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Proposal for a

# **REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

on the production and marketing of forest reproductive material, amending Regulations (EU) 2016/2031 and 2017/625 of the European Parliament and of the Council and repealing Council Directive 1999/105/EC (Regulation on forest reproductive material)

(Text with EEA relevance)

 $\{ SEC(2023) \ 414 \ final \} - \{ SWD(2023) \ 410 \ final \} - \{ SWD(2023) \ 414 \ final \} - \{ SWD(2023) \ 415 \ final \}$ 

# EXPLANATORY MEMORANDUM

# 1. CONTEXT OF THE PROPOSAL

#### • Reasons for and objectives of the proposal

Council Directive 1999/105/EC sets out rules on the production and marketing of forest reproductive material ('FRM Directive'). That Directive regulates forest reproductive material ('FRM') which is important for forestry purposes.

In the years since its adoption, several important developments have taken place, and most importantly:

- the adoption of the European Green Deal<sup>1</sup>, which includes European Climate Law<sup>2</sup>, the new EU Strategy on Adaptation to Climate Change<sup>3</sup>, the New EU Forest Strategy for 2030<sup>4</sup> and the EU Biodiversity Strategy for 2030<sup>5</sup>, and
- the update of the Rules and Regulations of the Organisation for Economic Cooperation and Development (OECD) Scheme for the Certification of Forest Reproductive Material Moving in International Trade<sup>6</sup> ('OECD Forest Seed and Plant Scheme').

In the light of those developments, the new policy priorities of the EU in relation to sustainability, climate change adaptation and biodiversity, as well as the experience gained during the implementation of Directive 1999/105/EC, it is appropriate to revise this part of the EU legislation on the production and marketing of forest reproductive material.

FRM refers to seeds, parts of plants and plants and is used for the creation of new forests ('afforestation'), the replanting of areas with trees ('reforestation') and other types of tree planting for different purposes: (i) wood and biomaterials production, (ii) biodiversity conservation, (iii) restoration of forest ecosystems, (iv) climate adaptation, (v) climate mitigation and (vi) conservation and sustainable use of forest genetic resources.

Seeds of agricultural crops are produced, certified, and harvested in cycles of one year, while in the case of FRM it may take 50-100 years before seeds and forest plants can be harvested from basic material. Because of these long production cycles, it is essential to produce high-quality FRM and ensure traceability to (i) the original

<sup>&</sup>lt;sup>1</sup> Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions - The European Green Deal (COM(2019)640 final).

Regulation (EU) 2021/1119 of the European Parliament and of the Council of 30 June 2021 establishing the framework for achieving climate neutrality and amending Regulations (EC) No 401/2009 and (EU) 2018/1999 ('European Climate Law') (OJ L 243, 9.7.2021, p. 1).

<sup>&</sup>lt;sup>3</sup> Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, Forging a climate-resilient Europe - the new EU Strategy on Adaptation to Climate Change (COM(2021) 82 final).

<sup>&</sup>lt;sup>4</sup> Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, New EU Forest Strategy for 2030 (COM(2021) 572 final).

<sup>&</sup>lt;sup>5</sup> Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, EU Biodiversity Strategy for 2030 Bringing nature back into our lives (COM(2020) 380 final).

<sup>&</sup>lt;sup>6</sup> Decision of the Council Establishing the OECD Scheme for the Certification of Forest Reproductive Material Moving in International Trade [OECD/LEGAL/0355].

parent trees from which that FRM has been harvested and (ii) the climatic and ecological conditions under which those parent trees were grown. The process that leads to the production and marketing of FRM is described hereafter.

FRM is harvested from parent trees (i.e. basic material). That basic material has been selected for a number of superior characteristics (e.g. morphological features, wood quality, health, and resistance) in view of the intended purpose for which the FRM will be used. The competent authorities of the Member States conduct an official inspection to approve that basic material. Basic material is registered in a national register with a unique register reference and with a so-called unit approval that delineates the area from which FRM can subsequently be harvested. Upon the harvesting of FRM a master certificate is issued. The master certificate serves to ensure traceability of the FRM to the location of the basic material from which it has been harvested. FRM has to comply with a number of quality requirements in order to be certified. In the case of seeds those quality requirements relate to the purity of the seeds and the number of viable seeds that can germinate (i.e. germination percentage). The official label is issued following an official inspection by the competent authorities which confirms that the FRM concerned.

FRM production in the different Member States is oriented depending on the specific needs. In certain Member States the timber and pulp industry are the most important economic activity and hence wood production is the main branch of the FRM policy. When selecting the 'parent trees' (i.e. basic material) from which FRM will be harvested, wood quality will be the most important selection criterion in those Member States.

In other Member States, FRM is produced to serve several purposes and create multifunctional ecosystems. Certain parts of the forests are accessible to humans and animals and fulfil social and cultural functions, while other parts of the forest are protected by fences with the aim of biodiversity conservation and conservation of forest genetic resources. In this case, a wide range of 'parent trees' with different characteristics will be selected (small versus big trees, diverse sizes of branches) to obtain a high degree of variation between those parent trees and ensure a high level of genetic diversity. A high level of genetic diversity of the FRM that will be harvested from those parent trees is also very important for climate adaptation as that FRM could be planted in areas that are climatically suitable or may in the future become climatically suitable for that FRM. This is the suitability of FRM for current and projected future climatic conditions.

The current legislation defines FRM in relation to its importance for forestry purposes in all or part of the Union, but it remains vague about the forestry purposes that are covered by the scope of the legislation. This lack of clarity has in certain cases led to situations where low-quality FRM has been planted. The planted trees may initially grow well but fail to produce seeds 10-20 years after having been planted. This may in the long-term lead to economic losses for the timber and pulp industry. In the worst-case scenario it could lead to failure of forest ecosystems because forests are more vulnerable to drought, pest attacks and other disturbances. It is therefore necessary to clarify the scope of the EU legislation by listing the purposes for which it is important to use high-quality FRM in the proposed Regulation.

Forests provide the raw material (wood and non-wood such as food and medical plants) for growing bioeconomy value chains substituting fossil-based or otherwise harmful products. Through the purpose of the production of wood and biomaterials, the proposed Regulation supports the extended forest-based value chains which currently count 4,5 million jobs in the  $EU^7$ .

As already mentioned above, it should furthermore be ensured that Member States can produce FRM for the purposes that are relevant in their territory. Member States must be thus allowed to decide on the selection criteria that will be applied to the basic material in view of the intended purpose of that FRM. Moreover, the planting of high-quality FRM in area with favourable climatic and ecological conditions contributes to achieving the intended purpose of that FRM.

For example, FRM can be harvested from basic material that has been assessed and approved for the purpose of wood production. If such FRM is planted under favourable conditions, it will produce a higher volume of wood compared to the average wood production of FRM that is not planted under favourable conditions. Likewise, FRM can be harvested from basic material that has been selected and assessed for its adaptation to the local and regional climatic and ecological conditions with respect to the biotic and abiotic factors in that area. Such FRM planted under favourable conditions for the purpose of climate adaptation will contribute to the resilience of forests to extreme weather and their adaptation to changing climatic conditions. Forested land is, by far, the main contributor to the EU carbon sink and will play an essential role in meeting the EU's ambitious objective of climate neutrality by 2050.

The proposed Regulation is replacing Directive 1999/105/EC, clarifying its scope and updating its provisions.

It has the following general objectives:

- (a) To ensure a level playing field for operators across the EU;
- (b) To support innovation and competitiveness of the EU FRM industry;
- (c) To contribute to addressing sustainability, biodiversity and climate-related challenges.

It has the following specific objectives:

- (a) To increase clarity and coherence of the legal framework through simplified, clarified and harmonised basic rules on fundamental principles presented in a modern legal form;
- (b) To enable the uptake of new scientific and technical developments (in particular, innovative production processes, bio-molecular techniques and digital solutions);
- (c) To ensure availability of FRM suitable for future challenges;
- (d) To support the conservation and sustainable use of forest genetic resources.
- (e) To harmonise the framework for official controls on FRM;
- (f) To improve coherence of FRM legislation with the Plant health legislation.

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Robert N., Jonsson R., Chudy R., Camia A. (2020) The EU Bioeconomy: Supporting an Employment Shift Downstream in the Wood-Based Value Chains? Sustainability 12, 758.

The proposed Regulation is part of the Regulatory Fitness Programme (REFIT).

# • Consistency with existing policy provisions in the policy area

The proposed Regulation has links to EU policies on plant health (Regulation (EU) 2016/2031 of the European Parliament and of the Council<sup>8</sup>) and official controls (Regulation (EU) 2017/625 of the European Parliament and of the Council<sup>9</sup>).

The rules in Regulation (EU) 2016/2031 concerning pests will also apply to the production and marketing of FRM. The official label for FRM will be combined with the plant passport established by that Regulation.

The FRM rules will be included in the scope of Regulation (EU) 2017/625 concerning official controls. This will ensure consistency with the other EU acts concerning the production and marketing of plants (Regulation (EU) 2016/2031 and the proposed Regulation on the production and marketing of plant reproductive material), which are also part of the EU legal regime of official controls.

# • Consistency with other EU policies

The forestry policy in the EU values the central and multi-functional role of forests and forest ecosystems and recognises that forests are under increasing pressure, caused by extreme weather events, pests and diseases as a result of the climate change. Increasing disturbance frequency and intensity, for example by bark beetle outbreaks, results in greenhouse gas emissions, biodiversity loss and economic loss. They may also cause abrupt increases of salvage logging with a direct impact on the market across countries.

The proposed Regulation contributes to the overall policies of the European Green Deal and related legislation and strategies: the European Climate Law, the new EU Strategy on adaptation to climate change, the New EU Forest Strategy for 2030 and the EU Biodiversity Strategy for 2030.

The proposed Regulation will help achieve the objectives of the European Climate Law and the EU Adaptation Strategy by facilitating the planting of the right tree in the right place. This will create significant benefits for foresters, the forest bioeconomy and the society as a whole.

The requirement for Member States to prepare national contingency plans will ensure a sufficient supply of FRM to reforest areas affected by extreme weather events, wildfires, disease and pest outbreaks, disasters or any other event. The contingency

<sup>&</sup>lt;sup>8</sup> Regulation (EU) 2016/2031 of the European Parliament of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC (OJ L 317, 23.11.2016, p. 4).

<sup>&</sup>lt;sup>9</sup> Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 882/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

plans policy reflects the general preparedness actions that Member States should take under the Union Civil Protection Mechanism including the conduct of national risk assessments<sup>10</sup>.

The proposed Regulation aims to contribute to the objectives of the New EU Forest Strategy for adapting forests to climate change and restoring forests affected by climate-related damage, by introducing measures promoting the production of FRM suitable for future climatic conditions. Through the establishment of national contingency plans and the planting of the right tree in the right place this Regulation helps ensure that future generations will continue to be able to enjoy the social and cultural functions of forests.

The proposed Regulation will help conserve forest genetic resources and enhance biodiversity, by facilitating the placing on the market of FRM intended for the conservation and sustainable use of forest genetic resources.

Finally, the proposed Regulation creates the framework for introducing digital technologies, to record all certification activities in an on-line platform in accordance with the objectives of the European Digital Strategy<sup>11</sup>.

# 2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

# Legal basis

The proposal introduces rules necessary for the pursuit of the objectives of the common agricultural policy, in the sector of the production and marketing of FRM in the EU.

In this respect, the following two legal bases have been selected:

 Article 43(2) of the Treaty on the Functioning of the European Union (TFEU), which provides the legal basis for adopting the provisions necessary for the pursuit of the objectives of the common agricultural policy.

# • Subsidiarity (for non-exclusive competence)

According to Article 4(2), point (d),) TFEU shared competence between the EU and the Member States applies in the area of agriculture and fisheries, excluding the conservation of marine biological resources.

Since the adoption of Directive 1999/105/EC, all fields of marketing of FRM have been regulated at EU level to a very large extent. This has been a major contributor to the establishment of an internal market in FRM. The impact assessments carried out in 2013 and 2023 confirmed that the EU rules in place on the marketing of FRM have had a generally positive impact on the free movement, the availability and quality of FRM on the EU market and have thus facilitated trade within the EU. A more harmonised approach with regard to the production and marketing of FRM, cannot be sufficiently achieved at Member State level, because of the complexity, and the international character. The response to the cross-border challenges in relation to climate change, biodiversity and sustainability would be better achieved at

<sup>&</sup>lt;sup>10</sup> Decision No 1313/2013/EU of the European Parliament and of the Council of 17 December 2013 on a Union Civil Protection Mechanism (OJ L 347, 20.12.2013, p. 924).

<sup>&</sup>lt;sup>11</sup> Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, 2030 Digital Compass: the European way for the Digital Decade (COM(2021)118 final).

EU level. The EU may therefore adopt measures regarding the production and marketing of high-quality FRM that is suitable for climatic and ecological conditions, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union.

# Proportionality

As discussed in Chapter 7.4 of the impact assessment accompanying this proposal, the measures proposed are limited to actions that need to be taken at EU level in order to be effective and efficient. To achieve these needs, Directive 1999/105/EC will be replaced by a Regulation on FRM. This type of instrument is considered most suitable, considering that a key element of the proposal is to establish more harmonised measures for Member States.

Uniform requirements for the production and marketing of FRM are the only way to (i) ensure that FRM has a high level of quality for users, that the internal market functions well and that there is a level playing field for the operators, (iii) ensure sustainable afforestation and reforestation, biodiversity conservation and restoration of forest ecosystems, and to (iv) support wood and biomaterials production, climate adaptation, climate mitigation and the conservation and sustainable use of forest genetic resources. To adapt the technical requirements to climatic and ecological conditions Member States may, under certain conditions, lay down more stringent national requirements. Moreover, for the registration of basic material and FRM certification, flexibility and harmonisation are balanced with the flexibility for Member States to implement those rules in a way that is adapted to their local climatic and ecological conditions. The legislation also contains measures to strengthen sustainability and respond to the call to adapt to climate change.

#### Choice of instrument

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 can be achieved most efficiently by fully harmonised requirements throughout the EU, ensuring free movement of FRM.

# 3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

#### • Ex-post evaluations/fitness checks of existing legislation

In 2019, the Council<sup>12</sup> asked the Commission to present a study on the Union's options to update the existing legislation on the production and marketing of plant reproductive material ('PRM study')<sup>13</sup>. That study was supported by an external data

<sup>&</sup>lt;sup>12</sup> Council Decision (EU) 2019/1905 of 8 November 2019 requesting the Commission to submit a study on the Union's options to update the existing legislation on the production and marketing of plant reproductive material, and a proposal, if appropriate in view of the outcomes of the study (OJ L 293, 14.11.2019, p. 105).

<sup>&</sup>lt;sup>13</sup> Commission Staff Working Document Study on the Union's options to update the existing legislation on the production and marketing of plant reproductive material (SWD(2021)90 final).

gathering study<sup>14</sup>. The PRM study identified 5 key problems with the existing legislation.

These concerned:

- (1) the non-harmonised implementation of the legislation causing a non-level playing field for operators;
- (2) complex and rigid procedures, creating a cumbersome decision-making process;
- (3) the rigidity of the legal framework posing difficulties to address policy issues identified in the European Green Deal and its related strategies;
- (4) the lack of a harmonised and risk-based framework for official controls, causing a non-level playing field for official controls;
- (5) the lack of provisions in the legal framework to take account of scientific and technological progress.

The 2019 Council request contained a revision clause that provided the Commission with a mandate to present a legislative proposal, if appropriate in view of the outcome of the aforementioned study.

#### Stakeholder consultations

The impact assessment accompanying the Regulation on FRM involved a wide range of consultations addressing all types of stakeholders comprising an inception impact assessment, a public consultation, working groups with competent authorities and stakeholders and bilateral meetings with stakeholder organisations.

- There were 66 responses to the consultation on the inception impact assessment from 16 countries and 2449 responses to the public consultation from 29 countries;
- Thirty-nine respondents to the inception impact assessment and 181 respondents to the public consultation submitted a position paper;
- There were targeted consultations to gather more specialised feedback from competent authorities and SMEs that resulted in 25 and 251 responses, respectively;
- A targeted survey carried out by an external consultant supporting the Commission's impact assessment returned 99 responses;
- The consultant furthermore conducted 13 in-depth interviews and organised a focus group containing 4 participants.

There was overall support for keeping the FRM legislation separated from the legislation on other PRM. All respondents called for the existing pillars of registration of basic material and FRM certification to be retained. The majority of respondents highlighted the necessity of retaining flexibility to allow Member States to decide which FRM is adapted to their local and regional climatic and ecological conditions.

<sup>&</sup>lt;sup>14</sup> ICF (2021) Data gathering and analysis to support a Commission study on the Union's options to update the existing legislation on the production and marketing of plant reproductive material; https://doi.org/10.2875/406165.

Because the scope of the Directive 1999/105/EC is vague about the purposes that are covered, Member States have had different interpretations and understanding of what is included in the scope of Directive 1999/105/EC. For example, agroforestry is considered within the scope of the Directive in some Member States but not in others. As a result, in those Member States where agroforestry is considered outside the scope of Directive 1999/105/EC, FRM from regulated species can be sold for agroforestry purposes without the approval of basic material. Respondents to the stakeholder consultations expressed mixed views as regards the purposes that should be covered by the scope of the FRM legislation.

Most operators agreed that aligning the requirements for official controls is desirable. Most stakeholders opposed to include the FRM legislation in the scope of the Official Controls Regulation because of the specificity of official controls in this sector, and called for official controls, to remain under the control of the respective competent forest authority. However, it is expected that the benefits of inserting the FRM legislation into the scope of the OCR will outweigh the disadvantages. Stakeholders also were concerned about the potential increase in administrative burden. Most stakeholders called for some flexibility to be maintained in the organisation of official controls and for the costs to be kept as low as possible.

Most stakeholders agreed that the use of bio-molecular techniques and digital solutions could bring benefits and called for the legal framework to allow the latest technologies to be applied, in line also with developments in international standards.

Detailed information about the stakeholder consultations can be found in chapter 5.2.5 and Annex 2 of the impact assessment.

# • Collection and use of expertise

An external consulting company contracted by the Commission conducted a study in support of the impact assessment<sup>15</sup>. The company and its experts worked closely with the relevant Commission departments during the various stages of the study.

The consultant gathered additional data and comments through desk research, a targeted survey, a focus group and in-depth interviews with stakeholders. The support study considered the problem definition, the case for EU action, the objectives of policy intervention and the baseline scenario. It assessed the potential impacts of three options, each including variations on up to 19 specific measures, being proposed by the Commission.

The support study served to refine the policy options and select the preferred policy option.

#### • Impact assessment

This proposal is based on an impact assessment which received a 'positive opinion with reservations' from the Regulatory Scrutiny Board on 17 February 2023.

There are two main problems identified with the current FRM legal framework:

1. There is a non-harmonised internal market characterised by divergent conditions for operators and marketed FRM across Member States. The implementation of various aspects of the legislation differs between Member

<sup>&</sup>lt;sup>15</sup> ICF (2022) Study supporting the Impact Assessment for the revision of the plant and forest reproductive material legislation; https://data.europa.eu/doi/10.2875/4381.

States because (i) the legislation leaves room for interpretation, (ii) Member States tried to find practical solutions to overcome rigid provisions and (iii) the legislation has not followed new developments in science and technology in good time.

2. The legislation is not aligned with the objectives of the European Green Deal and the related strategies. There are restrictions in relation to the genetic diversity of FRM, a lack of sustainability characteristics and the incomplete scope of the FRM legislation. There is an insufficient supply of high-quality certified FRM due to the increasing demand for FRM for reaching the EU target of planting 3 billion additional trees by 2030 aiming to double the number of trees planted per year and having in mind the purposes of wood and biomaterials production, biodiversity conservation and restoration of forest ecosystems. The increasing occurrence of extreme weather and disasters, in combination with an insufficient assessment of sustainability characteristics for the lower FRM categories, has put pressure on the supply of suitable FRM and thus on the resilience of forest ecosystems.

The general objective of this initiative is to ensure, for all types of users, the availability of FRM of high quality and diversity of choice, adapted to current and projected future climatic conditions. At a next level, this will in turn help protect biodiversity and restore forest ecosystems.

The impact assessment compiled all possible measures for analysis, based on (i) an external data gathering study supporting a Commission study on the EU's options to update the legislation on PRM, (ii) a study in support of the impact assessment conducted by an external consultant and (iii) the aforementioned stakeholder consultation activities.

The diverse, complex and often interrelated measures were grouped under three policy options, all of which are compared to a 'no policy change' scenario. Three options were assessed. Option 1 offered the most flexibility while option 3 offered the most harmonisation, so as to minimise differences in how the legislation is implemented. Option 2 balanced the need for flexibility with a higher degree of harmonisation to overcome the problems stemming from differences in interpretation.

All options contained a number of common elements: (i) simplified administrative procedures and a more flexible decision-making process and (ii) harmonisation with the plant health legislation.

- 1. Option 1 - Highest level of flexibility: Option 1 would lay down minimum requirements for FRM official controls, but without linking those to the Official Controls Regulation. It would adopt guidelines on the use of innovative production processes, bio-molecular techniques and digital solutions. The FRM legislation would only cover production for 'forestry purposes' ensure the availability of high-quality to FRM for afforestation/reforestation. Sustainability requirements would be extended to the lower FRM categories. Guidelines would be introduced on contingency planning for major FRM shortages, in the event of extreme weather and disasters.
- 2. Option 2 Balancing flexibility and harmonisation (preferred option): Option 2 would bring the official controls on FRM under the scope of the

Official Controls Regulation, but with simplified import controls at appropriate places within the EU, to ensure a more targeted and efficient enforcement of the existing rules. Basic principles would be included in the legislation for the use of innovative production processes, bio-molecular techniques and digital solutions. The FRM legislation would cover production for 'forestry' and 'non-forestry' purposes, to increase FRM availability and quality beyond afforestation/reforestation uses. Sustainability requirements would be extended to the lower FRM categories. General legal requirements would be introduced for contingency planning for major FRM shortages in the event of extreme weather and disasters.

3. Option 3 – Highest level of harmonisation: Option 3 would bring the official controls on FRM under the scope of the Official Controls Regulation, with stricter import controls at border control posts, requiring special import documentation to strengthen and fully harmonise enforcement. Detailed and binding rules would be included in the legislation for the use of innovative production processes, bio-molecular techniques and digital solutions. The FRM legislation would cover production for 'forestry' and 'non-forestry' purposes to increase FRM availability and quality beyond afforestation/reforestation uses. Sustainability requirements would be extended to the lower FRM categories and be subject to harmonised rules. Common rules would be introduced for contingency planning to prepare for major FRM shortages in the event of extreme weather and disasters.

Based on the outcome of the impact assessment, the Commission concluded that policy option 2 is the best option to effectively address all the objectives of the revision of FRM legislation in efficiently and consistently.

The preferred option will bring efficiency gains for operators and competent authorities through (i) the possibility for operators to print the official label under official supervision, (ii) harmonisation with the plant health legislation, (iii) the introduction of risk-based official controls and the possibility to use bio-molecular techniques and (iv) digital solutions in the registration and certification systems. FRM with improved sustainability characteristics will contribute to the adaptation and mitigation of the already visible impact of climate change on forests, therefore delivering important environmental benefits. National contingency plans will ensure a sufficient supply of FRM to reforest areas affected by extreme weather events, wildfires, disease and pest outbreaks, or other disasters. The risk of planting lowquality FRM will thus be reduced. Finally, benefits are expected for the conservation and sustainable use of forest genetic resources through a specific derogation.

The proposed Regulation clarifies that FRM is used for afforestation, reforestation and other types of tree planting for various purposes. As regards the scope of the Regulation, it was considered most appropriate that it explicitly covers the purposes for which it is deemed important to use high-quality FRM. This is necessary in order to ensure that only the most suitable FRM for those purposes is used and to avoid economic losses and environmental damages caused by the use of low-quality FRM.

# Regulatory fitness and simplification

The proposal introduces a simpler and less burdensome regulatory regime for FRM serving the purposes of conservation of genetic resources and their sustainable use, by replacing the approval procedure of basic material that is intended for the production of such FRM by a notification procedure.

It will enable professional operators to print the official label under official supervision by the competent authorities, if they so wish once the competent authorities have concluded that the FRM is certified. Several processes will be simplified. Those simplification measures, benefit both SMEs and micro-enterprises. Finally, the proposal introduces new features concerning the digitalisation of the FRM sector.

# • Fundamental rights

The proposed regulation respects all provisions of the Charter of Fundamental Rights of the European Union, and especially by setting out rules aiming at freedom to conduct business, avoidance of discrimination, and consumer and environmental protection.

# 4. **BUDGETARY IMPLICATIONS**

There are no budgetary implications.

# 5. OTHER ELEMENTS

#### • Implementation plans and monitoring, evaluation and reporting arrangements

By the fifth year after the date of application of this Regulation, and every five years thereafter, Member States are required to submit a report to the Commission on several aspects of the use of derogations and policies aiming to conservation of genetic resources, agro-biodiversity and simplified procedues for small producers. This is necessary in order to review the effectiveness of those new policies and examine whether improvements would be needed. Specifically, these concern reporting on the following elements:

- the annual quantities of certified FRM;
- the adopted national contingency plans;
- the information available to users on where to best plant FRM, on websites and/or in planters' guides;
- the number of FRM entries containing information on the suitability of FRM for climatic and ecological conditions;
- the number of FRM notifications for the purpose of conserving forest genetic resources;
- the quantities of imported FRM;
- the penalties imposed.

# Detailed explanation of the specific provisions of the proposal

#### (i) Scope

The proposed Regulation applies to FRM of species and artificial hybrids, which is used in afforestation, reforestation and other types of tree planting for the purposes of wood and biomaterials production, biodiversity conservation, restoration of forest ecosystems, climate adaptation, climate mitigation, and conservation and sustainable use of forest genetic resources.

(ii) Basic material and categories

Only basic material approved by the competent authorities may be used to produce and market FRM. For the same reason, only FRM derived from such basic material may be placed on the market.

The following 6 types of basic material, from which FRM could be harvested, are kept as they appear in Directive 1999/105/EC: seed source, stand, seed orchard, parents of family(ies), clone and clonal mixture.

The competent authorities will assess the sustainability characteristics of basic material during the procedure for approving that basic material. The characteristics concern the adaptation of the basic material to the local climatic and ecological conditions and the freedom of trees from pests and their symptoms.

The procedure for approving basic material will include the use of biomolecular techniques as a complementary method, and innovative clonal FRM production techniques.

After FRM is harvested, a master certificate will be issued by the competent authorities for all FRM derived from approved basic material. This certificate ensures that the FRM is identifiable, that it carries information about the origin of the basic material from which it has been harvested, and provides the most appropriate data for its users and the competent authorities responsible for its official controls. The master certificate may also be issued in electronic form.

FRM is to be certified as 'source-identified', 'selected', 'qualified' and 'tested' by the competent authorities, and marketed with a reference to those categories, in order to adapt to the respective standards of the OECD Forest Seed and Plant Scheme. Specific rules for the approval of basic material are set out for each category, which are largely identical to the ones established by Directive 1999/105/EC.

In the case of basic material intended for producing FRM in the 'sourceidentified' and 'selected' categories, the Member States will, for the relevant species, demarcate the regions of provenance, in order to identify an area or groups of areas with sufficiently uniform ecological conditions and containing basic material with similar phenotypic or genetic characteritsics.

This is necessary because the FRM produced from that basic material will be marketed with reference to those regions of provenance.

(iii) Professional operators.

Professional operators may be authorised by the competent authority to print, under official supervision, the official label for certain species and categories of FRM. Rules are set out withdrawing or modifying that authorisation, to make sure the system functions effectively.

They will be registered in accordance with Regulation (EU) 2016/2031 of the European Parliament and of the Council. This is necessary for the efficiency and avoidance of double registration, because the professional operators covered by this Regulation coincide to a great extent with the ones covered by the scope of Regulation (EU) 2016/2031.

Before purchasing FRM, professional operators will make available to the potential buyers of their FRM all necessary information concerning its suitability for climatic and ecological conditions.

# (iv) Registers of FRM and contingency plans

Each Member State will establish, publish and keep updated, in electronic format, (i) a national register of the basic material for the various species and artificial hybrids approved on its territory, and (ii) a national list, which should be presented as a summary of the national register. The national list should be presented in a common form for each unit of approval. It will contain information on the botanical name, category of FRM, purpose, basic material, register reference, location, altitude or altitudinal range, area, origin and in the case of FRM of the 'tested' category, whether it is genetically modified or has been produced by certain new genomic techniques<sup>16</sup>.

For the same reason, the Commission should publish in electronic format a Union list of approved basic material for producing FRM, on the basis of the national lists provided by each Member State. That Union list is referred to as the Commission's Forest Reproductive Material Information System ('FOREMATIS').

Each Member State must draw up and keep up to date a contingency plan to ensure a sufficient supply of FRM to reforest areas affected by extreme weather events, wildfires, disease and pest outbreaks, or other disasters

(v) Handling requirements and digitalisation

FRM will be kept separate by reference to individual units of approval and will be produced and marketed in lots.

Seeds will be marketed only if they conform to certain quality standards. They will be labelled and marketed only in sealed packages.

The proposed Regulation will meet the aim of the EU Digital Strategy to make the transformation to digital technologies work for people and businesses. It should therefore contain an empowerment that will establish rules regarding (i) the digital recording of all actions taken to issue the master certificate and the official label, respectively, and (ii) the establishment of a centralised platform facilitating the processing of, access to, and use of those records. In this respect, the use of electronic labels should also be allowed.

# (vi) Derogations and conservation purposes

During periods in which there are temporary difficulties in obtaining supplies of certain species of FRM, basic material satisfying less stringent requirements will be temporarily approved for the production of FRM belonging to the species concerned.

Temporary experiments will be organised at EU level to seek improved alternatives as regards provisions set out in this Regulation.

The requirements for basic material intended for the purpose of conservation and sustainable use of forest genetic resources will be different from those for basic material intended for producing FRM in the categories 'source-

<sup>&</sup>lt;sup>16</sup> Regulation (EU) [*Publications Office, please insert reference*] of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Directives 68/193/EEC, 1999/105/EC, 2002/53/EC, 2002/55/EC, and Regulation (EU) 2017/625 (OJ L ..., ...).

identified', 'selected', 'qualified' and 'tested'. The objective being to help increase diversity within a single tree species and respond to the decline in biodiversity.

# (vii) Imports

FRM will be imported from third countries only if it is established that it fulfils requirements equivalent to those applicable to FRM produced and marketed in the EU. This is necessary to ensure that such imported FRM offers the same level of quality as the FRM produced in the EU.

The professional operators will inform the respective competent authority in advance of the importation of seed, planting stock and other parts of plants, through the information management system for official controls (IMSOC) set up pursuant to Regulation (EU) 2017/625. Imported FRM will 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. An official label will be attached to that FRM.

The rules in Regulation (EU) 2016/2031 concerning pests will also apply to the production and marketing of FRM under the proposed Regulation. The proposed Regulation includes an amendment of Regulation (EU) 2016/2031, introducing the possibility that the official label for FRM is combined with the plant passport in a single format.

It further introduces an amendment to Regulation (EU) 2017/625 to include FRM rules under the scope of the EU legislation on official controls. The basic rules and principles of official controls will also apply for the production and marketing of FRM, including the ones for the powers of authorities, delegation of tasks, and certification. The Commission will be empowered to adopt special rules for official controls on FRM marketing and professional operators, as needed. In the case of imports, the general rules will apply on a risk basis.

The proposed Regulation will apply 3 years after its entry into force, to offer the appropriate time for the competent authorities and professional operators to adapt to the new rules. It will also give the Commission time to adopt the necessary delegated and implementing acts.

# 2023/0228 (COD)

# Proposal for a

# **REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

#### on the production and marketing of forest reproductive material, amending Regulations (EU) 2016/2031 and 2017/625 of the European Parliament and of the Council and repealing Council Directive 1999/105/EC (Regulation on forest reproductive material)

(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<sup>1</sup>,

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

Having regard to the opinion of the European Economic and Social Committee<sup>2</sup>,

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

Acting in accordance with the ordinary legislative procedure<sup>3</sup>,

Whereas:

- (1) Council Directive 1999/105/EC<sup>4</sup> sets out rules on the production and marketing of forest reproductive material ('FRM').
- (2) Forests cover some 45% of the land area in the Union and fulfil a multifunctional role that comprises social, economic, environmental, ecological and cultural functions. Forests have a premordial function as a carbon sink in the climate mitigation policy. High-quality, climate-adapted and diverse FRM is essential to cover these needs.
- (3) In the light of new technical and scientific developments, the update of the Rules and Regulations of the Organisation for Economic Co-operation and Development (OECD) Scheme for the Certification of Forest Reproductive Material Moving in International Trade<sup>5</sup> ('OECD Forest Seed and Plant Scheme'), the new policy priorities of the Union in relation to sustainability, climate change adaptation and biodiversity and in particular the European Green Deal<sup>6</sup>, as well as the experience

<sup>&</sup>lt;sup>1</sup> OJ C 199, 14.7.1999, p. 1.

<sup>&</sup>lt;sup>2</sup> OJ C 329, 17.11.1999, p. 15.

<sup>&</sup>lt;sup>3</sup> 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 ....

<sup>&</sup>lt;sup>4</sup> Council Directive 1999/105/EC of 22 December 1999 on the marketing of forest reproductive material (OJ L 11, 15.1.2000, p. 17).

<sup>&</sup>lt;sup>5</sup> Decision of the Council Establishing the OECD Scheme for the Certification of Forest Reproductive Material Moving in International Trade [OECD/LEGAL/0355].

<sup>&</sup>lt;sup>6</sup> Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions - The European Green Deal (COM/2019/640 final).

gained during the implementation of Directive 1999/105/EC, that Directive should be replaced by a new act. In order to ensure uniform application of the new rules throughout the Union, the act should take the form of a Regulation.

- (4) The aim of the OECD Forest Seed and Plant Scheme is to encourage the production and use of seeds, parts of plants and plants that have been collected, processed and marketed in a manner that ensures a high quality and availability of FRM. Due to the length of forest cycles and the cost of plantations and long-term forest investment, it is essential that foresters get fully reliable information on the origin and on the genetic characteristics of the FRM they use in plantation. The OECD Forest Seed and Plant Scheme meets that need by means of certification and traceability. It has a major role in helping the world's forests adapt to changing climatic conditions. Emphasis is placed on preserving species diversity and ensuring high genetic diversity within species and seed lots thereby enhancing the adaptive potential of FRM for the future replanting of an area with trees ('reforestation') and the creation of new forests ('afforestation'). Reforestation may be required when parts of an existing forest have been affected by extreme weather events, wildfires, outbreaks of disease and pest outbreaks, or other disasters.
- (5) The European Green Deal sets out the Commission's commitment for tackling climate change and environmentally-related challenges. It aims to transform the Union's economy for a sustainable future. The Union rules on the production and marketing of FRM need to be in line with Regulation (EU) 2021/1119 of the European Parliament and of the Council establishing the framework for achieving climate neutrality<sup>7</sup> and with the three implementing strategies of the European Green Deal: the new EU Strategy on Adaptation to Climate Change<sup>8</sup>, the new EU Forest Strategy for 2030<sup>9</sup> and the EU Biodiversity Strategy for 2030<sup>10</sup>.
- (6) Regulation (EU) 2021/1119 requires relevant Union institutions and Member States to ensure continuous progress in enhancing adaptive capacity, strengthening resilience and reducing vulnerability to climate change. One of the aims of the new EU Strategy on Adaptation to Climate Change is therefore to accelerate the adaptative capacity of the Union to climate change, by amending the rules on FRM, amongst others. The Union legislation should encourage the Union wide production and marketing of FRM. To this end, the possibility for Member States to restrict the approval of certain basic material and to prohibit the marketing of certain FRM to final users, as it it set out in Directive 1999/105/EC, should be abolished.
- (7) The new EU Forest Strategy for 2030 has as its key objectives effective afforestation, and forest preservation and restoration in the Union, to help increase the absorption of CO<sub>2</sub>, reduce the incidence and extent of forest fires, and promote the bio-economy, in

 <sup>&</sup>lt;sup>7</sup> Regulation (EU) 2021/1119 of the European Parliament and of the Council of 30 June 2021 establishing the framework for achieving climate neutrality and amending Regulations (EC) No 401/2009 and (EU) 2018/1999 ('European Climate Law') (OJ L 243, 9.7.2021, p. 1).

<sup>&</sup>lt;sup>8</sup> Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, Forging a climate-resilient Europe - the new EU Strategy on Adaptation to Climate Change (COM(2021) 82 final).

<sup>&</sup>lt;sup>9</sup> Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, New EU Forest Strategy for 2030 (COM(2021) 572 final).

<sup>&</sup>lt;sup>10</sup> Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, EU Biodiversity Strategy for 2030 Bringing nature back into our lives (COM(2020) 380 final).

full respect of ecological principles favourable to biodiversity. Ensuring forest restoration and reinforced sustainable forest management are essential for climate adaptation and forest resilience. In this regard, the new EU Forest Strategy states that adapting forests to climate change and restoring forests following climate damages will require large quantities of appropriate FRM. This implies efforts to secure and sustainably use the forest genetic resources on which a more climate-proof forestry depends. Efforts are also needed to increase the production and availability of such FRM, to provide better information on its suitability for climatic and ecological conditions and to enhance its collaborative production and transfer across national borders within the Union. Professional operators should thus be required to provide beforehand information to the users about the suitability of FRM for climatic and ecological conditions.

- (8) The EU Biodiversity Strategy for 2030 aims to put Union biodiversity on the path to recovery by 2030. Within the framework of that strategy, Union legislation is to place emphasis on the preservation of species diversity and ensure high genetic diversity within species and seed lots. This aims to facilitate the supply of high-quality and genetically diverse FRM that is adapted to current and projected future climatic conditions. The conservation and improvement of biodiversity of forests, including the genetic diversity of the trees, are essential to sustainable forest management and for supporting forests' adaptation to climate change. Tree species and artificial hybrids under this Regulation should be genetically suited to the local conditions and be of high quality.
- (9) There is a long-term cross-border dimension due to the fact that the already observed northward migration of vegetation zones is expected to accelerate significantly in the coming decades. Hence the requirement in this Regulation for providing information about the zones where seed can be planted or FRM is adapted to the local conditions would be an extremely useful asset to foresters. Competent authorities should therefore designate zones specifying that in these zones the seed is suited to the local conditions and can be sown ('seed transfer zones'). Likewise, they should designate areas specifying that in these areas FRM is adapted to the local conditions ('deployment areas').
- (10) Directive 1999/105/EC defines FRM in relation to its importance for forestry purposes in all or part of the Union but it remains vague about those forestry purposes. For the sake of clarity, the scope of this Regulation lists the purposes for which it is important to use high-quality FRM.
- (11) FRM may be produced for use in afforestation/reforestation and other types of tree planting and for several different purposes such as wood and biomaterials production, biodiversity conservation, restoration of forest ecosystems, climate adaptation, climate mitigation, and conservation and sustainable use of forest genetic resources.
- (12) Research has shown that the assessment and approval of basic material in relation to the specific purpose for which the FRM will be used are of utmost importance. In addition to that, the planting of high-quality FRM at the right place has a positive impact on the purpose for which that FRM is used. At the right place means that the FRM is genetically and phenotypically suited to the site where it is grown, including the relevant climate projections for it.
- (13) In order to ensure a sufficient supply of FRM in response to the increased demand for FRM, it is necessary to remove any actual or potential barriers to trade, which may

hinder the free movement of FRM within the Union. This aim can be achieved only if the respective Union rules on FRM impose the highest possible standards.

- (14) The Union rules on the production and marketing of FRM should take into account practical needs and should apply only to certain species and artificial hybrids which are are listed in Annex I to this Regulation. Those species and artificial hybrids are important for the production of FRM for afforestation, reforestation and other types of tree planting for the purpose of wood and biomaterials production, biodiversity conservation, restoration of forest ecosystems, climate adaptation, climate mitigation, and conservation and sustainable use of forest genetic resources.
- (15) The aim of this Regulation is to ensure the production and marketing of high-quality FRM. To help create resilient forests and restore forest ecosystems, users should be informed prior to the purchase of FRM about the suitability of that FRM for the climatic and ecological conditions of the area where it will be used.
- (16) To ensure that certified FRM will be adapted to the climatic and ecological conditions of the area where it is planted, the competent authorities should assess the sustainability characteristics of basic material during the procedure for approving that basic material. Those sustainability characteristics should concern the adaptation of that basic material to the climatic and ecological conditions and the freedom of trees from pests and their symptoms.
- (17) FRM should only be harvested from basic material that has been assessed and approved by the competent authorities in order to ensure the highest possible quality of that FRM. Approved basic material should registered in a national register with a unique register reference and with reference to a unit of approval.
- (18) In order to adapt to the scientific and technical developments of international standards, the use of bio-molecular techniques should be included as a complementary method in the procedure for the approval of basic material. Those bio-molecular techniques should be allowed to assess the origin of basic material or to screen the basic material for the presence of disease resistance traits through molecular markers.
- (19) A master certificate should be issued by the competent authorities of the respective Member States for all FRM that is derived (i.e. harvested) from approved basic material. Such master certificate ensures the identification of the FRM, contains information about its origin and provides the most appropriate details for its users and the competent authorities in charge of its official control. It should be allowed to issue the master certificate in an electronic form.
- (20) Only FRM that has been harvested from approved basic material should be allowed to be subsequently certified and placed on the market. FRM should be certified as 'source-identified', 'selected', 'qualified' and 'tested' by the competent authorities and be marketed with a reference to those categories. Those types of categories show which of the characteristics of the basic material have been assessed and they indicate the quality of the FRM. For lower quality FRM ('source-identified' and 'selected' categories), basic material will be checked for basic characteristics. For higher quality FRM ('qualified' and 'tested' categories), parent trees will be selected for outstanding characteristics and crossing schemes designed. In the case of FRM of the 'qualified' category, the superiority of the FRM estimated on the basis of the characteristics of the parent trees. In the case of the 'tested' category, the superiority of that FRM must be demonstrated in comparison with either the basic material from which that FRM has been harvested or with a reference population. The 'source-identified', 'selected',

'qualified' and 'tested' categories of FRM should be subject to uniform production and marketing requirements, to ensure transparency, equal terms of competition and the integrity of the internal market.

- (21) The certification rules should be clarified in the case of FRM that has been produced through innovative production processes and in particular FRM production techniques for the production of a specific type of FRM, namely clones. As the place of production of those clones may be different from the location of the original tree (i.e. basic material) from which the clone(s) has been derived, the rules should be amended to guarantee traceability.
- (22) The requirements for basic material intended for the purpose of conservation and sustainable use of forest genetic resources are different from those for basic material intended for the production of FRM for commercial purposes, because of the different selection criteria applied for these two types of basic material. For the purpose of conserving and sustainably using forest genetic resources, all trees from a stand of trees in the forest should be kept. This is necessary to help increase the genetic diversity within a single tree species. On the other hand, only trees with superior characteristics should be selected in the case of basic material intended for the production of FRM for commercial purposes. Member States should therefore be allowed to derogate from the applicable rules as regards the approval of basic material and notify this basic material intended for the purpose of conserving forest genetic authority.
- (23) The source-identified category is the minimum standard required for the marketing of FRM, because little or no phenotypic selection of the basic material intended for the production of FRM of the source-identified category has taken place. To ensure traceability, the professional operator should record the location of the basic material (i.e. provenance) from which FRM is collected. The origin of that basic material should be stated if known. This is in line with the OECD Forest Seed and Plant Scheme' and the experience gained with Directive 1999/105/EC.
- (24) Pursuant to the OECD Forest Seed and Plant Scheme and following the application of Directive 1999/105/EC, the competent authority should assess basic material intended for the production of FRM of the selected category based on the observation of the characteristics of that basic material, taking account of the specific purpose for which the FRM harvested from that basic material is to be used. The overall quality of that category should be ensured. As the population should show a high degree of uniformity, trees that have inferior characteristics (e.g. smaller size) in comparison to the average tree size in the overall population should be removed.
- (25) In order to produce FRM of the qualified category, the professional operator should select the components of the basic material that will be used in the crossing design at individual level due to their outstanding characteristics as regards, for example, adaptation to the local climatic and ecological conditions. The competent authority should approve the composition and proposed crossing design of those components, the field layout, the isolation conditions and location of that basic material. This is important in order to align with the applicable international standards pursuant to the OECD Forest Seed and Plant Scheme Scheme'and to take into account the experience gained from Directive 1999/105/EC.
- (26) Basic material that is intended for the production of FRM of the tested category should be subject to the most stringent possible requirements. Determining the superiority of FRM should be made by comparing it with one or preferably several approved or pre-

chosen standards. The professional operator selects those standards on the basis of the purpose for which the FRM of the tested category will be used. In this regard, if the purpose of that FRM will be climate adaptation, then the FRM will be compared with standards having a good performance as regards adaptation to the local climatic and ecological conditions (e.g. practical freedom from pests and their symptoms). Following the selection of the components of basic material, the professional operator should demonstrate the superiority of the FRM by comparative testing or estimate its superiority by evaluating the genetic components of that basic material. The competent authority should be involved in each step of this process. It should approve the experimental design and tests for the aproval of the basic material, verify the records provided by the professional operator and approve either the results of the tests concerning the superiority of the FRM or the genetic evaluation as appropriate. This is necessary, in order to align with the applicable international standards pursuant to the OECD Forest Seed and Plant Scheme and other applicable international standards, and to take into account the experience gained from Directive 1999/105/EC.

- (27) The assessment of basic material intended for the production of FRM of the tested category takes on average 10 years. In order to ensure faster market access of FRM of the tested category, while the assessment of the basic material is still ongoing, Member States should have the possibility to temporarily approve such basic material, for a maximum period of 10 years, in all or part of their territory. That approval should be granted only if the provisional results of the genetic evaluation or comparative tests indicate that that basic material will satisfy the requirements of this Regulation when the tests will be completed. This early assessment should be re-examined at a maximum interval of ten years.
- (28) Compliance of FRM with the requirements for the categories 'source-identified', 'selected', 'qualified' and 'tested' should be confirmed by inspections carried out by the competent authorities as appropriate for each category ('official certification') and should be attested by an official label.
- (29) Genetically modified FRM may only be placed on the market if it is safe for human health and the environment and has been authorised for cultivation pursuant to Directive 2001/18/EC of the European Parliament and of the Council<sup>11</sup> or Regulation (EC) 1829/2003<sup>12</sup> and if that FRM belongs to the tested category. FRM obtained by certain new genomic techniques may only be placed on the market if it complies with the requirements of Regulation (EU) [Publications Office, please insert reference to Regulation (EU) of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed<sup>13</sup> and if that FRM belongs to the tested category.
- (30) The official label should contain information on basic material that contains or consists of a genetically modified organism or that has been produced by certain new genomic techniques.

<sup>&</sup>lt;sup>11</sup> Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

<sup>&</sup>lt;sup>12</sup> Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1).

<sup>&</sup>lt;sup>13</sup> Regulation (EU) .../... of the European Parliament and of the Council .... (OJ ..., p.).

- (31) Professional operators should be authorised by the competent authority to print the official label under official supervision for certain species and categories of FRM. This will give more flexbility to the professional operators in relation to the subsequent marketing of that FRM. However, professional operators can only start printing the label once competent authority has certified the FRM concerned. That authorisation is necessary due to the official character of the official label and to guarantee the highest possible quality standards for the users of FRM. Rules should be set out for the withdrawal or modification of that authorisation.
- (32) Member States should be allowed to impose additional or more stringent requirements for the approval of basic material produced in their own territory, subject to authorisation granted by the Commission. This would enable the implementation of national or regional approaches concerning the production and marketing of FRM and aimed at improvement of the quality of the FRM concerned, protection of the environment, or contribution to the protection of biodiversity and the restoration of forest ecosystems.
- (33) In order to ensure transparency and more effective controls on the production and marketing of FRM, professional operators should be registered in the registers established by Member States pursuant to Regulation (EU) 2016/2031 of the European Parliament and of the Council<sup>14</sup>. Such registration reduces the administrative burden for those professional operators. It is necessary for the efficacy of the official register of professional and to avoid double registration. The professional operators under the scope of this Regulation are to a big extent covered by the scope of the official register of professional operators under Regulation (EU) 2016/2031.
- (34) Prior to the purchase of FRM, professional operators should make available to the potential buyers of their FRM all the necessary information concerning its suitability for the respective climatic and ecological conditions, in order to allow them to select the most appropriate FRM for their region.
- (35) In the case of basic material intended for the production of FRM of the 'sourceidentified' and 'selected' categories, the Member States should, for the relevant species, demarcate the regions of provenance, in order to identify an area or groups of areas with sufficiently uniform ecological conditions and containing basic material with similar phenotypic or genetic characteristics. This is necessary because the FRM produced from that basic material is to be marketed with reference to those regions of provenance.
- (36) To ensure an effective overview and transparency about the FRM that is produced and marketed throughout the Union, each Member State should establish, publish and keep updated, in electronic format, a national register of the basic material of the various species and artificial hybrids approved on its territory, and a national list which should be presented as a summary of the national register.
- (37) For the same reason, the Commission should publish in electronic format a Union list of approved basic material for the production of FRM, on the basis of the national lists provided by each Member State. That Union list should contain information on basic

<sup>&</sup>lt;sup>14</sup> Regulation (EU) 2016/2031 of the European Parliament and of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC (OJ L 317, 23.11.2016, p. 4).

material that contains or consists of a genetically modified organism or that has been produced by certain new genomic techniques.

- (38) Each Member State should draw up and keep up to date a contingency plan to ensure a sufficient supply of FRM, to reforest areas affected by extreme weather events, wildfires, disease and pest outbreaks, disasters or any other event. Rules should be set out concerning the content of that plan, in order to ensure proactive and effective action against such risks, if they emerge. Member States should be allowed to adapt the content of that plan to the specific climatic and ecological conditions in their territories. This requirement also reflects the general preparedness actions that Member States should take on a voluntary basis under the Union Civil Protection Mechanism<sup>15</sup>.
- (39) FRM should, during all stages of production, be kept separate by reference to individual units of approval. Those units of approval should be produced and marketed in lots, that must be sufficiently homogeneous and identified as distinct from other lots of FRM. A distinction should be made between seed lots and plant lots, to identify the type of FRM and ensure traceability to the approved basic material from which FRM has been harvested. This guarantees the maintenance of the identity and quality of that FRM.
- (40) Seeds should be marketed only if they conform to certain quality standards. They should be labelled and marketed only in sealed packages, in order to enable their appropriate identification, quality and traceability, and to avoid fraud.
- (41) In order to meet the aim of the EU Digital Strategy<sup>16</sup> to make the transformation to digital technologies work for people and businesses, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union ('TFEU') should be delegated to the Commission in respect of rules on rules on digital recording of all actions taken, for the purpose of issuing a master certificate and an official label and the establishment of a centralised platform facilitating the processing of, access to, and use of those records.
- (42) During periods in which there are temporary difficulties in harvesting sufficient supplies of FRM from certain species, basic material satisfying less stringent requirements should, subject to certain conditions, be temporarily approved. Those less stringent requirements should concern the approval of basic material intended for the production of different categories of FRM. This is necessary to ensure a flexible approach under adverse circumstances and to avoid disruptions of the internal market of FRM'.
- (43) FRM should only be imported from third countries, if it is established that it fulfils requirements equivalent to those applicable to FRM produced and marketed in the Union. This is necessary in order to ensure that such imported FRM affords the same level of quality as the FRM produced in the Union.
- (44) Where FRM is imported into the Union from a third country, the professional operator concerned should inform the respective competent authority in advance of the import

<sup>&</sup>lt;sup>15</sup> Decision No 1313/2013/EU of the European Parliament and of the Council of 17 December 2013 on a Union Civil Protection Mechanism (OJ L 347, 20.12.2013, p. 924).

<sup>&</sup>lt;sup>16</sup> Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, 2030 Digital Compass: the European way for the Digital Decade (COM(2021)118 final).

of FRM, through the information management system for official controls (IMSOC) set up pursuant to Regulation (EU) 2017/625 of the European Parliament and of the Council<sup>17</sup>. Moreover, imported FRM should be accompanied by a master certificate or an official certificate issued by the third country of origin, and records containing details of that FRM provided by the professional operator in that third country. An official label should be attached to that FRM, as this is necessary to ensure informed choices for the users of that FRM and facilitate the competent authorities with the conduct of the respective official controls.

- (45) In order to monitor the impact of this Regulation and to allow the Commission to assess the measures introduced, Member States should report every 5 years about the annual quantities of certified FRM, the adopted national contingency plans, the information available to users on where to best plant FRM through websites and/or planters' guides, the quantities of imported FRM and the penalties imposed.
- (46) In order to adapt to the movement of vegetation zones and tree species' ranges as a result of climate change, and any other developments of technical or scientific knowledge, including about climate change, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of amending the list of the tree species, and artificial hybrids thereof, to which this Regulation applies.
- (47) In order to adapt to the development of scientific and technical knowledge and of the OECD Forest Seed and Plant Scheme and other applicable international standards, and to take account of Regulation (EU) 2018/848 of the European Parliament and of the Council<sup>18</sup>, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of amending (i) the requirements concerning basic material intended for the production of FRM to be certified as 'source-identified', 'selected', 'qualified', and 'tested' and (ii) the categories under which FRM from the different types of basic material may be marketed.
- (48) In order to allow a more flexible approach for the Member States, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of setting out the conditions for temporarily authorising the marketing of FRM which does not meet all the requirements of the appropriate category.
- (49) In order to adapt 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 setting out the requirements to be fulfilled by fruit and seed lots of the species covered by this Regulation, to be fulfilled by parts of plants of the species and artificial hybrids covered by this Regulation, for external quality standards for *Populus*

<sup>&</sup>lt;sup>17</sup> Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

<sup>&</sup>lt;sup>18</sup> Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007 (OJ L 150, 14.6.2018, p. 1).

spp. propagated by stem cuttings or sets, to be fulfilled by planting stock of the species and artificial hybrids covered by this Regulation, and to be fulfilled by planting stock to be marketed to final users in regions having a Mediterranean climate.

- (50) In order to adapt with the EU Digital Strategy and the technical developments in the digitisation of services, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of establishing rules concerning digital recording of all actions taken by the professional operator and the competent authorities, in order to issue the master certificate, and concerning the establishment of a centralised platform that connects all the Member States and the Commission.
- (51) It is of particular importance that the Commission carry out appropriate consultations during its preparatory work for those delegated acts, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making<sup>19</sup>. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.
- (52) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission with respect to the establishment of specific conditions as regards the requirements and content of the notification of the basic material.
- (53) In order to ensure uniform conditions for the implementation of this Regulation, and facilitate the recognisibility and use of master certificates, implementing powers should be conferred on the Commission with respect to adopting the content and the model for the master certificate of identity for FRM derived from seed sources and stands, FRM derived from seed orchards or parents of family(ies), and FRM derived from clones and clonal mixtures.
- (54) In order to ensure uniform conditions for the implementation of this Regulation, and ensure a harmonised framework for the labelling and provision of information concerning FRM, implementing powers should be conferred on the Commission with respect to setting out the content of the official label, the additional information in the case of seeds and small quantities of seeds, the colour of the label for specific categories or other types of FRM, and additional information in the case of specific.
- (55) In order to ensure uniform conditions for the implementation of this Regulation, and adapt to the developments concerning the digitisation of the FRM sector, implementing powers should be conferred on the Commission with respect to setting out the technical arrangements for the issuance of electronic master certificates.
- (56) In order to ensure uniform conditions for the implementation of this Regulation, and to address urgent supply problems of FRM, implementing powers should be conferred on the Commission with respect to temporarily approving for marketing FRM of one or more species which satisfies less stringent requirements than the ones set out in this Regulation concerning the approval of basic material.

<sup>&</sup>lt;sup>19</sup> OJ L 123, 12.5.2016, p. 1.

- (57) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission with respect to deciding on the organisation of temporary experiments to seek improved alternatives to the requirements of this Regulation as regards the assessment and approval of basic material and the production and marketing of FRM.
- (58) To improve consistency of FRM rules with the Union plant health legislation, Articles 36, 37, 40, 41, 49, 53 and 54 of Regulation (EU) 2016/2031 should apply to the production and marketing of FRM pursuant to this Regulation. In order to ensure consistency with the rules of Regulation (EU) 2016/2031 on plant passports, it should be allowed to combine the official label for FRM with the plant passport.
- (59) Regulation (EU) 2017/625 should be amended in order to include in its scope rules on official controls in regards to FRM. This is to ensure more consistent official controls and enforcement of the rules across Member States concerning FRM, and consistency with other Union acts concerning the official controls of plants, in particular, Regulation (EU) 2016/2031 and Regulation (EU) .../... of the European Parliament and of the Council.
- (60) Regulations (EU) 2016/2031 and 2017/625 should therefore be amended accordingly.
- (61) For reasons of legal clarity and transparency, Directive 1999/105/EC should be repealed.
- (62) Since the objective of this Regulation, namely to ensure a harmonised approach with regard to the production and marketing of FRM, cannot be sufficiently achieved by the Member States but can rather, by reason of its effects, complexity, 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. In this view, and as necessary, it introduces derogations or specific requirements for certain types of FRM and professional operators.
- (63) In view of the time and resources required for the competent authorities and the professional operators concerned to adapt to the new requirements set out in this Regulation, this Regulation should apply from ... [3 years from the date of entry into force of this Regulation],

# HAVE ADOPTED THIS REGULATION:

# CHAPTER I GENERAL PROVISIONS

# Article 1

# Subject matter

This Regulation sets out rules concerning the production and marketing of forest reproductive material ('FRM') and in particular requirements for the approval of basic material intended for the production of FRM, the origin and traceability of that basic material, FRM categories, requirements for FRM identity and quality, certification, labelling, packaging, imports, professional operators, the registration of basic material and the national contingency plans.

#### Article 2

#### Scope

- 1. This Regulation applies to FRM of the tree species and artificial hybrids thereof, listed in Annex I.
- 2. The objectives of this Regulation are the following:
  - (a) ensure the production and marketing of high-quality FRM in the Union and the functioning of the internal market in FRM;
  - (b) help create resilient forests, conserve biodiversity and restore forest ecosystems;
  - (c) support wood and biomaterials production, climate adaptation, climate mitigation and the conservation and sustainable use of forest genetic resources.
- 3. The Commission shall be empowered to adopt delegated acts, in accordance with Article 26, amending the list set out in Annex I as specified in paragraph 3, taking into account:
  - (a) the movement of vegetation zones and tree species' ranges as a result of climate change;
  - (b) any developments of technical or scientific knowledge.

Those delegated acts shall add species and artificial hybrids to the list in Annex I, if such species and artificial hybrids fulfil at least one of the following elements:

- (a) represent a significant area and economic value of FRM production in the Union;
- (b) are marketed in at least two Member States;
- (c) are considered important for their contribution to adaptation to climate change, and
- (d) are considered important for their contribution to the conservation of biodiversity.

The delegated acts referred to in the first subparagraph shall remove species and artificial hybrids from the list in Annex, I if they no longer fulfil any of the elements set out in the first subparagraph.

- 4. This Regulation does not apply to the following:
  - (a) plant reproductive material referred to in Article 2 of Regulation (EU) .../... [Office of Publications, please insert reference to Regulation on production and marketing of plant reproductive material];
  - (b) propagating material of ornamental plants as defined in Article 2 of Directive 98/56/EC;
  - (c) FRM produced for export to third countries;
  - (d) FRM used for official testing, scientific purposes or selection work.

# Article 3

#### Definitions

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

- (1) 'forest reproductive material' ('FRM') means cones, infructescenses, fruits and seeds intended for the production of a planting stock, that belong to tree species and artificial hybrids thereof listed in Annex I to this Regulation and used for afforestation, reforestation and other tree planting for any of the following purposes:
  - (a) wood and biomaterials production;
  - (b) biodiversity conservation;
  - (c) restoration of forest ecosystems;
  - (d) climate adaptation;
  - (e) climate mitigation;
  - (f) conservation and sustainable use of forest genetic resources.
- (2) 'afforestation' means establishment of forest through planting and/or deliberate seeding on land that, until then, was under a different land use implies a transformation of land use form non-forest to forest<sup>20</sup>;
- (3) 'reforestation' means re-establishment of forest through planting and/or deliberate seeding on land classified as forest<sup>21</sup>;
- (4) 'seed unit' means cones, infructescenses, fruits and seeds intended for the production of a planting stock;
- (5) 'planting stock' means any plant or part of a plant used in plant propagation and comprises plants raised from seed units, from parts of plants, or from plants from natural regeneration;
- (6) 'parts of plants' means stem cuttings, leaf cuttings and root cuttings, explants or embryos used for micropropagation, buds, layers, roots, scions, sets and any other parts of a plant used for the production of a planting stock;
- (7) 'production' means all stages in the generation of the seed and plants, the conversion from seed unit to seed, and the raising of plants from a planting stock, with a view for the respective FRM to be marketed;
- (8) 'seed source' means the trees within an area, from which seed is collected;
- (9) 'stand' means a delineated population of trees possessing sufficient uniformity in composition;
- (10) 'seed orchard' means a plantation of selected trees, where each tree is identified by a clone, family or provenance, which is isolated or managed to avoid or reduce pollination from outside sources, and managed to produce frequent, abundant and easily harvested crops of seed;
- (11) 'parents of family(ies)' means trees used as parents to obtain progeny by controlled or open pollination of one identified parent used as a female ('mother tree'), with the pollen of one 'father tree', full sibling) or a number of identified or unidentified 'father trees' (half-sibling);

 <sup>&</sup>lt;sup>20</sup> FAO (2020) Global Forest Resources Assessment Terms and definitions. https://www.fao.org/3/I8661EN/i8661en.pdf.
<sup>21</sup> FAO (2020) Global Forest Pacources Assessment Terms and definitions.

<sup>&</sup>lt;sup>21</sup> FAO (2020) Global Forest Resources Assessment Terms and definitions. https://www.fao.org/3/I8661EN/i8661en.pdf.

- (12) 'clone' means a group of individuals (ramets) derived originally from a single individual (ortet) by vegetative propagation, for example by cuttings, micropropagation, grafts, layers or divisions;
- (13) 'clonal mixture' means a mixture of identified clones in defined proportions;
- (14) 'basic material' means any of the following: seed source, stand, seed orchard, parents of family(ies), clone or clonal mixtures;
- (15) 'unit of approval' means the entire area of basic material for the production of FRM that has been authorised by the competent authorities;
- (16) 'unit of notification' means the entire area of basic material for the production of FRM intended for the purpose of the conservation and sustainable use of forest genetic resources that has been notified to the competent authorities;
- (17) 'seed lot' means a set of seeds collected from approved basic material and processed uniformly;
- (18) 'plant lot' means a set of planting stock that has been grown from a single seed lot or a vegetatively propagated planting stock which has been raised in a delineable area and processed uniformly;
- (19) 'lot number' means the identification number of the seed lot or plant lot, as appropriate;
- (20) 'provenance' means the place in which any stand of trees is growing;
- (21) 'sub-species' means a group within a species that has become somewhat phenotypically and genetically different from the rest of the group;
- (22) 'region of provenance' means, in regard to 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 characteristics are found, taking into account altitudinal boundaries, where appropriate;
- (23) 'autochthonous stand' means a stand of native tree species which has been continuously regenerated either by natural regeneration or artificially from FRM collected in the same stand or stands of native tree species within close proximity;
- (24) 'indigenous stand' means an autochthonous stand or a stand raised artificially from seed, where the origin of this stand and the stand itself are located in the same region of provenance;
- (25) 'origin' means the following:
  - (a) for an autochthonous seed source or stand, the place in which the trees are growing;
  - (b) for a non-autochthonous seed source or stand, the place from which the seed or plants were originally introduced;
  - (c) for a seed orchard, the places where its components were originally located, such as their provenances or other relevant geographical information;
  - (d) for the parents of families, the places where their components were originally located, such as their provenances or other relevant geographical information;
  - (e) for a clone, the origin is the place, where the ortet is or was initially located or selected;

- (f) for a clonal mixture, the origins are the places, where the ortets are or were initially located or selected;
- (26) 'location of the basic material' means the geographical area or geographical position(s) of the basic material as appropriate for each category of FRM;
- (27) 'place of production of clones or clonal mixtures or parents of families' means the place or exact geographical position, where the FRM was produced;
- (28) 'foundation stock' means a plant, group of plants, FRM, DNA stock or genetic information of the clone, or clones in case of clonal mixture, that serves as a reference material for the control of the identity of the clone(s);
- (29) 'set' means a stem cutting without roots;
- (30) 'marketing' means the following actions conducted by a professional operator: sale, holding or offering for the purpose of sale or any other way of transferring, distribution within, or import into the Union, whether free of charge or not, of FRM;
- (31) 'professional operator' means any natural or legal person involved professionally in one or more of the following activities:
  - (a) production, including growing, multiplying and maintaining of the FRM;
  - (b) marketing of the FRM;
  - (c) storage, collection, dispatching and processing of the FRM;
- (32) 'competent authority' means a central or regional authority of a Member State, or, where applicable, the corresponding authority of a third country, responsible for the organisation of official controls, registration of basic material, certification of FRM and other official activities concerning the production and marketing of FRM, or any other authority to which that responsibility has been conferred, in accordance with Union law;
- (33) 'source-identified' means a category of FRM derived from basic material consisting of either a seed source or stand located within a single region of provenance and which meets the requirements set out in Annex II;
- (34) 'selected' means a category of FRM derived from basic material consisting of a stand located within a single region of provenance, which has been phenotypically selected at the population level and which meets the requirements set out in Annex III;
- (35) 'qualified' means a category of FRM derived from basic material consisting of seed orchards, parents of family(ies), clones or clonal mixtures, the components of which have been phenotypically selected at the individual level, and which meets the requirements set out in Annex IV;
- (36) 'tested' means a category of FRM derived from basic material consisting of stands, seed orchards, parents of family(ies), clones or clonal mixtures and which meets the requirements set out in Annex V;
- (37) 'official certification' means certification of source-identified, selected, qualified and tested FRM, if all relevant inspections and, where appropriate, sampling and FRM testing have been carried out by the competent authority and if it has been concluded that the FRM meets the respective requirements of this Regulation;
- (38) 'category' means FRM that qualifies as source-identified, selected, qualified or tested material;

- (39) 'genetically modified organism' means a genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC, excluding organisms obtained through the techniques of genetic modification listed in Annex I B to Directive 2001/18/EC;
- (40) 'NGT plant' means plants obtained by certain new genomic techniques as defined in Article 3, point 2 of Regulation (EU) [*Office of Publications, please insert reference to Regulation on plants obtained by certain new genomic techniques and their food and feed*] of the European Parliament and of the Council <sup>22</sup>;
- (41) 'seed transfer zones' means an area and/or altitudinal zones designated by the competent authorities for the movement of FRM belonging to the source-identified and selected categories, taking into account, as appropriate, the origin and provenance of the FRM, provenance trials, environmental conditions and future climatic change projections;
- (42) 'deployment area for seed orchards' means the area designated by the competent authorities, in which FRM belonging to the qualified and tested categories is adapted to the climatic and ecological conditions of that area, taking into account, as appropriate, the location of the seed orchards and its components, results of progeny and provenance trials, environmental conditions and future climatic change projections;
- (43) 'deployment area for clones and clonal mixtures' means the area designated by the competent authorities, in which FRM belonging to the qualified and tested categories is adapted to the climatic and ecological conditions of that area, taking into account, as appropriate, the origin or provenance of the clone(s), results of progeny and provenance trials, the environmental conditions and future climatic change projections;
- (44) 'FOREMATIS' means the Forest Reproductive Material Information System of the Commission;
- (45) 'natural regeneration' means the renewal of a forest by trees that develop from seeds which have fallen and germinated *in situ*
- (46) 'quality pests' means pests fulfilling all of the following:
  - (a) they are not Union quarantine pests, protected zone quarantine pests, or regulated non-quarantine pests ('RNQPs') within the meaning of Regulation (EU) 2016/2031, nor pests subject to the measures adopted pursuant to Article 30(1) of that Regulation;
  - (b) they occur during FRM production or storage; and
  - (c) their presence has an unacceptable adverse impact on the quality of the FRM, and an unacceptable economic impact as regards the use of that FRM in the Union;
- (47) 'practically free from pests' means completely free from pests, or a situation where the presence of quality pests on the respective FRM is so low that those pests do not affect adversely the quality of that FRM.

Regulation (EU) .../... of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Directives 68/193/EEC, 1999/105/EC, 2002/53/EC, 2002/55/EC, and Regulation (EU) 2017/625 (OJ ...).

# CHAPTER II BASIC MATERIAL AND FRM DERIVING FROM IT

#### Article 4

#### Approval of basic material for the production of FRM

- 1. Only basic material approved by the competent authorities may be used for the production of FRM.
- 2. Basic material intended for the production of FRM to be certified as 'sourceidentified' shall be approved, if it fulfils the requirements set out in Annex II.

Basic material intended for the production of FRM to be certified as 'selected' shall be approved, if it fulfils the requirements set out in Annex III.

Basic material intended for the production of FRM to be certified as 'qualified' shall be approved, if it fulfils the requirements set out in Annex IV.

Basic material intended for the production of FRM to be certified as 'tested' shall be approved, if it fulfils the requirements set out in Annex V.

The assessment of the requirements laid down in Annexes II to V for the approval of basic material, may include besides visual inspection, documentary checks, tests and analyses or other complementary methods, also the use of bio-molecular techniques, if they are considered more appropriate for the purpose of that approval.

The basic material for all categories shall be assessed for its sustainability characteristics as set out in Annexes II to V, to take into account the climatic and ecological conditions.

The approval of the basic material shall be carried out with a reference to the unit of approval.

The Commission is empowered to adopt delegated acts in accordance with Article 26 amending Annexes II, III, IV and V, as regards requirements for the approval of basic material intended for the production of:

- (a) FRM of 'source-identified' category, and in particular the requirements concerning types of basic material, effective size of the population, origin and region of provenance, sustainability characteristics;
- (b) FRM of the 'selected' category, and in particular the requirements concerning origin, isolation, effective size of the population, age and development, uniformity, sustainability characteristics, volume production, wood quality, and form or growth habit;
- (c) FRM of the 'qualified' category, and in particular the requirements concerning orchards, parents of family(ies), clones, and clonal mixtures;
- (d) FRM of the 'tested' category, and in particular the requirements concerning characteristics to be examined, documentation, setting up the tests, analysis and validity of the tests, the genetic evaluation of the components of basic material, the comparative testing of FRM, provisional approval and early tests;
- (e) FRM in accordance with the requirements of Regulation (EU) 2018/848 of the European Parliament and of the Council.

Those amendments shall adapt the rules for the approval of basic material to the development of scientific and technical knowledge, and the development of the OECD Forest Seed and Plant Scheme and other applicable international standards.

- 3. Only approved basic material shall be included under the form of a unit of approval in the national register pursuant to Article 12. Each unit of approval shall be identified by a unique register reference in a national register.
- 4. The approval of basic material shall be withdrawn, if the requirements set out in this Regulation are no longer met.
- 5. After approval, the basic material intended for the production of FRM under the selected, qualified and tested categories shall be re-inspected by the competent authorities at regular intervals.
- 6. The Commission is empowered to adopt delegated acts in accordance with Article 26 amending Annexes II, III, IV and V, in order to adapt them to the development of scientific and technical knowledge, in particular regarding the use of bio-molecular techniques and to the relevant international standards.

# Article 5

# Requirements for the marketing of FRM derived from approved basic material

- 1. FRM derived from approved basic material shall be marketed in accordance with the following rules:
  - (a) FRM of the species listed in Annex I may only be marketed, if it is of the categories 'source-identified', 'selected', 'qualified' or 'tested', and it has been derived from basic material that has been approved pursuant to Article 4 and if that basic material meets the requirements of Annexes II, III, IV and V, respectively;
  - (b) FRM of the artificial hybrids listed in Annex I may only be marketed, if it is of the 'selected', 'qualified' or 'tested' categories, and it has been derived from basic material that has been approved pursuant to Article 4 and if that basic material meets the requirements of Annexes III, IV and V, respectively;
  - (c) FRM of the tree species and artificial hybrids listed in Annex I, which are vegetatively reproduced, may only be marketed if:
    - (i) it is of the 'selected', 'qualified' or 'tested' categories, and
    - (ii) it has been derived from basic material which has been approved pursuant to Article 4 and which meets the requirements of Annexes III, IV and V, respectively;
    - (iii) FRM of the 'selected' category, may only be marketed if it has been mass propagated from seeds;
  - (d) FRM of the tree species and artificial hybrids listed in Annex I, which contains or consists in genetically modified organisms, may only be marketed if:
    - (i) it is of the 'tested' category, and
    - (ii) it has been derived from basic material which has been approved pursuant to Article 4 and which meets the requirements of Annex V; and

- (iii) it is authorised for cultivation in the Union pursuant to Article 19 of Directive 2001/18/EC or Articles 7 and 19 of Regulation (EC) 1829/2003, or, where applicable, in the respective Member State in accordance with Article 26b of Directive 2001/18/EC;
- (e) FRM of the tree species and artificial hybrids listed in Annex I, which contain or consist of a category 1 NGT plant as defined in Article 3(7) of Regulation (EU) .../... (Office of Publications, please insert reference to NGT Regulation ...), may only be marketed if:
  - (i) it is of the 'tested' category, and
  - (ii) it has been derived from basic material which has been approved pursuant to Article 4 and which meets the requirements of Annex V; and
  - (iii) the plant has obtained a declaration of category 1 NGT plant status pursuant to Article 6 or 7 of Regulation (EU) .../... (Office of Publications, please insert reference to NGT Regulation ...) or is progeny of such plant(s);
- (f) FRM of the tree species and artificial hybrids listed in Annex I, may only be marketed if it is accompanied by a reference to its master certificate number(s);
- (g) it complies with Articles 36, 37, 40, 41, 42, 49, 53 and 54 of Regulation (EU) 2016/2031 concerning Union quarantine pests, protected zone quarantine pests, RNQPs, and pests subject to the measures under Article 30 of that Regulation;
- (h) In the case of seeds, FRM of the tree species and artificial hybrids listed in Annex I, may only be marketed, if in addition to compliance with points (a) to (g), information is available as regards:
  - (i) purity;
  - (ii) germination percentage of the pure seed;
  - (iii) weight of 1000 pure seeds;
  - (iv) the number of germinable seeds per kilogram of product marketed as seed, or, where the number of germinable seeds is impossible or impractical to assess, the number of viable seeds per kilogram.
- 2. The categories under which FRM from the different types of basic material may be marketed are as set out in the table in Annex VI.
- 3. The Commission is empowered to adopt delegated acts in accordance with Article 26(2), amending the table of Annex VI concerning categories under which FRM from the different types of basic material may be marketed.

That amendment shall adapt those categories to the development of scientific and technical knowledge and of the relevant international standards.

# Article 6

# Requirements for FRM derived from basic material intended for the purpose of conserving forest genetic resources

In order for FRM derived from basic material subject to the derogation of Article 18 to be marketed, all the following conditions shall be fulfilled:

- (a) FRM of the species listed in Annex I may only be marketed, if it is of the 'sourceidentified' category;
- (b) FRM shall be of origin which is naturally adapted to the local and regional conditions; and
- (c) FRM shall be collected from all individuals of the notified basic material.

# Article 7

#### Temporary authorisation of marketing of FRM derived from basic material not meeting the category requirements

1. Competent authorities may temporarily authorise the marketing of FRM derived from approved basic material which does not meet all the requirements of the appropriate category referred to in Article 5(1), following the adoption of the delegated act referred to in paragraph 2.

The competent authorities of the respective Member State shall notify the Commission and the other Member States of those temporary authorisations and of the respective reasons justifying their approval.

2. The Commission is empowered to adopt delegated acts, in accordance with Article 26, supplementing this Article, by setting out the conditions for the granting of the temporary authorisation to the Member State concerned.

Those conditions shall include:

- (a) the justification for granting that authorisation to ensure achievement of the objectives of this Regulation;
- (b) the maximum duration of the authorisation;
- (c) obligations as regards official controls on the professional operators applying that authorisation;
- (d) the content and form of the notification referred to in paragraph 1.

#### Article 8

# Special requirements for certain species, categories and types of FRM

The Commission is empowered to adopt delegated acts, in accordance with Article 26, supplementing, as necessary, this Regulation as regards the requirements as appropriate for each type, species or category of FRM:

- (a) concerning fruit and seed lots of the species listed in Annex I as regards species purity;
- (b) concerning parts of plants of the species and artificial hybrids listed in Annex I as regards quality in relation to general characteristics, health and size;
- (c) for external quality standards for *Populus* spp. propagated by stem cuttings or sets as regards defects and minimum dimensions for stem cuttings and sets;
- (d) concerning planting stock of the species and artificial hybrids listed in Annex I as regards quality in relation to general characteristics, health, vitality and physiological quality;

(e) concerning planting stock to be marketed to users in regions having a Mediterranean climate as regards defects, size and age of the plants and, where appropriate, size of the container.

That delegated act shall be based on the experience gained by the application of the requirements as appropriate for each type, species or category of FRM as regards the provisions for inspections, sampling and testing, and isolation distances. It shall adapt those requirements based on the development of the respective international standards, the technical and scientific developments, or the climatic and ecological developments.

#### Article 9

#### Contingency plan and national register

1. Each Member State shall draw up one or more contingency plan to ensure a sufficient supply of FRM to reforest areas affected by extreme weather events, wildfires, disease and pest outbreaks, disasters or any other event, as relevant and identified in the national risk assessments develop in accordance with Article 6(1) of Decision No 1313/2013/EU<sup>23</sup>.

That contingency plan shall be prepared for those tree species and artificial hybrids thereof listed in Annex I, that are deemed suitable for the current and projected future climatic and ecological conditions of the Member State concerned.

The contingency plan shall take into account the projected future distribution of the relevant tree species and artificial hybrids thereof, on the basis of national and/or regional climate model simulations for the Member State concerned.

- 2. Member States shall, at an appropriate stage, consult all relevant stakeholders in the process of drawing up and keeping up to date such contingency plans.
- 3. Each contingency plan shall include the following:
  - (a) the roles and responsibilities of the bodies involved in the execution of the contingency plan in case of any event causing a major shortage of FRM, as well as the chain of command and procedures for the coordination of actions to be taken by competent authorities, other public authorities, delegated bodies or natural persons involved, laboratories and professional operators, including the coordination with neighbouring Member States and neighbouring third countries, where appropriate;
  - (b) access of competent authorities to supplies of FRM that have been maintained for the purpose of contingency planning, premises of professional operators, in particular forest nurseries and laboratories producing FRM, other relevant operators and natural persons;
  - (c) access of competent authorities, where necessary, to equipment, personnel, external expertise and resources necessary for the rapid and effective activation of the contingency plan;
  - (d) measures concerning the submission of information to the Commission, the other Member States, the professional operators concerned and the public, as regards the major FRM shortage, and the measures taken against it in the event of an officially confirmed or suspected major FRM shortage;

<sup>&</sup>lt;sup>23</sup> OJ L 347, 20.12.2013, p. 924.

- (e) arrangements for recording findings of the presence of any major FRM shortage;
- (f) the available assessments of the Member State as regards the risk of a major FRM shortage for its territory and its potential impact on human, animal and plant health, and the environment;
- (g) principles for the geographical demarcation of the area(s) where a major FRM shortage has occurred;
- (h) principles concerning the training of personnel of the competent authorities and, where appropriate, the bodies, public authorities, laboratories, professional operators and other persons referred to in point (a).

Member States shall regularly review and, where appropriate, update their contingency plans to take account of the technical and scientific developments in relation to climate model simulations addressing the projected future distribution of the relevant tree species and artificial hybrids thereof.

- 4. Member States shall establish a national register that:
  - (a) contains the tree species and artificial hybrids listed in Annex I, which are relevant for the current climatic and ecological conditions of the Member State concerned;
  - (b) takes account of the projected future distribution of those tree species and artificial hybrids thereof.

Within 4 years from the date of establishment of their national registers, Member States shall establish contingency plans for the species and artificial hybrids included in their registers.

- 5. Member States shall collaborate with each other and with all relevant stakeholders for the establishment of their contingency plans, on the basis of an exchange of best practices and experience gained with the establishment of those plans.
- 6. Member States shall make their contingency plans available to the Commission, the other Member States and all relevant professional operators through publication in FOREMATIS.

#### **CHAPTER III**

## REGISTRATION OF PROFESSIONAL OPERATORS AND BASIC MATERIAL, AND DEMARCATION OF REGIONS OF PROVENANCE

#### Article 10

#### **Obligations for professional operators**

1. Professional operators shall be registered in a register provided for in Article 65 of Regulation (EU) 2016/2031, in accordance with Article 66 of that Regulation.

They shall be established in the Union.

2. Professional operators shall make available to the users of their FRM all necessary information concerning its suitability for current and projected future climatic and ecological conditions. That information shall, prior to the transfer of the FRM

concerned, be provided to the potential purchaser through websites, planters' guides and other appropriate means.

#### Article 11

#### Demarcation of regions of provenance for certain categories

Member States shall, for the relevant species of basic material intended for the production of FRM of the 'source-identified' and 'selected' categories, demarcate the regions of provenance.

The competent authorities shall draw up and publish on their website maps showing the demarcations of the regions of provenance. They shall make those maps available to the Commission and other Member States through FOREMATIS.

#### Article 12

#### National register and national lists of basic material

1. Each Member State shall establish, publish and keep updated, in electronic format, a national register of the basic material of the various species approved on its territory pursuant to Articles 4 and 19 and notified pursuant to Article 18.

That register shall contain full details of each unit of approved basic material, together with its unique register reference.

By way of derogation from Article 4, the competent authorities shall immediately register in their national registers the basic material included, before ... [*OJ, please, insert the date of the of this Regulation*], in their respective national registers referred to in Article 10(1) of Directive 1999/105/EC, without applying the registration procedure set out in that Article.

- 2. Each Member State shall establish, publish and keep updated a national list of basic material, which shall be presented as a summary of the national register. It shall make that list available in electronic format to the Commission and the other Member States through FOREMATIS.
- 3. Member States shall present the national list in a common form for each unit of approval of basic material. For the categories 'source-identified' and 'selected', it may contain only a summary description of the basic material, on the basis of regions of provenance.

The national list shall provide in particular the following details:

- (a) botanical name;
- (b) category;
- (c) basic material;
- (d) register reference or, where appropriate, summary thereof, or identity code for region of provenance;
- (e) location of basic material: a short name, if appropriate, and one of the following sets of particulars:
  - (i) for the 'source-identified' category, region of provenance and the latitudinal, longitudinal and altitudinal range;

- (ii) for the 'selected' category, region of provenance and the geographical position defined by latitude, longitude and altitude or the latitudinal, longitudinal and altitudinal range;
- (iii) for the 'qualified' category, the exact geographical position(s) defined by latitude, longitude and altitude, where the basic material is maintained;
- (iv) for the 'tested' category, the exact geographical position(s) defined by latitude, and longitude and altitude, where the basic material is maintained;
- (f) area: the size of a seed source(s), stand(s) or seed orchard(s);
- (g) origin:
  - (i) indication whether the basic material is autochthonous/indigenous, nonautochthonous/non-indigenous or if the origin is unknown;
  - (ii) non-autochthonous/ non-indigenous basic material, an indication of the origin, if it is known;
- (h) purpose of use of FRM;
- (i) in the case of FRM of the 'tested' category, an indication whether it is:
  - (i) genetically modified; or
  - (ii) an NGT plant;
- (j) in the case of qualified and tested categories, information about the place of production of clone(s) or clonal mixture(s), where appropriate.

#### **Union List of Approved Basic Material**

1. On the basis of the national lists provided by each Member State in accordance with Article 12, the Commission shall publish a list entitled 'Union List of Approved Basic Material for the Production of Forest Reproductive Material'.

That list shall be made available in electronic format through FOREMATIS.

2. That list shall reflect the details given in the national lists referred to in Article 12(1) and show the area of utilisation.

### **CHAPTER IV**

## MASTER CERTIFICATE, LABELLING AND PACKAGING

#### Article 14

#### Master certificate of identity

1. The competent authorities shall issue, upon application of a professional operator, after harvesting the FRM from approved basic material, a master certificate of identity ('master certificate'), showing the unique register reference of basic material, for all FRM that has been harvested.

The master certificate shall attest compliance with the requirements of Article 4(2).

The Commission shall, by means of an implementing act, adopt the content and the model for the master certificate of identity for FRM:

- (a) Model master certificate for FRM that is derived from seed sources and stands;
- (b) Model master certificate for FRM that is derived from seed orchards or parents of family(ies); and
- (c) Model master certificate for FRM that is derived from clones and clonal mixtures.

That implementing act shall be adopted in accordance with the examination procedure referred to in Article 27(2).

- 2. Where in accordance with Article 15(2) a Member State adopts measures as regards subsequent vegetative propagation, a new master certificate shall be issued.
- 3. Where mixing takes place in accordance with Article 15(3), Member States shall ensure that the register references of the components of the mixtures are identifiable, and a new master certificate or other document identifying the mixture shall be issued.
- 4. Where a lot referred to in Article 15(1) is subdivided into smaller lots that are not processed uniformly and subjected to subsequent vegetative propagation, a new master certificate shall be issued and a reference shall be made to the previous master certificate number.
- 5. A master certificate may also be issued in an electronic form ('electronic master certificate').

The Commission may, by means of implementing acts, set out technical arrangements for the issuance of electronic master certificates, for ensuring their compliance with this Article and an appropriate, credible and effective mode for the issuance of electronic master certificates. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).

- 6. The Commission is empowered to adopt delegated acts, in accordance with Article 26, supplementing this Article, by setting out rules on:
  - (a) digital recording of all actions taken by the professional operator and the competent authorities, in order to issue the master certificate; and
  - (b) establishment of a centralised platform that connects all the Member States and the Commission, to facilitate the processing of, access to and use of those records.

#### Article 15

#### Lots

1. FRM shall, during all stages of production, be kept separated by reference to individual units of approval of basic material to ensure traceability of the FRM to the approved basic material from which it has been harvested. FRM shall be harvested from those individual units of approval and marketed in lots that shall be sufficiently homogeneous and identified as distinct from other lots of FRM.

Each lot of FRM shall be identified by the following:

- (a) lot number;
- (b) master certificate code and number;
- (c) botanical name;

- (d) category of FRM;
- (e) basic material;
- (f) register reference or identity code for region of provenance;
- (g) region of provenance for FRM of the 'source-identified' and 'selected' categories or other FRM if appropriate;
- (h) if appropriate, whether the origin of the basic material is autochthonous or indigenous, non-autochthonous or non-indigenous, or unknown;
- (i) in the case of seed units, the year of ripening;
- (j) age and type of planting stock of seedlings or cuttings, whether undercuts, transplants or containerised;
- (k) for the 'tested' category whether it is:
  - (i) genetically modified;
  - (ii) an NGT plant.
- 2. Without prejudice to paragraph 1 of this Article and to Article 5(1), point (c), Member States shall keep separately FRM, which is subject to subsequent vegetative propagation and shall identify it as such. Such FRM shall have been harvested from a single unit of approval in the 'selected', 'qualified' and 'tested' categories. In such cases, the produced FRM shall assume the same category as the original FRM.
- 3. Without prejudice to paragraph 1, the mixing of FRM shall be subject to the following conditions, as appropriate:
  - (a) within the 'source-identified' or 'selected' categories, mixing shall apply to FRM derived from two or more units of approval within a single region of provenance;
  - (b) in the case of mixing of FRM within a single region of provenance, from seed sources and stands in the 'source-identified category, the new combined lot shall be certified as 'FRM derived from a seed source';
  - (c) in the case of mixing of FRM derived from non-autochthonous or nonindigenous basic material with that from basic material of unknown origin, the new combined lot shall be certified as being 'of unknown origin';
  - (d) in the case of mixing of FRM derived from a single unit of approval from different years of ripening, the actual years of ripening and proportion of FRM from each year shall be recorded.

In the case of mixing in accordance with the first subparagraph, points (a), (b) or (c), the identity code for the region of provenance may be substituted for the register reference as in paragraph 1, point (f).

#### Article 16

#### **Official label**

- 1. An official label shall be issued by the competent authority for every lot of FRM attesting compliance of that FRM with the requirements referred to in Article 5.
- 2. Competent authorities shall authorise the professional operator to print the official label after the competent authority has attested compliance of that FRM with the

requirements referred to in Article 5. The professional operator is authorised to print that label, if, on the basis of an audit, the competent authority has concluded that the operator possesses the infrastructure and resources to print the official label.

3. The competent authority shall carry out regular controls to check whether the professional operator complies with the requirements referred to in paragraph 2.

Where, after having granted the authorisation referred to in paragraph 2, the competent authority finds that a professional operator does not fulfil the requirements referred to in that paragraph, it shall without delay withdraw, or modify as appropriate, the authorisation.

- 4. In addition to the information required under Article 15(1), the official label shall contain all the following information:
  - (a) master certificate number(s) issued in accordance with Article 14 or a reference to the other document identifying the mixture available in accordance with Article 14(3);
  - (b) name of the professional operator;
  - (c) quantity supplied;
  - (d) in the case of FRM of the 'tested' category, whose basic material is approved under Article 4, the words 'provisionally approved';
  - (e) whether the FRM has been vegetatively propagated.
- 5. The Commission shall, by means of implementing acts, set out the following elements concerning the official label:
  - (a) content of the official label;
  - (b) additional information in the case of seeds and small quantities of seeds;
  - (c) colour of the label for specific categories or other types of FRM;
  - (d) additional information in the case of specific genera or species.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).

6. An official label may also be issued in an electronic form ('electronic official label').

The Commission may, by means of implementing acts, set out technical arrangements for the issuance of electronic official labels, to ensure their compliance with this Article and an appropriate, credible and effective mode for the issuance of those official labels. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).

- 7. The Commission is empowered to adopt delegated acts, in accordance with Article 26, supplementing this Article, by setting out rules on:
  - (a) digital recording of all actions taken by the professional operators and the competent authorities in order to issue the official labels;
  - (b) the establishment of a centralised platform that connects the Member States and the Commission to facilitate the processing of, access to and use of those records.

#### Packages of seed units

Seed units may only be marketed in sealed packages with that become unserviceable once the package is opened.

### CHAPTER V DEROGATIONS FROM ARTICLE 4

#### Article 18

## Derogation from the obligation to be approved for basic material intended for the purpose of conserving forest genetic resources

- 1. By way of derogation from Article 4(1) and (2), the registration of basic material intended for the purpose of conserving forest genetic resources in the national register shall not be subject to approval by the competent authorities.
- 2. Any professional operator registering basic material for the purpose of conserving forest genetic resources used in forestry, shall notify that basic material to the competent authority of the Member State concerned.
- 3. Basic material referred to in paragraph 1 shall be notified to the competent authorities in accordance with the format of FOREMATIS.

The notification of the basic material shall be carried out with reference to the unit of notification.

Each unit of notification shall be identified by a unique register reference in a national register.

That notification shall contain the following information:

- (a) botanical name;
- (b) category;
- (c) basic material;
- (d) register reference or, where appropriate, summary thereof, or identity code for region of provenance;
- (e) location: a short name, if appropriate, and the region of provenance and the latitudinal, longitudinal and altitudinal range;
- (f) area: the size of a seed source(s) or stand(s);
- (g) origin: indication whether the basic material is autochthonous/indigenous, nonautochthonous/non-indigenous or whether the origin is unknown. For nonautochthonous/ non-indigenous basic material, indication of the origin if known;
- (h) purpose: conservation and sustainable use of genetic resources.
- 4. The Commission may, by means of implementing acts, establish the specific conditions as regards the requirements and content of that notification. Those implementing acts shall take account of the development of applicable international standards and shall be adopted in accordance with the examination procedure referred to in Article 27(2).

## Approval by professional operators of basic material intended for the production of FRM of the source–identified category

By way of derogation from Article 4(1) and (2), Member States may authorise professional operators to approve, for certain species, basic material intended for the production of FRM of the source-identified category, if the following conditions are fulfilled:

- (a) the region of provenance, where the basic material is located, is subject to extreme weather conditions; and
- (b) those weather conditions have an impact on the reproductive cycle of the basic material and decrease the frequency of harvesting FRM from that basic material.

That authorisation shall be subject to approval by the Commission.

#### Article 20

## Provisional approval of basic material intended for the production of FRM of the tested category

By way of derogation from Article 4(2), Member States may allow the approval, for a maximum period of 10 years, in all or part of their territory, of basic material intended for the production of FRM of the 'tested' category where, from the provisional results of the genetic evaluation or comparative tests referred to in Annex V, it can be assumed that once the tests are completed, the basic material will satisfy the requirements for approval under this Regulation.

#### Article 21

#### **Temporary difficulties in supply**

- 1. In order to overcome any temporary difficulties in the general supply of FRM that occur in one or more Member States, the Commission may, at the request of at least one Member States affected, temporarily authorise the Member States to approve for marketing, by means of an implementing act, FRM of one or more species that has been derived from basic material, which satisfies less stringent requirements than the ones set out in Article 4(1) and (2).
- 2. Where the Commission acts in accordance with paragraph 1, the official label issued pursuant to Article 16(1) shall state that the FRM concerned has been derived from basic material which satisfies less stringent requirements than the ones set out in Article 4(1) and (2).
- 3. The implementing act referred to in paragraph 1 shall be adopted in accordance with the examination procedure referred to in Article 27(2).

#### Article 22

#### Temporary experiments to seek improved alternatives to provisions of this Regulation

1. By way of derogation from Articles, 1, 4 and 5, the Commission may decide, by means of implementing acts, on the organisation of temporary experiments to seek improved alternatives to provisions of this Regulation concerning the species or artificial hybrids it applies to, the requirements for the approval of basic material and the production and marketing of FRM.

Those experiments may take the form of technical or scientific trials examining the feasibility and appropriateness of new requirements compared to the ones set out in Articles 1, 4 and 5 of this Regulation.

- 2. The implementing acts referred to in paragraph 1 shall be adopted in accordance with the examination procedure referred to in Article 27(2) and shall specify one or more of the following elements:
  - (a) the species or artificial hybrids concerned;
  - (b) the conditions of the experiments per species or artificial hybrid;
  - (c) the duration of the experiment;
  - (d) the monitoring and reporting obligations of the participating Member States.

Those acts shall take into account the evolution of:

- (a) the methods for the determination of the origin of the basic material including the use of biomolecular techniques;
- (b) the methods for the conservation and sustainable use of forest genetic resources taking into account applicable international standards;
- (c) the methods for reproduction, production including the use of innovative production processes;
- (d) the methods for the design of crossing schemes of components of basic material;
- (e) the methods for the assessment of characteristics of basic material and FRM;
- (f) the methods for the control of the FRM concerned.

Those acts shall adapt to the evolution of techniques for production of the FRM concerned, and be based on any comparative trials and tests carried out by the Member States.

3. The Commission shall review the results of those experiments and summarise them in a report, indicating, if necessary, the need to amend Articles 1, 4 or 5.

#### Article 23

#### Authorisation to adopt more stringent requirements

- 1. By way of derogation from Article 4, the Commission, by means of implementing acts, may authorise Member States to adopt, as regards the requirements for the approval of basic material and the production of FRM more stringent production requirements, than those referred to in that Article, in all or part of the territory of the Member State concerned. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).
- 2. For the purpose of 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.
- 3. The authorisation referred to in paragraph 1 shall be granted only if all the following conditions are fulfilled:

- (a) the measures requested ensure at least one of the following:
  - (i) the improvement of the quality of the FRM concerned;
  - (ii) the protection of the environment: adaptation to climate change or the contribution to the protection of biodiversity, restoration of forest ecosystems;
- (b) the measures requested are necessary and proportionate to their objective pursuant to point (a); and
- (c) the measures are justified on the basis of the specific climatic and ecological conditions in the Member State concerned.
- 4. Where Member States have adopted additional or more stringent requirements pursuant to Article 7 of Directive 1999/105/EC, the Member States concerned shall, by ... [one year after the *date of application of this Regulation*], review those measures and repeal or amend those measures to comply with this Regulation.

They shall inform the Commission and the other Member States of those actions.

### CHAPTER VI IMPORTS OF FRM

#### Article 24

#### Imports on the basis of Union equivalence

- 1. FRM may be imported from third countries to the Union only if it is established, pursuant to paragraph 2, that it fulfils requirements equivalent to those applicable to FRM produced and marketed in the Union.
- 2. The Commission may decide, by means of implementing acts, if FRM of specific genera, species or categories produced in a third country, fulfils requirements equivalent to those applicable to FRM produced and marketed in the Union, on the basis of all of the following:
  - (a) a thorough examination of the information and data provided by the third country concerned; and
  - (b) the satisfactory result of an audit carried out by the Commission in the third country concerned, where that audit has been considered necessary by the Commission;
  - (c) that third country participates in the OECD Scheme for the Certification of Forest Reproductive Material Moving in International Trade.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).

3. When adopting the decisions referred to in paragraph 1, the Commission shall consider whether the systems, for approval and registration of basic material and subsequent production of FRM from that basic material, applied in the third country concerned provide the same guarantees as those provided for in Articles 4, 5 and, where applicable, Article 11, for the 'source identified', 'selected', 'qualified' and 'tested' categories.

#### Notification and certificates of imported FRM

- 1. The professional operators importing FRM into the Union shall inform the respective competent authority in advance of the import through the information management system for official controls (IMSOC) referred to in Article 131 of Regulation (EU) 2017/625.
- 2. Imported FRM shall be accompanied by all of the following:
  - (a) a master certificate or another official certificate issued by the third country of origin;
  - (b) an official label; and
  - (c) records containing details of that FRM provided by the professional operator in that third country.
- 3. Following the import referred to in paragraph 1, the competent authority of the Member State concerned shall replace:
  - (a) the master certificate or official certificate referred to in paragraph 2, point (a) with a new master certificate issued in the Member State concerned; and
  - (b) the official label referred to in paragraph 2, point (b), with a new official label issued in the Member State concerned.

### CHAPTER VII PROCEDURAL PROVISIONS

#### Article 26

#### Exercise of the delegation

- 1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
- 2. The power to adopt delegated acts referred to in Article 2(2), Article 4(2) and(6), Article 5(3), Article 7(2), Article 8(1), Article 14(6) and Article 16(7) shall be conferred on the Commission for a period of 5 years from ... [*date of entry into force of this Regulation*]. The Commission shall draw up a report in respect of the delegation of power no later than 9 months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration unless the European Parliament or the Council opposes such extension not later than 3 months before the end of each period.
- 3. The delegation of power referred to in Article 2(2), Article 4(2) and (6), Article 5(3), Article 7(2), Article 8(1), Article 14(6) and Article 16(7) may be revoked at any time by the European Parliament or by the Council. A decision to revoke 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. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

- 5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
- 6. A delegated act adopted pursuant to Article 2(2), Article 4(2) and (6), Article 5(3), Article 7(2), Article 8(1), Article 14(6) and Article 16(7) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of 2 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 2 months at the initiative of the European Parliament or of the Council.

#### **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<sup>24</sup>. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011<sup>25</sup>.
- 2. 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 requests.

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

### CHAPTER VIII

# Reporting, penalties and amendments of Regulations (EU) 2016/2031 and 2017/625

#### Article 28

#### Reporting

By ... [Office of Publications, please insert date of 5 years after the date of application of this *Regulation*], and every 5 years thereafter, Member States shall transmit to the Commission a report on the following:

- (a) quantities of certified FRM per year;
- (b) number of adopted national contingency plans to prepare for FRM supply difficulties and the time needed to activate those contingency plans;

<sup>&</sup>lt;sup>24</sup> Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

<sup>&</sup>lt;sup>25</sup> 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 (OJ L 55, 28.2.2011, p. 13).

- (c) number of websites and/or national planters' guides containing information on where to best plant FRM;
- (d) quantities of FRM per genera and species imported from third countries under Union equivalence;
- (e) penalties imposed pursuant to Article 29.

The Commission shall, by means of implementing acts, specify the technical formats for the report provided for in paragraph 1 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).

#### Article 29

#### Penalties

- 1. Member States shall lay down the rules on effective, proportionate and dissuasive penalties for infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. Member States shall, without delay, notify the Commission of those rules and measures and of any subsequent amendment affecting them.
- 2. Member States shall ensure that financial penalties for violations of this Regulation, perpetrated through fraudulent or deceptive practices, reflect, in accordance with national law, at least either the economic advantage for the professional operator or, as appropriate, a percentage of the professional operator's turnover.

#### Article 30

#### Amendments of Regulation (EU) 2016/2031

Regulation (EU) 2016/2031 is amended as follows:

- (1) in Article 37, paragraph 4 is replaced by the following:
  - '4. The Commission shall, by means of an implementing act, where appropriate, set out measures to prevent the presence of Union regulated non-quarantine pests on the plants for planting concerned, as referred to in Article 36, point (f), of this Regulation. Those measures shall, where appropriate, concern the introduction into and the movement within the Union of those plants.';
- (2) in Article 83, the following paragraph is added:
  - '5a. In the case of plants for planting produced, or marketed, as categories sourceidentified, selected, qualified or tested, as referred to in Regulation (EU) .../...\*+, the plant passport shall be included, in a distinct form, in the official label produced in accordance with the respective provisions of that Regulation.

Where this paragraph applies,

- (a) the plant passport for movement within the Union territory shall contain the elements set out in Parts E and F of Annex VII to this Regulation;
- (b) the plant passport for introduction into, and movement within, a protected zone shall contain the elements set out in Part H of Annex VII to this Regulation.';

- Regulation (EU) .../... of the European Parliament and of the Council of ... ... (OJ ...).';
- + OJ: Please insert in the text the number of this Regulation and institutions and insert the number, date, title and OJ reference of this Regulation in the footnote.
- (3) Annex VII is amended in accordance with Annex VII to this Regulation.

#### Amendments of Regulation (EU) 2017/625

Regulation (EU) 2017/625 is amended as follows:

- (1) in Article 1(2), the following point is added:
  - (1) production and marketing of forest reproductive material.';
- (2) in Article 3, the following point is added:
  - '(52) 'forest reproductive material' means material as defined in Article 3(1) of Regulation (EU) .../... of ...\*+
  - \* Regulation (EU) .../... of the European Parliament and of the Council of ... ... (OJ ...).';

+ OJ: Please insert in the text the number of this Regulation and institutions and insert the number, date, title and OJ reference of this Regulation in the footnote.

(3) the following article is inserted after Article 22a:

*Article 22b* 

## Specific rules on official controls and for action taken by the competent authorities in relation to forest reproductive material

- 1. Official controls to verify compliance with the rules referred to in Article 1(2), point (l), shall include official controls on the production and marketing of forest reproductive material, and on operators subject to those rules.
- 2. The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation by laying down rules for the performance of official controls on forest reproductive material in order to check compliance with Union rules referred to in Article 1(2), point (1), applicable to those goods and for action taken by the competent authorities following the performance of those official controls.

Those delegated acts shall lay down rules on:

(a) specific requirements for the performance of such official controls on the production and marketing within, the Union of particular of particular forest reproductive material subject to the rules referred to in Article 1(2), point (l), to respond to non-compliance with the Union rules on forest reproductive material of a particular origin or provenance;

- (b) specific requirements for the performance of such official controls on the activities of professional operators related to the production of particular forest reproductive material subject to the rules referred to in Article 1(2), point (l), to respond to non-compliance with the Union rules on forest reproductive material of a particular origin or provenance; and
- (c) the cases where the competent authorities are to take one or more of the measures referred to in Article 137(2) and Article 138(2) in relation to specific non-compliances.
- 3. The Commission shall, by means of implementing acts, lay down rules on uniform practical arrangements for the performance of official controls on plant reproductive material in order to verify compliance with Union rules referred to in Article 1(2), point (1), applicable to those goods and for action taken by the competent authorities following such official controls on:
  - (a) uniform minimum frequency of such official controls, where a minimum level of official control is necessary to respond to recognised uniform risks of non-compliance with the rules on forest reproductive material of a particular origin or provenance;
  - (b) frequency of official controls performed by competent authorities on operators authorised to issue official labels under official supervision in accordance with Article 16(1) of Regulation (EU) .../...\*+

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

+ OJ: Please insert in the text the number of this Regulation and institutions and insert the number, date, title and OJ reference of this Regulation in the footnote.

### CHAPTER IX FINAL PROVISIONS

#### Article 32

#### Repeal of Directive 1999/105/EC

Directive 1999/105/EC is repealed.

References to that repealed act shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex VIII.

#### Article 33

#### Entry into force and application

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 ... [3 years after the date of entry into force of this Regulation].

<sup>\*</sup> Regulation (EU) .../... of the European Parliament and of the Council of ... ... (OJ ...).'

It shall be binding in its entirety and directly applicable in all Member States. Done at Brussels,

For the European Parliament The President For the Council The President



EUROPEAN COMMISSION

> Brussels, 5.7.2023 COM(2023) 415 final

ANNEXES 1 to 8

#### ANNEXES

to the

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the production and marketing of forest reproductive material, amending Regulations (EU) 2016/2031 and 2017/625 of the European Parliament and of the Council and repealing Council Directive 1999/105/EC (Regulation on forest reproductive material)

 $\{ SEC(2023) \ 414 \ final \} - \{ SWD(2023) \ 410 \ final \} - \{ SWD(2023) \ 414 \ final \} - \{ SWD(2023) \ 415 \ final \}$ 

#### ANNEX I 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 II

#### **REQUIREMENTS FOR THE APPROVAL OF BASIC MATERIAL INTENDED FOR THE PRODUCTION OF FRM OF THE 'SOURCE-IDENTIFIED' CATEGORY**

A. General requirement: The seed source or stand shall meet the criteria set by the competent authorities.

#### **B.** Specific requirements:

#### **1.** Type of basic material

The basic material shall be a seed source or stand located within a single region of provenance.

#### 2. Effective size of the population

The seed source or stand shall consist of one or more groups of trees. Those trees shall be well distributed and sufficiently numerous to maintain genetic diversity and ensure adequate cross-pollination between the trees in those seed sources or stands.

#### 3. Origin and region of provenance

- (a) The region of provenance, the location and the latitudinal, longitudinal and altitudinal range of the place(s), where the FRM is collected, shall be stated in the master certificate.
- (b) The professional operator shall determine either by historical evidence (bibliography, documentation kept by competent authorities, research institutes or any other organisations) or by other appropriate means (provenance trials), including internationally recognised bio-molecular techniques, whether the origin of the basic material is:
  - (i) autochthonous;
  - (ii) non-autochthonous;
  - (iii) indigenous;
  - (iv) non-indigenous;
  - (v) unknown.

In the case of non-autochthonous or non-indigenous basic material, the origin of that basic material shall be stated if known.

The competent authority shall verify the information provided by the professional operator.

#### 4. Sustainability characteristics

- (a) The trees shall be well-adapted to the climatic and ecological conditions including the biotic and abiotic factors prevailing in the region of provenance.
- (b) The trees shall in be practically free from pests and their symptoms.

#### ANNEX III

#### REQUIREMENTS FOR THE APPROVAL OF BASIC MATERIAL INTENDED FOR THE PRODUCTION OF FRM OF THE 'SELECTED' CATEGORY

**A. General requirement:** The competent authority shall assess the stand with respect to the specific purpose for which the FRM will be used and shall give due weight to requirements set out in Section B, depending on that purpose. The competent authority shall determine the criteria for selection on the basis of that specific purpose for use of the FRM. That purpose shall be indicated in the national register of the Member State concerned.

#### **B.** Specific requirements:

- 1. Origin: It shall be determined either by historical evidence (bibliography, documentation kept by competent authorities, research institutes or any other organisations) or by other appropriate means (provenance trials), including internationally recognised bio-molecular techniques, whether the stand is autochthonous/indigenous, non-autochthonous/non-indigenous or whether its origin is unknown. For non-autochthonous/non-indigenous basic material the origin shall be stated if known.
- 2. **Isolation:** Stands shall be situated at a sufficient distance from stands of poor quality of the same species or from stands of a related species which can form hybrids with the species in question. Particular attention shall be paid to this requirement when the stands surrounding autochthonous/indigenous stands are non-autochthonous/non-indigenous or of unknown origin.
- **3.** Effective size of the population: To maintain genetic diversity and ensure adequate cross-pollination, stands shall consist of one or more groups of trees. Those trees shall be well distributed and sufficiently numerous in a given area to maintain genetic diversity, to avoid the unfavourable effects of inbreeding and ensure adequate cross-pollination between those trees.
- 4. Age and development: The age or stage of development of the trees in the stands shall be such to allow the criteria given for the selection of those trees to be clearly judged.
- **5. Uniformity:** Stands shall show a normal degree of individual variation in morphological characteristics. When necessary, inferior trees shall be removed.
- 6. Sustainability characteristics:
  - (a) Stands shall be well-adapted to the climatic and ecological conditions, including the biotic and abiotic factors prevailing in the region of provenance.
  - (b) The trees shall be practically free from pests and their symptoms and show resistance to adverse site conditions in the place where they are growing.
- 7. Volume production: For the approval of selected stands, the volume of wood produced shall normally be superior to the accepted average volume produced under similar ecological and management conditions.
- 8. Wood quality: The quality of the wood shall be taken into account. The quality of the wood is an essential criterion, if the FRM will be used in the forestry industry for the purpose of producing timber, furniture or pulp. In that case the competent authority shall give more weight to this criterion.
- 9. **Form or growth habit:** Trees in stands shall show particularly good morphological features, especially straightness and circularity of stem, favourable branching habit,

small size of branches and good natural pruning. In addition, the proportion of forked trees and those showing spiral grain shall be low.

#### ANNEX IV

#### REQUIREMENTS FOR THE APPROVAL OF BASIC MATERIAL INTENDED FOR THE PRODUCTION OF FRM OF THE 'QUALIFIED' CATEGORY

#### **1.** Seed orchards

- (a) The competent authority shall approve and register the type and objective of the crossing design, the crossing design of component clones or families and field layout, the component clones or families, isolation and location and any changes of these.
- (b) The professional operator shall select component clones or families for their outstanding characteristics and shall give due weight to the requirements set out in points 4 and 6 to 9 of Section B of Annex III, taking into account the specific purpose for which the resulting FRM will be used.
- (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 professional operator shall manage seed orchards and harvest seed 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 FRM shall be determined by a verification test.

#### 2. Parents of family(ies)

- (a) The professional operator shall select parents for their outstanding characteristics or for their combining ability. In the case of a selection based on outstanding characteristics, due weight shall be given to the requirements set out in points 4 and 6 to 9 of Section B of Annex III, taking into account the specific purpose for which the resulting FRM will be used.
- (b) The objective, crossing design and pollination system, components, isolation and location and any significant changes of these shall be approved and registered with the competent authority.
- (c) The identity, number and proportion of the parents in a mixture shall 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 FRM shall be determined by a verification test.

#### 3. Clones

- (a) Clones shall be identifiable by distinctive characteristics which have been approved and registered with the competent authority.
- (b) The value of individual clones shall be established by the observation and the qualitative assessment of the characteristics of those clones or have been demonstrated by sufficiently prolonged experimentation.

- (c) Ortets used for the production of clones shall be selected for their outstanding characteristics and due weight shall be given to the requirements set out in points 4 and 6 to 9 of Section B of Annex III, taking into account the specific purpose for which the resulting FRM will be used.
- (d) Approval shall be restricted by the competent authority to a maximum number of years or a maximum number of ramets produced.

#### 4. Clonal mixtures

- (a) Clonal mixtures shall meet the requirements set out in point 3(a), (b) and (c).
- (b) The identity, number and proportion of the component clones of a mixture, and the selection method and foundation stock shall be approved and registered by the competent authority. Each mixture shall contain sufficient genetic diversity.
- (c) Approval shall be restricted by the competent authority to a maximum number of years or a maximum number of ramets produced.

#### ANNEX V

#### REQUIREMENTS FOR THE APPROVAL OF BASIC MATERIAL INTENDED FOR THE PRODUCTION OF FRM OF THE 'TESTED' CATEGORY

#### 1. **REQUIREMENTS FOR ALL TESTS**

#### (a) General

If the basic material is a stand, it shall satisfy the appropriate requirements set out in Annex III. If the basic material is a seed orchard(s), parents of family(ies), clones or clonal mixture(s), it shall satisfy the appropriate requirements set out in Annex IV. The competent authority shall determine the selection criteria based on the intended purpose for which the FRM will be used.

The professional operators shall prepare, lay out and conduct tests set up for the approval of the basic material. They shall interpret the results of those tests in accordance with the internationally recognised procedures. For comparative tests, the professional operator shall compare the FRM under test with one or preferably several approved or pre-chosen standards as described in point 3(b).

#### (b) Characteristics to be examined

- (i) The professional operator shall design tests to assess the relevant characteristics specified in point (ii) and shall indicate these for each test in the test records.
- (ii) Weight shall be given to adaptation, growth, biotic and abiotic factors of importance. In addition, other characteristics, 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 including current and future projected climatic conditions.

#### (c) **Documentation**

The professional operator shall keep records describing the test sites, including the location, climate, soil, past use, establishment, management and any damage due to abiotic/biotic factors. He shall make those records available to the competent authority upon request. The competent authority shall record the age of the basic material and the FRM and the results at the time of the evaluation.

#### (d) **Setting up the tests**

- (i) The professional operator shall raise, plant and manage each sample of FRM in an identical way as far as the types of plant material permit.
- (ii) The professional operator shall establish each experiment 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 professional operator shall analyse the data from experiments using internationally recognised statistical methods and shall present the results for each characteristic examined.
- (ii) The methodology used for the test and the detailed results obtained shall be made freely available.

- (iii) The competent authority of the Member State in which the test was carried out shall designate the suggested deployment area, and shall inform about any characteristics of the FRM, which might limit its usefulness.
- (iv) If during tests it is proved that the FRM does not possess at least the characteristics of the basic material from which that FRM was produced, including in particular the resistance/tolerance to plant pests of economic importance, then such FRM shall not be certified as tested material.

## 2. REQUIREMENTS FOR GENETIC EVALUATION OF THE 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 shall be required for approval of the basic material providing information about:

- (i) the identity, origin and pedigree of the evaluated components;
- (ii) the crossing design used to produce the FRM used in the evaluation tests.

#### (c) **Test procedures**

The following requirements shall be met:

- (i) The genetic value of each component shall be estimated in two or more evaluation test-sites, at least one of which shall be in an environment relevant for the intended deployment area of the FRM.
- (ii) The test period shall be of sufficient duration for the tested characteristics to be expressed.
- (iii) The estimated superiority of the FRM to be marketed shall be calculated on the basis of these genetic values and the specific crossing design.
- (iv) Evaluation tests and genetic calculations shall be approved by the competent authority.

#### (d) Interpretation

- (i) The estimated superiority of the FRM shall be calculated against a reference population for a characteristic or set of characteristics. The professional operator shall define the reference population in the breeding program and describe this reference population in the test reports.
- (ii) It shall be stated whether the estimated genetic value of the FRM is inferior to the reference population for any important characteristic.

#### 3. REQUIREMENTS FOR COMPARATIVE TESTING OF FRM

#### (a) **Sampling of the FRM**

- (i) The sample of the FRM for comparative testing shall be truly representative of the FRM derived from the basic material to be approved.
- (ii) Sexually produced FRM for comparative testing shall be:
- harvested in years of good flowering and good fruit/seed production, and

harvested by methods that ensure that the samples obtained are representative.
Artificial pollination may be utilised for the production of such FRM.

#### (b) Standards

- (i) The performance of standards used for comparative purposes in the tests shall, if possible, be known over a sufficiently long period in the region in which the test is to be carried out. The standards represent, in principle, basic material that has been shown to be useful for the intended purpose for forestry at the time that the test starts, and in ecological conditions for which it is proposed to certify the FRM. The standards used for comparative purposes in the tests shall be, as far as possible:
  - stands selected according to the criteria in Annex III; or

- basic material officially approved for the production of FRM of the tested category.

- (ii) For comparative testing of artificial hybrids, both parent tree species shall, if possible, be included among the standards.
- (iii) Several standards shall be used whenever possible. When justified, standards may be replaced by the most suitable of the FRM under test or the mean of the components of the test.
- (iv) The same standards shall 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 shall be demonstrated for at least one important characteristic.
- (ii) The professional operator shall report if there are any characteristics of economic or environmental importance which show significantly inferior results to the standards, and their effects shall be compensated for by favourable characteristics.

#### 4. PROVISIONAL APPROVAL

Preliminary assessment of young trials may be the basis for provisional approval. Claims of superiority based on an early assessment shall 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 provisional approval or for final approval, if it can be shown that there is a close correlation between the measured characteristic and the characteristics normally assessed in forest stage tests. Other characteristics to be tested shall meet the requirements set out in point 3.

#### ANNEX VI

#### CATEGORIES UNDER WHICH FRM FROM THE DIFFERENT TYPES OF BASIC MATERIAL MAY BE MARKETED

Basic material	Category of FRM (Label colour, if coloured official label used)			
	Source-identified (Yellow)	Selected (Green)	Qualified (Pink)	Tested (Blue)
Seed source	х			
Stand	х	х		х
Seed orchard			х	х
Parents of family(ies)			Х	Х
Clone			х	Х
Clonal mixture			х	Х

#### ANNEX VII

#### Amendment of Annex VII to Regulation (EU) 2016/2031

In Annex VII to Regulation (EU) 2016/2031, the following parts are added:

#### 'PART G

## Plant passports for movement within the Union territory, combined with the official label, as referred to in Article 83(5), second subparagraph

- (1) The plant passport for movement within the Union territory, combined in a joint label with the official label referred to in Article 83(5), shall contain the following elements:
  - (a) the words 'Plant Passport' in the upper right-hand corner of the joint label, in one of the official languages of the Union and in English, if different, separated by a slash;
  - (b) the flag of the Union in the upper left-hand corner of the joint label printed in colour or in black and white. The plant passport shall be positioned in the joint label immediately above the official label and have the same width as that official label.
- (2) Point (2) of Part A shall apply accordingly.

#### PART H

#### Plant passports for introduction into and movement within protected zones, combined with the official label, as referred to in Article 83(5), third subparagraph

- (1) The plant passport for introduction into and movement within protected zones, combined in a joint label with the official label for FRM referred to in Article 83(5), shall contain the following elements:
  - (a) the words 'Plant Passport PZ' in the upper right-hand corner of the joint label in one of the official languages of the Union and in English, if different, separated by a slash;
  - (b) immediately underneath those words, the scientific name(s) or code(s) of the protected zone quarantine pest(s) concerned;
  - (c) the flag of the Union in the upper left-hand corner of the joint label printed in colour or in black and white.

The plant passport shall be positioned in the joint label immediately above the official label and have the same width [as that official label.

(2) Point (2) of Part B shall apply accordingly.'

#### ANNEX VIII

#### **Correlation table**

Council Directive 1999/105/EC	This Regulation	
Article 1	Article 1, subparagraph 1	
Article 2	Article 3	
Article 3(1)	Article 2(1)	
Article 3(2)	Article 2(5)	
Article 3(3)	_	
Article 3(4)	Article 2(4), point (c)	
Article 4(1)	Article 4(1)	
Article 4(2), point (a)	Article 4(2), subparagraphs 1 to 4	
Article 4(2), point (b)	Article 4(2), subparagraph 7 and Article 4(3)	
Article 4(3), point (a)	Article 4(4)	
Article 4(3), point (b)	Article 4(5)	
Article 4(4)	Articles 6 and 18	
Article 4(5)	Article 21	
Article 5	-	
Article 6(1)	Article 5(1)	
Article 6(2)	Article 5(2)	
Article 6(3), subparagraph 1	Article 8(1)	
Article 6(3), subparagraph 2	Article 8(2)	
Article 6(4)	Article 10(1)	
Article 6(5), point (a)	Article 2(4), point (d)	
Article 6(5), point (b)	-	
Article 6(6)	-	
Article 6(7)	Article 7	
Article 6(8)	Article 4(6)	

Article 7	Article 23
Article 8	-
Article 9	Article 11
Article 10	Article 12
Article 11	Article 13
Article 12	Article 14
Article 13	Article 15
Article 14(1), subparagraph 1	Article 16(1)
Article 14(1), points (a) to (e)	Article 16(4)
Article 14(2) to (6)	-
Article 14(7)	Article 15(1)(j)
Article 15	Article 17
Article 16	Article 31
Article 17	-
Article 18	Article 21
Article 19	Article 24
Article 20	-
Article 21	Article 22
Article 22	Article 5(1)(g)
Article 23	Articles 2(2), 4(2), 4(6), 5(3)
Article 24	Articles 14(1), 14(5), 16(5), 16(6), 18(4), 21(3),
	22(1), 23(1)
Article 25	Article 26
Article 26	Article 27
Article 27	_
Article 28	-
Article 29	Article 32
Article 30	Article 33

Annex I	Annex I
Annex II	Annex II
Annex III	Annex III
Annex IV	Annex IV
Annex V	Annex V
Annex VI	Annex VI
Annex VII	Article 8
Annex VIII	Article 14