necessary to ensure the necessary resources for the overall system of registration of varieties, and that the main beneficiaries of that registration bear the costs for the functioning of that system. Rules concerning the fixing of those fees should be set out in this Regulation.

(43) In order to facilitate the registration of varieties which serve at combating genetic erosion in the Union, Member States should apply a reduced fee for varieties with officially recognised description and for heterogeneous material. Such reduced fees should be sufficiently low as not to constitute a deterrent or a barrier to the making available on the market of those varieties. In order to provide support to micro-enterprises, they should be fully exempted from the payment of fees.

(44) In order to protect the commercial interests and intellectual property of professional operators, the results of the examination and the description of the genealogical components should be treated as confidential, if the breeder so requests. For the sake of transparency, all descriptions of varieties listed in the national variety registers or in the Union variety register should be made publicly available.

(45) Forests cover a large area of the Union and fulfil social, economic, environmental, ecological and cultural functions. There is, therefore, a need for specific approaches and actions for the different types of forests, considering the wide range of conditions characterising the forests in the Union.

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

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[20] OJ L 162, 21.6.2008, p. 13–19.

[21] OJ L 312, 27.11.2009, p. 44–54.

(47) Requirements should be set for forest reproductive material as regards basic material, categories under which the material may be made available on the market, lots, labelling, small packages, to ensure the appropriate quality and marketing standards, and to adapt to the technical and scientific developments of the sector.

(48) In order to ensure flexibility and adaptation to particular circumstances, derogations should be provided, under conditions, for the production and making available on the market of forest reproductive material. Those derogations should concern the possibility for Member States to adopt more stringent requirements, the case of temporary difficulties of supply, the need of making seed rapidly available on the market, the conduct of temporary experiments and the adoption of emergency measures.

(49) In order to serve the interest of conservation and sustainable use of forestry plant genetic resources, Member States should be allowed to adopt less stringent requirements on forest reproductive material which is naturally adapted to the local and regional conditions and threatened by genetic erosion.

(50) The competent authorities should charge fees for the registration/approval of basic forest material and the issuance of master certificates for the forest material derived from registered/approved basic forest material. This would be necessary to ensure the necessary resources for the certification of forest reproductive material, and that the main beneficiaries of that certification bear the respective costs. In order to provide support to micro-enterprises, they should be fully exempted from the payment of fees. The rules concerning those fees should be set out in this Regulation, as they concern the effective production, registration and making available on the market of forest reproductive material.

(51) Regulation (EC) No 2100/1994 needs to be amended to include variety registration in the mission of the Agency and to amend its former title 'Community Plant Variety Office'.

(52) In order to ensure that the Annexes of this Regulation are adapted to the technical and scientific developments, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of amending the Annexes of this Regulation.

(53) In order to follow the technical and economic developments of the sector, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of listing the genera or species whose plant reproductive material may not be placed on the market as standard material.

(54) In order to follow the technical and economic developments of the sector, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of setting out the plant reproductive material which may be produced and made available on the market without belonging to a registered variety, and the requirements for its production and making available on the market.

(55) In order to ensure that plant reproductive material of listed genera or species, and certain types of forest reproductive material, fulfils the highest possible identity, quality and health requirements, as appropriate for the characteristics of the genera, species or categories concerned, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of adopting production and quality requirements, and certification schemes, for those genera or species, and in respect of adopting quality requirements for making available on the market specific

parts of plants and planting stock of species and artificial hybrids of forest reproductive material.

(56) In order to ensure that plant reproductive material is made available on the market under conditions adapted to the specific characteristics of particular genera or species to which it belongs, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the maximum size, composition and identification of lots, and the requirements concerning small packages, of plant reproductive material belonging to particular genera or species.

(57) In order to adapt the rules concerning the official labels and operators' labels to the characteristics of certain types of plant reproductive material, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of setting out additional rules concerning the label for specific categories and other groups of plant reproductive material, indications concerning a label number, indications of generations of pre-basic, basic, certified and standard material, the indication of variety types including intraspecific or interspecific hybrids, the indication of subdivisions of categories satisfying different conditions, in case of mixtures, the indication of the percentage by weight of the various components by species and, where appropriate, by variety, and indications concerning the intended use of the material.

(58) In order to ensure the ability of the professional operators to properly carry out a reliable certification of the plant reproductive material concerned, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of setting out more detailed requirements concerning the qualification of professional operators and of the inspectors which may be entrusted with certification activities, suitability of premises and availability of particular equipment to be used by the professional operators and laboratories.

(59) In order to ensure updated standards for the official supervision of certification carried out by operators as appropriate for the characteristics of particular genera or species, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of setting out more detailed requirements concerning the way competent authorities must supervise the certification.

(60) In order to ensure updated standards for post-certification as appropriate for the characteristics of particular genera or species, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of setting out requirements concerning proportion of samples to be submitted to tests and concerning testing procedures.

(61) In order to ensure that mixtures of plant reproductive material are produced and made available on the market pursuant to the appropriate quality requirements per genera and species, and in order to ensure informed choices for their users, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of adopting rules concerning the production and making available on the market of mixtures of plant reproductive material belonging to different genera or species listed in Annex I, or different varieties of those genera or species, and in respect of adopting rules concerning mixture of plant reproductive material belonging to genera or species listed in Annex I, with plant reproductive material belonging to genera or species not listed in Annex I.

(62) In order to ensure that plant reproductive material belonging to varieties, registration of which is pending, is made available on the market in a transparent manner and to a limited extent only, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of setting out requirements concerning labelling of packages and the maximum authorised quantities which may be made available on the market for specific genera or species.

(63) In order to ensure that niche market material is made available on the market in a limited and transparent manner, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of setting out the maximum size of packages, containers or bundles, and requirements concerning traceability, lots, and labelling of the niche market material concerned.

(64) It is important to ensure that plant reproductive material not finally certified, and seed not confirmed as complying with germination requirements, can be produced and made available on the market under particular conditions. Therefore, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of setting out specific rules for plant reproductive material concerning the packages, containers and bundles, rules on small packages and containers, the labelling of that material, the duration of period in which such seed may be made available on the market, and the content of the provisional analytical reports concerning germination.

(65) It is important to ensure that plant reproductive material imported from third countries fulfils the requirements of this Regulation. Therefore, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission, in respect of deciding whether plant reproductive material of specific genera, species or categories produced in a third country, or particular areas of a third country, fulfils requirements equivalent with those applicable to plant reproductive material produced and made available on the market in the Union.

(66) It is important to ensure that the production and making available on the market of plant reproductive material of particular genera or species responds to increased requirements of the society concerning their agricultural performance and quality characteristics for processing. In order to follow the technical and economic developments of the sector, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of listing the genera or species with particular importance for the satisfactory and sustainable development of agriculture in the Union.

(67) In order to ensure updated standards for the registration of varieties as appropriate for the characteristics of genera or species with particular importance for the sustainable development of agriculture in the Union, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of setting out rules for the registration of varieties of those genera or species concerning resistance to pests, reduced need for input of specific resources, decreased content of undesirable substances and increased adaptation to divergent agro-climatic environment.

(68) In order to ensure updated conditions for the suitability of variety denominations in particular cases, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of setting out rules concerning the relation of denominations to trade marks, their relation to geographical indications or designations of origin for agricultural products, written consents of holders of prior rights to remove impediments to the suitability of a denomination, specific criteria to

determine whether a denomination is misleading or confusing, and the use of a denomination in the form of a code.

(69) It is important to ensure that plant reproductive material belonging to clones may only be produced and placed on the market if it fulfils particular quality and health requirements, and also belongs to genera or species which have a particular value for particular market sectors. Therefore, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of adopting quality and health requirements for clones of particular genera or species, and in respect of listing the genera or species, to which the clones must belong in order to be made available on the market.

(70) In order to ensure that the information provided in the applications for registration of varieties remain up to date to the developments of the sector, and is relevant to the particular features of the varieties belonging to those genera or species, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of setting out additional items to be included in the application for particular genera or species.

(71) In order to ensure updated standards for the audits by the Agency and the competent authorities of premises of technical examinations and of the organisation of those examinations, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of setting out rules concerning those audits.

(72) In order to ensure updated standards for the technical examinations of varieties, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of setting out rules concerning obligations for the qualification and training of the staff of competent authorities or the applicants, the equipment necessary to carry out the technical examination, the establishment of variety reference collections, the establishment of quality management systems, and the conduct of growing trials and laboratory tests for particular genera or species.

(73) In order to ensure proportionate, fair and updated amounts for the fees to be paid by the applicants for the registration of a variety in the Union variety register, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of setting out the amount of the fees to be paid by the applicant.

(74) In order to ensure a comprehensive submission of information for particular categories or species of forest reproductive material, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of setting out conditions under which the operator's label be supplemented by another document produced by the professional operator.

(75) In order to avoid risks in relation to quality and health of the forest reproductive material concerned, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of supplementing the requirements set out in this Regulation concerning clones and clonal mixtures, by determining the maximum number of years or the maximum number of ramets to which the approval of clones or clonal mixtures should be restricted.

(76) In order to ensure that the exemption of small quantities of seeds of forest reproductive material, from the information requirements concerning germination or viability, is applied in a proportionate manner, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of setting out the

maximum quantities of those small quantities for particular types of forest reproductive material.

(77) In order to ensure that the cost items for the fees charged by the competent authorities on the registration of approved basic forest material and the issuance of master certificates are appropriate to the conducted work and updated, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of setting out those items.

(78) It is of particular importance that the Commission carry out appropriate consultations during its preparatory work for the adoption of delegated acts, including at expert level. The Commission, when preparing and drawing-up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

(79) Implementing powers should be conferred on the Commission in order to ensure uniform conditions for the implementation of the provisions of this Regulation concerning the following:

(a) authorisation of Member States to adopt more stringent requirements than those adopted pursuant to this Regulation concerning plant reproductive material of listed genera or species and forest reproductive material of listed species and artificial hybrids,

(b) adoption of emergency measures,

(c) authorisation of Member States to permit, for a maximum period of one year, the production and making available on the market of plant reproductive material belonging to a variety of listed genera or species not yet included in a national variety register or in the Union register,

(d) authorisation of Member States to permit, for a maximum period of one year, the making available on the market of plant reproductive material of listed genera or species complying with lower requirements that those adopted pursuant to this Regulation,

(e) the organisation of temporary experiments,

(f) the format of the national variety registers and the Union variety register,

(g) the format for the application for the registration of varieties,

(h) modalities concerning the submission of notifications concerning the registration of varieties,

(i) the form of national lists concerning forest reproductive material,

(j) the format of the notification of inclusion of forest reproductive material in the national list, and

(k) the format of master certificates for forest reproductive material.

(80) Those implementing powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers.

(81) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union and notably respect for private and family life, the right to property, the protection of personal data,

freedom to conduct business and the freedom of art and science. This Regulation should be applied by the Member States in accordance with those rights and principles.

(82) Since the objective of this Regulation, namely to establish the rules concerning production and making available on the market of plant reproductive material to ensure quality of the material and informed choices for the users, cannot be sufficiently achieved by the Member States and can therefore, by reason of its effect, complexity, trans-border and international character, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not exceed what is necessary in order to achieve that objective,

HAVE ADOPTED THIS REGULATION:

PART I
GENERAL PROVISIONS

Article 1
Scope

This Regulation lays down rules on:

(a) the production, with a view to making available on the market, of plant reproductive material; and

(b) the making available on the market of plant reproductive material.

Article 2
Exclusions

This Regulation shall not apply to plant reproductive material:

(a) intended solely for testing or scientific purposes;

(b) intended solely for breeding purposes;

(c) intended solely for, and maintained by, gene banks, organisations and networks of conservation of genetic resources, or persons belonging to those organisations or networks;

(d) exchanged in kind between persons other than professional operators.

Article 3
Definitions

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

(1) 'plants' means plants as defined in Article 2(1) of Regulation (EU) No …/… (*Office of Publications, please insert number of Regulation on protective measures against pests of plants*) on protective measures against pests of plants;

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

(3) 'mother plant' means an identified plant from which plant reproductive material is taken for reproduction of new plants;

(4) 'generation' means a group of plants constituting a single step in the line of descent of plants;

(5) ‘making available on the market’ means the holding for the purpose of sale within the Union, including offering for sale or for any other form of transfer, and the sale, distribution, import into, and export out of, the Union and other forms of transfer, whether free of charge or not;

(6) 'professional operator' means any natural or legal person carrying out, as a profession, at least one of the following activities with regard to plant reproductive material:

(a) producing*;*

(b) breeding;

(c) maintaining;

(d) providing services;

(e) preserving, including storing; and

(f) making available on the market.

(7) 'competent authorities' means competent authorities as defined in accordance with Article 2(5) of Regulation (EU) No …/…. [*Office of Publication, please insert number of Regulation on Official Controls*];

(8) 'genetically modified organism' means a genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC;

(9) 'forest reproductive material' means plant reproductive material intended for forestry purposes;

(10) 'lot' means a unit of plant reproductive material, identifiable by its homogeneity of composition and origin.

Article 4

Free circulation

Plant reproductive material shall be subject to no restrictions concerning its production and making available on the market, other than those laid down in this Regulation, in Directive 94/62/EC, Regulation (EC) No 338/97, Directive 2001/18/EC, Regulation (EC) No 1829/2003, Regulation (EC) No 1830/2003, Regulation (EU) No …/… [*Office of Publication, please insert number of Regulation on protective measures against pests of plants*] and in Union legislation restricting the production or making available on the market of invasive alien species.

PART II
PROFESSIONAL OPERATORS

Article 5

Registers of professional operators

Professional operators shall be registered in the registers referred to in Article 61 of Regulation (EC) No …/… (*Office of Publication, please insert number of Regulation on protective measures against pests of plants*) in accordance with the provisions of Article 62 of that Regulation.

Article 6

General responsibilities of professional operators

Professional operators shall ensure that plant reproductive material produced and made available on the market under their control fulfils the requirements of this Regulation.

Article 7

Specific responsibilities of professional operators producing plant reproductive material

Professional operators producing plant reproductive material shall:

(a) be available personally, or designate a 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, or of the making available on the market, which may influence the quality of the plant reproductive material;

(c) keep records of the monitoring of the critical points referred to in point (b), which shall be available for examination when requested by the competent authorities;

(d) ensure that lots remain separately identifiable;

(e) keep updated information on the premises and other locations used for the production of plant reproductive material;

(f) make sure that competent authorities 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 identity of the plant reproductive material in accordance with the applicable requirements of this Regulation;

(h) make available to the competent authorities, on request, any contracts with third parties.

Article 8

Traceability

1. Professional operators shall ensure that plant reproductive material is traceable at all stages of production and making available on the market.

2. For the purpose of paragraph 1, professional operators shall keep information allowing them to identify the professional operators, which have supplied them with plant reproductive material, and the material concerned.

   On request, they shall make such information available to the competent authorities.

3. For the purpose of paragraph 1, professional operators shall keep information allowing them to identify the persons to whom they have supplied plant reproductive material and the material concerned, unless that material has been supplied in retail.

   On request, they shall make such information available to the competent authorities.

4. In the case of plant reproductive material, other than forest reproductive material, professional operators shall keep records of the plant reproductive material referred to in paragraphs 2 and 3 for three years after that material has been respectively supplied to or by them.

   In the case of forest reproductive material, the respective period shall be ten years.

PART III
PLANT REPRODUCTIVE MATERIAL OTHER THAN FOREST REPRODUCTIVE MATERIAL

TITLE I
General Provisions

Article 9
Scope

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

Article 10
Definitions

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

(1) 'variety' means a plant grouping within a single botanical taxon of the lowest known rank, which fulfils all of the following requirements:

  (a) it is defined by the expression of the characteristics that results from a given genotype or combination of genotypes;

  (b) it is distinguished from any other plant grouping by the expression of at least one of the characteristics referred to in point (a); and

  (c) it is considered as a unit with regard to its suitability for being reproduced unchanged;

(2) 'official description' means a variety description that has been produced by a competent authority, includes the specific characteristics of the variety and makes the variety identifiable by examination of its distinctiveness, uniformity and stability;

(3) 'officially recognised description' means a description of a variety, which has been recognised by a competent authority, includes the specific characteristics of the variety, makes it identifiable and has been obtained by means other than examination of the variety's distinctiveness, uniformity and stability pursuant to the rules applicable at the time of registration of that variety in accordance with Article 79;

(4) 'clone' means an individual progeny, originally derived from another plant by vegetative reproduction, which remains genetically identical to the latter;

(5) 'variety maintenance' means the actions to ensure that a variety remains consistent with its description;

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

(7) 'basic material' means plant reproductive material which has been produced from pre-basic material, and is intended for the production of certified material;

(8) 'certified material" means plant reproductive material which has been produced from pre-basic or basic material;

(9) 'standard material' means plant reproductive material other than pre-basic, basic or certified material;

(10) 'category' means pre-basic material, basic material, certified material or standard material.

TITLE II
Production and making available on the market of plant reproductive material belonging to genera and species listed in Annex I

CHAPTER I
Introductive Provisions

Article 11
Scope

1. This Title shall apply to the production and making available on the market of plant reproductive material belonging to genera and species which comply with one or more of the following criteria:

   (a) they represent a significant area of production;

   (b) they represent a significant value of production;

   (c) they are produced or made available on the market by a significant number of professional operators in the Union;

   (d) they contain substances which, for all or particular uses, must be subject to particular rules concerning the protection of human and animal health, and the environment.

2. The genera and species referred to in paragraph 1 are listed in Annex I.

3. The Commission shall be empowered to adopt delegated acts, in accordance with Article 140, amending Annex I in order to adapt it to the developments of technical knowledge, scientific knowledge and economic data.

4. This Title shall also apply to rootstocks and other parts of plants (hereinafter jointly referred to as "rootstocks"), which belong to genera and species not listed in Annex I, if material of one of the genera or species listed in Annex I, or their hybrids, is grafted on them.

Article 12
Categories of plant reproductive material

1. Plant reproductive material may only be produced and made available on the market, under one of the following categories:

   (a) pre-basic material,

   (b) basic material,

(c) certified material,

(d) standard material.

2. Plant reproductive material may not be produced and made available on the market as standard material, if it belongs to genera or species for which the costs and certification activities necessary to produce and make available on the market plant reproductive material as pre-basic, basic and certified material are proportionate:

(a) to the purpose of ensuring food and feed security; and

(b) to the higher level of identity, health and quality of the plant reproductive material which result from the fulfilment of the requirements for pre-basic, basic and certified material compared to those for standard material.

3. The Commission shall be empowered to adopt delegated acts, in accordance with Article 140, listing the genera or species whose plant reproductive material may not be placed on the market as standard material, as referred to in paragraph 2.

4. By way of derogation to paragraph 2 and 3, plant reproductive material shall only be produced and made available on the market as standard material if one or more of the following cases apply:

(a) it belongs to a variety provided with an officially recognised description;

(b) it is heterogeneous material in the meaning of Article 14(3);

(c) it is niche market material in the meaning of Article 36(1).

CHAPTER II
Requirements for the production and making available on the market

SECTION 1
LIST OF REQUIREMENTS

Article 13

Production and making available on the market of pre-basic, basic, certified and standard material

1. Plant reproductive material produced and made available on the market shall comply with:

(a) the registration requirements set out in Section 2;

(b) the production and quality requirements set out in Section 3 for the relevant category;

(c) the handling requirements set out in Section 4;

(d) the identification, and, where applicable, certification requirements set out in Section 5.

2. Paragraph 1(b) shall not apply to production requirements of plant reproductive material referred to in Article 14(3) and Article 36.

Article 14

Requirement to belong to registered varieties

1. Plant reproductive material may be produced and made available on the market only if it belongs to a variety registered in a national variety register referred to in Article 51 or in the Union variety register referred to in Article 52.

2. By way of derogation to paragraph 1 of this Article, rootstocks may be produced and made available on the market without belonging to a variety registered in a national variety register or in the Union variety register.

3. The Commission shall be empowered to adopt delegated acts, in accordance with Article 140, setting out that, by way of derogation to paragraph 1 of this Article, plant reproductive material may be produced and made available on the market without belonging to a variety in the meaning of point (1) of Article 10 ('hereafter 'heterogeneous material') and not fulfilling the requirements on distinctiveness, uniformity and stability as set out in articles 60, 61 and 62 and satisfactory value for cultivation and/or use or sustainable value for cultivation and/or use as set out in articles 58 and 59.

   Those delegated acts may set out one or more of the following for heterogeneous material:

   (a) rules on labelling and packaging;

   (b) rules concerning description of the material, including the breeding methods and parental material used, description of the production scheme for the plant reproductive material and availability of standard samples;

   (c) rules relating to information and samples of production to be kept by the professional operators and the maintenance of the material;

   (d) establishment by the competent authorities of registers for heterogeneous material, modalities for registration and content of those registers;

   (e) establishment of fees, and cost items for the calculation of those fees, concerning the registration of heterogeneous material referred to in point (d) in a manner ensuring that the fee does not constitute a barrier to the registration of the heterogeneous material concerned.

   Those delegated acts shall be adopted by *[Office of Publications, please insert date of application of this Regulation…]*. They may be adopted per particular genera or species.

Article 15

Requirement to belong to registered clones

Plant reproductive material belonging to a clone may be produced and made available on the market only if that clone is registered in a national variety register referred to in Article 51 or in the Union variety register referred to in Article 52.

SECTION 2
PRODUCTION AND QUALITY REQUIREMENTS

Article 16

Production and quality requirements for plant reproductive material

1. Plant reproductive material shall be produced in accordance with the production requirements set out in Part A of Annex II and shall be made available on the market only if it fulfils the quality requirements set out in Part B of Annex II.

2. The Commission shall be empowered to adopt delegated acts, in accordance with Article 140, supplementing the requirements referred to in paragraph 1. Where appropriate, those delegated acts may specify those requirements set out in Part D of Annex II.

3. Those delegated acts shall take into account the relevant international technical and scientific standard recommendations:

   (a) the Seed Scheme Rules and Regulations of the Organisation for Economic Co-operation and Development (hereinafter: 'OECD');

   (b) the seed potato standards of the United Nations Economic Commission for Europe (hereinafter: 'UNECE');

   (c) the rules on sampling and testing of the International Seed Testing Association (hereinafter 'ISTA'); and

   (d) the rules of the European and Mediterranean Plant Protection Organisation (EPPO).

4. The Commission shall be empowered to adopt delegated acts, in accordance with Article 140, amending Part A and Part B of Annex II to adapt them to the technical and scientific developments.

SECTION 3
HANDLING REQUIREMENTS

Article 17

Lots

1. Plant reproductive material shall be made available on the market in lots. Those lots shall be sufficiently homogeneous and identified as distinct from other lots of plant reproductive material.

2. During processing, packaging, storage, transport or at delivery, lots of plant reproductive material of different origins may be merged into a new lot. In that case the professional operator shall keep records including data about the origin of the individual components of the new lot.

3. During processing, packaging, storage, transport or at delivery, lots of plant reproductive material may be split into two or more lots. In that case the professional operator shall keep records concerning the origin of the new lots.

4. The Commission shall be empowered to adopt delegated acts, in accordance with Article 140, establishing additional rules for particular genera or species in relation to one or more of the following elements:

(a) maximum size of lots to ensure homogeneity of the plant reproductive material concerned;

(b) composition of lots to ensure the maintenance of the identity of the plant reproductive material concerned;

(c) identification of lots to ensure the traceability of the plant reproductive material concerned.

Article 18

Packages, containers and bundles, and rules on small packages and containers

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

2. Packages and containers shall be closed in such a way that they cannot be opened without damaging the closure and, in the case of packaging, without the packaging showing signs of tampering.

3. Bundles shall be tied up in such a way that the material forming parts of the bundles cannot be separated without damaging the tie or ties.

4. The Commission shall be empowered to adopt delegated acts, in accordance with Article 140, setting out rules for specific genera or species one or more of the following elements:

(a) the closure, including sealing or resealing, of packages, containers or bundles to ensure the identity of the plant reproductive material concerned and to avoid uncontrolled mixtures of lots;

(b) the establishment of a requirement that plant reproductive material is to be made available on the market only in packages, containers or bundles in order to facilitate the traceability of the lots concerned.

5. The Commission shall be empowered to adopt delegated acts, in accordance with Article 140, setting out specific rules for the production and making available on the market of particular genera or species in small packages, containers or bundles. Those rules may concern one or more of the following elements:

(a) maximum size and volume of the small packages, containers or bundles;

(b) colour and content of labels, and methods of labelling, of the small packages, containers or bundles;

(c) examination of the small packages, containers or bundles and the contained plant reproductive material;

(d) closure of the small packages.

SECTION 4

CERTIFICATION, IDENTIFICATION AND LABELLING REQUIREMENTS

Article 19

Certification and identification of pre-basic, basic or certified material, and identification of standard material

1. Pre-basic, basic or certified material shall be certified and identified through an official label ('official label').

2. Official labels shall certify that pre-basic, basic or certified material complies with the relevant production and quality requirements as referred to in Article 16.

3. The certification referred to in paragraphs 1 and 2 shall be based on field inspections, sampling and testing carried out in accordance with the rules referred to in Article 20 (hereinafter: 'certification schemes') and with the provisions of Articles 22 to 26.

4. Standard material shall be identified through an operator's label ('operator's label').

5. Operators' labels shall attest that standard material complies with the relevant quality requirements as referred to in Article 16.

Article 20
Certification schemes

1. The certification schemes for pre-basic, basic or certified material are set out in Part C of Annex II.

2. The Commission shall be empowered to adopt delegated acts, in accordance with Article 140, supplementing the certification schemes. Where appropriate, those delegated acts may specify those schemes, as set out in Part D of Annex II.

3. Those delegated acts shall take into account the applicable international technical and scientific standard recommendations such as:

   (a) the Seed Scheme Rules and Regulations of OECD;

   (b) the seed potato standards of UNECE;

   (c) the rules on sampling and testing of ISTA; and

   (d) the rules of EPPO.

3. The Commission shall be empowered to adopt delegated acts, in accordance with Article 140, amending Part C and Part D of Annex II to adapt them to the technical and scientific developments.

Article 21
Content of the official label and operator's label

1. The official label and the operator's label shall contain the information set out in Part A of Annex III.

2. The official label and the operator's label shall be written in one of the official Union languages. They shall be legible, indelible, printed on one side, not previously been used and easily visible.

3. The official label shall have a distinct colour per category of plant reproductive material.

4. In case the issuance of a plant passport is required pursuant to Article 74(1) and Article 75(1) of Regulation (EU) No …/… [*Office of Publication, please insert number of Regulation on protective measures against pests of plants*], the official label shall include the plant passport as set out in Article 78(3) of that Regulation.

5. The Commission shall be empowered to adopt delegated acts, in accordance with Article 140, setting out requirements, further to the requirements referred to in paragraphs 1 and 2, for official labels and operators' labels. Those requirements shall concern one or more of the following elements:

(a) the colours of the label for specific categories and other groups of plant reproductive material;

(b) indications concerning a label number;

(c) indications of generations of pre-basic, basic, certified and standard material;

(d) the indication of variety types including intraspecific or interspecific hybrids;

(e) the indication of subdivisions of categories satisfying different conditions;

(f) in case of mixtures, the indication of the percentage by weight of the various components by species and, where appropriate, by variety;

(g) indications concerning the intended use of the material.

6. This Article shall apply without prejudice to Article 49(4) of Regulation (EC) No 1107/2009 concerning the label and the documents accompanying treated seeds in the meaning of that Regulation.

7. The Commission shall, by means of implementing acts, adopt the format(s) of the official label and operator's label. Those formats may be adopted per genera or species. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(3).

Article 22

Responsibility to produce and affix official labels

The official labels shall be produced and affixed by:

(a) the professional operator, under the official supervision of the competent authority; or

(b) the competent authority, if requested so by the professional operator, or if the professional operator concerned is not authorised pursuant to Article 23.

Article 23

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

1. Professional operators may be authorised by the competent authority to carry out the certification and produce the official labels under official supervision, as referred to in point (a) of Article 22, only if they fulfil all of the following conditions:

(a) they possess the necessary knowledge to fulfil the production and quality requirements and comply with the certification schemes adopted pursuant to Articles 16(2) and 20(2), and, where applicable, fulfil the requirements adopted pursuant to point (a) of paragraph 3 of this Article;

(b) they possess, or have access to, adequate equipment and laboratories to apply correctly and efficiently the requirements referred to in Articles 16(2) and 20(2), in particular equipment and laboratories complying with the requirements adopted pursuant to point (b) and (c) of paragraph 3;

(c) they have identified, and have the capability to monitor, the critical points of the production process which may influence the quality and identity of the plant reproductive material, and keep records of the results of that monitoring;

(d) they are capable to ensure that lots remain identifiable as referred to in Article 7;

(e) they have in place systems and provisions to ensure the fulfilment of the traceability requirements set out in Article 8;

(f) they use appropriately qualified inspection and laboratory staff, in particular inspection and laboratory staff, complying with the requirements adopted pursuant to point (c) of paragraph 3.

2. The authorisation referred to in paragraph 1 may be granted for particular or all genera or species.

3. The Commission shall be empowered to adopt delegated acts, in accordance with Article 140, supplementing the provisions of paragraph 1, to ensure the ability of the professional operators to properly carry out a reliable certification of the plant reproductive material concerned. Those delegated acts may concern one or more of the following elements:

(a) qualification, training and activities of professional operators, and of other persons which may be entrusted, by the professional operators, with field inspections, sampling and testing;

(b) suitability of premises and availability of particular equipment to be used by the professional operators concerned;

(c) requirements for laboratories which may be entrusted with testing by the professional operators.

Article 24

Official supervision by the competent authorities

1. For the purposes of the official supervision referred to in point (a) of Article 22, competent authorities shall, at least once per year, conduct audits to ensure that the professional operator fulfils the requirements referred to in Article 23.

2. For the purposes of the official supervision referred to in point (a) of Article 22, competent authorities shall furthermore carry out official inspection, sampling and testing on a proportion of the crops in the fields and the lots of plant reproductive material, to confirm compliance of that material with the production and quality requirements referred to in Article 16(2). That proportion shall be determined on the basis of the potential risk of non-compliance with those requirements.

3. In addition to the inspection, sampling and testing referred to in paragraph 2, the competent authorities may carry out further field inspections, sampling or testing, if requested so by the professional operator.

4. The Commission shall be empowered to adopt delegated acts, in accordance with Article 140, supplementing the provisions of paragraphs 1, 2 and 3. Those delegated acts may concern one or more of the following elements:

(a) the proportion of the crops in the fields to be subject to inspections, sampling and testing, as referred to in paragraph 2, for particular genera or species;

(b) monitoring activities to be carried out by the competent authorities.

Article 25

Official labels produced by the competent authorities

Where the official labels are produced by the competent authorities, as referred to in point (b) of Article 22, the competent authorities shall carry out all necessary field inspections, sampling and testing in accordance with the certification schemes, adopted pursuant to Article 20(2), to confirm compliance with the production and quality requirements adopted pursuant to Article 16(2).

Article 26

Withdrawal or modification of the authorisation

1. Where a competent authority finds, after granting the authorisation referred to in Article 23(1), that a professional operator does not fulfil the requirements referred to in that Article, it shall request the professional operator to take corrective actions within a specified period of time.

2. The competent authority shall without delay withdraw, or modify as appropriate, the authorisation if the professional operator does not apply the corrective measures referred to in paragraph 1 of this Article within the specified period of time.

Article 27

Notification of the intended production and certification of pre-basic, basic and certified material

Professional operators shall inform the competent authorities in due time about their intention to produce pre-basic, basic and certified material plant reproductive material, and to carry out the certification referred to in Article 19(1). That notification shall state the plant species and categories concerned.

Article 28

Production of operator's label for standard material

Operators' labels shall be produced and affixed by the professional operator after verifying through its own inspections, sampling and testing, that the plant reproductive material complies with the production and quality requirements as referred to in Article 16.

Article 29

Reference to lots

1. The official label and the operator's label shall be produced with reference to a lot. They shall be affixed, where applicable, to individual plants or on the outside of packages, containers and bundles.

2. If a lot is split into more lots, a new official label or operator's label shall be issued for each lot. If several lots are merged into a new lot, a new official label or operator's label shall be issued for that new lot.

CHAPTER III
Tests

Article 30

Post certification tests for pre-basic, basic and certified material

1. After the certification referred to in Article 19(1), the competent authorities may carry out tests on the plant reproductive material (hereinafter 'post certification tests') to confirm that it complies with the quality requirements as referred to in Article 16(2) and the certification schemes adopted pursuant to Article 20(2).

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. Post certification tests shall be carried out through samples taken by the competent authority. They shall assess the identity and purity of the plant reproductive material concerned.

4. The Commission shall be empowered to adopt delegated acts, in accordance with Article 140, setting out rules for the post certification tests of plant reproductive material belonging to particular genera or species. Those rules shall take into account the development of scientific and technical knowledge. They may concern the following:

   (a) the proportion of samples per genera and species and categories submitted to tests;

   (b) the testing procedure.

Article 31

Non-compliance of professional operators with quality requirements and certification schemes

1. Where the post certification tests show that pre-basic, basic or certified material has not been produced or made available on the market in compliance with the production and quality requirements referred to in Article 16(2), and with the certification schemes referred to in Article 20(2), the competent authorities shall ensure that the professional operator concerned takes the necessary corrective actions. Those actions shall ensure that the material concerned either complies with those requirements or is withdrawn from the market.

2. If it is repeatedly found, during the post certification tests, that a professional operator produces or makes available on the market plant reproductive material which does not comply with the quality requirements referred to in Article 16(2), or with the certification schemes referred to in Article 20, the provisions of Article 26(2) shall apply.

CHAPTER IV
Mixtures

Article 32

Mixtures of genera and species listed in Annex I

1. The Commission shall be empowered to adopt delegated acts, in accordance with Article 140, adopting rules concerning the production and making available on the market of mixtures of plant reproductive material belonging to different genera or species listed in Annex I, or different varieties of those genera or species. Those rules may derogate from the following provisions:

   (a) the production and quality requirements adopted pursuant to Article 16(2);

   (b) the provisions of Article 17 concerning lots;

   (c) the provisions of Article 18 concerning packages, containers and bundles, and rules on small packages and containers; and

   (d) the provisions of Article 21, concerning the content and format of the official label and operator's label.

2. The rules referred to in paragraph 1 shall concern one or more of the following elements:

   (a) maximum size and volume of lots, packages, containers or bundles;

   (b) colour and content of labels;

   (c) denomination of the mixture and description of the composition of the mixture;

   (d) closure of packages, containers or bundles;

   (e) requirements for the production and inspections of those mixtures;

   (f) requirements facilitating the traceability of the percentage by weight of the various components shown by species and, where appropriate, by variety.

Article 33

Preservation mixtures

1. Competent authorities may authorise the production and making available on the market of a mixture of plant reproductive material belonging to genera or species listed in Annex I, with plant reproductive material belonging to genera or species not listed in Annex I, if that mixture fulfils both of the following conditions:

   (a) it contributes to the conservation of genetic resources and the preservation of the natural environment;

   (b) it is naturally associated with a particular region (hereinafter: 'region of origin'). Hereinafter, such mixture is referred to as 'preservation mixture'.

2. When a competent authority authorises the production and making available on the market of a preservation mixture, it shall identify the region of origin taking into account information from plant genetic resource authorities or organisations.

3. The Commission shall be empowered to adopt delegated acts, in accordance with Article 140, setting out, with regard to all or particular genera or species, the following:

(a) a procedure for the authorisation referred to in paragraph 1;

(b) requirements for the authorisation referred to in paragraph 1, further to the requirements set out in that paragraph;

(c) requirements for the packages and containers of a preservation mixture;

(d) labelling requirements for preservation mixtures;

(e) rules on the identification of region of origin;

(f) the obligation for professional operators to report on the production and making available on the market of preservation mixtures;

(g) the obligation for Member States to report to the Commission on the application of the provisions of this Article.

CHAPTER V
Derogations

SECTION 1
DEROGATIONS FROM REGISTRATION REQUIREMENTS

Article 34

Plant reproductive material of varieties whose registration is pending

1. By way of derogation from Article 14(1), competent authorities may authorise professional operators, for a specified period of time, to make available on the market for tests and trials, on farms or other production premises, maximum quantities of plant reproductive material belonging to a variety not registered in a national variety register pursuant to Article 79 or the Union variety register pursuant to Article 94(1).

2. The authorisation referred to in paragraph 1 may only be granted if the plant reproductive material belongs to a variety for which an application has been submitted for registration in a national variety register pursuant to Article 66 or for registration in the Union variety register pursuant to Article 94.

3. In order to obtain the authorisation referred to in paragraph 1, the professional operator shall submit to the competent authorities of the Member States, where the relevant tests and trials are to take place, a request with the following information:

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

(b) the objectives pursued by those proposed tests and trials;

(c) the locations in which those tests and trials are to be carried out;

(d) the provisional denomination of the variety indicated in the application for registration;

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

(f) information about the authority before which the application for the registration of the variety is pending, and the reference assigned to that application;

(g) the duration of the authorisation requested;

(h) the quantities of the material to be made available on the market.

4. The Member States whose competent authorities have granted the authorisation referred to in paragraph 1 shall inform thereof the other Member States, the Commission and the European Agency for Plant Varieties (hereinafter: "the Agency").

5. By 31 March of each year, the Agency shall report to the Commission and the Member States on the authorisations granted pursuant to paragraph 1 and the information submitted pursuant to paragraph 3 during the preceding year.

6. The Commission shall be empowered to adopt delegated acts, in accordance with Article 140, supplementing paragraphs 1, 2 and 3 by setting out requirements concerning the following elements:

   (a) labelling of packages; and

   (b) the maximum quantities which may be made available on the market for specific genera or species pursuant to paragraph 1.

Article 35

Derogations from registration requirements in the case of temporary difficulties in supply

1. By way of derogation from Article 14(1), and in order to remove temporary difficulties in the general supply of plant reproductive material that may occur in the Union, the Commission may, by means of implementing acts, authorise Member States to permit, for a maximum period of one year, the production and making available on the market of plant reproductive material belonging to a variety not included in a national variety register or in the Union variety register. Those implementing acts may set out the maximum quantities which may be made available on the market per genera or species.

2. The implementing acts referred to in paragraph 1 shall be adopted in accordance with the examination procedure referred to in accordance with Article 141(3).

3. The authorisations referred to in paragraph 1 shall be granted on the basis of a reasoned request submitted by the Member State concerned.

4. Those authorisations shall only be granted if the derogation referred to in paragraph 1 is necessary and proportionate to the objective of removing the temporary difficulties in the general supply of the plant reproductive material concerned.

5. The label of the plant reproductive material made available on the market pursuant to paragraph 1 shall be brown. It shall state that the reproductive material in question belongs to a non-registered variety.

Article 36

Derogations from registration requirements in the case of niche market plant reproductive material

1. Article 14(1) shall not apply to plant reproductive material where all of the following conditions are fulfilled:

   (a) it is made available on the market in small quantities by persons other than professional operators, or by professional operators employing no more than ten persons and whose annual turnover or balance sheet total does not exceed EUR 2 million;

   (b) it is labelled with the indication 'niche market material'.

That plant reproductive material is hereinafter referred to as 'niche market material'.

2. The persons who produce niche market material shall keep records of the quantities of the material produced and made available on the market, per genera, species or type of material. On request, they shall make those records available to the competent authorities.

3. The Commission shall be empowered to adopt delegated acts, in accordance with Article 140, setting out, with regard to the production and making available on the market of niche material belonging to particular genera or species, one or more of the following:

(a) the maximum size of packages, containers or bundles;

(b) requirements concerning traceability, lots and labelling of the niche market material concerned.

(c) modalities of making available on the market.

SECTION 2
DEROGATION FROM PRODUCTION AND QUALITY REQUIREMENTS

Article 37

Reduced germination requirements, and other reduced quality requirements, in case of temporary difficulties in supply

1. In order to remove temporary difficulties in the general supply of plant reproductive material that may occur in a Member State, the competent authority of the Member State concerned may authorise the making available on the market of seed with a reduced germination rate, provided that such rate is reduced by less than 5% compared to the germination rate required pursuant to Article 16(2).

That authorisation shall be granted, on the basis of a reasoned request submitted by the professional operator concerned, for a specific period of time which shall not exceed four months.

The label of the seed referred to in paragraph 1 shall indicate the actual lower germination rate.

2. In order to remove temporary difficulties in the general supply of plant reproductive material that may occur in a Member State, the competent authority of the Member State concerned may authorise the making available on the market of plant reproductive material with reduced quality requirements, other than the reduced germination requirements as referred to in paragraph 1, compared to the quality requirements applicable pursuant to Article 16(2).

That authorisation shall be granted, on the basis of a reasoned request submitted by the professional operator concerned, for a specific period of time which shall not exceed four months.

The label of the plant reproductive material made available on the market pursuant to this paragraph shall be brown. It shall state that the reproductive material in question complies with lower quality requirements than those referred to in Article 16(2).

3. Member States shall notify the Commission and the other Member States of each authorisation granted pursuant to paragraphs 1 and 2.

4. The Commission may decide, by means of implementing acts, that the authorisations referred to in paragraphs 1 or 2 are to be repealed or amended, in case those measures are not in compliance with the conditions of those paragraphs, or are deemed inappropriate or disproportionate to achieve the objectives of those paragraphs. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(3).

SECTION 3
DEROGATIONS FROM LABELLING, CERTIFICATION AND IDENTIFICATION REQUIREMENTS

Article 38
Plant reproductive material which is not finally certified

1. Plant reproductive material, other than the seeds referred to in Article 39, which has been harvested in one Member State, but has not yet been finally certified as pre-basic, basic or certified material pursuant to Article 19(1), may be made available on the market by reference to those categories if:

   (a) prior to the harvesting, a field inspection has been carried out by the competent authority and has confirmed compliance of that material with the production and quality requirements referred to in Article 16(2);

   (b) the plant reproductive material is identified as not finally certified material pursuant to Article 19; and

   (c) the requirements set out in paragraphs 2 to 6 are fulfilled.

2. Plant reproductive material referred to in paragraph 1 may be made available on the market only once from one professional operator to another, without being further transferred to any other person.

3. The professional operator shall inform in advance the competent authority concerned of its intention to make available on the market plant reproductive material referred to in paragraph 1.

4. If the Member State, where the plant reproductive material has been harvested (hereinafter: 'Member State of production'), and the Member State where the plant reproductive material is certified pursuant to Article 19(1) (hereinafter: 'Member State of certification') are different, the competent authorities of the Member States concerned shall exchange the relevant information concerning the making available on the market of that material.

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

6. The Commission shall be empowered to adopt, in accordance with Article 140, delegated acts setting out specific rules for plant reproductive material referred to in paragraph 1, concerning the following elements:

   (a) packages, containers and bundles, and rules on small packages and containers;

   (b) the labelling of that material.

7. Plant reproductive material, other than the seeds referred to in Article 39, which has been harvested in a third country, but has not yet been finally certified as pre-basic, basic or certified material pursuant to Article 19(1), may be made available on the market by reference to those categories if:

(a) a decision on equivalence has been adopted pursuant to Article 44 concerning that third country,

(b) the requirements set out in paragraphs 1(a) and (b), 2 and 3 and adopted pursuant to paragraph 6 are fulfilled,

(c) the competent authorities of the Member State and third country concerned exchange the relevant information concerning the making available on the market of that material, and

(d) on request, the competent authorities of third country concerned supplies all relevant production information to the Member State of certification.

8. For that purpose references made in those paragraphs to the Member States of production shall be construed as references made to the third country concerned, and references made in those paragraphs to the requirements set out pursuant to Article 16(2) shall be construed as references made to equivalent requirements.

Article 39

Seeds not certified as complying with applicable germination requirements

1. Competent authorities may authorise the making available on the market of seeds for a specific period of time, as pre-basic, basic or certified material, without the germination requirements established pursuant to Article 16(2) having been yet confirmed, if this is considered necessary to make seed rapidly available on the market.

2. Seed referred to in paragraph 1 may be made available on the market only once, from one professional operator to another, without being further transferred to any other person, on the basis of a provisional analytical report concerning germination.

3. The Commission shall be empowered, in accordance with Article 140, to adopt delegated acts setting out the conditions under which seed of particular genera or species may be made available on the market as pre-basic, basic material or certified material pursuant to paragraphs 1 and 2. Those conditions may concern the following:

(a) labelling requirements;

(b) the duration of period in which such seed may be made available on the market; and

(c) the content of the provisional analytical reports concerning germination.

SECTION 4

DEROGATIONS FROM MISCELLANEOUS REQUIREMENTS

Article 40

More stringent quality requirements

1. The Commission may authorise Member States, by means of implementing acts, to adopt more stringent production and quality requirements than those referred to in

Article 16(2), or more stringent certification rules than those referred to in Article 20(1).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(3).

2. In order to obtain the authorisation referred to in paragraph 1, Member States shall submit to the Commission a request setting out:

(a) the draft provisions containing the proposed requirements;

(b) a justification on the necessity and proportionality of such requirements; and

(c) whether the proposed requirements would be permanent or for a specified period.

3. The authorisation referred to in paragraph 1 shall be granted only if the following conditions are fulfilled:

(a) the implementation of the draft provisions, as referred to in point (a) of paragraph 2, ensures improvement of the quality of the plant reproductive material concerned, protection of the environment or sustainability of agricultural development; and

(b) the draft provisions are necessary and proportionate to their objective.

Article 41

Emergency measures

1. Where plant reproductive material is likely to constitute a serious risk to human, animal and plant health and environment, and such risk cannot be contained satisfactorily by means of measures taken by the Member State concerned, the Commission shall take without delay, by means of implementing acts, any appropriate interim emergency measures. Those measures may include provisions restricting or prohibiting the making available on the market of the plant reproductive material concerned, depending on the gravity of the situation.

2. The measures referred to in paragraph 1 may be taken on the Commission's own initiative or at the request of a Member State. They shall be adopted in accordance with the examination procedure referred to in Article 141(3).

3. On duly justified imperative grounds of urgency to address a serious risk to human health, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 141(4).

4. Where a Member State officially informs the Commission of the need to take emergency measures and the Commission has not acted in accordance with paragraph 1, that Member State may adopt any appropriate interim emergency measures. Those measures may include provisions restricting or prohibiting within the territory of that Member State the making available on the market of the plant reproductive material concerned, depending on the gravity of the situation. The Member State concerned shall immediately inform the other Member States and the Commission of the measures adopted, stating the grounds for its decision.

5. The Commission may decide, by means of implementing acts, that the national interim emergency measures referred to in paragraph 4 are to be repealed or amended. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(3). The Member State concerned

may maintain its national interim emergency measures until the date of application of the implementing acts referred to in this paragraph.

6. 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 which prohibits or restricts the cultivation of genetically modified organisms.

Article 42
Temporary experiments

1. The Commission may, by means of implementing acts, decide the organisation of temporary experiments to identify improved alternatives to any measures set out in, or adopted under, this Part. Those implementing acts may provide for derogations from the provisions of this Part. They shall be adopted in accordance with the examination procedure referred to in Article 141(3).

2. The implementing acts referred to in paragraph 1 shall specify the genera or species concerned, the conditions of the experiments per genera or species, 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 plant reproductive material concerned.

3. The duration of an experiment shall not exceed seven growing cycles of the plant reproductive material concerned, and shall in any case, not exceed seven years.

CHAPTER VI
Imports from and exports to third countries

SECTION 1
IMPORTS

Article 43
Imports on the basis of Union equivalence

Plant reproductive material may be imported from third countries only if it is established, pursuant to Article 44, that it fulfils requirements equivalent to those applicable to plant reproductive material produced and made available on the market in the Union.

Article 44
Commission Decision on equivalence

1. The Commission may decide, by means of implementing acts, whether plant reproductive material of specific genera, species or categories produced in a third country, or particular areas of a third country, fulfils requirements equivalent with those applicable to plant reproductive material produced and made available on the market in the Union, on the basis of:

   (a) a thorough examination of information and data provided by the third country concerned pursuant to Article 124(1) of Regulation (EU) No …/… [*Office of Publications, please insert the number of the Regulation on official controls*]; and

(b) the satisfactory outcome of a control performed in accordance with Article 119(1) of Regulation (EU) No …/… [*Office of Publications, please insert the number of the Regulation on official controls*].

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(3).

2. When adopting the decisions referred to in paragraph 1, the Commission shall consider whether:

(a) the controls on variety maintenance carried out in the third country afford the same assurances as those provided for in Article 86, if varieties registered in a national variety register or in the Union variety register are to be maintained in the third country concerned; and

(b) the requirements in the third country concerning the production and making available on the market of plant reproductive material:

(i) afford the same assurances as the production requirements set out in Part A to Annex II, and the requirements adopted pursuant to Article 16(2);

(ii) afford the same assurances as the quality requirements set out in Part B to Annex II, and the requirements adopted pursuant to Article16(2);

(iii) afford the same assurances as the certification schemes of Part C to Annex II, and the requirements adopted pursuant to Article 20(1);

(iv) afford the same assurance as the controls carried out according to Regulation (EU) No …/… [*Office of Publications, please insert number of Regulation on Official Controls*].

3. For the purpose of adopting the decisions referred to in paragraph 1, the Commission may apply the provisions of Article 71 of Regulation (EU) No …/… [*Office of Publication, please insert number of Regulation on Official Controls*] concerning the approval of pre-export controls carried out by third countries.

Article 45

Information to be provided in the case of imports

1. Plant reproductive material imported from third countries shall be made available on the market with the following information:

(a) an indication that the plant reproductive material concerned 'meets EU rules and standards';

(b) the species, variety, category and lot number of the plant reproductive material concerned;

(c) the date of official closure, in case of making available on the market in containers, packages or bundles;

(d) the third country of production and the respective competent authority;

(e) where applicable, the last third country where the plant reproductive material is imported from;

(f) the declared net or gross weight of the imported plant reproductive material or declared number of imported lots of plant reproductive material;

(g) the person importing the plant reproductive material.

2. The information referred to in paragraph 1 shall be provided:

(a) in the case of pre-basic, basic or certified material, on an official document or on an additional official label;

(b) in the case of standard material, on the operator's label.

SECTION 2
EXPORTS

Article 46
Exports from the Union

1. Where the export of plant reproductive material to a third country is governed by an agreement with that third country, that export shall comply with that agreement.

2. Where the export of plant reproductive material to a third country is not governed by an agreement with that country, that export shall take place in accordance with the rules of the third country into which that plant reproductive material is to be exported.

3. Where the export of plant reproductive material to a third country is neither governed by an agreement with a third country nor by the rules of the third country into which that plant reproductive material is to be exported, the requirements for production and making available on the market of plant reproductive material within the Union territory, as set out in Articles 13 to 42, shall apply.

TITLE III
Production and making available on the market of plant reproductive material not belonging to genera or species listed in Annex I

Article 47
Scope

This Title shall apply to the production and making available on the market of plant reproductive material belonging to genera and species other than the ones listed in Annex I.

Article 48
Basic requirements

1. Plant reproductive material shall be made available on the market in accordance with the following requirements:

(a) it shall be visually free from any defects likely to impair its usefulness for the purposes it is intended;

(b) it shall have good vigour and appropriate dimensions, as appropriate for the genera and species concerned, to ensure its usefulness for the purposes it is intended;

(c) in the case of seeds, it shall have satisfactory germination, as appropriate for the genera and species concerned, to allow an appropriate number of plants per area after sowing, and to ensure the maximum yield and quality of the production;

(d) if made available on the market with reference to a variety, it shall have sufficient varietal identity and purity, as appropriate for the genera and species concerned, to ensure informed choices by its users;

(e) it shall at least on visual inspection, be substantially free from any pests impairing quality, or any signs or symptoms thereof, which reduce its usefulness.

2. Compliance with the requirements of points (a), (b), (c), (d) and (e) of paragraph 1 shall be assessed in light of the applicable international standard recommendations:

(a) the Seed Scheme Rules and Regulations of OECD;

(b) the seed potato standards of UNECE;

(c) the rules on sampling and testing of the International seed testing association ISTA for the genera or species concerned;

(d) and the rules of EPPO.

3. Where no international standard recommendations exist for genera or species concerned, compliance with the requirements of points (a), (b), (c), (d) and (e) of paragraph 1 shall be assessed in the light of, the relevant national standards of the Member State, where the plant reproductive material is for first time made available on the market

4. Plant reproductive material shall be made available on the market in lots. Where lots of plant reproductive material of different origins are merged into a new lot during packaging, storage, transport or at delivery, the professional operator shall keep records including data about composition and the origin of the individual components of the new lots.

If a lot is split into more lots, the professional operator shall keep records for each new lot and its origin.

Article 49
Labelling

1. Plant reproductive material, when made available on the market, shall be accompanied by a label, containing the information set out in Part B to Annex III.

2. The label referred to in paragraph 1 shall be produced by the professional operator and shall be clear and indelible. It shall be affixed on the outside of the package, the container or the bundle of plant reproductive material. It shall be printed in at least one of the official languages of the Union.

3. Where reproductive material is made available on the market with a reference to genera or species rather than a variety, the professional operator shall indicate on the label referred to in paragraph 1 the species or group of species in such a way as to avoid confusion with any varietal denomination.

4. The colour and form of the label shall be substantially distinct from the colour and the form of the official labels referred to in Articles 19(1).

5. This Article shall apply without prejudice to Article 49(4) of Regulation (EC) No 1107/2009 concerning the label and documents accompanying treated seeds in the meaning of that Regulation.

Article 50

Making available on the market with reference to varieties

1. Plant reproductive material shall be made available on the market with reference to a variety only in one or more of the following cases:

   (a) the variety is legally protected by a plant variety right in accordance with the provisions of Regulation (EC) No 2100/94 or in accordance with national provisions;

   (b) the variety is registered in a national variety register as referred to in Article 51 or in the Union variety register as referred to in Article 52;

   (c) the variety has been entered in any other public or private list with an official or officially recognised description and a denomination.

2. Plant reproductive material made available on the market pursuant to points (a) and (b) of paragraph 1 shall bear the same variety denomination in all Member States.

   Where the variety is not protected by a plant variety right or registered pursuant to Title IV, as referred to in points (a) and (b) of paragraph 1, but has been entered in a public or private list with an official or officially recognised description and a denomination as referred to in points (b) and (c) of that paragraph, the professional operator may request the advice of the Agency concerning the suitability of the denomination pursuant to the provisions of Article 64. Following that request, the Agency shall submit to the applicant a recommendation on the suitability of the variety denomination, as requested by the applicant, taking into account the requirements set out in Article 64.

TITLE IV
Registration of varieties in national and Union variety registers

CHAPTER I
Establishment of national and Union variety registers

Article 51

Establishment of national variety registers

1. Each Member State shall establish, publish and update a single national register of varieties and clones (hereinafter 'national variety register').

2. The Commission shall 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 141(3).

Article 52

Establishment of a Union variety register

1. The Agency shall establish, publish and update a single register of varieties and clones (hereinafter "Union variety register").

   The Union variety register shall include the following:

   (a) varieties and clones directly registered in the Union variety register in accordance with Chapter V; and

(b) varieties and clones registered in national variety registers in accordance with Chapter IV, as notified by the Member States to the Agency in accordance with Chapter VI.

2. The Commission shall adopt, by means of implementing acts, the format of the Union variety register. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(3).

CHAPTER II
Content of the national and Union variety registers

Article 53
Data concerning varieties

1. For varieties, the national and Union variety registers shall include at least:

(a) the name of the genus or species to which the variety belongs;

(b) the denomination of the variety and, for varieties made available on the market before the entry into force of this Regulation, where applicable, its synonyms;

(c) the name, and, where applicable, the reference number, of the applicant;

(d) the date of the registration of the variety and, where applicable, of the renewal of the registration;

(e) the date of the end of validity of registration;

(f) the official description of the variety, or, where, applicable, the officially recognised description of the variety with an indication of the region(s) where the variety has historically been grown and to which it is naturally adapted ("region(s) of origin");

(g) the name of the professional operator responsible for the maintenance of a variety;

(h) where applicable, the indication that the variety contains a genetically modified organism;

(i) where applicable, the indication that the variety is a component variety of another registered variety;

(j) where applicable, the indication that plant reproductive material belonging to the variety is only produced and made available on the market in rootstocks;

(k) where applicable, a summary of the results of the examinations for satisfactory value for cultivation and/or use as referred to in Article 58, or sustainable value for cultivation and/or use as referred to in Article 59.

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

Article 54

Data concerning clones

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

(a) the name of the genus or species to which the clone belongs;

(b) the reference under which the variety, to which the clone belongs, is registered in the national variety register or Union variety register;

(c) the denomination of the variety to which the clone belongs and, for varieties made available on the market before the entry into force of this Regulation, where applicable its synonyms;

(d) the date of the registration of the clone and, where applicable, of the renewal of the registration;

(e) the end of validity of the registration;

(f) where applicable, the indication that the variety to which the clone belongs has been registered with an officially recognised description, including the region of origin of that variety;

(g) where applicable, the indication that the clone contains, or consists of, a genetically modified organism.

Article 55

Additional data to be included in the Union variety register

In the case of a variety or clone, notified by a Member State to the Agency in accordance with Chapter VI, the Union variety register shall include, in addition to the data required pursuant to Articles 53 and 54:

(a) the name of the Member States having established the relevant national variety register(s); and

(b) the reference under which the variety or clone has been registered in the national variety register(s).

CHAPTER III

Requirements for registration in the national and Union variety registers

SECTION 1

VARIETIES

Article 56

Registration requirements for varieties

1. Varieties may be registered in a national variety register pursuant to Chapter IV, or in the Union variety register pursuant to Chapter V, only if they fulfil the following requirements:

   (a) they bear a denomination deemed suitable pursuant to Article 64;

   (b) they do not pose an unacceptable risk for human, animal and plant health, or the environment;

(c) in case of varieties belonging to a genetically modified organism, that organism is authorised for cultivation pursuant to Directive 2001/18/EC or Regulation (EC) 1829/2003.

2. In order to be registered in a national variety register pursuant to Chapter IV, varieties shall fulfil, in addition to the requirements set out in paragraph 1, the following requirements:

(a) they have an official description showing compliance with the requirements of distinctiveness, uniformity and stability set out in Articles 60, 61 and 62, or are provided with an officially recognised description pursuant to Article 57;

(b) in case they belong to genera or species with particular importance for the satisfactory development of agriculture in the Union, as referred to in paragraph 5, they have a satisfactory value for cultivation and/or use pursuant to Article 58;

(c) in case they belong to genera or species with particular importance for the sustainable development of agriculture in the Union, as referred to in paragraph 6, they have a sustainable value for cultivation and/or use pursuant to Article 59.

3. The requirements set out in paragraph 2(b) and (c) shall not apply to the following varieties:

(a) varieties provided only with an officially recognised description;

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

4. In order to be registered in the Union variety register pursuant to Chapter V, varieties shall fulfil, in addition to requirements set out in paragraph 1, the following requirements:

(a) they have an official description showing compliance with the requirements of distinctiveness, uniformity and stability set out in Articles 60, 61 and 62;

(b) they do not belong to genera or species with particular importance for the satisfactory development of agriculture in the Union, as referred to in paragraph 5;

(c) in case they belong to genera or species with particular importance for the sustainable development of agriculture in the Union, as referred to in paragraph 6, they have a sustainable value for cultivation and/or use pursuant to Article 59;

(d) they are not used as mere components for the creation or production of other varieties.

5. The Commission shall be empowered to adopt delegated acts, in accordance with Article 140, listing the genera or species with particular importance for the satisfactory development of agriculture in the Union. Those genera or species shall be listed in accordance with the criteria set out in Part A of Annex IV.

6. The Commission shall be empowered to adopt delegated acts, in accordance with Article 140, listing the genera or species with particular importance for the sustainable development of agriculture in the Union. Those genera or species shall be listed in accordance with the criteria set out in Part B of Annex IV.

Article 57

Registration of varieties provided with an officially recognised description

1. A variety may be registered in a national variety register on the basis of an officially recognised description if one of the following conditions are complied with:

   (a) in case the variety had been previously not registered in a national variety register or in the Union variety register and plant reproductive material belonging to that variety has been made available on the market before the entry into force of this Regulation;

   (b) in case the variety had been previously registered in any national variety register or in the Union variety register on the basis of a technical examination pursuant to Article 71, but has been deleted from those registers more than five years before the submission of the current application and would not fulfil the requirements laid down in Articles 60, 61 and 62 and, where applicable, Article 58(1) and Article 59(1).

2. In order to be registered on the basis of an officially recognised description, a variety shall comply, in addition to paragraph 1, with the following conditions:

   (a) it is produced in the region(s) of origin;

   (b) it is not included in a national variety register or in the Union variety register, as a variety with an official description;

   (c) it is not protected by a Union plant variety right as provided for in Article 62 of Council Regulation (EC) No 2100/94, or by a national plant variety right, and it is not the subject of a pending application for such a right.

3. After the registration of a variety in a national variety register pursuant to paragraph 2(a), competent authorities may approve additional region(s) of origin for that variety.

4. The officially recognised description shall comply with the following requirements:

   (a) it is based, where available, on information from plant genetic resources authorities or from organisations recognised for that purpose by the Member States; and

   (b) its accuracy is supported by the results of previous official inspections or unofficial examinations or knowledge gained from practical experience during cultivation, reproduction and use.

Article 58

Satisfactory value for cultivation and/or use

1. For the purpose of paragraph 2(b) of Article 56, varieties shall be deemed to have a satisfactory value for cultivation and/or use if, compared to other varieties examined under similar agro-climatic conditions and similar production systems, their characteristics, taken as a whole, offer, at least as far as production in any region is concerned, a clear improvement either for cultivation in general or for the specific uses which can be made of the crops or the products derived therefrom.

2. Member States shall adopt rules concerning the examinations to determine the satisfactory value for cultivation and/or use of the varieties to be registered in their national variety register. Those rules shall concern the characteristics of the varieties in one or more of the following areas:

(a) quality and agronomic characteristics, including yields;

(b) suitability for cultivation in resilience and low input production systems, including for organic agricultural production.

Each Member State shall publish those rules and notify them to the Agency, the Commission and the other Member States.

Article 59
Sustainable value for cultivation and/or use

1. For the purpose of paragraph 2(c) and paragraph 3(c) of Article 56, varieties shall be deemed to have a sustainable value for cultivation and/or use if, compared to other varieties examined under similar agro-climatic conditions and similar production systems, their characteristics, taken as a whole, offer, at least as far as susceptibility to pests, input of resources, susceptibility to undesirable substances or adaptation to divergent agro-climatic conditions are concerned, a clear improvement either for cultivation in general or for the specific uses which can be made of the crops or the products derived there from.

2. The Commission shall be empowered to adopt delegated acts, in accordance with Article 140, setting out rules concerning the examinations to determine the sustainable value for cultivation and/or use of the varieties. Those rules shall concern the characteristics of the varieties in one or more of the following areas:

(a) resistance to pests;

(b) reduced need for input of specific resources;

(c) decreased content of undesirable substances; or

(d) increased adaptation to divergent agro-climatic environment.

Those rules shall take into account, where applicable, the available technical protocols.

Article 60
Distinctness

1. For the purposes of the official description, referred to in point (a) of Article 56(2) and (3), a variety shall be deemed to be distinct, if it is clearly distinguishable, by reference to the expression of the characteristics that results from a particular genotype or combination of genotypes, from any other variety whose existence is commonly known on the date of the application determined pursuant to Article 70.

2. The existence of another variety, as referred to in paragraph 1, shall be deemed to be commonly known, if on the date of the application determined pursuant to Article 70 one or more of the following conditions are complied with:

(a) that variety is included in a national variety register or in a Union variety register;

(b) an application has been filed for registration of that variety in a national variety register pursuant to Article 66, or in the Union variety register pursuant to Article 95(1), or for the granting of a plant variety right in respect of that variety in the Union;

(c) an official description of that variety has been produced in the Union, and the technical examination has been conducted pursuant to the provisions of Article 69, Article 71 and, where applicable, Article 73 .

3. Where point (c) of paragraph 2 applies, the person(s) responsible for the technical examinations shall make available to the competent authorities and the Agency the official description of the variety examined by them.

Article 61
Uniformity

For the purposes of the official description, referred to in point (a) of Article 56(2) and (3), a variety shall be deemed to be uniform if, subject to the variation that may be expected from the particular features of its reproduction and type, it is sufficiently uniform in the expression of those characteristics which are included in the examination for distinctness, as well as in the expression of any other characteristics used for its official description.

Article 62
Stability

For the purposes of the official description referred to in point (a) of Article 56(2) and (3), a variety shall be deemed to be stable if the expression of those characteristics which are included in the examination for distinctness, as well as any other characteristics used for the variety description, remains unchanged after repeated reproduction or, in the case of cycles of reproduction, at the end of each such cycle.

Article 63
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 the legislation of a Member State, that variety shall be deemed to be distinct, uniform and stable, for the purpose of the official description as referred to in point (a) of Article 56(2) and (3) and to have a suitable denomination for the purposes of point (a) of Article 56(1).

Article 64
Denomination of varieties

1. For the purposes of point (a) of Article 56(1), 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 to, or may be confused with, a variety denomination under which another variety of the same or of a closely related species is entered in a national variety register or in the Union variety register, or under which material of another variety has been made available on the market in a Member State or in a Member of the International Union for the Protection of New Varieties of Plants, unless that other variety no longer remains in existence and its denomination has acquired no special significance;

(d) it is identical to, or may be confused with, other designations which are commonly used for the making available on the market of goods or which have to be kept free pursuant to other Union legislation;

(e) it is liable to give offence in one of the Member States or is contrary to public order;

(f) it is liable to mislead or to cause confusion concerning the characteristics, the value or the identity of the variety, or the identity of the breeder.

2. Without prejudice to paragraph 1, if a variety is already registered in other national variety registers, or in the Union variety register, the denomination shall only be deemed suitable if it is identical to that appearing in those registrations.

3. Paragraph 2 shall not apply if:

(a) the denomination is likely to mislead or cause confusion concerning the relevant variety in one or more Member States; or

(b) the rights of third parties impede the free use of that denomination in connection with the variety in question.

4. The Commission shall be empowered to adopt delegated acts, in accordance with Article 140, setting out specific rules concerning the suitability of variety denominations. Those rules may concern:

(a) their relation to denominations of trade marks;

(b) their relation to geographical indications or designations of origin for agricultural products;

(c) written consents of holders of prior rights to remove impediments to the suitability of a denomination;

(d) specific criteria to determine whether a denomination is misleading or confusing as referred to in paragraph 1(f); and

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

SECTION 2
CLONES

Article 65

Registration requirements for clones

1. A clone may be included in the national variety register, or in the Union variety register, only if it complies with the following requirements:

(a) it belongs to genera or species which have a particular value for particular market sectors and listed pursuant to paragraph 3;

(b) it belongs to a variety registered in a national variety register pursuant to Chapter IV or in the Union variety register pursuant to Chapter V;

(c) it has been subject to genetic selection;

(d) it bears a suitable denomination.

2. For the purpose of establishing whether a denomination is suitable as referred to in paragraph 1(d) of this Article, the provisions of Article 64 shall apply with the

necessary modifications. References made in Article 64 to varieties shall be construed as references to clones.

3. The Commission shall be empowered to adopt delegated acts, in accordance with Article 140, listing the genera or species, the clones of which have a particular value for particular market sectors.

4. The Commission shall be empowered to adopt delegated acts, in accordance with Article 140, setting out the following:

(a) that clones belonging to particular genera or species shall be subject to sanitary selection for the purpose of inclusion in a national variety register or in the Union variety register; and

(b) the requirements for the sanitary selection referred to in point (a);

CHAPTER IV
National variety register procedures

SECTION 1
VARIETY REGISTRATION PROCEDURE

Article 66
Submission of applications

1. Any person may submit to the competent authority an application for registration of a variety in the national variety register.

2. The application referred to in paragraph 1 shall be submitted in writing. That submission may take place electronically.

Article 67
Content of applications

1. The application for registration of a variety in a national variety register shall contain the following items:

(a) a request for registration;

(b) the identification of the botanical taxon (genus or species) to which the variety belongs;

(c) the reference number of the applicant, where applicable, and its name and address, or, where appropriate, the names and addresses of the joint applicants, and the credentials of any procedural representative;

(d) a provisional denomination;

(e) the name and address of the person responsible for the maintenance of the variety, and, where applicable, the reference number of that person;

(f) a description of the main characteristics of the variety and, if available, a completed technical questionnaire;

(g) a description of the procedure of variety maintenance;

(h) the geographic origin of the variety;

(i) information on whether the variety is registered in another national variety register, or the Union variety register, and on whether it is known to the applicant that an application for registration in one of those registers is pending;

(j) where the variety contains or consists of 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;

(k) where the application is based on an officially recognised description of the variety, a file containing that description and any document or publication supporting it;

(l) in the case of an application concerning varieties granted a plant variety right as referred to in Article 63, the proof that the variety is protected by such right, with the corresponding official description;

(m) where applicable, a declaration that the variety has satisfactory value for cultivation and/or a use as referred to in Article 58(1) and/or sustainable value for cultivation and/or use as referred to in Article 59(1).

2. The application for registration of a variety in a national variety register shall be accompanied by the submission of a sample of sufficient quality and quantity of the variety, as specified by the competent authority.

3. The Commission shall be empowered to adopt delegated acts, in accordance with Article 140, setting out additional items to be included in the application for particular genera or species, in relation with the particular features of the varieties belonging to those genera or species.

Article 68
Application format

The Commission shall adopt, by means of implementing acts, the format of the application referred to in Article 66. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(3).

Article 69
Formal examination of application

1. The competent authority shall register each application for registration in the national variety register it receives, and shall carry out the formal examination of that application. The formal examination of the application shall examine whether the application complies with:

(a) the content requirements laid down in Article 67; and

(b) the format adopted pursuant to Article 68.

2. If the application does not comply with the requirements laid down in Article 67 or the format adopted pursuant to Article 68, the competent authority shall give the applicant the possibility to make its application compliant within a given time.

Article 70

Date of application

The date of application for registration shall be the date on which an application complying with the content requirements laid down in Article 67 and the format adopted pursuant to Article 68 was submitted to the competent authority.

Article 71

Technical examination

1. Where, as a result of the formal examination, the application is found to comply with the content requirements referred to in Article 67 and the format adopted pursuant to Article 68, a technical examination of the variety shall be carried out for the purpose of establishing an official description.

2. The technical examination referred to in paragraph 1 shall verify:

   (a) the compliance with the requirements for distinctiveness, uniformity and stability of the variety, as laid down in Articles 60, 61 and 62;

   (b) where applicable, that the variety has a satisfactory value for cultivation and/or use, according to Article 58(1) and a sustainable value for cultivation and/or use according to Article 59(1).

3. The technical examination referred to in paragraph 1 shall be carried out by the competent authorities in accordance with the requirements referred to in Article 74.

   On request submitted by the applicant to the competent authority, the technical examination, or part of it, may be carried out by the applicant, in accordance with the provisions of Article 73 and the requirements referred to in Article 74.

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

5. By way of derogation from paragraph 4, the competent authority may decide that the technical examination referred to in paragraph 1 is necessary in the case of a variety the registration of which is requested pursuant to point (b) Article 57(1).

Article 72

Audit of the competent authority's premises and organisation

1. The competent authority may carry out the technical examination referred to in Article 71(1) only if its premises, which must be dedicated to this purpose, and its organisation have been audited by the Agency.

   That audit shall verify whether the premises and the organisation of the competent authority are suitable for carrying out the technical examination as regards:

   (a) compliance with the requirements for distinctiveness, uniformity and stability referred to in Articles 60, 61 and 62; and

   (b) compliance with the requirements of a sustainable value for cultivation and/or use referred to in Article 59(1).

2. The Commission shall be empowered to adopt delegated acts, in accordance with Article 140, setting out the rules concerning the audit referred to in paragraph 1.

3. On the basis of the audit referred to in paragraph 1, the Agency may recommend to the competent authority, if appropriate, actions to ensure the suitability of the premises and organisation of the competent authorities. Further to the audit referred to in paragraph 1, the Agency may carry out additional audits and, where applicable, recommend to the competent authorities corrective actions to ensure the suitability of their premises and organisation.

Article 73
Technical examination by the applicant

1. The applicant may carry out the technical examination referred to in Article 71(1), or part of it, only if it has been authorised thereto by the competent authority. Technical examination by the applicant shall be carried out in particular premises, which are dedicated to this purpose.

2. Prior to granting the authorisation to carry out the technical examination, the competent authority shall audit the premises and the organisation of the applicant. That audit shall verify whether the premises and organisation are suitable for carrying out the technical examination as regards:

   (a) compliance with the requirements for distinctiveness, uniformity and stability referred to in Articles 60, 61 and 62; and

   (b) compliance with the requirements of a satisfactory value for cultivation and/or use referred to in Article 58(1);

   (c) compliance with the requirements of a sustainable value for cultivation and/or use referred to in Article 59(1).

3. The Commission shall be empowered to adopt delegated acts, in accordance with Article 140, setting out the rules concerning the audit referred to in paragraph 2.

4. On the basis of the audit referred to in paragraph 1, the competent authority may recommend to the applicant, if appropriate, actions to ensure the suitability of the applicant's premises and organisation.

5. Further to the authorisation and audit referred to in paragraph 1, the competent authority may carry out additional audits and, where applicable, recommend to the applicant, within a specific period of time, corrective actions concerning the applicant's premises and the organisation.

In case the competent authority concludes that the applicant's premises and organisation are not suitable, it may revoke or modify the authorisation referred to in paragraph 1.

Article 74
Additional rules on technical examination

1. The Commission shall be empowered to adopt delegated acts, in accordance with Article 140, supplementing the requirements on the technical examination laid down in Articles 71, 72 and 73. Those delegated acts may concern:

   (a) qualification, training and activities of staff of the competent authority, or of the applicant, for the purposes of the technical examination referred to in Article 71(1);

   (b) the necessary equipment, including laboratories for disease resistance characteristics, necessary to carry out the technical examination;

(c) the establishment of a variety reference collection to assess distinctness, and the storage management of such reference collection;

(d) the establishment of quality management systems, including record of activities and protocols or guidelines, to be used for the technical examination;

(e) the conduct of growing trials and laboratory tests for particular genera or species.

Those delegated acts shall take into account the available technical and scientific protocols.

2. Where no requirements have been adopted pursuant to paragraph 1, technical examinations shall be carried out in accordance with national protocols as regards the elements referred in points (a) to (e) of paragraph 1.

Article 75
Confidentiality

1. Where, in the framework of the technical examination referred to in Article 71(1), an examination of the genealogical components is necessary, the results of that examination and the description of the genealogical components shall be treated as confidential, if the applicant so requests.

2. In the case of varieties of plant reproductive material intended exclusively for the production of agricultural raw materials for industrial purposes, and if so requested by the applicant, the results of the technical examination referred to in Article 71(1) and the intended uses of those varieties shall be treated as confidential.

Article 76
Provisional examination report and provisional official description

1. Following the technical examination referred to in Article 71(1), the competent authority shall produce a provisional examination report and, where it considers that the distinctiveness, uniformity and stability requirements, as referred to in Articles 60, 61 and 62, are complied with, a provisional official description of the variety on the basis of that report.

2. The provisional examination report may refer to findings of other examination reports, produced on the relevant variety, by the competent authority concerned, other competent authorities or the Agency.

3. The competent authority shall communicate the provisional examination report and the provisional official description of the variety to the applicant.

4. Where the competent authority does not consider the examination report to constitute a sufficient basis for a decision on the registration of the variety, it shall provide a complementary examination of its own motion, after consulting the applicant, or on request of the applicant. Any complementary examination carried out until a decision is taken pursuant to Article 79(1) shall be considered to be part of the technical examination referred to in Article 71(1).

Article 77

Examination report and official description

1. After having given the applicant an opportunity to comment on the provisional examination report and the provisional official description, the competent authority shall establish a final examination report and a final official description.

2. Competent authorities shall, on reasoned request, make available the examination reports to third parties, subject to national or Union provisions on data protection and applicable rules on confidentiality.

Article 78

Examination of the denomination

1. After the formal examination of the application referred to in Article 69, and prior to the registration of a variety in a national variety register pursuant to Article 79, the competent authority shall consult the Agency on the variety denomination proposed by the applicant.

2. The Agency shall submit to the competent authority a recommendation on the suitability of the variety denomination proposed by the applicant, in accordance with the requirements set out in Article 64. The competent authority shall inform the applicant on that recommendation.

Article 79

Decision on registration

1. If, on the basis of the procedure set out in Articles 66 to 78, it is concluded that the variety complies with the applicable requirements set out in Article 56, the competent authority shall decide 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:

   (a) it establishes that the applicable requirements set out in Article 56, are not fulfilled; or

   (b) the applicant has failed to comply with any obligations set out for it in Articles 66 to 74.

3. Decisions refusing the registration shall state the reasons justifying the refusal.

4. The competent authority shall communicate to the applicant a copy of the decision referred to in paragraphs 1 and 2.

Article 80

Already registered varieties and clones

1. By way of derogation from Articles 66 to 79, the competent authorities shall register in their national variety registers all varieties officially accepted or registered, before the entry into force of this Regulation, in the catalogues, lists or registers established by their Member States 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/EEC and all clones registered pursuant to Article 5 of Directive 68/193/EEC, Article 7(4) of Directive 2008/90/EC, Chapter II of Directive

2008/62/EC and Section I of Chapter II and Section I of Chapter III of Directive 2009/145/EC.

2. Varieties accepted in accordance with Article 3 of Directive 2008/62/EC and Article 3(1) of Directive 2009/145/EC shall be registered in the national variety registers as varieties provided with an officially recognised description.

Article 81

New denomination after registration

Where, after the registration of a variety, it is established by the competent authority that at the time of the registration the denomination of the variety was not suitable within the meaning of Article 64, the applicant shall submit an application for a new denomination. The competent authority shall decide on that application upon consultation with the Agency. The competent authority may permit the previous denomination to be used temporarily.

SECTION 2

REGISTRATION PERIOD AND VARIETY MAINTENANCE

Article 82

Validity period of the registration

1. The validity period 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, a genetically modified organism, the validity of the registration shall be limited to the period for which that genetically modified organism is authorised for cultivation pursuant to Directive 2001/18/EC or Regulation (EC) No 1829/2003.

Article 83

Duration of the renewal period

1. The registration of a variety in a national variety register may be renewed for further periods of 30 years, in accordance with the procedure and the conditions laid down in Article 84.

2. In the case of a variety consisting of or containing a genetically modified organism, the renewal shall be limited to the period for which that genetically modified organism is authorised for cultivation pursuant to Directive 2001/18/EC or Regulation (EC) No 1829/2003.

Article 84

Procedure and conditions for registration renewal

1. Any person intending to renew the registration of a variety shall submit an application, no earlier than 12 months, and no later than six months, before the expiration of the validity period as referred to in Article 82.

2. The application shall be submitted in writing. That submission may take place electronically. It shall be accompanied by evidence showing that the conditions set out in paragraphs 3 and 4 are fulfilled.

3. The renewal of the registration of a variety in a national variety register shall only be granted if the following conditions are met:

(a) the variety continues complying with the requirements of Article 56, and, where applicable of Article 57;

(b) the competent authority determines that a person is responsible for maintaining the variety in accordance with the provisions of Article 86.

4. The competent authority may renew the registration of a variety in a national variety register, without an application for renewal being submitted pursuant to paragraphs 1 and 2, where it considers that the renewal of that registration serves sustainable agricultural production and the preservation of genetic diversity, and that the conditions of paragraph 3 are fulfilled.

Article 85

Deletion from national variety registers

1. The competent authority shall decide to delete a variety from the national variety register, in the following cases:

(a) if the competent authority concludes, on the basis of any new evidence, that the requirements for registration, as set out in Article 56 are no longer fulfilled;

(b) if a request to delete the variety from the national variety register has been submitted by the applicant;

(c) if the applicant does not pay the annual fee pursuant to point (d) of Article 87(1)(e);

(d) if the person responsible for the maintenance of the variety, as referred to in Article 86(1), so requests, unless maintenance of the variety is assured by another person;

(e) if the variety is no longer maintained pursuant to requirements of Article 86;

(f) if the variety is maintained in a third country, that third country has not provided assistance on the controls of that maintenance pursuant to Article 86(8);

(g) if at the time of the application, false or fraudulent data were supplied concerning the facts on the basis of which the registration was decided;

(h) if, by the deadline to submit an application for renewal referred to in Article 84(1), the applicant has not submitted such an application and the validity period referred to in Article 82(1) has expired.

2. On request by the applicant, the competent authority may allow a 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.

That request shall be submitted no later than the date of the expiration of the registration period.

3. After a variety is deleted from the national variety register, the competent authority shall submit a sample of that variety, and its description, to a gene bank dedicated to the conservation of genetic resources.

Article 86

Variety maintenance

1. Varieties registered in a national variety register shall be maintained by the applicant or by any other person acting in mutual agreement with the applicant. That other person shall be notified by the applicant to the competent authority.

2. Variety maintenance shall take place in accordance with accepted practices concerning, as appropriate, genera, species or types of varieties.

3. The persons referred to in paragraph 1 shall keep records concerning the maintenance of the variety. It shall at all times be possible for the competent authority to check the maintenance of the variety from those records. Those records shall also cover the production of pre-basic, basic, certified and standard material, and the stages of production prior to pre-basic material.

4. Varieties provided with an officially recognised description shall be maintained in their region(s) of origin.

5. The competent authority shall carry out controls on the manner in which variety maintenance is carried out and may, to this purpose, take samples of the varieties concerned.

6. Where a competent authority finds that the person responsible for variety maintenance does not comply with paragraphs 1 to 4, it shall give that person the opportunity to take corrective action.

7. Where variety maintenance takes place in a Member State other than the Member State in whose national variety register the variety has been registered, the competent authorities of the two Member States concerned shall assist each other in the controls on variety maintenance.

8. Where variety maintenance takes place in a third country, the competent authorities of the Member State in whose national variety register the variety has been registered concerned shall request the third country's authorities assistance in the controls on variety maintenance.

SECTION 3
REGISTRATION FEES

Article 87

Registration fees

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

   (a) the formal examination of the application referred to in Article 69;

   (b) the technical examination and the audits referred to in Article 71 and Article 73(1);

   (c) the examination of the variety denomination referred to in Article 78;

   (d) the decision on registration referred to in Article 79, and any administrative appeal lodged pursuant to national rules against that decision;

   (e) the inclusion of the variety, or where applicable the clone, in the national variety register for each year of the duration of the registration;

(f) controls on the maintenance as referred to in Article 86(5).

2. The actions referred to in paragraph 1 shall only be carried out on demand submitted by the applicant to the competent authority, and after the respective fees have been paid. The demand shall be deemed not to have been made, if the fees have not been paid 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 140, setting out the specific cost items to be covered pursuant to paragraph 1(a) to (f).

Article 88

Fees for varieties provided with an officially recognised description

1. In the case of varieties provided with an officially recognised description, no fees shall be charged for the actions referred to in point (e) of Article 87(1).

2. In the case of varieties provided with an officially recognised description, the competent authorities shall reduce the amount of the fee for the actions referred to in of points (a), (c), (d), and (f) of Article 87(1). That reduction shall take place in a manner to ensure that the fee does not constitute a barrier to the registration of the variety concerned.

Article 89

Exemptions from the payment of registration fees

1. Fees provided for in Article 87 and 88 shall not directly or indirectly be refunded, unless unduly collected.

2. Applicants employing fewer than 10 persons and whose annual turnover or annual balance sheet total does not exceed EUR 2 million shall be exempted from the payment of the fees provided for in Article 87 and Article 88.

3. The costs referred to in Articles 87 and 88 shall not include those incurred for the performance of official controls on the applicants referred to in paragraph 2.

SECTION 4
REGISTRATION OF CLONES

Article 90

Applicable provisions

1. For the registration of a clone in a national variety register, Sections 1, 2 and 3 shall apply with the necessary modifications, excluding the following provisions:

   (a) the provisions on the content of applications as set out in Article 67;

   (b) the provisions referring to varieties provided with officially recognised descriptions;

   (c) the provisions referring to varieties with sustainable or satisfactory value for cultivation and/or use.

2. As regards the content of applications, Article 92 shall apply instead of Article 67.

Article 91

References

When applying Sections 1, 2 and 3 for the registration of a clone in a national variety register, references shall be construed as follows:

(a) references to varieties shall be construed as references to clones;

(b) references to Article 56 shall be construed as references to Article 65;

(c) references to the requirements set out in Articles 60, 61 and 62 shall be construed as references to requirements set out in Article 65(1)(b) and (3);

(d) references to Article 67, concerning the content of applications, shall be construed as references to Article 92.

Article 92

Content of applications

1. The application for registration of a clone in a national variety register shall contain the following items:

   (a) a request for registration;

   (b) the identification of the variety to which the clone belongs;

   (c) the name and address of the applicant, or, where appropriate, the joint applicants, and the credentials of any procedural representative;

   (d) a provisional denomination;

   (e) the name and address of the person responsible for the maintenance of the clone, and, where applicable, the reference number of that person;

   (f) a description of the main characteristics of the clone and, if available, a completed technical questionnaire;

   (g) the geographic origin of the clone;

   (h) information on whether the clone is registered in another national variety register or Union variety register, and on whether it is known to the applicant that an application for registration of the clone in those registers is pending;

   (i) in the case of a clone containing or consisting of 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.

2. The application for the registration of a clone in a national variety register shall be accompanied by the submission of a sample of sufficient quality and quantity of the clone.

CHAPTER V
Procedures concerning the Union variety register

SECTION 1
SCOPE OF THE CHAPTER

Article 93
Relevant varieties and clones

This Chapter shall apply to varieties and clones not registered in any national variety register pursuant to Article 79.

SECTION 2
REGISTRATION PROCEDURE

Article 94
Applicable provisions

1. For the registration of a variety or clone in the Union variety register, Chapter IV shall apply with the necessary modifications, excluding the following provisions:
   (a) the provisions on the examination of denominations set out in Article 78;
   (b) the provisions on variety maintenance set out in Article 86;
   (c) the provisions referring to varieties provided with an officially recognised description;
   (d) the provisions on exemptions from the payment of registration fees, set out in Article 89(2) and (3).
2. For the examination of denominations, for variety and clone maintenance and for exemptions from the payment of registration fees, Articles 95, 96 and 97 shall apply instead of the provisions referred to in paragraph 1(a), (b) and (d).
3. When applying Chapter IV for the registration of a variety or clone in the Union variety register, references shall be construed as follows:
   (a) references to the competent authority shall be construed as references to the Agency;
   (b) references to national variety registers shall be construed as references to the Union variety register;
   (c) references to Article 78 shall be construed as references to Article 95;
   (d) references to Article 86 shall be construed as references to Article 96;
   (e) references to administrative appeal lodged pursuant to national rules against the respective decision shall be construed as references to the appeal referred to in Article 98.

Article 95

Examination of the denomination

1. After the formal examination of the application referred to in Article 69, as applied pursuant to Article 94, and before a variety or clone is registered in the Union variety register, the Agency shall examine the denomination of the variety or clone proposed by the applicant.

2. The Agency shall decide on the suitability of the variety or clone denomination, in accordance with the requirements set out in Article 64.

Article 96

Maintenance of varieties and clones

1. Varieties and clones registered in the Union variety register shall be maintained by the applicant, or by any other person acting in mutual agreement with the applicant. The other person shall be notified to the Agency.

2. The maintenance shall take place in accordance with accepted practices, as appropriate per genera, species or types of varieties.

3. The person referred to in paragraph 1 shall keep records concerning the maintenance of the variety or the clone. It shall at all times be possible for the Agency to check the maintenance of the variety or the clone from those records. Those records shall also cover the production of pre-basic, basic, certified and standard material, and stages of production prior to pre-basic material.

4. The Agency shall check the way the maintenance is carried out and may, to this purpose, take samples of the varieties and the clones.

5. The competent authorities of the Member State where the maintenance of the variety or the clone concerned takes place, shall assist the Agency as regards controls on maintenance.

6. In case the Agency finds that the person responsible for the maintenance does not comply with the provisions of paragraphs 1, 2 and 3, it shall give that person the opportunity to take corrective action.

Article 97

Amount of fees

1. The Commission shall be empowered to adopt delegated acts, in accordance with the procedure referred to in Article 140, setting out the amount of the fees referred to in Article 87(1) as applied pursuant to Article 94.

2. The level at which the fees are set pursuant to paragraph 1 shall reflect the principle of sound financial management to allow the Agency to maintain a balanced budget.

SECTION 3
APPEALS

Article 98
Right of appeal

An appeal shall lie from decisions of the Agency which have been taken pursuant to Section 2. It shall be examined by the Board of Appeal of the Agency referred to in Article 46 of Regulation (EC) No 2100/1994.

Article 99
Provisions applicable to appeals

1. Chapters V and VI of Part Four of Regulation (EC) No 2100/1994 shall apply, with the necessary modifications, to appeals referred to in Article 98.

2. Notwithstanding paragraph 1 of this Article, the following provisions of Chapters V and VI of Part Four of Regulation (EC) No 2100/1994 shall not apply to appeals referred to in Article 98:

   (a) Article 67 (1) and (3);

   (b) Article 74;

   (c) Article 80(5).

Article100
References

For the purposes of Article 99(1), references contained in Chapters V and VI of Part Four of Regulation (EC) No 2100/1994 shall be construed as follows:

(a) the reference made in Article 68 to Article 82 shall be omitted;

(b) the reference made in Article 70(1) to "the body of the Office which has prepared the decision" shall be construed as a reference made to the Agency;

(c) the reference made in Article 76 to the "examination made pursuant to Articles 54 and 55" shall be construed as a reference made to the technical examination of the application for registration carried out by the Agency pursuant to this Regulation;

(d) the reference made in Article 78(3) and (4) to Article 90(2) shall be omitted;

(e) the reference made in Article 79 to the "competent offices" shall be construed as a reference made to the competent authorities;

(f) the reference made in Article 80(1) to the "applicant for a Community plant variety right or the holder" shall be construed as a reference made to the applicant for registration;

(g) the reference made in Article 80(3) to the "time limits specified in Article 52 (2), (4) and (5) shall be omitted;

(h) the reference made in Article 81 to the "staff of the Examination Offices" shall be omitted.

CHAPTER VI
Notification of varieties to the Union variety register

Article 101
Notification procedure

1. Each competent authority shall notify within five working days the Agency of the application for registration of a variety, the adoption of the decision referred to in Article 79, the new denomination after registration pursuant to Article 81, the renewal of the registration pursuant to Article 83, and the deletion of a variety pursuant to Article 85.

2. Each competent authority shall notify the Agency of the person responsible for the maintenance of the variety pursuant to Article 86. That notification shall take place within five working days from the date on which the competent authority has become aware of that person.

3. The Commission shall establish, by means of implementing acts, procedures for submission of the notifications referred to in paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(3).

CHAPTER VII
Keeping and handling of information

Article 102
Documentation on the national variety registers and on the Union variety register

1. The competent authority shall keep a file on each variety registered in the national variety register, containing the official description, the examination report and any complementary examination report pursuant to Article 76. Where applicable, the file shall only contain the officially recognised description of the variety, and the documents supporting that description.

2. The Agency shall keep a file on each variety registered in the Union variety register, containing the official description and the examination report issued pursuant to Article 94(1).

Article 103
Access to information of the national variety registers

1. Each Member State shall inform the other Member States, the Agency and the Commission on the access to its national variety register.

2. By 31 March of each year, each competent authority shall notify to the other competent authorities and the Commission any amendments of the respective national variety registers which took place during the preceding year.

3. Each competent authority shall, on request, make available to another competent authority, the Agency or the Commission:

   (a) where applicable, the examination reports of varieties registered in the respective national variety register, as referred to in Article 77(1);

(b) where applicable, the results of technical examinations referred to in Article 71(1);

(c) the list of varieties for which an application for registration is pending;

(d) any other information available in respect of registered or deleted varieties.

4. The competent authority shall take appropriate measures to make available the information contained in the files of the national variety register to any person requesting access to this information. This provision shall not apply where the information must be treated as confidential pursuant to Article 75.

Article 104

Access to information of the Union variety register

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

2. By 31 March of each year, the Agency shall notify the competent authorities and the Commission of any amendments of the Union variety register made during the preceding year with regard to the varieties registered pursuant to Article 94(1).

3. The Agency shall, on request, and with regard to varieties registered in the Union variety register pursuant to Article 94(1), make available to a competent authority or the Commission:

(a) the examination reports or the official description of the registered varieties;

(b) the results of technical examinations;

(c) the list of varieties for which applications for registration are pending;

(d) any other information available in respect of registered or deleted varieties.

4. The Agency shall take appropriate measures to make available the information contained in the files of the Union variety register to any person requesting access to that information. This provision shall not apply where the information must be treated as confidential under Article 75.

PART IV
PRODUCTION AND MAKING AVAILABLE ON THE MARKET OF FOREST REPRODUCTIVE MATERIAL

TITLE I
General provisions

Article 105
Scope

This Part shall apply to the production and making available on the market, of forest reproductive material.

Article 106
Definitions

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

(a) "basic forest material" means seed source, stand, seed orchard, parents of family, clone or clonal mixture;

(b) "seed source" means trees within a delimited area from which seed is collected;

(c) "stand" means a delineated population of trees possessing sufficient uniformity in composition;

(d) "seed orchard" means a plantation of selected clones or families, which is isolated or managed so as to avoid or reduce pollination from outside sources, and managed to produce frequent, abundant and easily harvested crops of seed;

(e) "parents of family" means trees used to obtain progeny by controlled or open pollination of one identified parent used as a female, with the pollen of one parent (full-sibling) or a number of identified or unidentified parents (half sibling);

(f) "clone" means group of individuals (ramets) derived originally from a single individual (ortet) by vegetative reproduction, including by cuttings, micro-propagation, grafts, layers or divisions;

(g) "clonal mixture" means a mixture of identified clones in known proportions;

(h) "Autochthonous stand" or "autochthonous seed source" means a stand or seed source which:

(i) has been continuously regenerated by natural regeneration; or

(ii) has been regenerated artificially from reproductive material collected in the same stand or seed source; or

(iii) has been regenerated artificially from reproductive material collected in stands or seed sources, within the close proximity, meeting the description in points (i) and (ii);

(i) "Indigenous stand" or 'indigenous seed source' means a stand or seed source raised artificially from seed, the origin of which is situated in the same region of provenance;

(j) "origin" means:

(i) for an autochthonous stand or seed source – the place in which the trees are growing;

(ii) for a non-autochthonous stand or seed source – the place from which the seed or plants were originally introduced;

(k) "provenance" means the place in which any stand is growing;

(l) "region of provenance" means, for a species or sub-species, the area or group of areas subject to sufficiently uniform ecological conditions in which stands or seed sources showing similar phenotypic or genetic characters are found, and is delimited, where appropriate, by altitudinal boundaries;

(m) "category" means any of the following groupings of derived forest reproductive material: source-identified, selected, qualified or tested reproductive material;

(n) "source-identified": means derived from basic forest material which may be either a seed source or stand located within a single region of provenance;

(o) "selected": means derived from basic forest material consisting of a stand located within a single region of provenance and which has been phenotypically selected at the population level;

(p) "qualified": means derived from basic forest material consisting of seed orchards, parents of families, clones or clonal mixtures, the components of which have been phenotypically selected at the individual level;

(q) "tested": means derived from basic forest material consisting of stands, seed orchards, parents of families, clones or clonal mixtures of superior quality;

(r) "planting stock" means one of the following:

(i) plants raised from seed units;

(ii) plants raised from parts of plants; or

(iii) plants raised from natural regeneration(s);

(s) "seed unit" means cones, infructescences, fruits and seeds intended for the production of planting stock;

(t) "parts of plants" means stem cuttings, leaf cuttings and root cuttings, explants or embryos for micro-propagation, buds, layers, roots, scions, sets and any parts of a plant intended for the production of planting stock;

(u) "area of utilisation" means the area where the forest reproductive material is used for a specified purpose.

TITLE II
Basic forest material

Article 107

Approval of basic forest material

1. Basic forest material shall be approved by the competent authority for the production of the relevant categories of forest reproductive material if it meets the requirements set out in Annexes V, VI, VII or VIII.

2. Each unit of approved basic forest material (hereinafter: 'unit of approval') shall be identified by a unique reference to the register referred to in Article 112(1).

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

4. The Commission shall be empowered to adopt delegated acts, in accordance with Article 140, supplementing the requirements set out in point 3 of Annex VII concerning clones, and point 4 of Annex VII concerning clonal mixtures, by determining the maximum number of years or the maximum number of ramets to which the approval of clones or clonal mixtures shall be restricted

Article 108

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

1. Basic forest material intended for the production of forest reproductive material under the 'tested' category, whose compliance with the requirements referred to in Article 107(1) has not been established, may provisionally be approved by the competent authorities for a maximum period of ten years, provided that it can be assumed that the basic forest material will, when tests have been completed, satisfy the requirements for approval. That assumption shall be based on the provisional results of the genetic evaluation or comparative tests referred to in Annex VIII.

2. The provisional approval referred to in paragraph 1 may cover all or part of the territory of the Member Stated concerned.

Article 109

Post approval inspections

After the approval referred to in Articles 107 and 108, basic forest material intended 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 to confirm compliance with those Articles.

Article 110

Demarcation of regions of provenance

1. The Member States shall demarcate the regions of provenance of basic forest material consisting of stands or seed sources and intended for the production of forest reproductive material under the ‘source-identified’ and ‘selected’ categories.

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 111

Notification of the intention to collect approved basic forest material

The professional operators shall inform the competent authorities in due time about their intention to collect material from approved basic forest material.

Article 112

National register and national list of approved basic forest material

1. Member States shall establish a national register of basic forest material approved on their territory pursuant to Article 107 and Article 108. That register shall contain information concerning the unit of approval together with its unique register reference.

2. Each Member State shall establish, publish and update a summary of the national register in the form of a national list.

3. The national list referred to in paragraph 2 shall be drawn up in a common form. It shall enumerate each unit of approval. However, for basic forest material intended for the categories 'source-identified- and 'selected', a further summarisation based on regions of provenance shall be permitted.

4. The national list referred to in paragraph 2 shall contain the following details:

   (a) botanical name;

   (b) category for the production of which the basic forest material is intended;

   (c) purpose of the forest reproductive material which will derive from the basic forest material;

   (d) type of basic forest material (seed source, stand, seed orchard, parents of family, clone or clonal mixture);

   (e) register reference to the unit of approval or, where appropriate, summary thereof or identity code of the region of provenance;

   (f) location: a short name, if appropriate, and any of the following sets of particulars:

      (i) for basic forest material intended for production of the ‘source-identified’ category, region of provenance and geographical position defined by the latitudinal and longitudinal range;

      (ii) for basic forest material intended for production of the ‘selected’ category, the region of provenance and the geographical position defined by latitude and longitude or the latitudinal and longitudinal range;

      (iii) for basic forest material intended for production of the ‘qualified’ category, the exact geographical position(s) where the basic material is maintained;

      (iv) for basic forest material intended for production of 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: whether the basic material is autochthonous/indigenous, non autochthonous/non-indigenous or if the origin is unknown. For non-autochthonous/non-indigenous basic material, the origin shall be stated if known;

(j) in the case of basic forest material intended for the 'tested' category, whether it is genetically modified.

5. The Commission shall, by means of implementing acts, adopt the common form in which national lists shall be established, as referred to in paragraph 3. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(3).

Article 113

Union List of Approved Basic Forest Material

1. Member States shall notify to the Agency, the Commission and the other Member States the national list referred to in Article 112(2) and any of its updates within five working days.

2. On the basis of the national lists notified by each Member State, the Agency shall establish, publish and update a register entitled 'Union List of Approved Basic Forest Material for the Production of Forest Reproductive Material'.

The Agency shall include in that register all elements of the Community List of Approved Basic Material for the Production of Forest Reproductive Material published pursuant to Article 11(1) of Directive 1999/105/EC.

3. That Union list shall reflect the details contained in the national lists referred to in Article 112 and indicate the area of utilisation, and any authorisations granted pursuant to Article 128.

4. The Commission shall adopt, by means of implementing acts, the format of the notification referred to in paragraph 1 and of the register referred to in paragraph 2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(3).

TITLE III
Making available on the market of material derived from basic forest material

Article 114

Scope

This title shall apply to the making available on the market of forest reproductive material derived from basic forest material.

CHAPTER I
List of requirements

Article 115

Requirements for making available on the market of forest reproductive material

Forest reproductive material may only be made available on the market if it complies with:

(a) the registration requirements set out in Chapter II;

(b) the quality requirements set out in Chapter III for the relevant category;

(c) the handling requirements set out in Chapter IV;

(d) the certification and identification requirements set out in Chapter V.

CHAPTER II
Registration requirements

Article 116

Forest reproductive material derived from basic forest material registered in a national register

Forest reproductive material may be made available on the market only if it is derived from approved basic forest material registered in a national register pursuant to Article 112(1) and approved for the relevant category pursuant to Title II.

CHAPTER III
Quality requirements

Article 117

Quality requirements

1. Forest reproductive material shall be made available on the market under the categories ‘source-identified’, ‘selected’, ‘qualified’ or ‘tested’.

2. Forest reproductive material belonging to the species and artificial hybrids listed in Annex IX may not be made available on the market under the source identified category if it is has been obtained from vegetative reproduction of other forest reproductive material.

3. Forest reproductive material belonging to the artificial hybrids listed in Annex IX shall only be made available under the categories ‘selected’, ‘qualified’ or ‘tested’.

4. Forest reproductive material belonging to the species and artificial hybrids listed in Annex IX may only be made available on the market under ‘selected’ category if it has been mass propagated from seeds

5. Notwithstanding paragraphs 1 and 2, forest reproductive material belonging to the species and artificial hybrids listed in Annex IX, which consists wholly or partly of genetically modified organisms may only be made available on the market under the ‘tested’ category.

6. The types of basic forest material which shall be used for the production of the various categories of forest reproductive material belonging to the species and artificial hybrids listed in Annex IX are set out in Annex X.

Article 118

Additional requirements for certain forms of forest reproductive material

Forest reproductive material belonging to the species and artificial hybrids listed in Annex IX and referred to in Annex XI may only be made available on the market if it meets the quality requirements set out in Annex XI, in addition to those applicable pursuant to Article 117.

Article 119

Additional requirements for certain parts of plants and planting stock

The Commission shall be empowered to adopt delegated acts, in accordance with Article 140, setting out quality requirements for making available on the market specific parts of plants and planting stock of species and artificial hybrids listed in Annex IX, supplementing the requirements referred to in Articles 117 and 118. Those requirements shall take into account the development of scientific and technical knowledge.

CHAPTER IV
Handling requirements

Article 120

Lots

1. Forest reproductive material shall, during all stages of production, be kept in separated lots by reference to individual units of approval from which it derives.

2. Forest reproductive material shall be made available on the market in lots.

Article 121

Packaging of seed units

Seed units shall be made available on the market only in sealed packages. The sealing device shall be such that it will become unserviceable when the package is opened.

CHAPTER V
Certification and identification requirements

Article 122

Master certificate

1. After harvesting, a master certificate showing the reference of the register referred to in point (e) of Article 112(4) shall be issued by the competent authority for all forest reproductive material derived from approved forest basic material.

2. The master certificate shall contain the relevant information set out, as applicable, in Part A, Part B and Part C of Annex XII.

3. For subsequent vegetative reproduction in accordance with Article 117(2), a new master certificate shall be issued.

4. Where mixing takes place in accordance with Article 126(1), (2), (3) or (5), a new master certificate, or other document, identifying the previous master certificates of the material composing the mixture shall be issued.

5. The Commission shall determine, by means of implementing acts, the model of the format of the master certificate as referred to in paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(3).

Article 123

Identification of lots

1. Each lot shall remain clearly identifiable through the entire process from collection to delivery to the end user.

2. Each lot of forest reproductive material shall be identified by the following information:

   (a) the master certificate code and number;

   (b) the botanical name;

   (c) the category of forest reproductive material;

   (d) the purpose;

   (e) the type of basic forest material from which the forest reproductive material derives (seed source, stand, seed orchard, parents or family, clone or clonal mixture);

   (f) the register reference of the basic forest material or identity code of the region of provenance of the basic forest material;

   (g) whether the basic forest material, from which the forest reproductive material derives, is autochthonous or indigenous, non-autochthonous or non-indigenous, or whether its origin is unknown;

   (h) in the case of seed units, the year of ripening;

   (i) the age of planting stock, of seedlings or of cuttings;

   (j) the type of planting stock (whether undercuts, transplants or containerised);

   (k) where applicable, the fact that it is genetically modified;

   (l) where applicable, the fact that it has been vegetatively reproduced.

Article 124

Labelling

1. Each lot shall be accompanied by a label produced by the professional operator (hereinafter 'operator's label'). The operator's label shall contain, in addition to the information required under Article 123, the following information:

   (a) the master certificate number(s) issued under Article 122(1) or the reference to the other document available according to Article 122(4);

   (b) the reference number, where applicable, and the name of professional operator;

   (c) the quantity supplied;

   (d) in the case of forest reproductive material of the ‘tested’ category derived from basic forest material which is provisionally approved under Article 108(1), the words ‘provisionally approved’.

2. In the case of seeds, the operator's label shall also include the following information:

   (a) the percentage by weight of pure seed, other seed and inert matter;

   (b) the germination rate of the pure seed, or, where germination rate 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 made available on the market 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 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. The Commission shall be empowered to adopt delegated acts, in accordance with Article 140, setting out the conditions under which the operator's label shall be supplemented by another document produced by the professional operator. Those delegated acts shall determine the information items to be included in that document.

Article 125

Labelling of forest reproductive material belonging to Populus spp. species

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

Article 126

Mixtures of forest reproductive material

1. Mixtures of forest reproductive material shall be produced and made available on the market in accordance with the provisions of this Article.

2. Mixing of forest reproductive material derived from two or more units of approval within the 'source-identified' category or within the 'selected' category may take place if the units of approval are located in the same region of provenance.

3. When forest reproductive material derived from different seed sources and stands is mixed pursuant to paragraph 2 within the 'source-identified' category, the new combined lot shall be certified as 'reproductive material derived from a seed source'.

4. When forest reproductive material derived from non-autochthonous or non-indigenous basic forest material is mixed pursuant to paragraph 2 with forest reproductive material derived from basic forest material of unknown origin, the new combined lot shall be certified as being 'of unknown origin'.

5. When mixing takes place in accordance with paragraph 4, the identity code of the region of provenance may not be substituted for the register reference as provided for in Article 123(f).

6. Mixing of forest reproductive material derived from a single unit of approval from different years of ripening may take place provided that the actual years of ripening and proportion of material from each year are recorded by the professional operator.

Article 127

Amendments to Annexes V to XII

The Commission shall be empowered to adopt delegated acts, in accordance with Article 140, amending Annexes V to XII. Those amendments shall take into account the development of scientific or technical knowledge and economic data.

TITLE IV
Derogations

Article 128

More stringent requirements and prohibitions

1. The Commission may, by means of implementing acts, authorise Member States:

   (a) to adopt more stringent quality requirements than those referred to in Article 117 and 118; and

   (b) to prohibit the making available on the market with a view to seeding or planting in all or part of its territory of specified forest reproductive material.

   The prohibition referred to in point(b) may be restricted to making available on the market to the end users only.

   Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(3).

2. In order to obtain the authorisation referred to in paragraph 1(a) and (b), Member States shall submit to the Commission a request setting out:

   (a) draft provisions concerning the proposed requirements or prohibitions;

   (b) a justification on the necessity and proportionality of such requirements or prohibitions;

   (c) whether the proposed requirements or prohibitions would be permanent or for a specified period.

3. The authorisation referred to in paragraph 1 shall be granted if the following conditions are fulfilled:

   (a) the implementation of the restrictions or prohibitions referred to in paragraph 1, ensures improvement of the quality of the forest reproductive material concerned, protection of the environment or conservation of genetic resources; and

   (b) the restrictions or prohibitions referred to in paragraph 1 are necessary and proportionate to their objective.

4. The authorisation referred to in paragraph 1 shall be granted on the basis of:

   (a) evidence relating to the region of provenance or the origin of the material, and documentation showing the differences in the respective climatic and ecological data; or

   (b) known results of trials, scientific research, or the results obtained from forestry practice concerning survival and development of planting stock, including growth, in relation to morphological and physiological characteristics.

Article 129

Temporary difficulties in supply

1. In order to remove temporary difficulties in the general supply of forest reproductive material that may occur in a Member State, the competent authority of the Member State concerned may authorise the making available on the market of forest

reproductive material belonging to the species and artificial hybrids listed in Annex IX with reduced requirements, compared to the requirements of Articles 117 and, where applicable, Article 118 and Article 119.

That authorisation shall be granted, on the basis of a reasoned request submitted by the professional operator concerned, for a specific period of time.

The label of the forest reproductive material made available on the market pursuant to this paragraph shall be brown. It shall state that the forest reproductive material complies with lower quality requirements than those referred to in Articles 117 and, where applicable, Article 118 and Article 119.

Member States shall notify the Commission and the other Member States of each authorisation granted pursuant to this paragraph.

2. The Commission may, by means of implementing acts, require a Member State to repeal or amend an authorisation granted pursuant to paragraph 1, if it concludes that that authorisation is unnecessary or not proportionate to the objective of removing the temporary difficulties in the general supply of forest reproductive material. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(3).

Article 130
Seed made rapidly available on the market

In order to make seed of the current season's crop rapidly available, forest reproductive material may be made available on the market as far as to the first buyer, without the information on germination or viability being included on the operator's label pursuant to Article 124(2)(b) and (d). The information referred to in Article 124(2)(b) and (d) shall be provided by the professional operator as soon as possible.

Article 131
Exemption for small quantities

1. In the case of seed made available on the market in small quantities, the information requirements concerning germination or viability as laid down in Article 124(2)(b) and (d) shall not apply.

2. The Commission shall be empowered to adopt delegated acts, in accordance with the Article 140, setting out the maximum size of the small quantities referred to in paragraph 1 for particular categories or species of forest reproductive material to ensure that the exemption of paragraph 1 is applied in a proportionate manner.

Article 132
Emergency measures

1. Where it is evident that forest reproductive material is likely to constitute a serious risk to human, animal and plant health or 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 making available on the market of the plant reproductive material concerned, depending on the gravity of the situation. Those

measures shall be adopted by means of implementing acts in accordance with the examination procedure referred to in Article 141(3).

2. On duly justified imperative grounds of urgency to address a serious risk to human health, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 141(4).

3. Where a Member State officially informed 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, within its territory, the making available on the market of the forest reproductive material concerned, depending on the gravity of the situation. It shall immediately inform the other Member States and the Commission thereof, stating the grounds for its decision. The Commission may adopt implementing acts requiring the Member State to amend or repeal the national interim emergency measures. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(3). The Member State may maintain its national interim emergency measures until the date of application of the implementing acts referred to in this paragraph.

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 genetically modified organisms.

Article 133

Temporary experiments

1. The Commission may decide, by means of implementing acts, to organise temporary experiments in order to identify improved alternatives to any provisions set out in Articles 107, 117 and, where applicable, Article 118 and Article 119. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(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, 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 years.

Article 134

Less stringent requirements to conserve genetic resources

1. Member States may adopt requirements less stringent than those set out in Articles 107, 117 and, where applicable, Article 118 and Article 119, in the interest of conservation and sustainable use of forest genetic resources. In doing so, they shall consider the need of producing and making available on the market forest reproductive material which is naturally adapted to the local and regional conditions and threatened by genetic erosion.

   Member States shall submit to the Commission and the other Member States a reasoned notification of those measures.

2. The Commission may, by means of implementing acts, require a Member State to repeal or amend the measures referred to in paragraph 1, if it concludes that those measures are not necessary or not proportionate to the objective of conservation and sustainable use of forest genetic resources. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(3).

TITLE V
Fees

Article 135
Registration and certification fees

1. Competent authorities shall charge fees for the following actions:
   (a) registration of approved basic forest material pursuant to Article 112; and
   (b) issuance of a master certificate pursuant to Article 122.
2. The actions referred to in paragraph 1 shall only be carried out on demand submitted by the professional operator to the competent authority. The demand shall be deemed not to have been made if the fees have not been paid 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 140, setting out the specific cost items to be covered pursuant to paragraph 1(a) and (b).

Article 136
Exemptions from the payment of registration fees

1. Fees provided for in Article 135(1) shall not directly or indirectly be refunded, unless unduly collected.
2. Applicants employing fewer than 10 persons and whose annual turnover or annual balance sheet total does not exceed EUR 2 million shall be exempted from the payment of the fees provided for in Article 135(1).
3. The costs referred to in Article 135(3) shall not include those incurred for the registration of approved basic forest material and the issuance of a master certificate referred to in paragraph 2.

TITLE VI
Imports from and exports of forest reproductive material to third countries

Article 137
Imports on the basis of Union equivalence

1. Forest reproductive material may be imported from third countries only if it is established, pursuant to Article 138, that it fulfils requirements equivalent to those applicable to forest reproductive material produced, and made available on the market in the Union.

2. Where seed and planting stock are imported into the Union, the professional operator importing that forest reproductive material shall inform the respective competent authority in advance of the import.

3. Imported forest reproductive material shall be accompanied by a master certificate, or an official certificate, issued by the third country of origin, and records containing details of that material provided by the professional operator in that third country.

Article 138
Commission Decision on equivalence

1. The Commission may decide, by means of implementing acts, whether forest reproductive material of specific genera, species or categories produced in a third country, or particular areas of a third country, fulfils requirements equivalent to those applicable to forest reproductive material produced and made available on the market in the Union, on the basis of:

   (a) a thorough examination of information and data provided by the third country concerned pursuant to Article 124(1) of Regulation (EU) No …/… [*Office of Publications, please insert number of Regulation on Official Controls*]; and

   (b) where appropriate, the satisfactory outcome of a control performed in accordance with Article 119(1) of Regulation (EU) No …/… [*Office of Publications, please insert number of Regulation on Official Controls*];

   Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 141(3).

2. When adopting the decisions referred to in paragraph 1, the Commission shall consider whether the systems for approval and registration of basic forest material and subsequent production of forest reproductive material from that basic forest material applied in the third country concerned afford the same assurance as those provided for in Articles 107 and 117, and, where applicable, Article 118 and Article 119, for the 'source identified', 'selected', 'qualified' and 'tested' categories.

3. For the purpose of adopting the decisions referred to in paragraph 1, the Commission may apply the provisions of Article 71 of Regulation (EU) No …/… [*Office of Publication, please insert number of Regulation on Official Controls*] concerning the approval of pre-export controls carried out by third countries.

Article 139
Export from the Union

1. Where the export of forest reproductive material to a third country is governed by an agreement with that third country, that export shall comply with that agreement.

2. Where the export of forest reproductive material to a third country is not governed by an agreement with that country, that export shall take place in accordance with the rules of the third country into which that forest reproductive material is to be exported.

3. Where the export of forest reproductive material to a third country is neither governed by an agreement with a third country nor by the rules of the third country into which that forest reproductive material is to be exported, the requirements for production and making available on the market of forest reproductive within the Union territory, as set out in Articles 105 to 134, shall apply.

PART V
PROCEDURAL PROVISIONS

Article 140
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(3), 13(3), 14(3), 15(5), 16(2), 17(4), 18(4), 18(6), 20(4), 21(5), 23(3), 30(4), 32(1), 33(3), 34(6), 36(4), 38(4), 39(3), 44(1), 56(5), 56(6), 59(2), 64(4), 65(3), 67(2), 72(2), 74(1), 119, 124(4), 127, 131(2) and 135(4) and 138(1) shall be conferred on the Commission for an indeterminate period of time from the date of the entry into force of this Regulation.

3. The delegation of power referred to in Articles 11(3), 13(3), 14(3), 15(5), 16(2), 17(4), 18(4), 18(6), 20(4), 21(5), 23(3), 30(4), 32(1), 33(3), 34(6), 36(4), 38(4), 39(3), 44(1), 56(5), 56(6), 59(2), 64(4), 65(3), 67(2), 72(2), 74(1), 119, 124(4), 127, 131(2), 135(4) and 138(1) 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(3), 13(3), 14(3), 15(5), 16(2), 17(4), 18(4), 18(6), 20(4), 21(5), 23(3), 30(4), 32(1), 33(3), 34(6), 36(4), 38(4), 39(3), 44(1), 56(5), 56(6), 59(2), 64(4), 65(3), 67(2), 72(2), 74(1), 119, 124(4), 127, 131(2) 135(4) and 138(1) 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 141
Committee procedure

1. The Commission shall be assisted by the Standing Committee on Plants, Animals, Food and Feed established by Article 58(1) of Regulation (EC) No 178/2002 of the European Parliament and of the Council. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

   Where the opinion of the committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the committee so decides or a simple majority of committee members so request.

3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the opinion of the committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the committee so decides or a simple majority of committee members so request.

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

PART VI
FINAL PROVISIONS

Article 142
Amendment of Regulation (EC) No 2100/94

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

(1) Article 4 is replaced by the following:

'Article 4
Union Agency

1. For purposes of the implementation of this Regulation, a European Agency on Plant Varieties, hereinafter referred to as 'Agency', is hereby established.

2. The Agency shall carry out the following tasks:

   (a) to offer recommendations on variety denominations, where requested so pursuant to Article 50(2) and 78(2) of Regulation (EU) No …/… [*Office of Publications, please insert number of this Regulation*];

   (b) to promote and coordinate development of uniform technical examination of varieties, including development of protocols, carried out pursuant to Article 71 and, where applicable, the acts adopted pursuant to Article 74 of Regulation (EU) No …/… *[Office of Publications, please insert number of this Regulation*]

   (c) to carry out audits of competent authorities, including their premises and organisation of work, carrying out technical examinations, as referred to in Article 72 of the PRM Regulation;

   (d) to offer, and participate in offering, training in its area of mission;

   (e) to provide technical support to the Commission in the areas within its mission;

   (f) to commission studies necessary for the accomplishment of its mission;

   (g) 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;

   (j) to establish, publish and update a database on reference collections of varieties.'

3. The Agency shall also manage and support the Union variety register, established in accordance with Article 52 of Regulation (EU) No …/… [*Office of Publications, please insert number of this Regulation*]. It shall implement the procedure for the registration of varieties in the Union variety register in

accordance with Chapter V of Title IV of Regulation (EU) No …/… [*Office of Publications, please insert number of this Regulation*]'.

(2) The following Article 4a is inserted:

'Article 4a
References to the Community Plant Variety Office (Office)

References made in this Regulation to the Office and references made in Union legislation to the Community Plant Variety Office shall be construed as references to the European Agency on Plant Varieties established by Article 4.'

Article 143
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 those 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.

Article 144
Repeals

1. The acts referred to in Annex XIII 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 XIV.

Article 145
Transitional Provisions

1. Member States shall, by [*Office of Publications, please insert date of application of this Regulation*], review the measures adopted pursuant to Article 5 of Directive 66/401/EEC, Article 5 of Directive 66/402/EEC, Article 4(1) of Directive 68/193/EEC, Article 7 of Directive 2002/54/EC, Article 24 of Directive 2002/55/EC, Article 5 of 2002/56/EC and Article 7 of 2002/57/EC, and take one of the following actions:

   (a) repeal those measures; or

   (b) amend those measures to comply with the applicable Union legislation on the plant reproductive material concerned.

2. Member States shall notify to the Commission and the other Member States:

   (a) all measures adopted pursuant to the Directives referred to in paragraph 1 by [Office of Publications, please insert date of application of this Regulation]; and

   (b) any action taken pursuant to points (a) or (b) of paragraph (1).

Article 146

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 *[Office of Publications please insert date counting 36 months from the entry into force]*.

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*

ANNEX I

GENERA AND SPECIES AS REFERRED TO IN ARTICLE 11

Abies alba Mill.

Abies cephalonica Loudon

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 hypogaea L.

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

Asparagus officinalis L.

Avena nuda L.

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

Avena strigosa Schreb.

Beta vulgaris L.

Betula pendula Roth.

Betula pubescens Ehrh.

Brassica juncea (L.) Czern.

Brassica napus L.

Brassica nigra (L.) W.D.J. Koch

Brassica oleracea L.

Brassica rapa L.

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 Mill. (rootstocks)

Cedrus atlantica (Endl) Manetti ex Carr.

Cedrus libani A. Richard

Cichorium endivia L.

Cichorium intybus L.

Citrullus lanatus (Thunb.) Matsum. & Nakai

Citrus L.

Corylus avellana L.

Corylus L. (rootstocks)

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 Schreb.

Festuca filiformis Pourr.

Festuca ovina L.

Festuca pratensis Huds.

Festuca rubra L.

Festuca trachyphylla (Hack.) Krajina

xFestulolium Asch. et Graebn.

Ficus carica L.

Foeniculum vulgare Mill.

Fortunella Swingle

Fragaria L.

Fraxinus angustifolia Vahl.

Fraxinus excelsior L.

Galega orientalis Lam.

Glycine max (L.) Merrill

Gossypium L.

Hedysarum coronarium L.

Helianthus annuus L.

Hordeum vulgare L.

Juglans regia L.

Juglans L. (rootstocks)

Lactuca sativa L.

Larix decidua Mill.

Larix kaempferi (Lamb.) 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.

Malus domestica Borkh.

Malus Mill. (rootstocks)

Medicago lupulina L.

Medicago sativa L.

Medicago × *varia* T. Martyn

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. (formerly *Phleum bertolonii* DC.*)*

Phleum pratense L.

Picea abies (L.) H. Karst.

Picea sitchensis (Bong.) Carr.

Pinus brutia Ten.

Pinus canariensis C. Smith

Pinus cembra L.

Pinus contorta Douglas ex Loud.

Pinus halepensis Mill.

Pinus leucodermis Antoine

Pinus nigra Arnold

Pinus pinaster Aiton

Pinus pinea L.

Pinus radiata D. Don

Pinus sylvestris L.

Pistacia vera L.

Pistacia L. (rootstocks)

Pisum sativum L.

Poa annua L.

Poa nemoralis L.

Poa palustris L.

Poa pratensis L.

Poa trivialis L.

Poncirus Raf.

Populus spp. and artificial hybrids between those species

Prunus amygdalus Batsch

Prunus armeniaca L.

Prunus avium (L.) L.

Prunus cerasus L.

Prunus domestica L.

Prunus persica (L.) Batsch

Prunus salicina Lindley

Prunus L. (rootstocks)

Pseudotsuga menziesii (Mirb.) Franco

Pyrus communis L.

Pyrus L. (rootstocks)

Quercus cerris L.

Quercus ilex L.

Quercus petraea (Matt.) Liebl.

Quercus pubescens Willd.

Quercus robur L.

Quercus rubra L.

Quercus suber L.

Raphanus sativus L.

Rheum rhabarbarum L.

Ribes L.

Robinia pseudoacacia L.

Rubus L.

Scorzonera hispanica L.

Secale cereale L.

Sicyos angulatus L. (rootstocks)

Sinapis alba L.

Solanum lycopersicum Lam. (formerly *Lycopersicon esculentum* Mill.)

Solanum lycopersicum Lam.x Solanum spp. (rootstocks)

Solanum melongena L.

Solanum tuberosum L.

Sorghum bicolor (L.) Moench

Sorghum bicolor (L.) Moench × *Sorghum sudanense* (Piper) Stapf.

Sorghum sudanense (Piper) Stapf

Spinacia oleracea L.

Tilia cordata Mill.

Tilia platyphyllos Scop.

Trifolium alexandrinum L.

Trifolium hybridum L.

Trifolium incarnatum L.

Trifolium pratense L.

Trifolium repens L.

Trifolium resupinatum L.

Trigonella foenum-graecum L.

Trisetum flavescens (L.) P. Beauv.

xTriticosecale Wittm. ex A. Camus

Triticum aestivum L.

Triticum durum Desf.

Triticum spelta L.

Vaccinium L.

Valerianella locusta (L.) Laterr.

Vicia faba L.

Vicia pannonica Crantz

Vicia sativa L.

Vicia villosa Roth.

Vitis L.

Zea mays L.

ANNEX II

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

PART A

REQUIREMENTS FOR THE PRODUCTION OF PLANT REPRODUCTIVE MATERIAL AS REFERRED TO IN ARTICLE 16(2)

The following requirements for fields and crops shall apply, depending on the characteristics of each genus or species:

1. Sowing or planting:

   (a) the identity of the plant reproductive material, including where applicable mother plants, shall be determined to ensure the traceability of the plant reproductive material. The label of the material or the records on the mother plant shall be kept.

   (b) the material shall be planted and /or sowed in a way that there is:

      (i) sufficient distance from pollen sources of the same species and/or the same varieties, according to isolation rules per botanical characteristics and breeding techniques, to ensure protection from any undesirable foreign pollination and to avoid cross pollination with other crops;

      (ii) an appropriate source and level of pollination to ensure the subsequent reproduction;

      (iii) an appropriate rotation (previous cropping and duration between cropping period with the same species) to avoid impurities;

   (c) appropriate attention shall be paid to the machines and any equipment used to ensure absence of weed or other species which are difficult to distinguish at seed level in laboratory tests;

   (d) the material shall be sown and planted in a manner to ensure that the presence of Union quality pests or their vectors, as listed in an implementing act adopted in accordance with Article 37(2) of Regulation EU (No) …/… (*Office of Publications, please insert number of Regulation on protective measures against pests of plants*), complies with the provisions of that act.

2. Cultivation:

   (a) Off-types shall be absent to ensure varietal identity and purity, and efficient production. Where this is not possible due to the characteristics of the plant reproductive material concerned, they shall be present up to the lowest possible level.

   In case of presence of off-types or other plant species, appropriate treatment and/or elimination shall be applied to ensure varietal identity and purity.

   (b) Mother plants shall be treated or excluded as a source of reproductive material in case of positive test results or visual symptoms of pests or defects.

   (c) Harvesting:

The plant reproductive material shall be harvested in bulk or as individual plants, as appropriate to ensure the identity and purity of the harvested material.

(d) Maintenance:

Plant reproductive material, including where applicable mother plants, shall be maintained in a way to ensure the identity of the variety. That maintenance shall be based on the official description or the officially recognised description of the variety.

(e) Union quality pests

The plant reproductive material shall be cultivated in a manner to ensure that the presence of Union quality pests, as listed pursuant to the implementing act referred to in Article 37(2) of Regulation (EU) No …/… (*Office of Publications, please insert number of Regulation on protective measures against pests of plants*), in that plant reproductive material complies with the provisions of that act.

(f) Where appropriate, the cultivation of plant reproductive material shall take place separately from the cultivation of material belonging to the same genera or species for food or feed purposes, to ensure health of the material concerned.

(g) Where applicable, micro-propagation may also be used for the reproduction of plant reproductive material.

PART B

REQUIREMENTS FOR THE QUALITY OF PLANT REPRODUCTIVE MATERIAL REFERRED TO IN ARTICLE 16(2)

Plant reproductive material shall fulfil one or more of the following quality requirements, depending on the characteristics of each genus or species:

(a) it shall have minimum germination to allow an appropriate number of plant per square meter (m^2) after sowing, and consequently to secure the yield and quality of the production;

(b) it shall have a maximum content of hard seed to allow an appropriate number of plant per square metre (m^2);

(c) it shall have minimum purity to secure the highest level of varietal identity;

(d) it shall have maximum moisture content to ensure the preservation of the material during processing, storage and making available on the market;

(e) it shall have maximum content of plant reproductive material of other genera or species to ensure the lowest presence of undesirable plants in the lot;

(f) it shall have minimum vigour, defined dimension, and specific grading, to ensure appropriateness of the material and sufficient homogeneity of the lot for sowing or planting;

(g) it shall have maximum presence of earth or extraneous matter to prevent fraudulent practices and technical impurities;

(h) it shall be free from specific defects and damages to ensure quality and health of the material;

(i) the presence of Union quality pests, as listed pursuant to the implementing act referred to in Article 37(2) of Regulation (EU) No […] on protective measures against pests, in plant reproductive material shall comply with the provisions of that act.

PART C

REQUIREMENTS FOR THE CERTIFICATION OF PLANT REPRODUCTIVE MATERIAL AS INDICATED IN ARTICLE 20(1)

A. Frequency and methods of field inspections

The frequency of inspections and the relevant growth stage(s) of the plant reproductive material for inspections shall ensure efficient observations and inspections.

The methods for inspections shall be such ensure the reliability of the observations.

Where applicable, the mother plants shall be inspected, at least by visual inspection, at the most appropriate period(s) of the year to check the presence of pests or their vectors

The mother plants shall be maintained in all phases of cultivation under conditions to enable the production of plant reproductive material and permit the verification of the identity based on the description of the variety.

Inspections shall concern, where appropriate, compliance with the rules set out pursuant Article 37(2) of Regulation (EU) No …/… [*Office of Publications, please insert number of Regulation on protective measures against plants*] concerning the presence of quality pests on the plant reproductive material concerned. The quality of soil, substrates, mother plants and the immediate environment shall be checked to avoid presence of pests or their vectors.

B. Sampling and testing

1. The sampling method shall fulfil the following requirements:

   (a) the sample to be drawn from a lot shall have the appropriate minimum weight for determining content of certain weeds, to ensure representative sampling and suitable size for the analysis of the material to assess whether the quality requirements have been fulfilled.

   (b) the intensity of sampling, the equipment of sampling, and methods to be used, shall ensure that reliable samples are collected for testing.

2. Testing shall be carried out in accordance with methods, equipment and growing media established per species, as well as per reference collection for purity analysis, to ensure that the quality requirements have been fulfilled. Testing shall include, where appropriate, retesting of germination rate to ensure the adequate germination after a certain period or mixing of plant reproductive material.

3. Inspections shall concern, where appropriate, compliance with the rules set out pursuant Article 37(2) of Regulation (EU) No …/… [Office of Publications, please insert number of Regulation on protective measures against plants] concerning the presence of quality pests on the plant reproductive material concerned. The quality of soil, substrates, mother plans and the immediate environment shall be checked to avoid presence of pests or their vectors.

PART D

ELEMENTS FOR THE ADOPTION OF THE REQUIREMENTS FOR THE PRODUCTION AND QUALITY OF PLANT REPRODUCTIVE MATERIAL REFERRED TO IN ARTICLE 16(2), AND FOR THE CERTIFICATION OF PLANT REPRODUCTIVE MATERIAL AS REFERRED TO IN ARTICLE 20(1)

The production and quality requirements referred to in Parts A and B, and the certification schemes referred to in Part C, may be laid down per one or more of the following elements:

(a) genera, species, categories, and sub-divisions inside the category, including generations;

(b) the types of variety or plant reproductive material (heterogeneous material or niche market material), including intraspecific or interspecific hybrids;

(c) the specific uses of the genera, species, or types of plant reproductive material concerned;

(d) type of reproduction.

ANNEX III

PART A

CONTENT OF OFFICIAL LABEL AND OPERATOR'S LABEL AS REFERRED TO IN ARTICLE 21(1)

The official label and operator's label shall contain the following:

(a) the botanical name, or names in case of mixture, of the plant species concerned, in roman characters;

(b) the common name, or names in case of mixture, of the plant species concerned in one of the official Union languages;

(c) the two-letter code indicated in norm ISO 3166-1 alpha 2[22] for the Member State and, where appropriate, the name or acronym of the respective competent authority(ies) with which the professional operator is registered;

(d) the registration number of the registered professional operator or, in absence of such number, the name and address of the operator;

(e) the lot number of the plant reproductive material concerned, and, where relevant, a reference to a unique traceability data carrier, such as bar code, hologram or chip;

(f) the indication of the denomination of the variety or variety denominations in case of mixture components, when making available on the market in reference to varieties;

(g) the indication 'EU rules and standards';

(h) references to the country of production or countries in case of mixture, with the two letter code referred to in point (c);

(i) references to declared number of seeds, rootstocks or other units of reproductive material, or, where applicable, the net or gross weight;

(j) indications concerning category of plant reproductive material and, where appropriate, sub-divisions of categories;

(k) references to month and year of labelling or references to month and year of last sampling;

(l) the indication, where appropriate, that the plant reproductive material belongs to a variety with officially recognised description only, and indication of the region of origin of that variety;

(m) the indication, where appropriate, that the respective plant reproductive material is a clone or rootstock;

(n) the indication, where applicable, that the plant reproductive material consists of, or contains, genetically modified organisms.

[22] ISO 3166-1:2006, Codes for the representation of names of countries and their subdivisions – Part 1: Country codes. International Organization for Standardization, Geneva.

PART B

INFORMATION TO BE CONTAINED IN THE LABEL FOR GENERA OR SPECIES OTHER THAN THE SPECIES LISTED IN ANNEX I, AS REFERRED TO IN ARTICLE 47

The label shall contain the following:

(a) the species, indicated with the botanical name and in roman characters;

(b) the common name in one of the official languages of the Union;

(c) the denomination of the variety, if the plant reproductive material is respectively made available on the market with reference to a variety;

(d) the name and address of the professional operator, and its registration number;

(e) the reference number of the lot given by the operator;

(f) declared number of seeds, rootstocks or other units of reproductive material, or, where applicable, the net or gross weight;

(g) the indication 'EU quality';

(h) the date of the issuance of the label;

(i) in the case of import from third countries, indication of the country of harvesting, with the two letter code as referred to in point (h) of Part A;

(j) the place of production;

(k) where applicable, the indication that the respective plant reproductive material belongs to a clone or rootstock, and the denomination of the variety to which that clone or rootstock may belong to;

(l) where plant reproductive material is produced and made available on the market together with forest reproductive material, the respective label of plant reproductive material shall indicate 'not for forestry purposes'.

ANNEX IV

PART A

CRITERIA FOR GENERA OR SPECIES WITH SATISFACTORY VALUE FOR CULTIVATION AND/OR USE

The requirements set out in Article 58(2) on satisfactory value for cultivation and/or use shall apply to genera and species which comply with one or more of the following criteria:

(a) they are of vital importance for food and feed security;

(b) they are of vital importance for food processing, feed processing or industrial processing;

(c) they are of vital importance for resilience and low-input agriculture, including organic agricultural production.

PART B

CRITERIA FOR GENERA OR SPECIES WITH SUSTAINABLE VALUE FOR CULTIVATION AND/OR USE

The requirements set out Article 59(1) on sustainable value for cultivation and/or use shall apply to genera and species which comply with one or more of the following criteria:

(a) they are substantially susceptible to pests;

(b) they are subject to particular requirements concerning efficiency of resources;

(c) they are susceptible to the presence of undesirable substances;

(d) they are susceptible to adaptation to diverse agro-climatic conditions.

ANNEX V

REQUIREMENTS FOR THE APPROVAL OF BASIC MATERIAL INTENDED FOR THE PRODUCTION OF FOREST 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. A formal inspection must be made where the material is destined for a specific forestry purpose.

2. 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 by the professional operator concerned to the competent authority. It must be stated whether the basic material is:

   (a) autochthonous or non-autochthonous or the origin is unknown; or

   (b) indigenous or non-indigenous or the origin is unknown. In the case of non-autochthonous or non-indigenous basic material the origin must be stated if known.

ANNEX VI

REQUIREMENTS FOR THE APPROVAL OF BASIC MATERIAL INTENDED FOR THE PRODUCTION OF FOREST 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 importance shall be given to requirements 1- 9, depending on the specific purpose. The criteria used for the selection of the forest reproductive material and the purpose of that material shall be indicated in the National Register.

1. **Origin:** It must be determined either by historical evidence or other appropriate means whether the stand is autochthonous/indigenous, non-autochthonous/non-indigenous or the origin is unknown and for non-autochthonous/ non-indigenous basic material the origin must be stated if known.

2. **Isolation:** Stands must be situated at a sufficient distance from poor stands, including non-autochthonous/nonindigenous or of unknown origin, of the same species or from stands of a related species or variety which can form hybrids with the species in question.

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. Where necessary, inferior trees shall be removed.

6. **Adaptedness:** Adaptation to the ecological conditions prevailing in the Region of Provenance must be evident.

7. **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.

8. **Wood Quality:** The quality of the wood shall be taken into account.

9. **Form or Growth Habit:** Trees in stands must show particularly good morphological features, including straightness and circularity of stem, favourable branching habit, small size of branches and good natural pruning. In addition, the proportion of forked trees and those showing spiral grain must be low.

ANNEX VII

REQUIREMENTS FOR THE APPROVAL OF BASIC MATERIAL INTENDED FOR THE PRODUCTION OF FOREST 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 competent authority;

(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 competent authority 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 thinning and registered with the competent authority;

(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 in accordance with 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 competent authority;

(c) The identity, number and proportion of the parents in a mixture must be approved and registered with the competent authority;

(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 competent authority;

(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 in accordance with the requirements 4, 6, 7, 8, 9 and 10 of Annex III.

4. Clonal Mixtures

(a) Clonal mixture shall meet the requirements in points 3(a), 3(b) and 3(c);

(b) The identity, number and proportion of the component clones of a mixture, and the selection method and foundation stock must be approved and registered with the competent authority. Each mixture must contain sufficient genetic diversity.

ANNEX VIII

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

1. REQUIREMENTS FOR ALL TESTS

(a) General

The basic material must satisfy the applicable requirements in Annex V or VI.

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 forest 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 competent authority. Age of the material and results at the time of the evaluation must be recorded with the competent authority.

(d) Setting up the tests

(i) Each sample of reproductive material shall be raised, planted and managed in an identical way as far as the types of plant material permit;

(ii) Each experiment must be established in a valid statistical design with a sufficient number of trees in order that the individual characteristics of each component under examination can be evaluated.

(e) Analysis and validity of results

(i) The data from experiments must be analysed using internationally recognised statistical methods and the results presented for each character examined;

(ii) The methodology used for the test and the detailed results obtained shall be made freely available;

(iii) A statement of the suggested region of probable adaptation within the country in which the test was carried out and characteristics which might limit its usefulness must also be given;

(iv) If during tests it is proved that the reproductive material does not possess at least the characteristics of the basic material, 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 competent authority.

(d) Interpretation

(i) The estimated superiority of the reproductive material shall be calculated against a reference population for a character or set of characters;

(ii) It shall be stated whether the estimated genetic value of the reproductive material is inferior to the reference population for any important character.

3. REQUIREMENTS FOR COMPARATIVE TESTING OF REPRODUCTIVE MATERIAL

(a) Sampling of the reproductive material

(i) The sample of the reproductive material for comparative testing must be truly representative of the reproductive material derived from the basic material to be approved;

(ii) Sexually produced reproductive material for comparative testing shall be:

harvested in years of good flowering and good fruit/seed production; artificial pollination may be utilised,

harvested by methods that ensure that the samples obtained are representative.

(b) Standards

(i) The performance of standards used for comparative purposes in the tests shall if possible have been known over a sufficiently long period in the region in which the test is to be carried out. The standards represent material that has been shown useful for forestry at the time that the test starts, and in ecological conditions for which it is proposed to certify the material. They shall come as far as possible from stands selected according to the criteria in Annex III or from basic material officially approved for production of tested material;

(ii) For comparative testing of artificial hybrids, both parent species must, if possible, be included among the standards;

(iii) Whenever possible several standards are to be used. When necessary and justified, standards may be replaced by the most suitable of the material under test or the mean of the components of the test;

(iv) The same standards will be used in all tests over as wide a range of site conditions as possible.

(c) Interpretation

(i) A statistically significant superiority as compared with the standards must be demonstrated for at least one important character;

(ii) It will be clearly reported if there are any characters of economic or environmental importance which show significantly inferior results to the standards and their effects must be compensated for by favourable characters.

4. CONDITIONAL APPROVAL

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

5. EARLY TESTS

Nursery, greenhouse and laboratory tests may be accepted by the competent authority 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 forest field tests. Other characters to be tested must meet the requirements set out in paragraph 3.

ANNEX IX

LIST OF TREE SPECIES AND ARTIFICIAL HYBRIDS

Abies alba Mill.

Abies cephalonica Loud.

Abies grandis Lindl.

Abies pinsapo Boiss.

Acer platanoides L.

Acer pseudoplatanus L.

Alnus glutinosa Gaertn.

Alnus incana Moench.

Betula pendula Roth.

Betula pubescens Ehrh.

Carpinus betulus L.

Castanea sativa Mill.

Cedrus atlantica Carr.

Cedrus libani A. Richard

Fagus sylvatica L.

Fraxinus angustifolia Vahl.

Fraxinus excelsior L.

Larix decidua Mill.

Larix x eurolepis Henry

Larix kaempferi Carr.

Larix sibirica Ledeb.

Picea abies Karst.

Picea sitchensis Carr.

Pinus brutia Ten.

Pinus canariensis C. Smith

Pinus cembra L.

Pinus contorta Loud.

Pinus halepensis Mill.

Pinus leucodermis Antoine

Pinus nigra Arnold

Pinus pinaster Ait.

Pinus pinea L.

Pinus radiata D. Don

Pinus sylvestris L.

Populus spp. and artificial hybrids between those species

Prunus avium L.

Pseudotsuga menziesii Franco

Quercus cerris L.

Quercus ilex L.

Quercus petraea Liebl.

Quercus pubescens Willd.

Quercus robur L.

Quercus rubra L.

Quercus suber L.

Robinia pseudoacacia L.

Tilia cordata Mill.

Tilia platyphyllos Scop.

ANNEX X

CATEGORIES UNDER WHICH REPRODUCTIVE MATERIAL FROM THE DIFFERENT TYPES OF BASIC MATERIAL MAY BE MADE AVAILABLE ON THE MARKET

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

ANNEX XI

PART A
Requirements to be met by fruit and seed lots of the species listed in Annex IX

1. Fruit and seed lots of the species listed in Annex IX 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 IX, excluding artificial hybrids, the species purity of the fruit or seed lot shall be stated if it does not reach 99 %.

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

Parts of plants of the species and artificial hybrids listed in Annex IX 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, within the meaning of Part B, 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;

      (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:

      (i) their wood is more than three years old;

      (ii) they have less than five well formed buds;

      (iii) they are affected by necroses;

      (iv) they show signs of desiccation, overheating, mould or decay;

      (v) they have injuries other than pruning cuts;

      (vi) they have multiple stems;

(vii) they have excessive stem curvature.

b. Size classes for sets

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

PART D

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

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 or decay;

   (f) the plants are not well balanced.

2. Size of the plants

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

3. Size of the container, where used

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

ANNEX XII

PART A

Information to be included in the master certificate of identity for reproductive material derived from seed sources and stands

1. Title with the text 'Issued in accordance with Regulation EU (No) …/… [*Office of Publications, please insert number of this Regulation*]'
2. Member State
3. Number of certificate and code of Member State
4. The following indication: 'It is certified that the forest reproductive material described below has been produced: (a) in accordance with Regulation EU (No) …/… [*Office of Publications, please insert number of this Regulation*]'; (b) under transitional arrangements.'
5. Botanical name
6. Nature of forest reproductive material (seed unit, part of plants or planting stock)
7. Category of forest reproductive material (source identified, selected or tested)
8. Type of basic material (seed source or stand)
9. Purpose
10. National register reference or identity of basic material in national register
11. The indication 'autochthonous', 'non-autochthnonous', 'indigenous', 'non-indigenous' or 'unknown'
12. Origin of basic material (for non-autochthonous/non-indigenous material, if known)
13. Member State and region of provenance of basic material
14. Altitude or altitudinal range of site of basic material
15. Year in which seeds ripened
16. Quantity of forest reproductive material
17. Indication whether the material covered by this certificate is the result of a subdivision of a larger lot covered by a previous Union certificate, and, where applicable, indication of previous certificate number or quantity in initial lot
18. Length of time in nursery
19. Indication on whether there has been subsequent vegetative reproduction of material derived from seed
20. Other relevant information
21. Name and address of professional operator
22. Name and address of competent authority
23. Stamp of competent authority and date

PART B

Information to be included in the master certificate of identity for reproductive material derived from seed orchards or parents of family(ies)

1. Title with the text 'Issued in accordance with Regulation EU (No) …/… [*Office of Publications, please insert number of this Regulation*]
2. Member State
3. Number of certificate and code of Member State
4. The following indication: 'It is certified that the forest reproductive material described below has been produced: (a) in accordance with Regulation EU (No) …/… [Office of Publications, please insert number of this Regulation]'; (b) under transitional arrangements."
5. Botanical name
6. Nature of basic material (as mentioned in the catalogue)
7. Nature of forest reproductive material (seed unit, part of parts or planting stock)
8. Category of forest reproductive material (qualified or tested)
9. Type of basic material (seed orchard or parents of family(ies)
10. Purpose
11. National register reference or identity of basic material in the national register
12. Where appropriate, indication 'autochthonous', 'non-autochthonous', 'indigenous', 'non-indigenous' or 'unknown'
13. Origin of basic material (for non-autochthonous/non-indigenous material, if known)
14. Member State and region of provenance or location of basic material
15. Indication whether seed is derived from open pollination, supplemental pollination or controlled pollination
16. Year in which seed ripened
17. Quantity of forest reproductive material
18. Indication whether the material covered by the certificate is the result of a subdivision of a larger lot covered by a previous Union certificate (with reference to previous certificate number and quantity in initial lot)
19. Length of time in nursery
20. Number of components represented, including indication of families and clones)
21. Altitude or altitudinal range of site of basic material
22. Indication whether genetic modification has been used in the production of the basic material
23. For forest reproductive material derived from parents or family(ies), indication on crossing design and range of percentage composition of component families
24. Indication whether there has been subsequent vegetative reproduction of material derived from seed, including indication of method of reproduction and number of cycles of reproduction
25. Indication 'other relevant information'

26. Name and address of the professional operator
27. Name and address of the competent authority
28. Stamp of competent authority and date
29. Name and signature of responsible officer

PART C

Information to be included in the master certificate of identity for reproductive material derived from clones and clonal mixtures

1. Title with the text 'Issued in accordance with Regulation EU (No) …/… [*Office of Publications, please insert number of this Regulation*]
2. Member State
3. Number of certificate and code of Member State
4. The following indication: 'It is certified that the forest reproductive material described below has been produced: (a) in accordance with Regulation EU (No) …/… [Office of Publications, please insert number of this Regulation]'; (b) under transitional arrangements.'
5. Botanical name
6. Name of clone or clonal mixture
7. Nature of forest reproductive material (part of plants or planting stock)
8. Category of forest reproductive material (qualified or tested)
9. Type of basic material (clones or clonal mixtures)
10. Purpose
11. National register reference or identity of basic material in the national register
12. Where appropriate, the indication 'autochthonous', 'non-autochthonous', 'indigenous', 'non-indigenous' or 'unknown'
13. Origin of basic material (for non-autochthonous/non-indigenous material, if known)
14. Member State and region of provenance or location of basic material
15. Indication whether the seed derives from open pollination, supplemental pollination or controlled pollination
16. Year in which seeds ripened
17. Quantity of forest reproductive material
18. Indication whether the material covered by this certificate is the result of a subdivision of a larger lot covered by a previous Union certificate, and, where applicable, indication of previous certificate number or quantity in initial lot
19. Length of time in nursery
20. Altitude or altitudinal range of site of basic material
21. Indication whether genetic modification has been used in the production of the basic material
22. Where forest reproductive material derives from parents of family(ies), indication of crossing design and range of percentage composition of component families
23. Indication on whether there has been subsequent vegetative reproduction of material derived from seed
24. Indication 'Other relevant information'
25. Name and address of professional operator

26. Name and address of competent authority

27. Stamp of competent authority and date

ANNEX XIII

REPEALED ACTS AS REFERRED TO IN ARTICLE 144

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

ANNEX XIV
CORRELATION TABLES

1. Council Directive 66/401/EEC

Council Directive 66/401/EEC	This Regulation	Regulation (EU) No …/…. (*Office of Publication, please insert number of Regulation on Official Controls*)	Regulation (EU) No …/… (*Office of Publication, please insert number of Regulation on protective measures against pests of plants*)
Article 1	Article 1	—	—
Article 1a	Article 3, Article 2	—	—
Article 2(1), point A	Article 11(1), (2)	—	—
Article 2(1), points B, C, D, E	Article 16(2), Article 20(2)	—	—
Article 2(1), points F, G	Article 18(5)	—	—
Article 2(1a)	Article 11(3)	—	—
Article 2(1b)	—	—	—
Article 2(1d)	—	—	—
Article 2(2)	—	—	—
Article 2(3), (4)	Article 20(2), Article 24	—	—
Article 3(1)	Article 12(1)	—	—
Article 3(1a)	—		
Article 3(2)	Article 12(2)		
Article 3(3)	Article 12(3)		
Article 3(4)	Article 16(3)		
Article 3a	Article 12(1)		
Article 4(a)	Article 38	—	—
Article 4(b)	Article 39	—	—
Article 4a(1), first subparagraph	Article 2	—	—
Article 4a(1), second subparagraph	Article 4	—	—
Article 4a(2)	—	—	—
Article 4a(3)	—	—	—
Article 5	Article 40	—	—
Article 5a	Article 20(2)	—	—
Article 6	Article 75	—	—
Article 7	Article 20(2), Article 24	—	—
Article 8(1)	Article 17(1)	—	—
Article 8(2)	Article 17(4), Article 18(5)	—	—
Article 9	Article 18	—	—

Article 10	Article 19, Article 21(1)	—	—
Article 10a	Article 18(5)	—	—
Article 10b	Article 18(5)	—	—
Article 10c	Article 18(5)	—	—
Article 10d	Article 18(4)	—	—
Article 11	Article 19(4), (5)	—	—
Article 11a	Article 21(1)	—	—
Article 12	Article 21(6)	—	—
Article 13	Article 32, Article 33	—	—
Article 13a	Article 42	—	—
Article 14(1)	Article 4	—	—
Article 14(1a)	Article 40	—	—
Article 14a	Article 20(2), Article 21	—	—
Article 15	Article 38	—	—
Article 16	Article 44	—	—
Article 17	Article 35, Article 37	—	—
Article 18	Article 46	—	—
Article 19(1)	—	Article 8	—
Article 19(2)	—	—	—
Article 20	—	Article 93	—
Article 21	Article 141	—	—
Article 21a	Article 16(2)		
Article 22	Article 16(2), Article 20(2)	—	—
Article 23	Article 12(4), point (a)	—	—
Article 23a	Article 145(1), (2)	—	—
Article 24	—	—	—
	—	—	—

2. Council Directive 66/402/EEC

Council Directive 66/402/EEC	This Regulation	Regulation (EU) No …/…. (*Office of Publication, please insert number of Regulation on Official Controls*)	Regulation (EU) No …/… (*Office of Publication, please insert number of Regulation on protective measures against pests of plants*)
Article 1	Article 1	—	—
Article 1a	Article 3, Article 2	—	—
Article 2(1), point A	Article 11(1), (2)	—	—

Article 2(1), point B	Article 10(1)	—	—
Article 2(1), points C, Ca, D, E, F, G, H	Article 16(2), Article 20(2) Article 11(3)	— —	— —
Article 2(1a)	Article 16(2), Article 20(2)	—	—
Article 2(1b)	—	—	—
Article 2(1c)	—	—	—
Article 2(1e)	Article 16(2), Article 20(2)	—	—
Article 2(2)	Article 20(2), Article 24	—	—
Article 2(3), (4)	Article 12(1), (2)	—	—
Article 3(1)	Article 16(2)	—	—
Article 3(2)	Article 20(2)	—	—
Article 3(3)	Article 12(1)		
Article 3a	Article 38	—	—
Article 4(1), first subparagraph (a)	Article 39	—	—
Article 4(1), first subparagraph (b)	Article 39		
Article 4(1), second subparagraph		Article 20(c)	
Article 4(4)	Article 2	—	—
Article 4a(1), first subparagraph	Article 4	—	—
Article 4a(1), second subparagraph	—	—	—
Article 4a(2)	—	—	—
Article 4a(3)	Article 40	—	—
Article 5	Article 20(2)	—	—
Article 5a	Article 75	—	—
Article 6	Article 20(2), Article 24	—	—
Article 7	Article 17(1)	—	—
Article 8(1)	Article 17(4), Article 18(5)	—	—
Article 8(2)	Article 18	—	—
Article 9	Article 19, Article 21(1)	—	—
Article 10	Article 18(5)	—	—
Article 10a	Article 19(4), (5)	—	—
Article 11	Article 21(1)	—	—
Article 11a	Article 21(6)	—	—
Article 12	Article 32, Article 33	—	—
Article 13	Article 42	—	—
Article 13a	Article 4	—	—
Article 14(1)	Article 40	—	—
Article 14(1a)	Article 20(2), Article 21	—	—
Article 14a	Article 38	—	—
Article 15	Article 44	—	—
Article 16	Article 35, Article 37	—	—

Article 17	Article 46	—	—
Article 18	—	Article 8	—
Article 19(1)	—	—	—
Article 19(2)	—	Article 93	—
Article 20	Article 141	—	—
Article 21	Article 16(2), Article 20(2)	—	—
Article 21a, Article 21b	Article 12(4), point (a)	—	—
Article 22	Article 57	—	—
Article 22a	Article 145(1), (2)	—	—
Article 23	—	—	—
Article 23a	—	—	—
Article 24			

3. Council Directive 68/193/EEC

Council Directive 68/193/EEC	This Regulation	Regulation (EU) No …/…. (*Office of Publication, please insert number of Regulation on Official Controls*)	Regulation (EU) No …/… (*Office of Publication, please insert number of Regulation on protective measures against pests of plants*)
Article 1	Article 1	—	—
Article 2(1)	Article 3	—	—
Article 2(2)	—	—	—
Article 3(1)	Article 12(1), (2)	—	—
Article 3(2)	—	—	—
Article 3(3), first subparagraph, points (a) and (b) and second subparagraph	Article 12(1), (2)	—	—
Article 3(3), first subparagraph, point (c)	Article 12(4), point (a)		
Article 3(3), third subparagraph	Article 4	—	—
Article 3(4)	Article 16(2)	—	—
Article 3(5)	Article 12(1), (2)	—	—
Article 4	Article 40	—	—
Article 5(1)	Article 51	—	—
Article 5(2)	Article 14(1)	—	—
Article 5(3)	Article 15(1), Article 51	—	—
Article 5a	Article 56(2), point (a)	—	—
Article 5b(1)	Article 60	—	—
Article 5b(2)	Article 61	—	—

Article 5b(3)	Article 62	—	—
Article 5ba	Article 4, Article 56(1), point (b)	—	—
Article 5c	Article 4	—	—
Article 5d(1), (2)	Article 71, Article 74	—	—
Article 5d(3)	Article 64(2)	—	—
Article 5e(1)	Article 85(1)	—	—
Article 5e(2), first sentence	Article 103(3)	—	—
Article 5e(2), second sentence	Article 52	—	—
Article 5f	Article 53(1), point (h)	—	—
Article 5g	Article 86	—	—
Article 7	Article 17(1)	—	—
Article 8(1)	Article 18(1), (2), (3), (4)	—	—
Article 8(2)	Article 18(5)	—	—
Article 9	Article 18	—	—
Article 10(1)	Article 19(1), Article 22	—	—
Article 10(2)	Article 17(2), Article 29(2)	—	—
Article 10(3)	—	—	—
Article 10(4)	Article 21(4)	—	—
Article 10(5)	—	—	—
Article 10(6)	—	—	—
Article 10a	Article 21(1)	—	—
Article 11(1)	—	Article 8	—
Article 11(2)	Article 45	—	—
Article 12	Article 4	—	—
Article 12a	Article 4	—	—
Article 13	Article 38	—	—
Article 14	Article 35, Article 36	—	—
Article 14a	Article 42	—	—
Article 15(1)	Article 46	—	—
Article 15(2)	Article 44	—	—
Article 16	—	Article 93	—
Article 16a	—	—	—
Article 16b	—	—	—
Article 17	Article 141	—	—
Article 17a	—	—	—
Article 18	—		
Article 18a	—	—	—
Article18b	—		
Article 19	—	—	—

Article 20	Article 145	—	—

4. Council Directive 98/56/EC

Council Directive 98/56/EC	This Regulation	Regulation (EU) No …/…. (*Office of Publication, please insert number of Regulation on Official Controls*)	Regulation (EU) No …/… (*Office of Publication, please insert number of Regulation on protective measures against pests of plants*)
Article 1(1)	Article 1	—	—
Article 1(2), (3)	Article 2	—	—
Article 2	Article 3	—	—
Article 3	Article 6	—	—
Article 4	Article 4	—	—
Article 5(1)	Article 16(2), Article 48(1)	—	—
Article 5(2)	Article 64(1)	—	—
Article 5(3), (4)	Article 16(2)	—	—
Article 5(5)	—		
Article 6	Article 5	—	—
Article 7(1)	Article 7	—	—
Article 7(2)	—	—	Article 9
Article 7(3)	Article 8	—	—
Article 7(4)	—	—	—
Article 8(1)	Article 17, Article 48(2)	—	—
Article 8(2), (3)	Article 19(4), Article 49	—	—
Article 8(4)	—	—	—
Article 9(1)	Article 50	—	—
Article 9(2)	Article 50(2), Article 64(4)	—	—
Article 9(3)	—	—	—
Article 9(4)	—	—	—
Article 10	Article 35, Article 37	—	—
Article 11(1)	Article 44	—	—
Article 11(2)	Article 43	—	—
Article 11(3)	—	—	—
Article 11(4)	—	—	—
Article 12	—	Article 8	—
Article 13	—	Article 64(1)	—
Article 14	—	Article 93	—
Article 15	Article 4	—	—
Article 16	—	—	—

Article 17	Article 141	—	—
Article 18	Article 141	—	—
Article 19	—	—	—
Article 20	—	—	—
Article 21	Article 145	—	—

5. Council Directive 1999/105/EC

Council Directive 1999/105/EC	This Regulation	Regulation (EU) No …/…. (*Office of Publication, please insert number of Regulation on Official Controls*)	Regulation (EU) No …/… (*Office of Publication, please insert number of Regulation on protective measures against pests of plants*)
Article 1	Article 105	—	—
Article 2	Article 106	—	—
Article 3(1)	Article 119	—	—
Article 3(2)	Article 4	—	—
Article 3(3), first subparagraph	Article 105, Article 3(9)	—	—
Article 3(3), second subparagraph	Article 8(4)	—	—
Article 3(4)	Article 139	—	—
Article 4(1)	Article 114	—	—
Article 4(2)	Article 107(1), (2)	—	—
Article 4(3), point (a)	Article 107(3)	—	—
Article 4(3), point (b)	Article 109	—	—
Article 4(4)	Article 134	—	—
Article 4(5)	Article 108	—	—
Article 5	Article 4	—	—
Article 6(1)	Article 115, point (b)	—	—
Article 6(2)	Article 117(5)	—	—
Article 6(3), first subparagraph	Article 118	—	—
Article 6(3), second subparagraph	—	—	—
Article 6(4)	Article 5	—	—
Article 6(5)	Article 2, point (a)	—	—
Article 6(6)	—	—	—
Article 6(7)	Article 134	—	—
Article 6(8)	—	—	—
Article 7	Article 128	—	—
Article 8	—	—	—
Article 9	Article 110	—	—

Article 10	Article 112	—	—
Article 11	Article 113	—	—
Article 12	Article 122	—	—
Article 13(1)	Article 123	—	—
Article 13(2)	Article 117(2)	—	—
Article 13(3)	Article 126	—	—
Article 14(1), (2)	Article 124(1), (2)	—	—
Article 14(3)	Article 130	—	—
Article 14(4)	Article 131	—	—
Article 14(5)	Article 125	—	—
Article 14(6)	Article 124(3)	—	—
Article 14(7)	Article 4	—	—
Article 15	Article 121	—	—
Article 16(1)	—	Article 8	—
Article 16(2)	—	Article 100(1)	—
Article 16(3), (4), (5)	—	—	—
Article 16(6)	—	Article 106(2)	—
Article 17(1)	Article 4	—	—
Article 17(2)	Article 128	—	—
Article 17(3)	—	—	—
Article 17(4)	Article 128(1), point (b)	—	—
Article 18	Article 129	—	—
Article 19	Article 137, Article 138	—	—
Article 20	—	—	—
Article 21	Article 133	—	—
Article 22	Article 4	—	—
Article 23	Article 127	—	—
Article 24	—	—	—
Article 25	—	—	—
Article 26	Article 141	—	—
Article 27	—	—	—
Article 28	—	—	—
Article 29	Article 144	—	—
Article 30	Article 145(1), (2)	—	—
Article 31	—	—	—

6. Council Directive 2002/54/EC

Council Directive 2002/54/EC	This Regulation	Regulation (EU) No …/…. (*Office of Publication, please insert number of Regulation on Official Controls*)	Regulation (EU) No …/… (*Office of Publication, please insert number of Regulation on protective measures against pests of plants*)
Article 1, first subparagraph	Article 1	—	—
Article 1, second subparagraph	Article 46	—	—
Article 2(1)	Article 3, Article 10	—	—
Article 2(2)	Article 20(2)	—	—
Article 2(3)(A)	Article 20(2), Article 23	—	—
Article 2(3)(B)	Article 20(2), Article 143	—	—
Article 2(4)	Article 24	—	—
Article 3(1)	Article 12(1), (2)	—	—
Article 3(2)	Article 20(2)	—	—
Article 4	Article 12(1)	—	—
Article 5, first subparagraph, point (a)	Article 37	—	—
Article 5, first subparagraph, point (b)	Article 39	—	—
Article 5, second subparagraph	—	—	—
Article 5, third subparagraph	—	Article 100	—
Article 6(1), first subparagraph, point (a)	Article 2, points (a) and (b)	—	—
Article 6(1), first subparagraph, point (b)	Article 34(1)	—	—
Article 6(1), second subparagraph	Article 4	—	—
Article 6(2)	Article 34(6)	—	—
Article 6(3)	—	—	—
Article 7	Article 40	—	—
Article 8	Article 75(1)	—	—
Article 9(1)	Article 20(2), Article 24	—	—
Article 9(1a)	Article 23(1)		
Article 9(1b)	Article 23(1), point (a)		
Article 9(2)	Article 20(2)	—	—
Article 10(1)	Article 17(1)	—	—
Article 10(2)	Article 17(4)	—	—
Article 11(1)	Article 18	—	—
Article 11(2)	Article 18(4)	—	—

Article 11(3)	Article 18(5)	—	—
Article 12(a)	Article 19, Article 21	—	—
Article 12(b)	—	—	—
Article 13	Article 18(5)	—	—
Article 14	Article 18(5)	—	—
Article 15	Article 18	—	—
Article 16	—	—	—
Article 17	Article 21(1)	—	—
Article 18	Article 21(6)	—	—
Article 19	Article 42	—	—
Article 20	Article 4	—	—
Article 21	Article 16(2)	—	—
Article 22(1)	Article 38(1)	—	—
Article 22(2)	Article 38(6)	—	—
Article 22(3)	Article 44(2), point (b)(iii)		
Article 23	Article 44	—	—
Article 24	Article 37	—	—
Article 25(1)	—	Article 8	—
Article 25(2)	—	—	—
Article 26	—	Article 93	—
Article 27	Article 16(3)	—	—
Article 28	Article 141	—	—
Article 29	Article 4	—	—
Article 30(1), point (a)	Article 16(2)	—	—
Article 30(1), point (b)	Article 12(4), point (a)	—	—
Article 30(1), point (c)			
Article 30(2)	—	—	—
Article 30A	—	—	—
Article 31	—	—	—
Article 32	—	—	—
Article 33	Article 144	—	—
Article 34	Article 145(1)	—	—
Article 35	—	—	—

7. Council Directive 2002/55/EC

Council Directive 2002/55/EC	This Regulation	Regulation (EU) No …/…. (*Office of Publication, please insert number of Regulation on Official Controls*)	Regulation (EU) No …/… (*Office of Publication, please insert number of Regulation on protective measures against pests of plants*)
Article 1, first subparagraph	Article 1	—	—
Article 1, second subparagraph	Article 46	—	—
Article 2(1), point (a)	Article 3(5)	—	—
Article 2(1), point (b)	Article 11(2)	—	—
Article 2(1), point (c)	Article 10(7)	—	—
Article 2(1), point (d)	Article 10(8)	—	—
Article 2(1), point (e)	Article 10(9)	—	—
Article 2(1), point (f)	—	—	—
Article 2(1), point (g)	Article 18(5)	—	—
Article 2(2)	Article 11(3)	—	—
Article 2(3)	Article 53(1), point (i)	—	—
Article 2(4)	Article 20(2), Article 24(4)	—	—
Article 3(1)	Article 14(1)	—	—
Article 3(2)	Article 51	—	—
Article 3(3)	Article 52	—	—
Article 3(4)	Article 14(1)	—	—
Article 4(1)	Article 56(2), point (a)	—	—
Article 4(2), (3)	Article 4	—	—
Article 4(4)	Article 57	—	—
Article 5(1)	Article 60	—	—
Article 5(2)	Article 61	—	—
Article 5(3)	Article 62	—	—
Article 6	Article 14(1)	—	—
Article 7(1)	Article 71	—	—
Article 7(2)	Article 74	—	—
Article 7(3)	Article 75	—	—
Article 7(4), (5)	Article 4	—	—
Article 8	Article 66, Article 67	—	—
Article 9(1)	Article 51, Article 86	—	—
Article 9(2), (3)	Article 64	—	—
Article 9(4)	Article 102(1)	—	—
Article 9(5)	Article 53(1), point (h)	—	—

Article 9(6)	Article 64(1)	—	—
Article 10(1), (2), (3), (4)	Article 103	—	—
Article 10(5)	Article 76(3), (4)	—	—
Article 11	Article 86	—	—
Article 12(1)	Article 82	—	—
Article 12(2)	Article 83	—	—
Article 12(3)	Article 84(4)	—	—
Article 13(1)	—	—	—
Article 13(2)	Article 85(1)	—	—
Article 13(3)	Article 81	—	—
Article 13(4)	—	—	—
Article 14(1), (2)	Article 85(1)	—	—
Article 15(1)	Article 85(1)	—	—
Article 15(2)	Article 85(2)	—	—
Article 15(3)	—	—	—
Article 16(1)	Article 4	—	—
Article 16(2)	Article 4, Article 56(1), point (c)	—	—
Article 17	Article 52, Article 53	—	—
Article 18	Article 41	—	—
Article 19	—	—	—
Article 20(1), (2), (3)	Article 12	—	—
Article 20(4)	Article 20(2)	—	—
Article 21	Article 2	—	—
Article 22(a)	Article 37	—	—
Article 22(b)	Article 39	—	—
Article 23(1), point (a)	Article 2	—	—
Article 23(1), point (b)	Article 34(1)	—	—
Article 23(2)	Article 34(6)	—	—
Article 23(3)	—	—	—
Article 24	Article 40	—	—
Article 25(1)	Article 16(2), Article 20(2)	—	—
Article 25(1a)	Article 23(1)		
Article 25(1b)	Article 23(1), point (a)		
Article 25(2)	Article 20(2)	—	—
Article 26(1)	Article 17(1)	—	—
Article 26(2)	Article 18(5)	—	—
Article 26(3)	Article 32(1)		
Article 27	Article 18	—	—
Article 28(1)	Article 19(1), Article 21	—	—

Article 28(2)	Article 18(5)	—	—
Article 28(3)	Article 19(4)	—	—
Article 28(4)	—	—	—
Article 29	Article 18(5)	—	—
Article 30	Article 21(5)	—	—
Article 31	Article 21(1)	—	—
Article 32	Article 21(6)	—	—
Article 33	Article 42	—	—
Article 34(1)	Article 4	—	—
Article 34(2)	Article 12(1), (2)	—	—
Article 35	Article 20(2), Article 21(1)	—	—
Article 36(1)	—	—	—
Article 36(2)	Article 19(1), (2)	—	—
Article 36(3)	—	—	—
Article 37	Article 44	—	—
Article 38	Article 35, Article 37	—	—
Article 39	—	Article 8	—
Article 40	Article 30	—	—
Article 41	Article 20(2), Article 28	—	—
Article 42	Article 31	—	—
Article 43	—	Article 93	—
Article 44	Article 14(4), Article 56	—	—
Article 45	Article 16(2), Article 20(2)	—	—
Article 46	Article 141	—	—
Article 47	Article 4	—	—
Article 48	Article 32, Article 33	—	—
Article 48(1)(b)	Article 12(4), point (a)		
Article 49	—	—	—
Article 50	—	—	—
Article 51	Article 144	—	—
Article 52	Article 145(1), (2)	—	—
Article 53	—	—	—

8. Council Directive 2002/56/EC

Council Directive 2002/56/EC	This Regulation	Regulation (EU) No …/…. (*Office of Publication, please insert number of Regulation on Official Controls*)	Regulation (EU) No …/… (*Office of Publication, please insert number of Regulation on protective measures against pests of plants*)
Article 1, first subparagraph	Article 1	—	—
Article 1, second subparagraph	Article 46	—	—
Article 2	Article 3	—	—
Article 3(1), first sentence	Article 12(1), Article 16(2)	—	—
Article 3(1), second sentence	—	—	—
Article 3(1), third sentence	—	—	—
Article 3(2), (3), (4)	Article 16(2)	—	—
Article 4	Article 12(1)	—	—
Article 5	Article 40	—	—
Article 6(1), first subparagraph	Article 2	—	—
Article 6(1), second subparagraph	Article 4	—	—
Article 6(2)	—	—	—
Article 6(3)	—	—	—
Article 7	Article 20(2)	—	—
Article 8	Article 16(2)	—	—
Article 9	Article 16(2)	—	—
Article 10(1)	Article 16(2)	—	—
Article 10(2)	Article 17(4)	—	—
Article 10(3)	Article 17(4)	—	—
Article 11(1)	Article 17, Article 18	—	—
Article 11(2)	Article 18(5)	—	—
Article 12(1)	Article 18(2), (4)	—	—
Article 12(2)	Article 18(4)	—	—
Article 12(3)	Article 18(5)	—	—
Article 13(1)	Article 19(3), Article 21	—	—
Article 13(2)	Article 18(5)	—	—
Article 14	—	—	—
Article 15	Article 21(1)	—	—
Article 16	Article 21(6)	—	—
Article 17(1)	Article 4	—	—
Article 17(2), first sentence	Article 40	—	—
Article 17(2), second sentence	—	—	Article 16, Article 31

Article 18	Article 16(2)	—	—
Article 19	Article 42	—	—
Article 20	—	Article 93	—
Article 21	Article 44	—	—
Article 22(1)	Article 35, Article 37	—	—
Article 22(2)	Article 34	—	—
Article 22(3)	—	—	—
Article 23(1)	—	Article 8	—
Article 23(2)	Article 45	—	—
Article 24	Article 16(2)	—	—
Article 25	Article 141	—	—
Article 26	Article 4	—	—
Article 27(1), point (a)	Article 16(2)	—	—
Article 27(1), point (b)	Article 12(4), point (a)	—	—
Article 27(1), point (c)	—	—	—
Article 27(2)	Article 16(2)	—	—
Article 28	—	—	—
Article 29	Article 144	—	—
Article 30	Article 145(1)	—	—
Article 31	—	—	—

9. Council Directive 2002/57/EC

Council Directive 2002/57/EC	This Regulation	Regulation (EU) No …/…. (*Office of Publication, please insert number of Regulation on Official Controls*)	Regulation (EU) No …/… (*Office of Publication, please insert number of Regulation on protective measures against pests of plants*)
Article 1, first subparagraph	Article 1	—	—
Article 1, second subparagraph	Article 46	—	—
Article 2(1)(a)	Article 3, Article 10	—	—
Article 2(1)(b)	Article 11(1), (2), (4)	—	—
Article 2(1)(c), (d), (e), (f), (g), (h), (i), (j), (k)	Article 16, Article 20	—	—
Article 2(2)	Article 11(3)	—	—

Article 2(3)	—	—	—
Article 2(3a)	—	—	—
Article 2(4)(a)	Article 16(2)	—	—
Article 2(4)(b)	Article 20(2)	—	—
Article 2(5)	Article 20(2)	—	—
Article 2(6)	Article 20(2)	—	—
Article 3(1), (2), (3)	Article 12(3)	—	—
Article 3(4)	Article 16(3)		
Article 4	Article 12(1)	—	—
Article 5, first subparagraph (a)	Article 37	—	—
Article 5, first subparagrpah (b)	Article 39	—	—
Article 5, second subparagraph	Article 44	—	—
Article 5, third subparagraph	—	Article 100(1)	—
Article 6(1), first subparagraph, point (a)	Article 2	—	—
Article 6, first subparagraph, point (b)	Article 4	—	—
Article 6(1), second subparagraph	Article 34		
Article 6(2)	—	—	—
Article 6(3)	—	—	—
Article 7	Article 40	—	—
Article 8	Article 75(1)	—	—
Article 9	Article 20(2)	—	—
Article 10(1)	Article 17(1), Article 18(1)	—	—
Article 10(2)	Article 18(5)	—	—
Article 11	Article 18	—	—
Article 12(1)	Article 19(1), Article 20(1)	—	—
Article 12(2)	—	—	—
Article 12(3)	Article 21(5), point (g)	—	—
Article 13	—	—	—
Article 14	Article 21(1)	—	—
Article 15	Article 21(6)	—	—
Article 16	Article 42	—	—
Article 17	Article 4	—	—
Article 18	Article 20(2)	—	—
Article 19	—	—	—
Article 19a	Article 20(2)	—	—
Article 20	Article 42	—	—

Article 21(1)	Article 37	—	—
Article 21(2)	Article 19	—	—
Article 21(3)	—		
Article 22(1)	—	—	—
Article 22(2)	—	—	—
Article 23	—	—	—
Article 24	Article 20(2)	—	—
Article 25	Article 141	—	—
Article 26	Article 4	—	—
Article 27(1), point (a)	Article 16(2)	—	—
Article 27(1), point (b)	Article 12(4), point (a)		
Article 27(1), point (c)	—	—	—
Article 27(2)	Article 57(2)		
Article 28	—	—	—
Article 29	—	—	—
Article 30	—	—	—
Article 31	Article 144	—	—
Article 32	Article 145	—	—
Article 33	Article 145	—	—

10. Council Directive 2008/90/EC

Council Directive 2008/90/EC	This Regulation	Regulation (EU) No …/…. (*Office of Publication, please insert number of Regulation on Official Controls*)	Regulation (EU) No …/… (*Office of Publication, please insert number of Regulation on protective measures against pests of plants*)
Article 1(1)	Article 1	—	—
Article 1(2)	Article 11(2)	—	—
Article 1(3)	Article 4	—	—
Article 1(4)	Article 46	—	—
Article 2	Article 3	—	—
Article 3(1)	Article 12(1)	—	—
Article 3(2)	Article 4	—	—
Article 3(3)	Article 4	—	—
Article 3(4)	Article 2	—	—
Article 4	Article 16, Article 20	—	—
Article 5	Article 5	—	—
Article 6(1)	Article 7	—	—

Article 6(2)	—	—	Article 9(1)
Article 6(3)	Article 8	—	—
Article 6(4)	—	—	—
Article 7(1)	Article 14, Article 50(1)	—	—
Article 7(2), first subparagraph	Article 14, Article 50(1)	—	—
Article 7(2), second subparagraph	Article 12(4), point (a)		
Article 7(3)	Article 50(2)	—	—
Article 7(4)	Article 57	—	—
Article 7(5)	Article 56	—	—
Article 7(6)	Article 51, Article 52	—	—
Article 8(1)	Article 17(1)	—	—
Article 8(2)	Article 17(2)	—	—
Article 9(1), point (a)	Article 19 (4), (5)	—	—
Article 9(1), point (b)	Article 19 (1), (2)	—	—
Article 9(1), second subparagraph	Article 21(5)	—	—
Article 9(2)	—	—	—
Article 9(3)	Article 21(1)	—	—
Article 10	—	—	—
Article 11	Article 37	—	—
Article 12	Article 44	—	—
Article 13	—	Article 8 and Article 20, point (b)	—
Article 14(1)	—	Article 13(1)	—
Article 14(2)	—	Article 93	—
Article 14(3)		Article 93(3), point (d)	
Article 14(4)		Article 93(3), point (b)	
Article 14(5)		Article 161, point (a)(ii)(b)	
Article 14(6)		Article 161, point (a)(ii)(b)	
Article 14(7)		Article 93	
Article 15	—	Article 115	—
Article 16	—	Article 118	—
Article 17(1)	Article 4	—	—
Article 17(2)	Article 40	—	—
Article 18	Article 11(3)	—	—

Article 19	Article 141	—	—
Article 20	—	—	—
Article 21	—	—	—
Article 22	Article 144	—	—
Article 23	Article 145 (1), (2)	—	—
Article 24	—	—	—

11. Council Directive 2002/53/EC

Council Directive 2002/53/EC	This Regulation	Regulation (EU) No …/…. (*Office of Publication, please insert number of Regulation on Official Controls*)	Regulation (EU) No …/… (*Office of Publication, please insert number of Regulation on protective measures against pests of plants*)
Article 1(1)	Article 52(1)	—	—
Article 1(2)	Article 52(1), point (b)	—	—
Article 1(3)	Article 46	—	—
Article 2	—	—	—
Article 3(1)	Article 51	—	—
Article 3(2)	Article 56(3), (4)	—	—
Article 3(3)	Article 4	—	—
Article 4(1)	Article 56	—	—
Article 4(2)	Article 56(2)	—	—
Article 4(3)	—	—	—
Article 4(4), (5)	Article 4	—	—
Article 4(6)	Article 57	—	—
Article 5(1)	Article 60	—	—
Article 5(2)	Article 61	—	—
Article 5(3)	Article 62	—	—
Article 5(4)	Article 58	—	—
Article 6	Article 4	—	—
Article 7(1)	Article 71	—	—
Article 7(2)	Article 74	—	—
Article 7(3)	Article 75	—	—
Article 7(4)	Article 4	—	—
Article 7(5)	Article 4	—	—
Article 8	Article 67(1), point (i)	—	—
Article 9(1)	Article 53(1)	—	—
Article 9(2), (3)	Article 64	—	—

Article 9(4)	Article 102(1)	—	—
Article 9(5)	Article 53(1), point (g)	—	—
Article 9(6)	Article 64(1)	—	—
Article 10(1), (2), (3), (4)	Article 103	—	—
Article 10(5)	Article 76(3)	—	—
Article 11	Article 86	—	—
Article 12(1)	Article 82	—	—
Article 12(2)	Article 83(1), Article 84	—	—
Article 12(3)	Article 84(4)	—	—
Article 13(1)	—	—	—
Article 13(2)	Article 85(1)	—	—
Article 13(3)	Article 81	—	—
Article 13(4)	—	—	—
Article 14	Article 85	—	—
Article 15	Article 85	—	—
Article 16(1)	Article 4	—	—
Article 16(2)	Article 4, Article 85(1)	—	—
Article 17	Article 52, Article 55	—	—
Article 18	Article 45, Article 85(1)	—	—
Article 19	Article 84(4)	—	—
Article 20(1)	—	—	—
Article 20(2)and 20(3), point (a)	Article 57	—	—
Article 20(3), point (b)	—		
Article 21	—		
Article 22	Article 44	—	—
Article 23	Article 141	—	—
Article 24	—	—	—
Article 25	—	—	—
Article 26	Article 144	—	—
Article 27	Article 145(1), (2)	—	—
Article 28	—	—	—
		—	—

12. Council Directive 2008/72/EC

Council Directive 2008/72/EC	This Regulation	Regulation (EU) No …/…. (*Office of Publication, please insert number of Regulation on Official Controls*)	Regulation (EU) No …/… (*Office of Publication, please insert number of Regulation on protective measures against pests of plants*)
Article 1(1)	Article 1	—	—
Article 1(2)	Article 11(1), (2), (4)	—	—
Article 1(3)	Article 11(3)	—	—
Article 2	Article 46	—	—
Article 3	Article 3, Article 10	—	—
Article 4	Article 16(2)	—	—
Article 5(1)	Article 6	—	—
Article 5(2)	Article 7, Article 8	—	—
Article 5(3)	—	—	Article 9, Article 15
Article 5(4)	—	—	—
Article 6(1)	Article 5	—	—
Article 6(2)	—	Article 36	—
Article 6(3)	—	—	Article 64
Article 6(4)	Article 24	—	—
Article 7	—	Article 115	—
Article 8(1)	Article 5	—	—
Article 8(2), points (a) and (b)	Article 2	—	—
Article 8(2), point (c)	Article 12(4), point a		
Article 8(3)	—	—	—
Article 9(1), (2)	Article 14(1)	—	—
Article 9(3)	Article 52	—	—
Article 10(1)	Article 17(1)	—	—
Article 10(2)	Article 17(2)	—	—
Article 10(3)	—	Article 8	—
Article 11(1), first subparagraph	Article 17(1), Article 28	—	—
Article 11(1), second subparagraph	—	—	—
Article 11(2)	—	—	—
Article 12	—	—	—
Article 13	Article 35, Article 37	—	—
Article 14	Article 4	—	—
Article 15	Article 4, Article 40	—	—
Article 16	Article 43, Article 44	—	—

Article 17	Article 24	Article 8, Article 13	—
Article 18	—	Article 20	—
Article 19	Article 20, point (d)	—	—
Article 20	—	Article 93	—
Article 21	Article 141	—	—
Article 22	—	—	—
Article 23(1)	—	Article 8	—
Article 23(2)	Article 4	—	—
Article 24	—	—	—
Article 25	Article 144	—	—
Article 26	Article 145(1), (2)	—	—
Article 27	—	—	—