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### **NOTE**

From:	General Secretariat of the Council
To:	Permanent Representatives Committee
Subject:	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)
	- Mandate for negotiations with the European Parliament

# I. <u>INTRODUCTION</u>

1. On 5 July 2023 the Commission adopted two closely related legislative proposals to revise and update the rules on the production and marketing of plant reproductive material (PRM) and forest reproductive material (FRM) in the EU. These were submitted to the Council on 6 July 2023 as part of the Commission food and biodiversity package, a set of legislative proposals that also cover soil health, new genomic techniques and the partial revision of the Waste Framework Directive.

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- 2. At present, the applicable legislation is Council Directive 1999/105/EC, which sets out rules on the production and marketing of forest reproductive material ('FRM Directive'). FRM is marketed across Member States but the conditions for operators diverge. Moreover, the legislation has not kept pace with recent developments in science and technology, and is not in line with the increasing demand that is needed to reach the EU target of planting 3 billion additional trees by 2030. The growing occurrence of extreme weather events 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.
- 3. The proposed Regulation on FRM¹ aims to replace Council Directive 1999/105/EC, clarifying its scope and updating its provisions. It is based on two pillars: (i) the harvesting of forest reproductive material from registered parent trees (i.e. basic material) to ensure traceability and (ii) the certification of FRM to guarantee the high quality of the seed. This takes into account recent developments in the field of forestry, including the New EU Forest Strategy for 2030 and the new OECD standards on the Forest Seed and Plant Scheme.
- 4. The Regulation has the following objectives:
  - To clarify and modernise the current rules,
  - To ensure a level playing field for operators,
  - To support innovation and the competitiveness of the FRM sector in the Union,
  - To contribute to addressing sustainability and climate-related challenges,
  - To adapt to new scientific and technical developments such as biomolecular techniques and digitalisation,
  - To ensure the conservation and sustainable use of forest genetic resources, and
  - To improve the consistency with the legislation on official controls and plant health.

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<sup>1 11503/23 +</sup> ADD 1.

5. The proposal is based on Article 43(2) of the Treaty on the Functioning of the European Union (TFEU) (ordinary legislative procedure).

# II. WORK WITHIN THE EUROPEAN PARLIAMENT AND OTHER UNION BODIES

- 6. In the European Parliament, the Committee on Agriculture and Rural Development has the lead responsibility and Mr Herbert Dorfmann (EPP, Italy) has been re-appointed as rapporteur. The European Parliament adopted its position at first reading on 24 April 2024<sup>2</sup>.
- 7. The European Economic and Social Committee adopted its opinion on 13 December 2023<sup>3</sup>.

## III. STATE OF PLAY OF WORK WITHIN THE COUNCIL PREPARATORY BODIES

- 8. The Commission presented the proposal and its impact assessment<sup>4</sup> at an informal videoconference of the members of the Working Party on Genetic Resources and Innovation in Agriculture (hereinafter 'the Working Party') on 6 July 2023 and to the Agriculture and Fisheries (AGRIFISH) Council on 25 July 2023.
- 9. The examination of the proposal began under the Spanish Presidency and continued under the Belgian and Hungarian Presidencies. The Presidencies presented progress reports to the AGRIFISH Council in December 2023<sup>5</sup>, June 2024<sup>6</sup> and December 2024<sup>7</sup>, respectively. On 6 November 2024 the Permanent Representatives Committee was invited to provide guidance on the way forward regarding the official control provisions<sup>8</sup>.

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Texts adopted - Production and marketing of forest reproductive material - 24 April 2024.

<sup>&</sup>lt;sup>3</sup> 5402/24.

<sup>4 11694/23.</sup> 

 $<sup>^{5}</sup>$  16142/23 + COR 1.

<sup>&</sup>lt;sup>6</sup> 11145/24.

<sup>&</sup>lt;sup>7</sup> 16068/24.

<sup>8 14909/24.</sup> 

- 10. Since January 2025 the Working Party has held 3 physical meetings. Building on the progress made during the Spanish, Belgian and Hungarian Presidencies, the Polish Presidency has redrafted a number of provisions to take into account the written and oral comments provided by delegations, including on official control provisions. Moreover, it has thoroughly reviewed the entire text (including the recitals) to ensure its overall coherence.
- 11. The harmonisation of the framework for official controls on FRM is an essential part of the Commission proposal. The advantages and disadvantages of including the FRM legislation within the scope of Regulation (EU) 2017/625 on official controls have been thoroughly discussed by the Working Party since July 2023 and also at the Permanent Representative Committee meeting in November 2024<sup>9</sup>. Successive Presidencies have worked intensively to address the concerns raised by delegations while at the same time preserving the objective of harmonising official controls on FRM at EU level. After having tested various options the Polish Presidency eventually suggested a new approach whereby FRM would not be under the scope of the OCR, specific provisions on controls of FRM would be laid down in the FRM Regulation (Article 25a) and a cross reference to a limited number of Articles of the OCR would be inserted in a new Article 31 (to avoid repeating in extenso the content of each of these Articles in the FRM Regulation).
- 12. The Presidency considered that its latest text<sup>10</sup> represented a solid basis to obtain a mandate from the Permanent Representative Committee with a view to the negotiations with the European Parliament. With a view to preparing for the corresponding meeting of the Permanent Representative Committee, the Presidency organised bilateral consultations with all delegations on 15 and 16 May and identified eight provisions requiring further adjustments.

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<sup>10</sup> 8514/25

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- 13. On 2 June 2025, the Presidency organised a meeting of the Attachés where it presented suggestions for these eight provisions<sup>11</sup>. The discussion showed that on (some of) these provisions further adjustments were needed as follows:
  - a) Article 2 (Scope and objectives): the drafting of the new paragraph proposed to provide clarity that Member States may take additional measures in case of certain species and artificial hybrids that are not subject to the regulation has been further improved. The text now makes clear that Member States can adopt less stringent measures but can also adopt stricter ones.

Moreover, the requirement on the registration of service providers processing FRM aimed at avoiding the risk of a break in traceability, has been further finetuned (to exclude the providers of transport services) and inserted in a new subparagraph in this Article (instead of a new paragraph in Article 10).

- b) Article 15(3) (d) (Lots): "And" was replaced with "or" in the text introducing "parts of plants" to take into account mixtures of cuttings (e.g. poplar) or planting stocks, as provided for in the current directive. No amendments were finally made to Annex VI as they were deemed redundant.
- c) Article 16 (Official label and professional operator's document): the drafting of this amendment which purpose is to avoid unnecessary administrative burden for operators as well as for authorities regarding the use of official labels when the lot is not yet marketed has been improved.
- **d)** Article 25(a) (Official controls on forest reproductive material): The possibility to collect fees or charges was introduced in Article 25(a)(4) (instead of adding a cross reference to the corresponding Article of the OCR in Article 31).

The Presidency revised compromise text has been adapted accordingly and is set out in the Annex to this note.

<sup>11</sup> WK 6975/25

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## IV. CONCLUSION

In light of the above, Coreper is invited to examine the revised Presidency compromise text as set out in the Annex to this note, solve any outstanding issues that may arise during the meeting and reach an agreement on the Coreper mandate, with the view to the forthcoming negotiations with the European Parliament.

In accordance with the approach to legislative transparency endorsed by Coreper on 14 July 2020<sup>12</sup>, and in full consistency with Regulation (EC) No 1049/2001 and the Council's Rules of Procedure, the text of the mandate thus agreed will be made public unless the Permanent Representatives Committee objects.

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#### Draft

# REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the production and marketing of forest reproductive material, amending Regulations (EU) 2016/2031 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>13</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>14</sup>,

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

Acting in accordance with the ordinary legislative procedure<sup>15</sup>,

#### Whereas:

- (1) Council Directive 1999/105/EC<sup>16</sup> sets out rules on the production with a view to marketing 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 primordial function as a carbon sink in the climate mitigation policy. High-quality, climate-adapted and diverse FRM of proven identity is essential to cover these needs.

OJ C 199, 14.7.1999, p. 1.

OJ C 329, 17.11.1999, p. 15.

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 ....

Council Directive 1999/105/EC of 22 December 1999 on the marketing of forest reproductive material (OJ L 11, 15.1.2000, p. 17).

- In the light of new technical and scientific developments the development of scientific or technical knowledge, 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>17</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>18</sup>, as well as the experience 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 ensuring high genetic diversity within species and on preserving species diversity, including by diversification in forest plots and seed lots thereby enhancing. As a result, the adaptive potential of FRM forest would be maintained and improved for the future replanting of an area with trees ('reforestation') and the creation of new forests ('afforestation'). Reforestation may be required as a part of sustainable forest management or 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

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Decision of the Council Establishing the OECD Scheme for the Certification of Forest Reproductive Material Moving in International Trade [OECD/LEGAL/0355].

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).

- establishing the framework for achieving climate neutrality<sup>19</sup> and with the three implementing strategies of the European Green Deal: the new EU Strategy on Adaptation to Climate Change<sup>20</sup>, the new EU Forest Strategy for 2030<sup>21</sup> and the EU Biodiversity Strategy for 2030<sup>22</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 full respect of ecological principles favourable to biodiversity. Ensuring forest restoration and reinforced sustainable forest management are essential **for adaptation to climate change** 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

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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).

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).

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).

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).

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 of FRM. This aims to facilitate the supply of high-quality and genetically diverse FRM of proven identity that is adapted or adaptable to current and projected future climatic conditions. The conservation and improvement of biodiversity of forests, including the genetic diversity of the trees within individual tree species, are essential to sustainable forest management and conservation of forest genetic resources 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 **should list** the purposes for which it is important to use high-quality FRM.
- (11) FRM may be produced for <u>intended</u> use in afforestation, reforestation, <u>diversification in a</u>

  <u>forest plot</u> and other <u>types of</u> tree planting <u>and for several</u> <u>for one or more of the following</u>

  <u>different</u> purposes: <u>multifunctional forestry</u>, <u>production of such as</u> wood, <u>and</u>

  biomaterials <u>production</u>, <u>biodiversity conservation</u>, <u>restoration of forest ecosystems</u>,

- elimate adaptation, elimate mitigation, and conservation, biomass or other forest products 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.
- (12a) Upon approval of basic material, a distinction should be made between autochthonous and indigenous seed sources or stands by the competent authorities. Professional operators should have the option to make this distinction on the professional operator's document.
- (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 their hybrids which are listed in Annex I to this important for the objectives of this Regulation. Those species should be listed accordingly. 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 of proven identity. To help ereate maintain and establish resilient forests and restore forest ecosystems, support their ecosystem services and establish other tree plantings, users should be informed prior to the purchase of FRM about the suitability of that FRM for specific climatic and ecological conditions where the respective material has grown of the area where it will be used.
- (16) To ensure that certified FRM will be adapted to the **specific** climatic and ecological conditions of the area where it is **intended to be sown or** planted, the competent authorities

should assess the sustainability characteristics of basic material during the procedure for approving that basic material its approval. Those sustainability characteristics should concern the adaptation of that basic material to the specific climatic and ecological conditions, and the freedom of trees from pests and their symptoms including the biotic and abiotic factors prevailing in the region of provenance and the resistance or tolerance to pests and the adverse climatic and site conditions in which they are growing.

- (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 <u>be</u> registered in a national register with a unique register reference and with reference to a unit of approval. <u>In order to allow competent authorities</u>

  to organise those controls, professional operators should notify their intention prior to harvesting.
- (17a) However in order to ensure a more flexible approach with regard to the FRM of source-identified category, competent authorities should have the possibility, upon the approval of the Commission, to authorise professional operators to approve, for certain species, basic material intended for the production of the FRM of that category, in the case of extreme climatic conditions.
- In order to adapt to the scientific and or technical developments of international standards, the use of bio-biochemical and molecular techniques (BMT), should be possible to 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.
- (18a) 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 their hybrids approved on its territory, and a national list which should be presented as a summary of the national register.
- (18b) 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

- <u>provided by each Member State. That Union list should also contain information on</u>

  <u>basic material that contains or consists of a genetically modified organism [or that has been produced by certain new genomic techniques.</u>
- (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 'sourceidentified', '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 and to create equal conditions for professional operators across the Union.
- (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 resources to the competent authority.

- The source-identified category is the minimum standard required for the marketing of FRM, because <u>there is</u> little or no phenotypic selection of the basic material intended for the production of FRM of <u>this source-identified</u> category. 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 On the basis of experience gained from the application of Directive 1999/105/EC, and taking into account the OECD Forest Seed and Plant Scheme, 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. The reproductive population should have a minimum degree of uniformity. 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, **wood production or** 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 Those standards should be determined 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 the basic material, the professional operator should demonstrate the superiority of the FRM should be <u>demonstrated</u> by comparative testing or estimate<u>d</u> 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.
- The assessment of basic material intended for the production of FRM of the tested category takes on average at minimum 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 10 years.
- (28) Compliance of <u>marketed</u> FRM with the requirements for the categories 'source-identified', 'selected', 'qualified' and 'tested' <u>should be confirmed by inspections carried out by the competent authorities as appropriate for each category ('official certification') and</u>

should be attested by an official label. <u>Before marketing or direct seeding using</u>, <u>harvested FRM should bear a provisional label to ensure traceability until the official</u> label is issued.

- 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 possible to issue the master certificate in an electronic form.
- (28a) In addition to the official label, professional operators should also issue an professional operator's document. It should contain all information from the official label, as well as supplementary information. This is necessary in order to inform the user as comprehensively as possible about the FRM, and to retain that information in the most effective manner.
- Genetically modified FRM may should 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>23</sup> or Regulation (EC) 1829/2003<sup>24</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>25</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.

Regulation (EU) .../... of the European Parliament and of the Council .... (OJ ..., p.).

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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).

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).

- (31) Professional operators should be authorised by the competent authority to print It should be possible for the competent authorities to authorise professional operators to issue and print the official label under official supervision for certain species and categories of FRM. This will give more flexibility to the professional operators in relation to the subsequent marketing of that FRM. However, professional operators ean only start printing the label once competent authority has certifie the FRM concerned should only be allowed to start issuing and printing the label once the FRM has been found to comply with the respective requirements. 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. **Member States should also be allowed, subject to authorisation granted by the Commission, to restrict in their territory the approval of basic material intended for the production of FRM of the category "source-identified", as well as to prohibit the marketing to the end user of specified reproductive material, in case that the respective FRM is not suitable for forestry ecological conditions and purposes of the respective Member State.**
- (32a) Insofar as certain species and their hybrids are not subject to the measures contained in this Regulation, Member States may take such measures, in respect of their own territory, or apply more or less stringent measures.
- (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>26</sup>. Such registration reduces the administrative burden for those professional

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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

- operators. It <u>This</u> is necessary for the efficacy of the official register of professional operators 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 provide access to the potential buyers of their FRM-all the necessary to the available 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 the intended use of that FRM and the location concerned.
- (35) In the case of basic material intended for the production of FRM of the 'source-identified' 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 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 <u>have the possibility to</u> draw up and keep up to date a contingency plan to ensure a sufficient supply, for one or more of the relevant tree <u>species by ensuring a sufficient access to supplies</u> of FRM, to reforest areas affected by extreme weather events, wildfires, disease and pest outbreaks, disasters or any other event.

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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).

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 also have the possibility to adapt the content of that plan to the specific climatic and ecological conditions in their territories. This requirement also reflects Those possibilities should also reflect the general preparedness actions that Member States should take on a voluntary basis under the Union Civil Protection Mechanism<sup>27</sup>.

- In order to ensure traceability FRM should, during all stages of production and marketing, be kept separated in lots, 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. For reasons of transparency and traceability, each lot of FRM should be identified by the lot code and master certificate code, upon issuance of the master certificate.
- (40) Seeds should be marketed only if they conform to comply with certain quality standards.

  With the exception of large quantities, they should be labelled and marketed only in sealed packages closed packages which are sealed, 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 <u>or FRM</u> satisfying less stringent <u>quality</u> requirements should, subject to certain conditions, be temporarily approved. Those less

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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).

- stringent requirements should concern the approval of basic material intended for the production of different categories of FRM <u>or marketing of FRM fulfilling less stringent</u> <u>quality requirements.</u> This is necessary to ensure a flexible approach, <u>in the affected</u> <u>areas</u>, 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.
- 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 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>28</sup>. Moreover, imported FRM should be accompanied by a master certificate or an official certificate issued an OECD certificate or an equivalent 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 OECD label or equivalent 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 by categories per

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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).

- <u>year, quantities of FRM per genera and species imported from third countries under Union equivalence, penalties imposed and the number of registered professional operators.</u>
- 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 provisions of this Regulation to the ecological changes, shift of tree species and their ranges as a result of climate change, as well as to any development of scientific or technical knowledge, 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 adding tree species, and artificial hybrids thereof, to which this Regulation applies to, or removing them from, the list of species subject to this Regulation, if they fulfil certain criteria.
- In order to adapt to take account of the development of scientific and/or 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>29</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 of the approval of basic material intended for the production of FRM to be certified as of 'source-identified', 'selected', 'qualified', and 'tested' categories 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 <u>the development</u> of <u>scientific or technical knowledge</u>, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of setting out <u>the certain</u> requirements <u>to be fulfilled by concerning fruit and seed seed units</u> lots of the <u>tree</u> species covered by this Regulation, <u>other than their hybrids</u>, <del>to</del>

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).

be fulfilled by concerning parts of plants of the such species and their artificial hybrids covered by this Regulation, for concerning external quality standards for *Populus* spp. propagated by stem cuttings or sets, to be fulfilled by concerning planting stock of the tree species and their artificial hybrids covered by this Regulation, and to be fulfilled by concerning planting stock to be marketed to final users in regions having a Mediterranean elimate with particular eco-climatic conditions.

- (49a) In order to increase the credibility of the system for the authorisation of the professional operators and the official supervision by the competent authorities, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of setting out the procedure for the application submitted by the professional operator to be authorised, and the actions to be taken by the competent authority to confirm compliance with the respective requirements.
- In order to adapt with meet the aim of the EU Digital Strategy to make the transformation to digital technologies work for people and businesses, and to take account of the technical developments in the digitalisation 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 master certificates, of the official labels and of the professional operator's documents 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 on** 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>31</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

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).

OJ L 123, 12.5.2016, p. 1.

- 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.
- (52a) In order to ensure a proportionate approach, in the case of small quantities, certain requirements for the marketing of seeds should not have to be fulfilled. In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission with respect to determining the small quantities for the species to be excluded from certain marketing requirements.
- (52b) In order to ensure uniform conditions for the implementation of this Regulation, and to address temporary difficulties in the general supply of FRM, implementing powers should be conferred on the Commission with respect to authorising one or more Member States to temporarily allow the marketing of FRM satisfying, or deriving from basic material which satisfies, less stringent requirements than the ones set out by this Regulation.
- In order to ensure uniform conditions for the implementation of this Regulation, and facilitate the <u>recognisability</u> 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 as well as to laving down rules concerning the mechanisms and technical arrangements to ensure the issuance of accurate and reliable master certificates, and prevent risk of fraud, the procedures to be followed in the case of withdrawal of master certificates and for the issuance of replacement certificates, rules for the production of certified copies of master certificates, and rules for the issuance of electronic certificates and for the use of electronic signatures.
- (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 format** 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 genera or species and the professional operator's document for all or specific categories of FRM. In order to ensure alignment with the respective international standards, Member States may decide to use colours, when they decide to do so they should use the colours as defined in the Rules and Regulations of the OECD Forest Schemes.

- (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, electronic official labels and electronic professional operators' documents.
- (55a) In order to ensure uniform conditions for the implementation of this Regulation, and to ensure the approval of basic material of the source-identified category by the professional operators, implementing powers should be conferred on the Commision with the respect to granting such approval subject to certain conditions.
- (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.
- (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.
- (57a) In order to ensure uniform conditions for the implementation of this Regulation,
  implementing powers should be conferred on the Commission with respect to
  authorising Member States, under certain conditions, to adopt more stringent or
  additional production requirements for the approval of basic material and the
  production of FRM, to restrict the approval of basic material intended for the
  production of FRM of the category "source-identified" or to prohibit the marketing to

- the end user with a view to sowing or planting in all or part of its territory of specified reproductive material.
- (57b) In order to ensure uniform conditions for the implementation of this Regulation,
  implementing powers should be conferred on the Commission with respect to deciding
  if FRM of specific genera, species, or categories and, where appropriate, deriving from
  specific types of basic material or of a specific region of provenance, produced in a
  third country fulfils requirements equivalent to those applicable to FRM produced and
  marketed in the Union.
- (57c) In order to ensure uniform conditions for the implementation of this Regulation,
  implementing powers should be conferred on the Commission with respect to laying
  down certain rules on uniform practical arrangements for the performance of the
  official controls to verify compliance with the rules on FRM.
- (57d) In order to ensure uniform conditions for the implementation of this Regulation,
  implementing powers should be conferred on the Commission with respect to
  specifying the technical format, including digital submission and processing, for the
  reports submitted by the Member States to the Commission every 5 years on quantities
  of certified FRM by categories per year, quantities of FRM per genera and species
  imported from third countries, penalties, number of registered professional operators.
- (57e) The implementing powers conferred on the Commission under this Regulation should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council<sup>32</sup>.
- (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., FRM marketed in accordance with this Regulation, should also comply with the rules set out in, or pursuant to the relevant provisions of Regulation (EU) 2016/2031 concerning Union quarantine pests, protected zone quarantine pests and Union regulated non-quarantine pests, and with the measures

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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 the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13, ELI: http://data.europa.eu/eli/reg/2011/182/oj).

- adopted pursuant to Article 30(1) of that 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.
- Because of the specificities of the FRM sector, this Regulation contains specific provisions on the official controls of FRM and does not fall as such under the scope of Regulation 2017/625. However, in order to ensure that official controls are applied consistently across Member States and in order to create synergies with the system of official controls concerning similar sectors in particular that of plants in addition to enabling Member States to use existing instruments and tools such as IMSOC for the verification of compliance with the rules on FRM, provisions on official controls in this Regulation should be supplemented by the necessary provisions of Regulation 2017/625. 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 (EU) 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 ... [3–5 years from the date of entry into force of this Regulation].

(63a) FRM produced, before [date of application] in accordance with the provisions of

Directive 1999/105/EC or national rules, should be allowed to continue to be marketed
until exhaustion of the respective stocks. FRM produced in accordance with Directive
1999/105 should be allowed to continue to be marketed with a master certificate issued
pursuant to that Directive. This is necessary, in order to avoid any disruption of the
production and marketing of FRM in the Union,

HAVE ADOPTED THIS REGULATION:

# CHAPTER I GENERAL PROVISIONS

#### Article 1

## Subject matter

This Regulation sets out rules concerning the production and with a view to marketing, 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 of that basic material and traceability of that basic material, FRM, requirements for official controls, 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 and objectives

- 1. This Regulation applies to FRM of the tree species <u>listed in Annex I</u> and <u>their artificial</u> hybrids <u>thereof</u>, <u>listed in Annex I</u> <u>considered as such if at least one of the parent species is listed in Annex I</u>.
- 2. The objectives of this Regulation are the following are to contribute to the maintenance and establishment of resilient forests, the restoration of forest ecosystems, to support their ecosystem services and the establishment of other tree plantings in particular through:

- (a) **ensure** the **sustainable** production, **and** marketing **and traceability** 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) <u>the support of sustainable production of wood and biomaterials production</u>, climate adaptation, climate mitigation and the conservation and sustainable use of forest genetic resources;
- (d) the support of sustainable production of biomaterials, biomass and other forest products;
- (db) the support of the conservation of forest genetic resources;
- (e) the contribution to adaptation of FRM and forests to climate change;
- (f) the contribution to mitigation of climate change;
- (g) the contribution to protection against soil erosion.
- 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 the ecological changes, shift of tree species and their ranges as a result of climate change;
  - (b) any developments of scientific technical or technical and scientific knowledge.
- 3a. Those The delegated acts referred to in paragraph 3 shall add tree 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) <u>they</u> represent a significant area and economic value of FRM production in the Union;
  - (b) they are marketed as FRM in at least two Member States;
  - (c) <u>they</u> are considered important for their contribution to adaptation to climate change, and/or conservation of forest genetic resources.

- (d) are considered importand for their contribution to the conservation of biodiversity.
- 3b. The delegated acts referred to in the first subparagraph paragraph 3 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 paragraph 3a.
- 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 <u>solely with the intention to</u> export to third countries, <u>under the</u> <u>condition that it is identified as such</u>;
  - (d) FRM used <u>solely</u> for official testing, scientific purposes or selection work, <u>under the</u> <u>condition that it is identified as such through labelling and traceability</u>;
  - (da) FRM when subject to service contracts for the purposes of cleaning,
    disinfection, treatments, and transport, provided that all the conditions are
    fulfilled:
    - (i) the provider of services does not acquire title to either that FRM or the product of the harvest;
    - (ii) the traceability of that FRM is ensured; and
    - (iii) the professional operator producing that FRM has provided upon request the competent authority with a copy of the relevant parts of the contract made with the provider of services including the standards and conditions met by the FRM provided.

- (iv) the provider of service processing that FRM for the purposes of cleaning, disinfection, treatments with the exception of transport services is registered in a register referred to in article 10 (1) b).
- 5. For tree species not listed in Annex I of this Regulation and their hybrids, considered as such, if none of the parent species are listed in Annex I, Member States may take measures contained in this Regulation, or less stringent measures, or stricter measures, in respect of their own territory.

#### Article 3

#### **Definitions**

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

- (1) 'forest reproductive material' ('FRM') means eones, infructescenses, fruits and seeds intended for the production of seed units, parts of plants and planting stock, that belong to tree species and artificial hybrids thereof listed in Annex I to this Regulation and their hybrids and are intended to be used for afforestation, reforestation, diversification in a forest plot, and other tree planting, for any one or more of the following purposes:
  - (o)multifunctional forestry;
  - (a) production of wood, and biomaterials production, biomass or other forest products;
  - (c) restoration of forest ecosystems;
  - (d) climate adaptation;
  - (e) climate mitigation;
  - (f) conservation and sustainable use of forest genetic resources.
- (4) 'seed unit' means cones, infructescenses, fruits and seeds intended for the production of a planting stock **or for direct sowing**;

- (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, stem-cutting without roots and any other parts of a plant used for the production of a planting stock;
- 'afforestation' means establishment of forest through planting and/or deliberate seeding on land that, until then, was under a different land use and implies a transformation of land use from non-forest to forest<sup>33</sup>;
- (3) 'reforestation' means re-establishment of forest through planting and/or deliberate seeding and/or vegetative propagation and/or natural regeneration on land classified as forest<sup>34</sup>;
- (14) '<u>type of</u> basic material' means any of the following: seed source, stand, seed orchard, parents of family(ies), clone or clonal mixtures;
- (8) 'seed source' means the trees within an area, from which FRM 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 individual** is identified by a clone, **or** 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 **units**;
- (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

FAO (2020) Global Forest Resources Assessment Terms and definitions. https://www.fao.org/3/I8661EN/i8661en.pdf.

FAO (2020) Global Forest Resources Assessment Terms and definitions. <a href="https://www.fao.org/3/I8661EN/i8661en.pdf">https://www.fao.org/3/I8661EN/i8661en.pdf</a>.

- of one 'father tree' parent (full sibling) or a number of identified or unidentified parents 'father trees' (half-sibling);
- 'clone' means a <u>single individual</u> or group of individuals (ramets) derived originally from a single individual (ortet) by vegetative propagation, for example by cuttings, micropropagation, grafts, layers or divisions, <u>or derived originally from cell lines</u>;
- (13) 'clonal mixture' means a mixture of identified clones in defined proportions;
- (15) 'unit of approval' means the entire area <u>or individual(s)</u> 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 <u>originally</u> collected from approved basic material and processed uniformly;
- (18) 'plants lot' means a set of plants 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;
- (18a) Lot means a set of FRM;
- (18b) 'seed units lot' means a set of seed units originally collected from approved basic material and processed uniformly;
- (18d) 'parts of plants lot' means a set of parts of plants originally collected and processed uniformly;
- (19) 'lot number code means the identification number of the seed lot or plant lot, as appropriate code of the lot;
- (20) 'provenance' means the <u>name of the</u> place in which any <u>seed source or stand of trees is</u> growing;
- (21) 'sub-species' means a group within a species that has become somewhat phenotypically and genetically different from the rest of the group;

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- '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;
- 'autochthonous <u>seed source or</u> stand' means a <u>stand of native tree species which has</u>

  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 a seed source or stand which has been continuously and naturally

  regenerated or artificially regenerated from FRM collected in the same seed source or

  stand or in other autochthonous seed sources or stands in the close proximity;
- 'indigenous <u>seed source or</u> stand' <u>means an autochthonous stand or a stand raised</u>

  artificially from seed, where the origin of this stand and the stand itself are located in

  the same region of provenance <u>means a seed source or stand of tree species located in</u>

  a specific region of provenance that is part of the natural distribution range of that

  species, raised from seed or vegetatively propagated, the origin of which is situated

  within 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 **or cell line** is or was initially located or selected;
  - (f) for a clonal mixture, the origins are the places, where the ortets or cell lines are or were initially located or selected;

- 'location of the basic material' means the geographical area or geographical position(s) of the basic material as appropriate for each category of FRM;
- 'place of production of clones or clonal mixtures or parents of families' means the place or exact geographical position, where the FRM was produced;
- '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;
- (31) 'professional operator' means any natural or legal person **involved** professionally in **charge** of 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;
- (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, of lots of FRM, including harvest, collection, storage, processing and conversion of seed units lots and parts of plants lots, growing, multiplying, maintaining, storage and harvest of plants lots with a view for the respective FRM to be marketed;
- (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 (with the exception of external transport services) within, or import into the Union, whether free of charge or not, of FRM;
- '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 reponsibility has been conferred, in accordance with Union law;

- (a) a central or regional authority of a Member State including that designated in accordance with Article 4 of the Regulation (EU) 2017/625, responsible for the organisation of the official controls 3 and other official activities; or,
- (b) a central or regional authority of a Member State, or, where applicable, the corresponding authority of a third country, responsible for the registration of basic material and professional operators and, certification of FRM;
- (32a) 'delegated body' means a separate legal person to which the competent authorities

  have delegated certain official control tasks or certain tasks related to other official
  activities;
- (38) 'category' means **FRM that qualifies** the classification of FRM as source-identified, selected, qualified or tested material;
- (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;
- orchards, parents of family(ies), clones or clonal mixtures, where the superiority of that

  FRM has been demonstrated by comparative testing or an estimate of the superiority

  of the FRM has been calculated on the basis of the genetic evaluation of the

  components of the basic material, 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 the procedure leading to the issuance of a master certificate and the issuance itself, by the competent authority, as well as the issuance of the official label, according to the rules provided for in this Regulation;
- (37a) 'official controls' means activities performed by the competent authorities responsible

  for the organisation of the official controls to verify the compliance with the respective
  requirements of this Regulation;
- (37aa) 'other official activities' means activities other than official controls concerning the production and marketing of FRM;
- (37d) 'documentary check' means the examination of the master certificates and other documents;
- (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 A**, **part 2** 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>35</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

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 ...).

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 natural processes;
- (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.

## 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 'source-identified' 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 biochemical and molecular techniques (BMT), 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 <u>the</u> '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/or technical knowledge, including the use of biochemical and molecular techniques (BMT), and the development of the OECD Forest Seed and Plant Scheme and other applicable to the relevant 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

- O. FRM of the source-identified, selected, qualified or tested category may only be marketed within the Union:
  - (a) <u>if it is accompanied by:</u>
    - (i) an official label issued by the competent authorities; or
    - (ii) <u>an official label issued by the professional operator under the official</u> supervision of the competent authorities;
  - (b) if it complies with paragraph 1;
  - (c) <u>if it is accompanied by an professional operator's document, as referred to in</u>
    Article 16.
- 1. FRM derived from approved basic material shall be marketed **by professional operators** in accordance with the following rules:
  - (a) FRM of the <u>tree</u> species listed in Annex I <u>and their natural hybrids</u> 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 of the tree species 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 and their hybrids which contains or consists in of 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 and their hybrids, 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 FRM marketed in accordance with this Regulation, shall also comply with the rules set out in, or pursuant to the relevant provisions of Regulation (EU) 2016/2031 concerning Union quarantine pests, protected zone quarantine pests and RNQPs Union regulated non-quarantine pests, and pests subject to the measures under Article 30-and with the measures adopted pursuant to Article 30(1) of that Regulation;
- (h) In the case of seeds <u>lots</u>, FRM of the tree species <del>and artificial hybrids</del> listed in Annex I <u>and their hybrids</u> may only be marketed if, in addition to compliance with points (a) to (g), information is available as regards to:
  - (i) the purity, as measured by the percentage by weight of pure seed, other seed and inert matter;
  - (ii) the germination percentage of the pure seed, or in cases where germination testing is impossible or impractical, the viability percentage assessed by reference to a specified method;
  - (iii) <u>the</u> weight of 1000 pure seeds;
  - (iv) the number of germinable seeds per kilogram <u>or liter</u> 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 <u>or liter</u>;
  - (v) for artificial hybrids, the hybrid percentage.

In the case of small quantities, the requirements as laid down in subparagraph (ii), (iv) and (v) do not have to be fulfilled. The Commission shall, by means of implementing acts, determine the quantities for the respective species. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 27(2).

1a. By way of derogation from paragraph 1, point (h), in order to make seed of the current season's crop rapidly available, notwithstanding the fact that the examination in respect of germination as laid down in paragraph (h) points (ii) and (iv) has not been concluded, marketing of FRM may take place as far as to the first buyer. The respect of the conditions as laid down in paragraph (h) points (ii) and (iv), shall be

stated by the professional operator as soon as possible. A professional operator that intends to make use of this derogation shall notify the competent authorities, once, its intention to make use of the derogation.

- 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/or technical knowledge and to 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 'source-identified' 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 satisfying less stringent requirements or deriving from basic material satisfying less stringent requirements

0. In order to remove any temporary difficulties in the general supply of FRM satisfying the requirements of this Regulation that occur in one or more Member States and

9694/1/25 REV 1 43 ANNEX LIFE.3 **LIMITE EN**  cannot be overcome within the Union, the Commission may, by means of implementing act, authorise one or more Member States to temporarily allow the marketing of FRM satisfying less stringent requirements than the ones referred to in Article 5(1) points (a), (b) and (h) and Article 8, or deriving from basic material which satisfies less stringent requirements than the ones referred to in Article 4(2). That implementing act shall determine the conditions of such authorisation:

- (a) the maximum duration of the authorisation, which authorisation can be at maximum 12 months;
- (b) obligations as regards official controls on the professional operators applying that authorisation;
- (c) the Member State(s) that are concerned by the temporary authorisation;
- (d) the areas, professional operators, species concerned for each Member State, as appropriate;
- (e) other conditions for marketing as necessary for each Member State;
- (f) the area in which the FRM may be marketed;
- (g) restriction to certain categories.

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

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.

1a. FRM referred to in paragraph 0 shall be accompanied by an official label and professional operator's document issued pursuant to Articles 16(1) and 16(1b). In

addition, that professional operator's document shall state that the FRM concerned satisfies less stringent requirements than the ones referred to in Article 5(1) points (a), (b) and (h) and (c) and Article 8. or has been derived from basic material which satisfies less stringent requirements than the ones set out in Article 4(2).

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 seed units of the tree species listed in Annex I other than their hybrids as regards species purity, if technically feasible;
- (b) concerning parts of plants of the species and artificial hybrids the tree species listed in Annex I and their hybrids 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 artifical hybrids the tree species listed in Annex I and their hybrids 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 elimate\_with particular eco-climatic conditions 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 the development of scientific or technical knowledge, or the climatic and ecological developments.

#### Article 9

# Contingency plan and national register

1. Each Member State shall may draw up one or more contingency plans to ensure preparedness and capacity to establish a sufficient supply of FRM to reforest areas affected by extreme weather events, wildfires, diseases and pest outbreaks, disasters or any other event, as relevant and identified in the national risk assessments developed in accordance with Article 6(1) of Decision No 1313/2013/EU<sup>36</sup>.

## Those plans may be coordinated between neighboring countries.

That contingency plan shall may be prepared for those tree species and artificial hybrids thereof one or more of the tree species listed in Annex I and their hybrids, that are deemed suitable for the on the basis of an evaluation made by the Member State, economically and/or ecologically relevant as stand forming species, under current and projected future climatic and ecological conditions of the Member State concerned.

<sup>&</sup>lt;sup>36</sup> OJ L 347, 20.12.2013, p. 924.

The contingency plans shall take into account, when available, 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 <u>as appropriate for the conditions of every Member State</u>, 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;
  - (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 appropriate competence 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 **the development of scientific or technical knowledge** in relation to climate model simulations addressing the projected future distribution of the relevant tree species and artificial hybrids therof.

- 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 IIb**

# REGISTRATION AND AUTHORISATION OF PROFESSIONAL OPERATORS AND BASIC MATERIAL, AND DEMARCATION OF REGIONS OF PROVENANCE OFFICIAL SUPERVISION BY THE COMPETENT AUTHORITIES

#### 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.
  - (a) They shall be established in the Union;
  - (b) be registered in a register in each Member State where they have activities related to the production and marketing of FRM, as provided for in Article 65 of Regulation (EU) 2016/2031, for the activities related to the production and marketing of FRM, in accordance with Article 66 of that Regulation;
  - (c) <u>be available personally or designate another person, to liaise with the competent authorities for facilitating the official controls;</u>
- 1a. The professional operators shall inform the competent authorities about any changes regarding points (a), (b) and (c) and the competent authorities shall update that register accordingly.
- 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.
- 2. Professional operators shall ensure traceability and identification of FRM at all stages of production and marketing, including information on the suppliers and

buyers, and information contained in the official label and the professional operator's document. The professional operator shall have a system that allows monitoring the information relevant for traceability and identification of FRM for the purpose of own checks and official controls.

- 2a. The information referred to in paragraph 2 shall be stored forgery-proof for at least 10 years. That period shall begin at the end of the year in which the professional operator's document has been created. The information may be stored in digitally readable form. The Member States are allowed to regulate the content of the records and to require only digital records.
- 3. The professional operators shall facilitate the access of users to the existing available information on FRM concerning its suitability for specific climatic and ecological conditions. That information shall, prior to the transfer of the FRM concerned, be provided to the potential user through websites, planters' guides or other appropriate means. The professional operators may refer to websites managed by the competent authorities or public institutes if those are available.
- 4. To the extent that this is necessary for the performance of official controls,

  professional operators shall, where required by the competent authorities, give staff
  of the competent authorities access to:
  - (a) the equipment, premises and other places, including basic material, under their control;
  - (b) their computerised information management systems;
  - (c) the forest reproductive material under their control;
  - (d) their documents and any other relevant information.
- 5. During official controls, professional operators shall assist and cooperate with the staff of the competent authorities in the accomplishment of their tasks.
- 6. The obligations of professional operators set out in paragraphs 4, and 5 and 6 shall also apply in cases where official controls are performed by delegated bodies and natural persons to which certain official control tasks or certain tasks related to have been delegated.

#### Article 10a

Authorisation of a professional operator under official supervision by the competent authority for production and marketing of FRM

1. Competent authorities may, upon application by a professional operator, authorise the professional operator to perform all or certain activities required for the production and marketing of FRM under official supervision of the competent authority and to issue an official label for them that FRM.

In order to be granted such authorisation, and depending on the activities to be authorised for, the professional operator shall:

- (a) possess the necessary knowledge for complying with the requirements referred to in Article 5;
- (b) be qualified or employ qualified personnel, to carry out one or more of the following activities to ensure compliance with the requirements referred to in Article 5:
  - (i) inspections;
  - (ii) sampling;
  - (iii) testing;
- (c) have identified, and have the capability to monitor the critical points of the production process which may influence the quality and identity of the FRM, and keep records of the results of that monitoring;
- (d) have in place systems to ensure the fulfilment of the requirements concerning lots pursuant to Article 15 and issuance of the official label pursuant to Article 16.
- 2. The Commission is empowered to adopt delegated acts in accordance with Article 26, supplementing paragraph 1 by setting out one or more of the following elements:
  - (a) the procedure for the application submitted by the professional operator;

(b) specific actions to be taken by the competent authority, in order to confirm the compliance with paragraph 1, points (a) to (d).

## Article 10b

Withdrawal or modification of the authorisation of a professional operator

- 1. Where an authorised professional operator no longer fulfils the requirements set out in Articles 10(1)c, 10(2) and 10a(1), the competent authority shall request that the professional operator to take corrective actions within a specified period of time.
- 2. The competent authority shall without delay withdraw, or modify as appropriate, the authorisation, if the professional operator does not apply the corrective actions referred to in paragraph 1 within the specified period of time. In case it is concluded that the authorisation had been granted following fraud, the competent authority shall impose the appropriate penalties to the professional operator.
- 3. When the professional operator no longer performs the activities it is authorised for, on a temporary or permanent basis, it shall request the temporary suspension or withdrawal of its authorisation according to the instructions of the competent authority. This provision does not apply to business closures.

#### Article 10c

## Official supervision by the competent authorities

- 1. For the purposes of the activities under official supervision, the competent

  authorities, shall conduct regular checks to ensure that the professional operator

  fulfils the requirements referred to in Article 10a(1).
- 2. The checks referred to in paragraph 1 shall consist, as necessary, of official inspections, sampling and testing of the FRM in order to confirm compliance of that material with the requirements referred to in Article 5.
  - The frequency of those checks shall be determined on the basis of the assessment of the potential risk of non-compliance of the FRM with those requirements.

3. Those checks may include the introduction of reference systems for the genetic verification of identity of FRM, such as biochemical and molecular techniques (BMT).

# **CHAPTER III**

# REGISTRATION OF BASIC MATERIAL AND DEMARCATION OF REGIONS OF PROVENANCE

#### 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 <u>referred to in paragraph 1</u>, the basic material included, before ... [OJ, please, insert the <u>application</u> date of <u>the-this Regulation</u>], 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 and in accordance with the format of 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 scientific name of the genus and species and, if so decided by the competent authority, common name in an official Union language;
- (b) category **of FRM**;
- (c) type of basic material, as referred to in the table of Annex VI;
- (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 <u>the exact</u>

    <u>geographical position(s) defined by latitude, longitude, and altitude or</u> 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 or the latitudinal, longitudinal and altitudinal range, where the basic material is maintained;

(iv) for the 'tested' category, the exact geographical position(s) defined by latitude, and longitude and altitude or the latitudinal, longitudinal and altitudinal range, where the basic material is maintained;

In points (i) to -(iv) a uniform coordinate system as defined in the Forest

Reproductive Material Information System of the Commission (FOREMATIS)

shall apply;

- (f) area: the size of a seed source(s), stand(s) or seed orchard(s), indicated in hectares or number of trees;
- (g) origin:
  - (i) indication whether the basic material is **autochthonous**/indigenous, **non-autochtonous**/non-indigenous or **if the origin is**-unknown **and, in the case it** is indigenous, whether it is autochthonous or not;
  - (ii) non-authochtonous/non-indigenous basic material, an indication of the origin, if it is unknown; information about the origin, if it is known;
  - (iii) in the case of seed orchards, provenances or other relevant geographic information where its components were originally located shall be stated if known. For seed orchards representing a more advanced stage of breeding, information from breeding records may substitute the information about origin and region(s) of provenance;
- (h) one or more purposes of use of FRM as referred to in Article 3 point (1);
   (ha) other information relevant for the characterisation of the basic material;
- (i) in the case of FRM of the 'tested' category, an indication whether it is:
  - (i) it is authorised for cultivation as a genetically modified organism, for cultivation in the respective Member State 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; of

- (ii) <u>it contains or consists of a category 1 an-NGT plant as defined in Article</u>

  3(7) of Regulation (EU) .../... (Office of Publications, please insert

  reference to NGT Regulation ...);
- (iii) it contains or consists of a category 2 NGT plant as defined in Article 3(8) of Regulation (EU) .../... (Office of Publications, please insert reference to NGT Regulation...);
- (j) in the case of qualified and tested categories, information about the place of production of <u>offsprings of parents of families</u>, clone(s) or clonal mixture(s) <u>where</u> <u>appropriate</u>, <u>which means the place or exact geographical position</u>, <u>where the</u> <u>FRM was produced</u>;
- (k) where a database of the competent authority is freely accessible, a link to that data base including the master certificates and codes corresponding to the respective units of approval and/or a link to the database referred to in Article 14(13).

#### Article 13

#### **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 13a

# Harvest and collection from basic material

- 1. The professional operator shall notify the competent authority of its intention to

  harvest FRM, within a reasonable period prior to harvesting, in order to allow the

  competent authority to organise controls.
- 2. In the case where FRM from the tree species listed in Annex I and their hybrids is

  harvested with the intention not to be marketed as FRM within the Union, the

  professional operator referred to in Article 3(31) shall indicate this in the notification.
- 3. During the collection and processing of FRM before marketing or direct use, the harvested FRM shall bear a provisional label issued by the professional operator, containing the unique reference to the basic material, the collection date, the name of the professional operator, and the harvested quantity. That label shall be replaced by the official label, referred to in Article 16, once the respective requirements are fulfilled.
- 4. The competent authority may define the technical conditions to be considered during harvesting and collection.
- 4a. The harvesting of FRM shall not compromise the regeneration of approved basic material for the purpose of conservation of forest genetic resources.
- 5. The professional operator responsible for FRM harvesting, extraction, cleaning and packaging shall ensure that the seed units lots and parts of plants lots are sufficiently homogenous prior to marketing or use in accordance with the applicable international standards.
- 6. Professional operators shall maintain for a period of at least 10 years and upon request, supply the competent authority with records which shall contain details of all consignments that have been detained and marketed.

#### 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).

- 1. The master certificate of identity ('master certificate') shall attest that the FRM:
  - (a) derives from a single unit of approved basic material in accordance with the requirements of Article 4(2);
  - (b) derives from a mixture of seed lots according to Article 15(3);
  - (c) is imported and its offical certificate is replaced in accordance with Article 25(3), point (a);
  - (d) derives from a subsequent vegetative propagation according to Article 15(2).

The competent authorities shall issue the master certificate, bearing a unique code upon application of a professional operator, as soon as possible, after harvesting or extraction of the seeds depending on the circumstances and on the nature of the

material, or after importing the FRM, showing the unique register reference of basic material, for the FRM.

- 1a. The Commission shall, by means of an implementing act, adopt the content and the model for the master certificate of identity for FRM, and in particular for all of the following:
  - (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);
  - (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 <u>persuant to paragraph 1</u> or other document identifying the mixture shall be issued. The professional operator shall notify the competent authority of its intention to carry out that mixing, within a reasonable period prior to that operation. The competent authority may decide to supervise the mixing process.
- 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 <a href="mailto:number-code">number-code</a>.
- 4a. Professional operators may request the competent authorities to issue a master certificate, pursuant to paragraph 1, to replace a master certificate issued pursuant to Directive 1999/105/EC.

- 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 master certificates and
  - (b) the 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 master certificates.
- 7. The Commission may, by means of implementing acts, lay down rules concerning:
  - (a) the mechanisms and technical arrangements to ensure the issuance of accurate and reliable master certificates, and prevent risk of fraud;
  - (b) the procedures to be followed in the case of withdrawals of master certificates and for the issuance of replacement certificates;
  - (c) rules for the production of certified copies of master certificates;
  - (d) rules for the issuance of electronic certificates and for the use of electronic signatures.

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

#### Article 15

#### Lots

1. FRM shall, during all stages of production <u>and marketing</u>, be kept separated <u>in lots</u>, by reference to individual units of approval <del>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.</del>

Each lot of FRM shall be identified by the following:

- (a) lot number code; (at the time of harvest, the master certificate reference may be the lot code);
- (b) master certificate code and number, upon issuance of the master certificate;
- (c) botanical name scientific name of the genus and species and, if so decided by the competent authority, common name in an official Union language;
- (d) category of FRM;

#### (da) purpose of FRM use;

- (e) type of 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) <u>origin</u>, if appropriate, whether the <u>origin of the</u> basic material is <u>autochthonous or</u> indigenous, <u>non-autochthonous or</u> non-indigenous or unknown <u>and</u>, in the case it <u>is indigenous</u>, whether it is autochthonous or not;
- (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 it is authorised for cultivation as a genetically modified organism, for cultivation in the respective Member State 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;
  - (ii) an NGT plant it contains or consists of a category 1 NGT plant as defined in Article 3(7) of Regulation (EU) .../... (Office of Publications, please insert reference to NGT Regulation ...);
  - (iii) it contains or consists of a category 2 NGT plant as defined in Article 3(8) of Regulation (EU) .../... (Office of Publications, please insert reference to NGT Regulation).
- 2. Without prejudice to paragraph 1, of this Article and to Article 5(1), point (e), 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.

  professional operators shall keep separately FRM, which is subject to subsequent vegetative propagation and shall identify it as such. In such cases, the produced FRM shall assume the same category as the original FRM.
- 3. Without prejudice to paragraph 1, the mixing <u>lots</u> of <u>seeds</u> <u>and or parts of plants</u> <u>FRM</u>-shall be subject to all of the following conditions, as <u>appropriate</u> <u>applicable</u>:
  - (a) within the 'source-identified' or 'selected' categories, mixing shall apply to **seed FRM** lots derived from two or more units of approval within a single region of provenance;

#### (aa) it shall only take place within the same species, region of provenance and category;

(b) in the case of mixing of **seed FRM**-lots within a single region of provenance, from seed sources and stands in the 'source-identified category, the new combined lot shall be certified as '**seed FRM**-lots derived from a seed source';

- (c) in the case of mixing of <u>seed FRM</u>-lots derived from non-indigenous 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 <u>lots</u> of <u>seeds and or parts of plants</u> <u>FRM\_lots</u> derived from a single unit of approval from <u>one or</u> different years of ripening, the actual years of ripening and proportion of <u>seed or parts of plants</u> <u>FRM\_from each year shall be recorded.</u>

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). The resulting lot shall be mixed in such a way that it is homogeneous.

#### Article 16

#### Official label and professional operator's document

- 1. An official label shall be issued by the competent authority and printed for every each lot of FRM attesting compliance of that FRM with the requirements referred to in Article 5 for marketing with reference to a master certificate code and lot code by each lot for marketing, with the exception of holding and offering for the purpose of sale by:
  - (a) the authorised professional operator or a person contracted by that professional operator under the official supervision of the competent authority;
  - (b) the competent authority.
  - (c) This official label shall attest compliance with the requirements of Articles 5, 8 as applicable, and 15.

An official label does not need to be issued and printed in the case of a lot of FRM held and offered for the purpose of sale. However, in that case a reference to the master certificate code and lot code shall be ensured.

1a. That label shall ensure unique identification and traceability of the lot by accompanying that lot during all stages of marketing as referred to in paragraph 1.

- 1b. In case of delivery of lots of FRM to another user, the professional operator, in addition to the official label, shall issue and print a professional operator's document for each delivered lot which may be combined with a delivery note or an invoice.
- 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 all elements listed in points (a), (b), (c), (d), (da), (f) and (k) of Article 15(1), as well as:
  - (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 profesional operator the registration code of the supplying

    professional operator issuing the official label or to whom the official label has

    been issued by the competent authority;
  - (e) 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.

The official label may further include a digital element, such as a QR code, containing any of the above elements, and the elements of the professional operator's document as referred to in paragraph 4a.

In a non-official part, that label may also include one or more elements of the professional operator's document as referred to in paragraph 4a.

- 4a. The professional operator's document shall contain all of the following elements:
  - (a) all elements identifying the lot of the official label as referred to in paragraph 4;
  - (b) all elements as referred to in Article 15(1) not mentioned in paragraph 4;
  - (c) the address and name of the professional operator and registration code;
  - (d) the quantity of FRM supplied;
  - (e) Member State(s) of production and / or where applicable third country of origin of the respective FRM;
  - (f) the name and address of the recipient of the respective FRM;
  - (fa) date of issuing the professional operator's document;
  - (fb) number of the professional operator's document;
  - (g) whether the FRM has been vegetatively propagated;
  - (h) <u>additional information in the case of seed lots as referred to in Article 5(1) point</u>
    (h);
    - (i) purity, as measured by the percentage by weight of pure seed, other seed and inert matter of the product marketed as a seed lot;
    - (ii) germination percentage of the pure seed, or in cases where germination testing is impossible or impractical, the viability percentage assessed by reference to a specified method;
    - (iii) the weight of 1000 pure seeds;

- (iv) the number of germinable seeds per kilogram or liter 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 or liter;
- (v) for artificial artificial hybrids, the hybrid percentage, if appropriate.

  In the case of small quantities of seed, as referred to in Article 5(1)(h), the information as required by this paragraph, subparagraph (ii) and (iv), may not be indicated on the professional operator's document.
- 4b. The professional operator's document may also include:
  - (a) an indication whether FRM is derived from autochthonous or nonautochthonous basic material, if so registered pursuant to Article 12(3) point (g):
  - (b) any additional information that the professional operator might consider appropriate for the marketing of the FRM concerned.
- 4c. In case of seeds, the official label shall be affixed to the outside of the package as referred to in Article 17.
- 5. The Commission shall-may, by means of implementing acts, set out the following element 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.

format of the official label and the professional operator's document for all or specific categories or other types of FRM.

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

- 5a. Member States may decide to use coloured labels. If coloured labels are used, they shall be in accordance with the OECD Forest Seed and Plant Scheme's colours.
- 6. An official label or <u>professional operator's document</u> may also be issued in an electronic form ('electronic official label'/ <u>'electronic professional operator's document'</u>). <u>In such case, a printed reference, such as QR-code, shall accompany the FRM concerned.</u>

The Commission may, by means of implementing acts, set out technical arrangements for the issuance of electronic official labels <u>or professional operator's documents</u>, to ensure their compliance with this Article and an appropriate, credible and effective mode for the issuance of those official labels <u>or professional operator's documents</u>. 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 and the professional operator's documents;
  - (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.

#### Article 17

# Packagesing of seed units

Seeds units may only be marketed in sealed closed packages with that become unserviceable once the package is opened, including nets or other containers, which are sealed. Those packages shall be sealed in such a way, that any of their opening is visible and traceable.

However, that sealing shall not be required in the case of recalcitrant seeds.

# **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;

- (c) 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).

#### Article 19

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 competent authorities may, upon the approval of the Commission, 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 climatic** conditions; **and**
- (b) those <u>extreme climatic weather</u> conditions have an impact on the reproductive cycle of the basic material and decrease the frequency <u>of harvesting FRM from that basic</u>

  <u>material of mast years, reducing the frequent availability of high quality FRM;</u>
- (c) the place of harvesting is remote and highly difficult for the competent authorities to access during the time of harvesting of FRM.

That authorisation shall be subject to approval by the Commission.

The Commission shall, by means of an implementing act, grant the approval for each Member State for a certain defined period. The approval shall be granted if the conditions (a), (b) and (c) are fulfilled upon the request of the Member State concerned.

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

#### 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\_approve**, 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.

The Commission may, by means of an implementing act, specify the maximum number of units of FRM and the maximum area size that is to be subject to that approval.

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

#### 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 the tree species listed in Annex I and their hybrids it applies to, the requirements for the approval of basic material and the production and marketing of FRM.

Those experiments may only be carried out if at least two Member States participate, upon their request.

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 <u>tree</u> species or artificial hybrids concerned <u>and</u>, if appropriate, the provenance;
  - (b) the conditions of the experiments per tree 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 biochemical and molecular techniques (BMT);
- (b) the methods for the conservation <u>and sustainable use</u> of forest genetic resources taking into account applicable international standards;
- (c) the methods for <u>production and</u> reproduction, <u>production</u> 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

- By way of derogation from Article 4, the Commission, by means of implementing acts, may authorise Member States <u>upon their request</u> to:
  - adopt, as regards the requirements for the approval of basic material and the production of FRM, more stringent or additional production requirements, than those referred to in that Article, in all or part of the territory of the Member State concerned provided that those more stringent or additional production requirements do not impose, or result in, any prohibitions or restrictions on the introduction into, or movement within and through, the Union territory of FRM which complies with this Regulation.
  - (b) restrict, in their territory, the approval of basic material intended for the production of FRM of the category "source-identified";

(c) prohibit the marketing to the end user with a view to sowing or planting in all or part of its territory of specified reproductive material, in case that FRM is not suitable for forestry ecological conditions and purposes of the respective Member State.

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 Before changing the requirements** referred to in paragraph 1, Member States shall submit to the Commission a **notification 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 **validated 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*], **ensure that review**-those measures **and repeal or amend those measures to shall** 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 and, where appropriate, deriving from specific types of basic material or of a specific region of provenance, 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 <u>or has a comparable certification system.</u>

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

3. When adopting the decisions referred to in paragraph + 2, the Commission shall consider whether the systems, for approval and registration of basic material and subsequent production and marketing 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 imported from third countries

- 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) <u>an OECD certificate or an equivalent</u> a master certificate or another official certificate issued by the third country of origin;
  - (b) an OECD-official-label or an equivalent 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 <u>OECD certificate or the equivalent</u> 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 <u>OECD label or the equivalent</u> official label, referred to in paragraph 2, point (b) <u>by with</u> a new official label <u>issued in the Member State concerned, or a new official label shall be attached in addition to that OECD label or the equivalent label. This new official label shall be issued, under the official supervision of the competent authority, either by the professional operator or by a person contracted by the professional operator. The new official label shall be accompanied with an professional operator's document, in accordance with Article 16(1b).</u>
- 4. The new master certificate and the new official label referred to in paragraph 3, points (a) and (b), shall contain a reference to the original documents, respectively.

# CHAPTER VIa OFFICIAL CONTROLS

#### Article 25a

#### Official controls on forest reproductive material

- 1. Member States shall designate the competent authority or authorities on which they confer the responsibility to organise or perform official controls and other official activities. Those competent authorities may be the same authorities as those designated in accordance with Article 4 of Regulation (EU) 2017/625.
- 2. The competent authorities shall have arrangements in place to ensure:
  - a) the effectiveness and appropriateness of official controls and other official activities;
  - b) the impartiality, quality and consistency of official controls and other official activities;
  - c) that staff performing official controls and other official activities are free from any conflict of interest: commercial activities related to FRM which are carried out by such staff on behalf of their Member State do not represent any conflict of interest;
  - d) <u>that staff performing official controls and other official activities are suitably</u> <u>qualified, experienced and trained for the performance of their duties; and</u>
  - e) that appropriate facilities and equipment are at the disposal of the staff for the performance of official controls and other official activities.
- 3. Competent authorities shall have the legal powers to perform official controls and other official activities and the legal procedures in place to ensure that staff have access to the premises of, and documents kept by, professional operators.
- 4. Competent authorities shall perform official controls on all professional operators on a risk basis and with appropriate frequency, taking into account of:

- a) <u>identified risks of non-compliance with this regulation and the evolution of those</u> risks;
- b) the activities under the control of professional operators; and
- c) <u>any information indicating the likelihood that buyers of FRM might be misled,</u> in particular as to the nature, identity, properties, composition, quantity, country of origin or place of provenance of FRM.

Member States may collect fees or charges to cover the costs of official controls and other official activities

- 5. Member States shall ensure that adequate financial resources are available to provide the staff and other resources necessary for the competent authorities to perform official controls and other official activities. This also applies in case of delegation of certain official control tasks and official activities.
- 6. Competent authorities may delegate certain official control tasks to delegated bodies or natural persons in application of Articles 28(1) and 29-31 of Regulation (EU)

  2017/625. Competent authorities that have delegated certain official control tasks to delegated bodies or natural persons, or certain tasks related to other official activities to delegated bodies or natural persons, shall organise audits or inspections of such bodies or persons, as necessary to ensure the appropriate performance of those tasks.

  Competent authorities shall avoid duplication of audits and inspections taking into account any accreditation of the delegated bodies in accordance to standards relevant to the delegated tasks.
- 6a. Member States shall ensure that the Commission is informed of the contact details

  and of any changes regarding the competent authorities designated in accordance

  with paragraph 1. That information shall also be made available by Member States to
  the public, including on the internet.
- 7. The Commission may, by means of implementing acts, lay down rules on uniform practical arrangements for the performance of the official controls to verify compliance with the rules on FRM regarding:
  - (a) specification of the arrangements referred to in paragraph 2;

- (b) <u>specific reporting obligations of the delegated bodies and natural persons</u> <u>referred to in paragraph 6.</u>
- Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).
- 8. Any decision taken by the competent authority in application of Article 66 (3) and (6),

  Article 137(3) and Article 138 (1) and (2) of Regulation (EU) 2017/625 concerning

  natural or legal persons shall be subject to such persons' right of appeal in

  accordance with national law.
- 9. Methods used for sampling and laboratory analyses, tests and diagnoses for the purpose of determining the information as referred to in Article 5(1) point (h), shall comply with ISTA rules, or other comparable international standards, establishing those methods or the performance criteria for those methods.

# 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(23), Article 4(2) and (6), Article 5(3), Article 7(2), Article 8(1), Article 10a(2), Article 14(613) 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(23), Article 4(2) and (6), Article 5(3), Article 7(2), Article 8(1), Article 10a(2), Article 14(613) 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(23), Article 4(2) and (6), Article 5(3), Article 7(2). Article 8(1), Article 10a(2), Article 14(613) 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.

#### Article 27

#### **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>37</sup>. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011<sup>38</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 **by categories** per year;

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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).

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).

- (b) number of adopted national contingency plans to prepare for FRM supply difficulties and the time needed to activate those contingency plans;
- (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 as referred to in Article 24;
- (e) penalties imposed pursuant to Article 29;

#### (f) number of registered professional operators.

The Commission shall, by means of implementing acts, specify the technical formats, <u>including</u> <u>digital submission and processing</u>, 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.' Those measures shall be adopted in accordance with the principles set out in Section 2 of Annex II to this Regulation;
- in Article 83, the following paragraph is added:
  - '5a. In the case of plants for planting produced, or marketed, as categories source-identified, selected, qualified or tested, as referred to in Regulation (EU) .../...\*+, the plant passport shall be **included combined**, in a distinct form, **in with** 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  $\mathbf{H}\mathbf{F}$  of Annex VII to this Regulation.';

- + 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.

Article 31

Amendments of Regulation (EU) 2017/625

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

(1)	in Article 1(2), the following <u>paragraph</u> point is <u>inserted</u> added:
	'(l) production and marketing of forest reproductive material.';
	(2a) Articles 8, 28-33 except 29(b)iv and 33 (a), 43-46, 65-72, 75, 88-89, 102-108, 120, 130-138 shall apply, as applicable, to controls performed for the verification of
	compliance with requirements laid down in Regulation on;
(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.
(2)	in Articles 31, 44, 45(3), 65, 66, 67, 71, 88, 102, 106, 107, 108, 120, 130, 131, 132, 133(1)
	first subparagraph, 138, where reference is made to Article 1(2), the following point is added after the reference to Article 1(2):
	<u>'and 1 (2a)'.</u>
	* 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
	<u>footnote.</u>
(3)	the following article is inserted after Article 22a:

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

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 forest reproductive material subject to the rules referred to in Article 1(2), point (1), 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).

*	Regulation (I	E <del>U)/ of</del> t	the European	Parliament a	nd of the C	<del>ouncil of</del>
(	<del>(OJ).'</del>					

+ 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 32a

#### **Transitional measures**

- 1. FRM produced, before [date of application] in accordance with the provisions of Directive 1999/105/EC or national rules, may continue to be marketed until exhaustion of the respective stocks. FRM produced in accordance with Directive 1999/105/EC may continue to be marketed with a master certificate issued pursuant to that Directive.
- 2. FRM produced in accordance with the provisions of Directive 1999/105/EC or national rules shall be accompanied with a label stating that it concerns 'FRM not approved according to the rules of [enter title of this Regulation].

#### 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 ... [5] 3 years after the date of entry into force of this Regulation].

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

#### **ANNEX I**

#### **LIST OF TREE SPECIES**

Abies alba Mill. Picea abies (L.) H. Karst.

Abies cephalonica Loud Picea sitchensis Carr. (Bong.) Carrière

Abies grandis Lindl (Douglas ex D.Don) Pinus brutia Ten.

Lindl.

Abies pinsapo Boiss. Pinus canariensis C. Smith

Abies nordmanniana (Steven) Spach Pinus cembra L.

Acer campestre L. Pinus contorta <u>Douglas ex</u> Loudon

Acer monspenssulanum L. Pinus halepensis Mill.

Acer opalus Millna. Pinus leucodermis Antoine

Acer platanoides L. <u>Pinus heldreichii H.Christ</u>

Acer pseudoplatanus L. <u>Pinus mugo Turra</u>

Alnus cordata (Loisel.) Duby Pinus nigra Arnold J. F. Arnold

Alnus glutinosa (L.) Gaertn. Pinus peuce Griseb.

Alnus incana Moench (L.) Moench Pinus pinaster Ait. Aiton

Alnus lusitanica Vít. Douda & Mandák. Pinus pinea L.

Betula pendula Roth Pinus radiata D. Don

Betula pubescens Ehrh. Pinus sylvestris L.

Carpinus betulus L. Pinus taeda L

<u>Carpinus orientalis Mill.</u> <u>Pinus uncinata Mill. ex Mirb</u>

Castanea sativa Mill. Populus spp\_and artificial hybrids between

those species

Cedrus atlantica Carr. (Endl.) G. Manetti Prunus avium L.

ex Carrière

Cedrus libani A. Richard A. Rich Prunus padus L.

Celtis australis L.

Ceratonia siliqua L.

Chamaecyparis lawsoniana (A. Murray

Franco

Pseudotsuga menziesii Franco (Mirb.)

bis) Parl.

<del>-, -: -:</del>

Pyrus pyraster (L.) Burgsd.

Cupressus sempervirens Smith

Fagus orientalis Lipsky

Corylus colurna L.

Fagus sylvatica L. Quercus cerris L.

Fraxinus angustifolia Vahl. <u>Quercus frainetto Ten.</u>

Fraxinus excelsior L. Quercus ilex L.

Fraxinus ornus L Quercus petraea Liebl. (Matt.) Liebl.

<u>Juglans spp.</u> Quercus pubescens Willd.

Larix decidua Mill. (L.)Mill. Quercus robur L.

*Larix x eurolepsis Henry* Quercus rubra L.

Larix kaempferi Carr. (Lamb.) Carriere Quercus suber L.

Larix sibirica Ledeb.

 $Robinia\ pseudoacacia\ L$ 

Malus sylvestris (L.) Mill.

Olea europaea L. Salix alba L.

Ostrya carpinifolia Scop.

#### Sorbus aria (L.) Crantz

Sorbus aucuparia L.

Sorbus domestica L.

Sorbus torminalis (L.) Crantz

#### Taxus baccata L.

Thuja plicata Donn ex D.Don.

Thuja plicata Donn ex D.Don.

Tilia cordata Mill

#### Tilia tomentosa Moench

Tilia platyphyllos Scop.

#### Ulmus glabra Huds

Ulmus laevis Pall.

Ulmus minor Mill.

#### **ANNEX II**

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

A.	<b>General requirements:</b>	The seed source or	stand shall me	et 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.

#### 1. Assessment of basic material

The competent authority shall assess the seed source or stand with respect to the purpose(s) for which the FRM will be used, according to Article 3(1), and determine the criteria for selection on the basis of that (those) purpose(s). That (those) purpose(s) shall be indicated in the national register of the Member State concerned. There is little or no phenotypic selection of the basic material intended for the production of FRM of this category.

#### 2. 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 biochemical and molecular techniques (BMT), whether the seed source or stand is indigenous, non-indigenous or whether its origin is unknown and, in the case it is indigenous, whether it is autochthonous or not. For non-indigenous basic material the origin shall be stated if known.

#### 3. Type of basic material and location

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

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

#### 1. Number of harvestable and sexually mature trees

Seed sources or stands shall consist of one or more groups of sexually mature trees (if possible). Those trees shall be well distributed and sufficiently numerous in a given area to maintain genetic diversity, according to the available scientific knowledge, to avoid the unfavourable effects of inbreeding and ensure adequate cross-pollination between those trees (if possible). FRM shall be collected from an optimal number of individuals of the approved basic material, taking into account natural conditions.

#### 2. Uniformity

Stands shall show a normal degree of individual variation in morphological characteristics (if possible). When necessary, inferior trees shall be removed.

No requirements for seed sources.

#### 3. Sustainability characteristics

Seed sources or stands shall be well-adapted to the climatic and ecological conditions, including the biotic and abiotic factors prevailing in the region of provenance (if possible).

The trees show resistance or tolerance to pests and the adverse climatic and site conditions in the place where they are growing (if possible).

#### 4. Additional requirements

Additional requirements for specific traits or products shall be adopted and assessed-by the competent authorities and be made available on request to the Commission and other Member States.

#### 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.

#### A. General requirement:

#### 1. Assessment of basic material

The competent authority shall assess the stand with respect to the purpose(s) for which the FRM will be used, according to Article 3(1), and determine the criteria for selection on the basis of that (those) purpose(s). That (those) purpose(s) shall be indicated in the national register of the Member State concerned.

#### 2. 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 biochemical and molecular

techniques (BMT), whether the stand is indigenous, non-indigenous or whether its origin is unknown and, in the case it is indigenous, whether it is autochthonous or not. For non-indigenous basic material the origin shall be stated if known.

#### 3. Age and development

The age or stage of development of the trees in the stand shall be such to allow the criteria given for the selection of those trees to be clearly judged.

#### 4. Type of basic material and location

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

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

- 1. Isolation
- <u>a)</u> <u>purposes 'multifunctional forestry', 'production of wood, biomaterials, biomass or other forest products':</u>

Stands shall be situated, if possible, 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.

#### b) purpose 'conservation of forest genetic resources':

Stands shall be situated, if possible, at a sufficient distance from stands 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.

#### 2. Number of harvestable and sexually mature trees

a) purposes 'multifunctional forestry', 'production of wood, biomaterials, biomass or other forest products':

Stands shall consist of one or more groups of sexually mature 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 crosspollination between those trees.

b) purpose 'conservation of forest genetic resources':

Stands shall consist of one or more groups of sexually mature trees (if possible).

Those trees shall be well distributed and sufficiently numerous in a given area to maintain genetic diversity, according to the available scientific knowledge, to avoid the unfavourable effects of inbreeding and ensure adequate cross-pollination between those trees (if possible). FRM shall be collected from an optimal number of individuals of the approved basic material, taking into account natural conditions.

- 3. <u>Uniformity</u>
- <u>a)</u> <u>purposes 'multifunctional forestry', 'production of wood, biomaterials, biomass or other forest products':</u>

Stands shall show a normal degree of individual variation in morphological characteristics (not apply for biomass production). When necessary, inferior trees shall be removed.

- b) purpose 'conservation of forest genetic resources':
  - Stands shall show a normal degree of individual variation in morphological characteristics (if possible). When necessary, inferior trees shall be removed.
- 4. Sustainability characteristics
- <u>a)</u> <u>purposes 'multifunctional forestry', 'production of wood', 'production of wood</u> biomaterials, biomass or other forest products':

Stands shall be well-adapted to the climatic and ecological conditions, including the biotic and abiotic factors prevailing in the region of provenance. The trees show resistance or tolerance to pests and the adverse climatic and site conditions in the place where they are growing.

b) purpose 'conservation of forest genetic resources':

Stands shall be well-adapted to the climatic and ecological conditions, including the biotic and abiotic factors prevailing in the region of provenance (if possible). The trees show resistance or tolerance to pests and the adverse climatic and site conditions in the place where they are growing (if possible).

- **<u>5.</u>** Volume production
- <u>a)</u> <u>purposes:"multifunctional forestry", 'production of wood', 'production of wood,</u> biomaterials, biomass or other forest products':

The volume of production shall normally be superior to the accepted average volume produced under similar ecological and management conditions.

b) purposes "conservation of forest genetic resources":

No requirements.

- **<u>6.</u>** Wood quality
- a) purpose 'multifunctional forestry':

The wood quality shall normally be superior to the accepted average quality under similar ecological and management conditions.

<u>b)</u> <u>purposes 'production of wood, biomaterials, biomass or other forest products',</u>
'conservation of forest genetic resources':

No requirements.

- 7. Form or growth habit
- <u>a) purpose 'multifunctional forestry':</u>

Trees 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 - when necessary such trees shall be removed.

b) purposes 'production of wood, biomaterials, biomass or other forest products','conservation of forest genetic resources':

No requirements.

#### **8.** Additional requirements

Additional requirements for specific traits or products shall be adopted and assessed by the competent authorities and be made available on request to the Commission and other Member States.

		<u>Purposes</u>		
		Multifunctional forestry	Production of wood, biomaterials, biomass or other forest products	Conservation of forest genetic resources
	<b>Isolation</b>	<u>X</u>	<u>X</u>	<u>X</u>
Specific requirements	Number of harvestable and sexually mature trees	<u>x</u>	<u>x</u>	<u>x</u>
	<u>Uniformity</u>	<u>X</u>	<u>X</u>	<u>X</u>
	Sustainability characteristics	<u>x</u>	<u>X</u>	<u>X</u>
ic re	<b>Volume production</b>	<u>x</u>	<u>X</u>	
Specif	Wood quality	<u>x</u>		
	Form or growth habit	<u>X</u>		
	Additional requirements (specific traits or products)	If necessary	If necessary	If necessary

#### 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.

#### I. Seed orchards

#### A. General requirements

- 1. The competent authority shall approve the purpose(s) of the seed orchard according to the purpose(s) given in article 3(1). That (those) purpose(s) shall be indicated in the national register of the Member State concerned. The clones or families (individuals) shall be selected for their outstanding characteristics according to the selected purpose(s).
- 2. The competent authority shall approve and register the crossing design of component clones or families and field layout, the component clones or families and if appropriate the degree of relationship of component clones, their numbers and numbers of individuals (ramets) per clone in the case of clonal seed or chards, isolation or, if possible, limitation of pollen flow and location and any changes of these.
- 3. 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. The optimal balance between the effective number of clones or families and genetic gain needs to be considered.
- 4. Thinning carried out in seed orchards shall be described together with the selection criteria used for such thinning and registered by the competent authority.
- 5. The seed orchards shall be managed, and seed harvested, in such a way that the purposes of the orchards are attained. In the case of a seed orchard intended for the production of artificial hybrids, the percentage of hybrids in the FRM shall be determined by a molecular techniques.

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

Requirements for specific traits or products (selection criteria for component clones or families) shall be adopted and assessed by the competent authorities and be made available on request to the Commission and other Member States, taking into account, as appropriate, age and development, sustainability characteristics, volume production, wood quality, and form or growth habit and other usefull specific traits.

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

#### A. General requirements

- 1. The competent authority shall approve the purpose(s) of the parents of family(ies) according to the purpose(s) given in article 3(1). That (those) purpose(s) shall be indicated in the national register of the Member State concerned. The parents of family(ies) shall be selected for their outstanding characteristics according to the selected purpose(s).
- 2. The purpose, crossing design and pollination system, components, isolation and/or limitation of pollen flow, if possible, location and any significant changes of these characteristics shall be approved and registered by the competent authority.
- 3. The identity, number and proportion of the parents in a mixture shall be approved and registered by the competent authority.
- 4. In the case of parents intended for the production of artificial hybrids, the percentage of hybrids in the FRM shall be determined by a molecular techniques.

#### B. Specific requirements

Requirements for specific traits or products (selection criteria) shall be adopted and assessed by the competent authorities and be made available on request to the Commission and other Member States, taking into account, as appropriate, age and development, sustainability characteristics, volume production, wood quality, and form or growth habit and other usefull specific traits.

#### III. Clones

#### A. General requirements

- 1. The competent authority shall approve and register clones that shall either be identifiable by distinctive characteristics or traceable through propagation cycles and/or molecular techniques, as appropriate.
- 2. 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.

- 3. Ortets or cell lines used for the production of clones shall be selected for their outstanding characteristics taking into account the purpose(s) for which the resulting FRM will be used, as given in article 3(1).
- 4. Approval shall be restricted by the competent authority to a maximum number of years or a maximum number of ramets produced.

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

Requirements for specific traits or products (selection criteria) shall be adopted and assessed by the competent authorities and be made available on request to the Commission and other Member States, taking into account, as appropriate, age and development, sustainability characteristics, volume production, wood quality, and form or growth habit and other usefull specific traits.

#### IV. Clonal mixtures

- A. General requirements
- 1. Clonal mixtures shall meet the requirements set out in point III A. (1), (2) and (3).
- 2. 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.
- 3. Approval shall be restricted by the competent authority to a maximum number of years or a maximum number of ramets produced.
- **B.** Specific requirements

Clonal mixtures shall meet the requirements set out in point III B.

#### 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 **any of the following:** 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).

Tests set up for the approval of the basic material are to be prepared, laid out, conducted and their result interpreted in accordance with the internationally recognised procedures. For comparative tests, FRM shall be compared 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. Tests must be designed to assess those characteristics specified in point (ii) and these shall be indicated 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. characteristics considered important in

view of the intended specific purpose. They 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.

The competent authorities or, where applicable, the professional operators, shall keep records describing the following elements: the test sites, including the location, climate, soil, past use, establishment, management and any damage due to abiotic/biotic factors, alongside with all the results at the time of the evaluation. In the case where those records are kept by the professional operators, they shall be made available to the competent authority.

#### (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. Each sample of FRM shall be raised, planted and managed 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. Each experiment shall be established in a valid statistical design 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. The data from the experiments shall be analysed

### using internationally recognised statistical methods and the results shall be presented for each characteristic examined.

- (ii) The methodology used for the test and, if possible, the detailed results obtained, shall be made freely accessible.
- (iii) The competent authority of the Member State in which the test was carried out <u>may</u> 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 <u>using information from</u> 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 programme 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 comparison** 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\_relevant** 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\_comparison** 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 It shall be reported 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 target 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

	<u> </u>				
	Category of FRM				
Basic material	Source-identified	Selected	Qualified	Tested	
Seed source	x				
Stand	x	X		X	
Seed orchard			Х	X	
Parents of family(ies)			X	x	
Clone			x	X	
Clonal mixture			х	X	

#### 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 E

### 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 F**

## 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

