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Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the production and marketing of plant reproductive material in the Union, amending Regulations (EU) 2016/2031, 2017/625 and 2018/848 of the European Parliament and of the Council, and repealing Council Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 2002/53/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90/EC (Regulation on plant reproductive material)

(Text with EEA relevance)

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

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

Rules for the production and marketing of plant reproductive material ('PRM') of agricultural crops, vegetables, vine, and fruit plants have been in place at Union level since the 1960s. It comprises the following Directives (collectively known as the 'PRM marketing Directives'):

- Council Directive 66/401/EEC on the marketing of fodder plant seed¹,
- Council Directive 66/402/EEC on the marketing of cereal seed²,
- Council Directive 68/193/EEC on the marketing of material for the vegetative propagation of the vine³,
- Council Directive 2002/53/EC on the common catalogue of varieties of agricultural plant species⁴,
- Council Directive 2002/54/EC on the marketing of beet seed⁵,
- Council Directive 2002/55/EC on the marketing of vegetable seed⁶,
- Council Directive 2002/56/EC on the marketing of seed potatoes⁷,
- Council Directive 2002/57/EC on the marketing of seed of oil and fibre plants⁸,
- Council Directive 2008/72 on the marketing of vegetable propagating and planting material, other than seeds⁹, and
- Council Directive 2008/90/EC on the marketing of fruit plant propagating material and fruit plants intended for fruit production¹⁰.

Moreover, Council Directive 98/56/EC¹¹ regulates the marketing of propagating material of ornamental plants.

¹ Council Directive 66/401/EEC of 14 June 1966 on the marketing of fodder plant seed (OJ 125, 11.7.1966, p. 2298).

² Council Directive 66/402/EEC of 14 June 1966 on the marketing of cereal seed (OJ 125, 11.7.1966, p. 2309).

³ Council Directive 68/193/EEC of 9 April 1968 on the marketing of material for the vegetative propagation of the vine (OJ L 93, 17.4.1968, p. 15).

⁴ Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species (OJ L 193, 20.7.2002, p. 1).

⁵ Council Directive 2002/54/EC of 13 June 2002 on the marketing of beet seed (OJ L 193, 20.7.2002, p. 12).

⁶ Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed (OJ L 193, 20.7.2002, p. 33).

⁷ Council Directive 2002/56/EC of 13 June 2002 on the marketing of seed potatoes (OJ L 193, 20.7.2002, p. 60).

⁸ Council Directive 2002/57/EC of 13 June 2002 on the marketing of seed of oil and fibre plants (OJ L 193, 20.7.2002, p. 74).

⁹ Council Directive 2008/72/EC of 15 July 2008 on the marketing of vegetable propagating and planting material, other than seed (OJ L 205, 1.8.2008, p. 28).

¹⁰ Council Directive 2008/90/EC of 29 September 2008 on the marketing of fruit plant propagating material and fruit plants intended for fruit production (OJ L 267, 8.10.2008, p. 8).

¹¹ Council Directive 98/56/EC of 20 July 1998 on the marketing of propagating material of ornamental plants (OJ L 226, 13.8.1998, p. 16).

The PRM marketing Directives were first evaluated in 2008. This evaluation and further studies carried out in 2013 and 2022, in relation respectively to a previous proposal to revise the legislation and to this proposal confirmed that the Directives have had a significant impact on the free movement, availability and quality of PRM on the EU market. This legislation has thus been of major importance for the creation of the single market of PRM in the EU. However, these studies also identified that there is complexity and fragmentation of the legislative framework, that are likely to perpetuate existing uncertainties and discrepancies in its implementation by Member States. This creates unequal marketing opportunities for professional operators and for the marketing of PRM throughout the Union. The legislative framework also needs to be aligned with recent scientific and technological developments and with new policy objectives as regards sustainability, climate change and biodiversity challenges.

This proposal introduces a new approach, with a single regulation replacing all PRM marketing Directives. The proposed regulation on plant reproductive material aims to harmonise implementation, increase efficiency, reduce administrative burden and support innovation. In particular, it takes account of the need to ensure that production of PRM can adapt to evolving agricultural, horticultural and environmental conditions, face the challenges of climate change, to foster the protection of agro-biodiversity, and to meet increasing farmer and consumer expectations related to the quality and sustainability of PRM.

The proposal also aims to facilitate the technical progress in PRM production and plant breeding, in accordance with the rapid evolution of European and global standards. It creates a framework for the introduction of digital technologies, and for the adoption of novel technologies, such as the use of bio-molecular techniques for the identification of varieties.

The general objective of this initiative is to ensure, for all types of users, PRM of high quality and diversity of choice, adapted to current and future projected climatic conditions that will in turn contribute to food security, protection of biodiversity and restoration of forest ecosystems. The availability and access to varieties and basic material with strengthened sustainability characteristics are essential to improve sustainability by ensuring the stability of yield of agricultural production and of the productivity of forest ecosystems. More specifically:

- To increase clarity and coherence of the legal framework through simplified, clarified and harmonised basic rules on fundamental principles presented in a modern legal form;
- To enable the uptake of new scientific and technical developments;
- To ensure availability of PRM suitable for future challenges;
- To support the conservation and sustainable use of plant and forest genetic resources.
- To harmonise the framework for official controls on PRM;
- To improve coherence of PRM legislation with the plant health legislation.

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

After consultations with Member States and stakeholders, it has been concluded that Council Directive 98/56/EC still adequately covers the needs of the sector of

propagating material of ornamental plants, therefore it is not included in the scope of this proposed regulation.

- **Consistency with other Union policies**

In recent years, agricultural policy in the Union has come to be seen as strategically important for self-sufficiency, agri-food security and safety.

The proposed Regulation is submitted within this context. It is also part of the overall policies of the European Green Deal¹² and the related strategies: the Farm to Fork Strategy¹³, the Biodiversity Strategy¹⁴ and the EU Strategy on adaptation to climate change¹⁵.

The proposal is consistent with the Farm to Fork Strategy, which intends to make food systems fair, healthy and environmentally friendly and thus more sustainable while ensuring the availability of PRM and thus the security of agricultural production and food security. It aims to contribute to sustainable food production and climate change adaptation by steering plant breeding in a more sustainable direction. It does so by introducing rules for testing and marketing of varieties with value for sustainable cultivation and use.

The proposal additionally aims to support the conservation and sustainable use of plant genetic resources and to contribute to agro-biodiversity by introducing lighter and adapted rules on organic varieties, conservation varieties, seed conservation networks and exchange of seed in kind between farmers. It also facilitates the production and marketing of PRM of heterogeneous material, which does not belong to any variety.

Finally, the proposal creates the framework for introducing digital technologies to record all certification activities, the electronic submission of variety data by Member States through one single portal (EU Plant Variety Portal), and the possibility to issue electronic official labels at a later stage, in line with European Digital Strategy¹⁶.

2. **LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY**

- **Legal basis**

This proposal introduces rules on the production and marketing of plant reproductive material in the EU, which are necessary for pursuing the objectives of the common

¹² 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).

¹³ 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, A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system (COM(2020) 381 final).

¹⁴ 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).

¹⁵ 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).

¹⁶ 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).

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

- **Subsidiarity (for non-exclusive competence)**

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

Since the adoption of the PRM marketing Directives, all fields of marketing of PRM have to a very large extent been regulated at Union level. The Directives adoption has been a major contributor to the establishment of the internal market in PRM. The impact assessments carried out in 2013 and 2023 confirmed that the EU rules in place on the marketing of PRM have had a generally positive impact on the free movement, the availability and quality of PRM on the Union market, and have thus facilitated trade within the Union. Fragmentation of the PRM market into 27 different national systems would introduce serious obstacles to the movement of PRM on the internal market and increase the financial burden associated with variety registration and the necessary controls on its quality and identification. Therefore, the respective policy objectives can be better achieved by exclusively regulating at Union level.

- **Proportionality**

As discussed in Chapter 7.4 of the impact assessment accompanying this proposal, the measures proposed are limited to actions that need to be taken at Union level in order to be effective and efficient. To achieve these needs and take account of the important differences between the species and different types of PRM, the PRM Marketing Directives will be replaced by a single regulation on PRM, which aims at addressing all elements necessary for the production and marketing of a wide variety of PRM: from seeds and rootstocks, to branches, tubers, small plants, entire trees, agricultural crops, potatoes, vegetables, vine, fruit plants and others.

This type of instrument is considered most suitable, considering that a key element of the proposal is to establish harmonised rules for the production and marketing of PRM. Uniform requirements for PRM are the most appropriate way to ensure (i) a high level of its quality for users, (ii) the proper functioning of the internal market and a level playing field for operators; and (iii) sustainable agricultural and food production.

There is a need to ensure that all Member States apply the same high standards, many of them agreed at international level, and thus reduce the possibilities for derogations to lower standards, unless otherwise allowed by the proposed Regulation. Such standards also protect the interests of the professional operators and competition by eliminating the application of different and discriminatory rules across Member State's borders.

To adapt technical requirements to their specific agro-ecological conditions, Member States may, under certain conditions and temporarily, and if duly justified lay down more stringent national requirements for PRM quality under the authorisation by the Commission. Member States are further given the flexibility to implement rules on examination of varieties for the value for sustainable cultivation and use, in ways that are adapted to local agro-ecological conditions.

- **Choice of the instrument**

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

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

- ***Ex-post* evaluations/fitness checks of existing legislation**

In 2019, the Council¹⁷ asked the Commission to present a study on the Union's options to update the existing legislation on the production and marketing of plant reproductive material¹⁸. The study was supported by an external data gathering study¹⁹. That study identified five key problems with the existing legislation. Those concerned:

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

The 2019 Council request contained a revision clause. That clause allowed the Commission to present a legislative proposal if the outcome of the aforementioned study made this an appropriate course of action.

- **Stakeholder consultations**

The impact assessment accompanying the proposed Regulation on plant reproductive material involved a wide range of consultations addressing all types of stakeholders. The types of consultation comprised: an inception impact assessment, a public consultation, working groups with competent national authorities and stakeholders, and bilateral meetings with stakeholder organisations.

- The consultation on the inception impact assessment gathered 66 responses from 16 countries, while the public consultation received 2449 responses from 29 countries.

¹⁷ Council Decision (EU) 2019/1905 of 8 November 2019 requesting the Commission to submit a study on the Union's options to update the existing legislation on the production and marketing of plant reproductive material, and a proposal, if appropriate in view of the outcomes of the study (OJ L 293, 14.11.2019, p. 105).

¹⁸ Commission Staff Working Document Study on the Union's options to update the existing legislation on the production and marketing of plant reproductive material (SWD(2021)90 final).

¹⁹ ICF (2021) Data gathering and analysis to support a Commission study on the Union's options to update the existing legislation on the production and marketing of plant reproductive material. <https://doi.org/10.2875/406165>.

- Position papers were submitted by 39 respondents to the inception impact assessment and by 181 respondents to the public consultation.
- There were targeted consultations to gather more specialised feedback from competent national authorities and SMEs, resulting in 25 and 251 responses, respectively.
- A targeted survey by an external consultant supporting the Commission's impact assessment returned 99 responses.
- The consultant also conducted 43 in-depth interviews and organised a focus group with 10 participants.

Stakeholder consultations showed that there is overall support in the PRM sector for maintaining the current regulatory system and its two basic pillars of variety registration (based on Distinctness, Uniformity, Stability ('DUS') and, where applicable, Value for cultivation and use ('VCU') and PRM certification. Competent national authorities and all stakeholders representing the seed industry stressed that the current system works well and that the PRM industry in the Union receives international recognition for the high quality of the seed produced and traded.

One of the main objectives of the revision is to extend the assessment of characteristics of PRM contributing to sustainable production. Plant breeders and most competent national authorities recognised that the current VCU requirements for agricultural plant species already contribute to this objective, as they allow for the acceptance of varieties with characteristics such as disease resistance, nutrient efficiency, drought tolerance and increased yield. Stakeholders supported the introduction of requirements for the examination of new varieties of vegetables, fruit plants and vine for such characteristics, though not in the form of the current VCU for agricultural plant species, as the uses especially for vegetable PRM are very diverse. The need for flexibility to address the different conditions across Europe was stressed by almost all respondents.

All stakeholders agreed with the need for derogations from the basic system of variety registration and PRM certification to meet objectives relevant to conservation and sustainable use of plant genetic resources, organic production and production in marginal areas. However, views differed as to the degree of such derogations, ranging from calls for a total exception of exchange in kind, conservation activities and marketing to amateur gardeners, to the opinion that existing derogations are sufficient and do not need to be extended. Several NGOs called for the new legislation to explicitly implement farmers' rights as defined in the International Treaty on Plant Genetic Resources for Food and Agriculture and the United Nations Declaration on the Rights of Peasants. The main arguments against total exemption are the concerns about plant health, respect for plant variety rights and the avoidance of unequal competition, as well as the need to guarantee minimum quality and traceability of PRM.

Most operators agreed that harmonising the requirements for official controls is desirable. Views were split on whether to include official controls under the PRM legislation in the scope of Regulation (EU) 2017/625 of the European Parliament and of the Council²⁰ due to concerns over a potential increase in administrative burden.

²⁰

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

Almost all competent national authorities and operators were against including the PRM certification system as such under the Official Controls Regulation. Most competent national authorities and operators saw benefits from inclusion in terms of more efficient marketing and import controls. Most stakeholders in all categories called for maintaining some flexibility in the organisation of official controls and keeping costs as low as possible.

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

Detailed information about the stakeholder consultations can be found in Chapter 5.2.5. and Annex 2 of the impact assessment for the proposed PRM regulation.

- **Collection and use of expertise**

An external consultant engaged by the Commission conducted a study in support of the impact assessment²¹. The consultant and its experts worked closely with the relevant Commission departments during the various stages of the study.

The consultant gathered additional data and comments through desk research, a targeted survey, a focus group, in-depth interviews with stakeholders, a case study on the exchange in kind of seed between farmers, and a qualitative comparative analysis of Member State experiences with conservation varieties of fruit plants and vine. The support study considered the problem definition, the case for EU action, the objectives of policy intervention and the baseline scenario. It went to assess the potential impacts of three options proposed by the Commission, each including variations on up to 19 specific measures.

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

- **Impact assessment**

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

There are two main problems that this proposal aims to address, as identified with the current PRM legal framework:

1. There is a non-harmonised internal market characterised by divergent conditions for operators and marketed plant reproductive material across Member States. The implementation of various aspects of the legislation differs among Member States, because (i) the legislation leaves room for interpretation, (ii) Member States try to find practical solutions to overcome

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).

²¹ ICF (20223) Study supporting the Impact Assessment for the revision of the plant and forest reproductive material legislation. <https://data.europa.eu/doi/10.2875/4381>.

rigid provisions and (iii) the legislation has not followed the new developments in science and technology in good time.

2. The legislation is not aligned with the objectives of the European Green Deal and the related strategies. In particular, and under the current legislation, genetically diverse varieties, PRM subject to activities of seed conservation networks and seed exchanged by farmers are still subject to requirements for variety registration. This is rather disproportionate as such varieties, seed and material cannot always meet those requirements. Moreover, the increasing occurrence of extreme weather events, in combination with insufficient assessment of sustainability characteristics in the registration of new varieties, puts pressure on the stability of yields and thus on the resilience of agri-food production.

The general objective of this initiative is thus to ensure, for all types of users, the availability of PRM of high quality and diversity of choice that is adapted to current and future projected climatic conditions.

The impact assessment compiled all possible measures for analysis. This was based on: (i) an external data gathering study supporting a Commission study on the Union's options to update the legislation on plant reproductive material, (ii) a study in support of the impact assessment conducted by an external consultant, (iii) various stakeholder consultation activities, (iv) an online public consultation and (v) in-depth interviews.

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

All options contained a number of common elements: (i) simplified administrative procedures and a more flexible decision-making process; (ii) streamlined rules for organic and conservation varieties; and (iii) harmonisation with the plant health legislation.

1. **Option 1 - Highest degree of flexibility:** Option 1 would lay down minimum requirements for official controls on plant reproductive material, but without linking them to the Official Controls Regulation. Guidelines on the use of innovative production processes, bio-molecular techniques and digital solutions would be adopted. The existing assessment of new varieties of agricultural plant species for characteristics contributing to sustainable production would be strengthened. A voluntary assessment would be introduced for vegetables and fruit plants. The activities of seed conservation networks, marketing to amateur gardeners and exchange in kind of PRM between farmers would be exempted from the legislation's scope.
2. **Option 2 - Balancing flexibility and harmonisation (preferred option):** Option 2 would bring the official controls on plant reproductive material under the scope of the Official Controls Regulation, but with simplified import controls at appropriate places within the Union to ensure a more targeted and efficient enforcement of the existing rules. Basic principles for the use of

innovative production processes, bio-molecular techniques and digital solutions would be included in the legislation. The assessment of new varieties for characteristics contributing to sustainable production would become a requirement for all crop groups, but with flexibility for Member States to implement it according to their own agro-ecological conditions. The activities of seed conservation networks, marketing to amateur gardeners and exchanges in kind between farmers would be subject to lighter rules to stimulate the increase in genetic diversity of PRM but also to guarantee a minimum quality.

3. **Option 3 - Highest degree of harmonisation:** Option 3 would bring the official controls on PRM/FRM under the scope of the Official Controls Regulation, with stricter import controls at border control posts requiring special import documentation to strengthen and fully harmonise enforcement. Detailed and binding rules for the use of innovative production processes, bio-molecular techniques and digital solutions would be included in the legislation. The assessment of new varieties for characteristics contributing to sustainable production would become a requirement for all crops, with detailed and harmonised requirements and methodologies for all Member States. The activities of seed conservation networks, marketing to amateur gardeners and exchanges in kind between farmers would be subject to the general requirements of the PRM legislation to achieve homogenous rules for all market segments.

Based on the outcome of the impact assessment, the Commission concluded that Option 2 is the best option to effectively address all the objectives of the revision of the PRM legislation in an efficient and consistent manner.

The preferred option will bring efficiency gains for operators and competent national authorities through; (i) extended possibilities for operators to undertake activities under official supervision, (ii) harmonisation with the plant health legislation, (iii) the introduction of risk-based official controls and (iv) the possibility to use bio-molecular techniques and digital solutions in the variety registration and PRM certification systems. Mandatory strengthened sustainability requirements combined with flexibility to adapt to local agro-ecological conditions will contribute to more sustainable agri-food production and food security, as varieties which are more suitable for the changing agro-climatic conditions will have a more stable yield.

The preferred option presents considerable economic costs for operators and competent national authorities due to the need for additional investments to conduct additional sustainability assessments for varieties of vegetables and fruit. These are, however, proportionate to the objectives and will be in balanced in the medium term by the benefits coming from the sustainability of agri-food production. They will also be balanced with the adaptation to climate changes in relation to e.g. the reduced use of resources or higher yield stability. Other measures do not result in new obligations for operators but provide them with new options or lighter conditions for accessing the market.

- **Regulatory fitness and simplification**

The proposal introduces a simpler and less burdensome regulatory regime in particular for marketing to amateur gardeners and PRM, serving the purposes of conservation and sustainable use of plant genetic resources.

The proposal gives professional operators the option to carry out certification of PRM under the official supervision of the competent authorities, if they wish so. It also offers the option to carry out technical examinations for the testing of varieties to prove that such varieties have a value for sustainable cultivation and use ('VSCU'), in breeders premises under the official supervision of the competent authority. Both of those options offer to professional operators more flexibility and options to make their business planning.

Moreover, the proposal introduces lighter and adjusted rules concerning:

- (a) access to market for organic and conservation varieties;
- (b) PRM intended for final users (such as amateur gardeners);
- (c) PRM intended solely for, and retained by, certain gene banks, organisations and networks;
- (d) seed exchanged in kind between farmers.

Several processes will be simplified. All the simplification measures benefit a significant number of both SMEs and micro-enterprises, which constitute the vast majority of the sector's business. In addition, the proposal excludes fully from its scope PRM sold or transferred in any other way, whether free of charge or not, between any persons for their own private use and outside their trade, as well as PRM used solely for official testing, breeding, inspections, exhibitions or scientific purposes. Finally, the proposal introduces new measures concerning the digitalisation of the PRM sector and rules on the bio-molecular techniques as to increase the efficiency and efficacy of variety registration and PRM certification.

- **Fundamental rights**

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

4. BUDGETARY IMPLICATIONS

There are no budgetary implications.

5. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

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

- quantities of certified and standard PRM and areas used for their production per year and species, specifying the quantities used for organic varieties suitable for organic production;

- quantities of marketed PRM of heterogeneous material and areas used for their production per year and species;
- quantities of marketed PRM of conservation varieties per year and species;
- the number of professional operators using the derogations for marketing to final users, the species concerned and total quantities of PRM per species;
- the number of gene banks, organisations and networks with a statutory or other declared objective to conserve plant genetic resources, and species concerned;
- the quantities, as determined per species, for seed exchanged in kind between farmers;
- the quantities authorised per species for PRM intended for tests and trials for the breeding of new varieties;
- quantities of PRM per genera and species used in case of temporary difficulties in supplies;
- quantities of PRM per genera and species imported from third countries;
- the number of professional operators established in the Member State's territory.
- **Explanatory documents (for directives)**
Not applicable
- **Detailed explanation of the specific provisions of the proposal**

(i) Scope

The proposed regulation will replace the 10 PRM marketing Directives. It will apply to a list of species of agricultural crops, vegetables, fruit plants and vine, with particular economic and social importance, such as food security, for the Union.

It will not cover forest reproductive material, which is currently regulated by Council Directive 1999/105/EC. A separate proposal has been submitted to replace that Directive by a new regulation of the European Parliament and of the Council.

The proposal will also not cover reproductive material for ornamental plants.

It will also exclude PRM exported to third countries.

(ii) Requirements for production and marketing

The proposed regulation retains the two main pillars of the PRM marketing Directives, namely the registration of varieties and the certification of individual PRM lots.

The proposal introduces the general rule that PRM is permitted to be produced and marketed, only if it belongs to varieties registered in national variety registers and to predefined categories: 'pre-basic', 'basic', 'certified' and 'standard' material or seed. It also provides for the registration of heterogeneous material, which is not a variety nor a mixture of varieties, and of clones, selected clones, multiclinal mixtures and polyclonal PRM.

PRM as pre-basic, basic, certified and standard seed or material must be produced and marketed in accordance with the applicable international

standards for those categories and the respective species. Those standards are in particular the Rules and Regulations of the Organisation for Economic Co-operation and Development (OECD) Schemes for the Varietal Certification or the Control of Seed Moving in International Trade ⁽²²⁾ ('OECD Seed Schemes'), the seed potato standards of the United Nations Economic Commission for Europe (UNECE), and the rules on seed sampling and testing of the International Seed Testing Association (ISTA).

Compliance of PRM with the requirements for the categories of pre-basic, basic and certified seed or material must be confirmed by inspections, sampling, and testing carried out by the competent authorities ('official certification') and attested by an official label. The proposal introduces a list of species, the seeds of which may only be produced and marketed as pre-basic, basic or certified seeds. This reflects the current rules of the PRM marketing Directives and the respective international standards. Moreover, lighter rules on standard seed and material for certain categories are laid down.

As part of the modernisation of the certification system, responsibilities are entrusted to professional operators. Under the proposal, it will also be possible for the competent authority to authorise professional operators to: (i) perform PRM certification ('certification under official supervision') and (ii) print the official label.

The proposal introduces rules for the labelling, packaging, sealing and lots of PRM. These are largely based on the OECD Seed Scheme Rules and Regulations and the experience gained from implementing of the PRM marketing Directives.

Seed varieties will be allowed to be produced and marketed in mixtures with other seed varieties of the same or other genera or species covered by this Regulation. However, Member States have the possibility to allow the production and marketing of a mixture of seeds with seeds not falling under the Regulation's scope, for the purposes of conserving genetic resources and preserving the natural environment.

Finally, control plot tests will be conducted to verify the varietal identity and purity of individual seed lots. Bio-molecular tests may be used for verifying varietal identity and purity.

(iii) Derogations

The proposal introduces a flexible approach for certain activities, PRM and varieties. In those cases, less stringent requirements are set based on the experience gained from the PRM marketing Directives, international standards, and in particular the need to support agro-biodiversity and conservation of genetic resources.

In this light, the proposal introduces less stringent rules for conservation varieties, heterogeneous material, PRM sold to final users (like amateur gardeners), PRM marketed to or between gene banks, organisations and networks, and seeds exchanged in kind between farmers.

²²

Decision Revising the OECD Schemes for the Varietal Certification or the Control of Seed Moving in International Trade [[OECD/LEGAL/0308](#)] ('OECD Seed Schemes').

The proposal further establishes derogations for the marketing of (i) PRM for breeders in order to develop new varieties, (ii) PRM of not yet registered varieties used for PRM multiplication or for trials, (iii) PRM in cases of temporary difficulties in its supply, (iv) seeds not yet finally certified. It also establishes derogations for emergency measures and temporary experiments.

(iv) Imports

The import of PRM from third countries will only be allowed, if an assessment establishes that such PRM fulfils requirements equivalent to those applicable to PRM produced and marketed in the Union. Such assessment will be based on a thorough examination of the information provided by the third country and its relevant legislation. It will also be based on the satisfactory outcome of an audit carried out by the Commission in the respective third country, where that audit has been considered necessary.

(v) Professional operators

Professional operators must be registered in the registers to be kept and updated under Regulation (EU) 2016/2031 for reasons of simplification as, to a very large extent, they are already covered by the scope referred to in that Regulation. Professional operators must fulfil some basic requirements to ensure appropriate knowledge on, and handling of, the PRM under their control. PRM marketed between professional operators will be subject to traceability requirements.

(vi) Variety registration

The proposal introduces the general rule that PRM must belong to registered varieties. It further sets out the procedure and conditions for registration of those varieties.

The proposal stipulates that a variety must be included in at least one national variety register. That fact will be enough to immediately allow the variety to be marketed throughout the EU. That variety will also be submitted in a Union variety register using the EU Plant Variety Portal, which will provide an overview of all varieties allowed for marketing.

Varieties will be registered under two categories:

- (i) varieties with an official description, which undergo a test for their distinctness, uniformity and stability (DUS); and
- (ii) conservation varieties with an officially recognised description, with no need to be tested for DUS and subject to less stringent marketing requirements.

Varieties subject to DUS testing (official description) will further undergo testing for their value for sustainable cultivation and use (VSCU). The proposed Regulation extends the scope of the VSCU assessment from agricultural crops (current scope of PRM Directives) to vegetables and fruit species too, in order to ensure a wider and more sustainable approach for the entire PRM sector. In order to be registered, those varieties must, as a whole, bring an improvement compared to the other varieties of the same genera or species concerning the following aspects:

- yield, including yield stability and yield under low-input conditions;

- tolerance/resistance to biotic stresses, including plant diseases caused by nematodes, fungi, bacteria, viruses, insects and other pests;
- tolerance/resistance to abiotic stresses, including adaptation to climate change conditions;
- more efficient use of natural resources, such as water and nutrients;
- reduced need for external inputs, such as plant protection products and fertilisers;
- characteristics that enhance the sustainability of storage, processing and distribution;
- quality or nutritional characteristics.

Those aspects are important to ensure that new varieties contribute to a sustainable agricultural production, which serves economic, environmental and broader societal needs.

On account of the importance of DUS testing, such testing will only be carried out by the competent authorities. The premises used for that testing will be audited by the Community Plant Varieties Office (CPVO) due to its expertise in this sector.

However, testing for VSCU can be carried out also by the professional operators under the official supervision of the competent authorities. This is justified as the scope of VSCU is extended to more species and there is need to ensure availability of testing facilities. The premises used by the professional operators will be audited by the competent authorities.

Varieties that have been granted a plant variety right pursuant to Council Regulation (EC) No 2100/94, or pursuant to the legislation of a Member State, will be deemed to be DUS and to have a suitable denomination for the purposes of the proposed regulation. Competent authorities may also use the DUS and VSCU testing of other Member State authorities in order to register a variety in their national registers.

The proposal further sets out rules concerning the submission, content, formal examination and date of submission of applications for variety registration, technical examinations, and organisation, additional rules on technical examination, confidentiality, the provisional examination report and the provisional official description, the examination report and the final official description, the examination of the denomination of a variety, and the decision on the registration of a variety in the national variety register.

The period of the registration of a variety will be 10 years, in order to encourage innovation and replacement of those varieties by new ones. For varieties of fruit plants and vine propagating material the registration period will be 30 years. This is due to the longer time required to complete the productive cycle of such species. The period of registration will be subject to renewal.

The proposal sets out rules for the maintenance, documentation and sampling of the registered varieties, in order to ensure their identification and effective control throughout the period of their registration.

(vii) Amendments of other Union acts and final provisions

The proposed regulation includes an amendment of Regulation (EU) 2016/2031 of the European Parliament and of the Council²³, by clarifying that regulated non-quarantine pests (RNQPs) are exclusively regulated under that Regulation. It further introduces the possibility that the OECD label for imported PRM be combined with the plant passport in a single format.

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

Finally, the proposed regulation amends Regulation (EU) 2018/848 of the European Parliament and of the Council²⁴ for organic production, in order to update the content of the ‘plant reproductive material’ and ‘organic heterogeneous material’ as referred to in that Regulation. It also ensures that all rules on PRM of heterogeneous material, both organic and non-organic heterogeneous material, are set out exclusively by the proposed Regulation.

The proposed regulation will apply 3 years after its entry into force, in order to give the competent authorities and professional operators the appropriate time to adapt to the new provisions. It will also give the Commission time to adopt the necessary delegated and implementing acts. An additional transition period of 2 years will apply for the application of the new requirements for VSCU testing of new varieties of fruit plants and vegetables.

²³ Regulation (EU) 2016/2031 of the European Parliament and of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC (OJ L 317, 23.11.2016, p. 4).

²⁴ 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).

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
on the production and marketing of plant reproductive material in the Union, amending Regulations (EU) 2016/2031, 2017/625 and 2018/848 of the European Parliament and of the Council, and repealing Council Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 2002/53/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90/EC (Regulation on plant 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,
After transmission of the draft legislative act to the national parliaments,
Having regard to the opinion of the European Economic and Social Committee¹,
Acting in accordance with the ordinary legislative procedure,
Whereas:

- (1) Rules for the production and marketing of plant reproductive material ('PRM') of agricultural crops, vegetables, vine and fruit plants have been established at Union level since the 1960s. The production and marketing of PRM on the Union territory is regulated by Council Directives 66/401/EEC⁽²⁾; 66/402/EEC⁽³⁾; 68/193/EEC⁽⁴⁾; 2002/53/EC⁽⁵⁾; 2002/54/EC⁽⁶⁾; 2002/55/EC⁽⁷⁾; 2002/56/EC⁽⁸⁾; 2002/57/EC⁽⁹⁾;

¹ Not published yet.

² Council Directive 66/401/EEC of 14 June 1966 on the marketing of fodder plant seed (OJ 125, 11.7.1966, p. 2298).

³ Council Directive 66/402/EEC of 14 June 1966 on the marketing of cereal seed (OJ 125, 11.7.1966, p. 2309).

⁴ Council Directive 68/193/EEC of 9 April 1968 on the marketing of material for the vegetative propagation of the vine (OJ L 93, 17.4.1968, p. 15).

⁵ Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species (OJ L 193, 20.7.2002, p. 1).

⁶ Council Directive 2002/54/EC of 13 June 2002 on the marketing of beet seed (OJ L 193, 20.7.2002, p. 12).

⁷ Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed (OJ L 193, 20.7.2002, p. 33).

⁸ Council Directive 2002/56/EC of 13 June 2002 on the marketing of seed potatoes (OJ L 193, 20.7.2002, p. 60).

⁹ Council Directive 2002/57/EC of 13 June 2002 on the marketing of seed of oil and fibre plants (OJ L 193, 20.7.2002, p. 74).

2008/72/EC⁽¹⁰⁾ and 2008/90/EC⁽¹¹⁾ (the ‘PRM marketing Directives’). These legal acts have formed the legal framework for the production and marketing of PRM and therefore have been of major importance for the creation of the internal market of PRM in the Union.

- (2) The impact assessments carried out by the Commission in 2013 and 2023 confirmed that those Directives have had a significant impact on the free movement, availability and high quality of PRM on the Union market and have thus facilitated the trade of PRM within the Union.
- (3) However, the rules on production and marketing of PRM need to be adapted to the scientific and technical developments in the areas of agricultural and horticultural production techniques and plant breeding. Moreover, the legislation needs to be updated on the basis of changes in international standards and experience gained by the application of the PRM Directives. Those rules need to be clarified in order to facilitate a more harmonised implementation. Therefore, the PRM marketing Directives should be replaced by a single Regulation on the production and marketing of PRM within the Union.
- (4) PRM constitutes the starting material for plant production in the Union. Therefore, it is critical for the production of raw material for food and feed purposes and for the efficient use of plant resources. It contributes to environmental protection and the quality of the food chain and food supply in the Union as a whole. In this regard, the availability, quality and diversity of PRM appears to be of outmost importance to achieve the transition to sustainable food systems called for in the Farm to Fork Strategy¹², agriculture, horticulture, environmental protection, climate change mitigation and adaptation, food and feed security, and the economy in general.
- (5) In order to achieve this transition to sustainable food systems, the Union legislation should therefore take account of the need to ensure the adaptability of the PRM production to the changing agricultural, horticultural and environmental conditions, to face the challenges of climate change, to protect and restore biodiversity and to meet increasing farmers’ and consumers’ expectations related to quality and sustainability of PRM.
- (6) The scope of this Regulation should only cover the PRM of certain genera and species of increased economic and social importance. That importance should be assessed depending on whether such genera and species represent a significant area of production and value in the Union, on their role for the security of food and feed production in the Union, and on whether they are marketed in at least two Member States. That area of production and value may concern several technical aspects. Depending on the circumstances, it may be calculated on the basis of factors such as the total size of productive land in several different areas of the Union, the marketing value of PRM in relation to specific sectors, or the demands for those species by farmers, final users and industry.

¹⁰ Council Directive 2008/72/EC of 15 July 2008 on the marketing of vegetable propagating and planting material, other than seed (OJ L 205, 1.8.2008, p. 28).

¹¹ Council Directive 2008/90/EC of 29 September 2008 on the marketing of fruit plant propagating material and fruit plants intended for fruit production (OJ L 267, 8.10.2008, p. 8).

¹² 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, A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system (COM(2020) 381 final).

- (7) Those genera and species should be listed and classified by their intended use, namely as agricultural crops, vegetables, fruit plants or vine. That classification is necessary to ensure a proportionate approach, as some species are only important for certain uses.
- (8) Furthermore, some varieties may have certain characteristics that, when cultivated under certain conditions, could have undesirable agronomic effects that would undermine the objective of the Regulation to contribute to the sustainability of agricultural production. This objective can only be achieved if such varieties are subject to appropriate cultivation conditions under which those undesirable agronomic effects are avoided. Those conditions should apply to the cultivation of those varieties for the production of food, feed or industrial materials and not only when intended for the production and marketing of PRM. Therefore, this Regulation should cover the conditions under which those varieties are cultivated, also for the production of food, feed or other products.
- (9) PRM should be defined in a comprehensive manner, including all plants capable of, and intended for, producing entire plants. This Regulation should, therefore, cover seeds, as well as all other forms of plants at any growth stage, capable of and intended for producing entire plants.
- (10) This Regulation should not cover forest reproductive material due to its particular characteristics, and very different concepts and applicable terminology. For this reason, forest reproductive material is subject to a separate legal act, and namely Regulation (EU) .../... of the European Parliament and of the Council¹³ +.
- (11) This Regulation should not cover propagating material of ornamental plants, because after consultations with Member States and stakeholders it has been concluded that Council Directive 98/56/EC (¹⁴) still adequately covers the needs of that sector.
- (12) This Regulation should cover neither PRM exported to third countries, nor PRM used solely for official testing, breeding, inspections, exhibitions or scientific purposes. This is because such categories of PRM do not require particular harmonised identity or quality standards and do not compromise the identity and quality of other PRM marketed in the Union.
- (13) This Regulation should not cover PRM sold or transferred in any other way, whether free of charge or not, between any persons for their own private use and outside their trade. It would be disproportionate to set out rules for such use of PRM, as this kind of transfer is usually limited to very small amounts, has no commercial purposes and is restricted to private activities.
- (14) In order to allow for informed choices by the users, PRM should be produced and marketed only if it belongs to varieties registered in national a variety register.
- (15) However, it is appropriate to exempt, where necessary, rootstocks from the requirement to belong to a variety, as although of a significant value, they frequently do not fall under the definition of a variety.

¹³ Regulation (EU) .../... of the European Parliament and of the Council (OJ...., p....).

+ OJ: Please insert in the text the number of the Regulation contained in document (... (COD)) and insert the number, date, title and OJ reference of that Regulation in the footnote.

¹⁴ Council Directive 98/56/EC of 20 July 1998 on the marketing of propagating material of ornamental plants (OJ L 226, 13.8.1998, p. 16).

- (16) In order to ensure the identity, quality and transparency and to enable informed choices by the users, PRM should as a general rule be produced or marketed under predefined categories. Those categories should reflect different generation stages and quality levels, and, on the basis of the internationally established terminology, be named ‘pre-basic’, ‘basic’, ‘certified’ and ‘standard’ seed, and ‘pre-basic’, ‘basic’, ‘certified’ and ‘standard’ material, in the case of PRM other than seeds, and .
- (17) PRM of each of those categories should be produced and marketed in accordance with the applicable international standards, in order to ensure the highest possible level of its identification and quality, and to be in line with the latest technical and scientific developments. Those standards should include, as applicable, the Schemes for the Varietal Certification or the Control of Seed Moving in International Trade ⁽¹⁵⁾ (‘OECD Seed Schemes’), the seed potato standards of the United Nations Economic Commission for Europe (UNECE) and the rules on seed sampling and testing of the International Seed Testing Association (ISTA).
- (18) In accordance with those standards, compliance of PRM with the requirements for the categories pre-basic, basic or certified should be confirmed by inspections, sampling, testing and official control plot testing carried out by the competent authorities (‘official certification’) and should be attested by an official label.
- (19) Specific rules should be established for the production and marketing of clones, selected clones, multiclonal mixtures and polyclonal PRM, due to their increased importance and use in the PRM sector. In order to ensure transparency, informed choices for their users and effective official controls, the clones should be registered in a special public register established by the competent authorities. Rules for the maintenance of the clones should also be established to ensure their preservation and identification.
- (20) Professional operators should be authorised by the competent authority to perform certification under official supervision of PRM belonging to certain species and categories and print the official label. Rules should be set out for the respective official supervision by the competent authority and the withdrawal of that authorisation or its modification. Those rules are necessary to ensure that the entire certification system functions effectively.
- (21) In order to ensure the maximum possible purity and homogeneity of PRM, PRM should be kept in separate lots, and separate from other material different to PRM, such as grain for food or feed.
- (22) In view of the large diversity of PRM, professional operators should be able to market the PRM lots in the form of individual plants, packages, bundles or containers, or in bulk.
- (23) Rules should be adopted for the labelling of PRM to ensure the appropriate identification of that material per category through the attestation of compliance with the respective requirements concerning pre-basic, basic, certified and standard seed and material.
- (24) In the case of pre-basic, basic and certified seed and material, an official label should be issued by the competent authority, while for standard seed or material an operator’s

¹⁵ Decision Revising the OECD Schemes for the Varietal Certification or the Control of Seed Moving in International Trade [OECD/LEGAL/0308] (‘OECD Seed Schemes’).

label should be issued. This is necessary to make a distinction between PRM subject to certification (official certification or certification under official supervision) and PRM produced under the responsibility of the professional operator. Issuing of a specific label aims at facilitating informed choices by the professional operators and consumers who may wish to select PRM of different standards. It would also facilitate the work of the competent authorities in designing their official controls in accordance with the respective requirements of each category.

- (25) The official label should be printed and affixed by authorised professional operators and under the official supervision of the competent authorities. However, and since certain professional operators may not have the resources to carry out all the certification activities and print official labels, it should be provided that any certification steps may also be carried out by the competent authorities upon request of professional operators.
- (26) Rules should be set out concerning the contents and form of the official label and operator's label, to ensure a uniform application of the respective production and marketing requirements for each category and the identification of those labels.
- (27) Each official label and operator's label should contain a serial number, so as to guarantee the appropriate identification and traceability of the PRM concerned and the effectiveness of the official controls.
- (28) The PRM marketing Directives and international practice and standards require that seeds belonging to certain species are only produced and marketed as pre-basic, basic or certified seeds, due to their importance for food security and industrial processing, and for the protection of the interests of the farmers using them. For this reason, certain seeds should only be produced and marketed as pre-basic, basic or certified seeds, if the costs for their production and marketing are proportionate to the purpose of ensuring quality seed for the farmers, food and feed security, or are proportionate to the purpose of ensuring high value of industrial processing. Those costs should also be proportionate to the achievement of the highest standards concerning the identity and quality of the seed, in line with the requirements for pre-basic, basic and certified seed. A list of those species of seeds for which seed may only be produced and marketed as pre-basic, basic or certified seeds should thus be established.
- (29) Seeds are frequently marketed in varietal mixtures of same species or species mixtures. However seeds of genera or species, covered by this Regulation, should be allowed to be produced and marketed in mixtures only with seeds of the genera or species covered by this Regulation. This is necessary to ensure that the respective production and marketing standards are respected. However, Member States should have the possibility to allow the production and marketing of a mixture of seeds covered by this Regulation, with seeds not belonging to genera or species covered by this Regulation, for the purposes of conservation of genetic resources and preservation of the natural environment. This is because those species are the ones most appropriate for the purpose of that preservation. Rules should be set out concerning those mixtures to ensure their identity and quality.
- (30) Requirements should be established concerning the re-packaging and re-labelling of pre-basic, basic and certified seed, in order to guarantee that the identity and the quality of the respective PRM will not be subject to change during those operations.
- (31) Control plot tests should be conducted to verify the varietal identity and purity of individual seed lots. Specific rules should be set out concerning those tests on pre-

basic, basic, certified and standard seed, on the basis of the applicable international standards and the experience gained by the application of the PRM marketing Directives.

- (32) Certain types of varieties do not fulfil the established requirements concerning distinctness, uniformity and stability. However, they are important for the conservation and sustainable use of plant genetic resources. They are traditionally grown or new locally produced varieties under specific local conditions and adapted to those conditions. They are characterised, in particular, by reduced uniformity due to a high level of genetic and phenotypical diversity between individual reproductive units. Those varieties are referred to as ‘conservation varieties’. The production and marketing of those varieties contribute to the objectives of the International Treaty on Plant Genetic Resources for Food and Agriculture to promote the conservation and sustainable use of plant genetic resources for food and agriculture ⁽¹⁶⁾. As a party to the Treaty the Union has committed to support those objectives.
- (33) In view of those special characteristics of the conservation varieties, and by way of derogation from the established requirements for production and marketing, the production and marketing of PRM belonging to them should be allowed under less stringent requirements. That objective is in line with the principles of the European Green Deal, and in particular, with the principle of protection of the biodiversity. It is thus appropriate to allow for that material to comply with the requirements for standard material for the species concerned. That PRM belonging to conservation varieties should therefore be labelled with the indication ‘Conservation varieties’. Those varieties should also be registered, to enable their control by the competent authorities and guarantee the informed choices for their users and the effectiveness of official controls.
- (34) Experience from the application of the marketing Directives has shown that final users of PRM (amateur gardeners and others) are often interested in using more diverse PRM that responds to different needs, without necessarily having the same quality demands as the professional operators. It is therefore appropriate to allow, by way of derogation from certain rules, that PRM may be marketed to final users without having to comply with the requirements for variety registration and without having to comply with the certification requirements or with the requirements for standard material. That derogation is necessary to ensure a wider variety for consumer offer, while respecting the general quality requirements. Moreover, for reasons of transparency and better control, rules should be set out for the packaging and labelling of PRM intended for final users only. For the same reason, professional operators using this derogation for marketing to final users should notify that activity to the competent authorities.
- (35) Many gene banks, organisations and networks operate in the Union with an objective to conserve plant genetic resources. In order to facilitate their activity, it is appropriate to allow that PRM which is marketed to them, or among them, derogates from the established production and marketing requirements, and that instead it complies with less stringent rules.
- (36) Farmers habitually exchange in kind small quantities of seeds in order to carry out dynamic management of their own seed. It is thus appropriate that a derogation from

¹⁶ Council Decision 2004/869/EC of 24 February 2004 concerning the conclusion, on behalf of the European Community, of the International Treaty on Plant Genetic Resources for Food and Agriculture (OJ L 378, 23.12.2004, p. 1).

the established requirements is provided for the exchanges of small quantities of seeds between farmers. Such derogation could apply if those seeds do not belong to a variety for which plant variety rights have been granted in accordance with Council Regulation (EU) 2100/94⁽¹⁷⁾. Member States should be allowed to define those small quantities for specific species per year, in order to ensure that there is no misuse of such derogation impacting the marketing of seeds.

- (37) According to the PRM marketing Directives, derogations from the established requirements are allowed for the marketing of PRM belonging to not yet registered varieties; of varieties that have not yet been fully tested; of seed not complying with the applicable requirements to be made rapidly available on the market; of seed not yet finally certified; of PRM to be temporarily authorised to address temporary difficulties in the supply; and of PRM for the conduct of temporary experiments to seek improved alternatives to certain provisions of the applicable legislation concerning the requirements for the PRM to belong to a registered variety and to fulfil certain identity and quality requirements. Those derogations have been useful and necessary for the professional operators and the competent authorities, without creating problems for the internal market of PRM. Therefore, they should be maintained. Conditions should be set out concerning those derogations, to ensure that they are not misused and that they do not affect adversely the internal market of PRM.
- (38) The use of PRM that does not belong to a variety pursuant to this Regulation, but rather belongs to a plant grouping within a single botanical taxon, with a high level of genetic and phenotypic diversity between individual reproductive units ('heterogeneous material'), could have benefits especially in organic production and low input agriculture, through improving resilience and increasing the within-species genetic diversity of cultivated plants. Therefore, PRM of heterogeneous material should be allowed to be produced and marketed without having to comply with the requirements for variety registration and the other production and marketing requirements of this Regulation. Specific requirements for the production and marketing of that material should be set out.
- (39) Union production and marketing of PRM needs to comply with the highest possible standards. Therefore, the import of PRM from third countries should only be allowed if an assessment of their applicable identity and quality standards and certification system establishes that such PRM fulfils requirements equivalent to those applicable to PRM produced and marketed in the Union. Such assessment should be based on a thorough examination of the information provided by the third country and its relevant legislation. It should also be based on the satisfactory outcome of an audit carried out by the Commission in the respective third country, where that audit is considered necessary by the Commission.
- (40) Rules should be set out concerning labelling and information to be provided for the imported PRM for the purposes of its proper identification, traceability, and informed choices by its users and for enabling official controls.
- (41) In order to ensure transparency and more effective controls on the production and marketing of PRM, professional operators should be registered. It is appropriate that they register in the registers established by Member States pursuant to Regulation

¹⁷ Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights (OJ L 227, 1.9.1994, p. 1).

(EU) 2016/2031 of the European Parliament and of the Council ⁽¹⁸⁾, in order to reduce the administrative burden for those professional operators. This is also proportionate because the vast majority of professional operators producing and marketing PRM are already registered in the professional operators' registers of that Regulation.

- (42) Specific obligations should be introduced for professional operators active in the area of the production and marketing of PRM, to ensure their accountability, more effective official controls and proper application of this Regulation.
- (43) Experience has shown that the reliability and quality of the marketed PRM can be jeopardised where it is impossible to trace material not complying with the applicable standards. It is therefore necessary to establish a comprehensive traceability system allowing withdrawals from the market or the submission of information to users of PRM or competent authorities. For that reason, the keeping of information and records on transfers from and to professional users should be mandatory for the professional operators. However, such record keeping is not appropriate for marketing in retail.
- (44) It is important to ensure that, as a general rule, all PRM of the genera and species within the scope of this Regulation are subject to the registration of the variety to which that PRM belongs, the description of the variety and the corresponding rules.
- (45) Varieties should be registered in a national variety register, to ensure informed choices by their users and more effective official controls.
- (46) The national variety register should include two types of varieties: varieties registered on the basis of an official description, if they fulfil the requirements of distinctness, uniformity and stability ('DUS'), and varieties registered on the basis of an officially recognised description in the case of conservation varieties. The existence of those two different descriptions is necessary to separate the two categories of varieties, whereby the first one is based on DUS testing results, while the other one is based on historical data concerning the use of the variety and practical experience. In addition, such approach can offer the necessary information about the characteristics of the varieties and their identity.
- (47) The registered varieties should be further notified by the competent authorities via the EU Plant Variety Portal to the Union variety register, to ensure an overview of all varieties allowed for marketing in the Union.
- (48) Herbicide tolerant varieties are varieties that have been bred to be intentionally tolerant to herbicides, in order to be cultivated in combination of the use of those herbicides. If such cultivation is not done under appropriate conditions, it may lead to development of weeds resistant to those herbicides, spread of such resistance genes in the environment or to the need to increase of quantities of herbicides applied. As this Regulation aims to contribute to the sustainability of agricultural production, the competent authorities of Member States responsible for the registration of varieties should be able to subject the cultivation of those varieties in their territory to cultivation conditions appropriate for avoiding those undesirable effects. Moreover, where varieties have particular characteristics, other than tolerance to herbicides, that

¹⁸ Regulation (EU) 2016/2031 of the European Parliament and of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC (OJ L 317, 23.11.2016, p. 4).

could have undesirable agronomic effects, they should also be subject to cultivation conditions, in order to address those agronomic effects. Those conditions should apply to the cultivation of those varieties for any purpose, including food, feed and other products, and not only for purposes of production and marketing of PRM. This is necessary to achieve the objectives of this Regulation to contribute to sustainable agricultural production beyond the stage of production and marketing of PRM.

- (49) In order to contribute to the sustainability of agricultural production and serve economic, environmental and broader societal needs, new varieties of all genera or species should show an improvement compared to the other varieties of the same genera or species registered in the same national variety register, concerning certain aspects. Among those aspects are their yield, including yield stability and yield under low input conditions; tolerance/resistance to biotic stresses, including plant diseases caused by nematodes, fungi, bacteria, viruses, insects and other pests; tolerance/resistance to abiotic stresses, including adaptation to climate change conditions; more efficient use of natural resources, such as water and nutrients; reduced need for external inputs, such as plant protection products and fertilisers; characteristics that enhance the sustainability of storage, processing and distribution; and quality or nutritional characteristics ('value for sustainable cultivation and use'). For the purpose of deciding on the variety registration and in order to provide sufficient flexibility to register varieties with the most desirable characteristics, those aspects should be considered for a given variety as a whole.
- (50) As organic varieties suitable for organic production as defined in Article 3 of Regulation (EU) 2018/848 are characterised by a high level of genetic and phenotypical diversity between individual reproductive units, it is appropriate that their registration is subject to adjusted DUS, and in particular as regards the requirements concerning uniformity. Furthermore, in order for that such varieties to be better adapted to the specific needs of organic production, their examination of the value for sustainable cultivation and use should be conducted under organic conditions.
- (51) For reasons of efficiency and reduction of the administrative burden, varieties that have been granted a plant variety right pursuant to Article 62 of Regulation (EC) No 2100/94, or pursuant to the legislation of a Member State, should be deemed to be distinct, uniform and stable and to have a suitable denomination for the purposes of this Regulation.
- (52) The procedure of variety registration should be precisely defined, in order to ensure legal certainty for the applicants and the competent authorities, and a level playing field for all applicants. For this reason, rules should be set out concerning the submission, content, formal examination and date of submission of the applications, technical examinations, audit of the competent authority's premises and organisation, additional rules on technical examination, confidentiality, provisional examination report and provisional official description, examination report and final official description, examination of the denomination of a variety and decision on the registration of a variety in the national variety register.
- (53) For reasons of efficiency and in order to reduce administrative burden for competent authorities and applicants, the competent authorities should register in their national variety registers all varieties officially accepted or registered, before the entry into force of this Regulation, in the catalogues, lists or registers established by their respective Member States pursuant to Directives 2002/53/EC, 2002/55/EC,

2008/90/EC and 68/193/EEC. As those varieties are already marketed in the Union and used by farmers and other professional operators, they should not be subject to a new registration procedure.

- (54) Rules should be set out concerning the technical examination of varieties, in order to conclude whether they are distinct, uniform and stable. Due to the importance of that examination for the variety breeding sector and the fact that it leads to the production of an official description, that technical examination should be carried out only by the competent authority.
- (55) However, there should be the possibility to carry out the technical examination for the satisfactory value for sustainable cultivation and use of a variety on the premises of the applicant and under the official supervision of the competent authority. This is necessary in order to ease the administrative burden, ensure the availability of testing facilities and reduce costs for the competent authorities. However, the competent authority should be in charge of the testing arrangements. Moreover, professional operators involved in the breeding of new varieties, and on the basis of their co-operation with the competent authorities, have proven qualified to carry out such examinations as they possess the respective expertise, knowledge and appropriate resources.
- (56) In order to ensure the credibility and high quality of the examinations on distinctness, uniformity and stability, the premises of the competent authorities where they take place should be audited by the Community Plant Variety Office ('CPVO'). The premises of the applicants where the examination for the satisfactory value for sustainable cultivation and use takes place under official supervision, should be audited by the respective competent authorities, to ensure compliance with the applicable requirements.
- (57) The period of the registration of a variety should be 10 years, so as to encourage innovation in the breeding sector, and the removal from the market of old varieties and their replacement by new ones. However, that period should be 30 years for varieties of genera or species of fruit plants and vine, due to the longer time required for the completion of the productive cycle of those genera or species.
- (58) Upon a request of any interested person, the period of registration of a variety should be subject to renewal, in order to allow for the continuation of marketing of certain varieties if a need is established and they still fulfil applicable requirements.
- (59) Rules should be set out concerning variety maintenance in accordance with accepted practices. This is necessary to ensure the varietal identity during the period of its registration, which can only be ensured if the maintenance of the respective variety is carried out by the applicant, or other persons notified by the applicant to the competent authority, pursuant to certain requirements and subject to official controls by the competent authorities.
- (60) Rules should be set out concerning the content of the national variety registers and the Union variety register, and the keeping of samples of the registered varieties ('official sample' or 'standard sample') which is a living description of the variety. This is important to ensure accessibility to the necessary information on the variety, its identification during the period of its registration and the availability of standard samples for control plot testing in the context of PRM certification.
- (61) The PRM marketing Directives should be repealed, as this Regulation replaces them. As a consequence, Regulation (EU) 2016/2031 should be amended to remove

references to those Directives and to ensure that Regulated Non-Quarantine Pests ('RNQPs') are exclusively regulated by that Regulation.

- (62) Regulation (EU) 2017/625 of the European Parliament and of the Council¹⁹ should be amended to include in its scope the production and marketing of PRM in line with this Regulation. This is important in order to guarantee a uniform approach as regards official controls for the entire plant production and food chain, since Regulation (EU) 2017/625 also applies to the scope of Regulation (EU) 2016/2031, and Regulation (EU) 2018/848 of the European Parliament and of the Council²⁰.
- (63) In this respect, the Commission should be empowered to adopt specific rules on official controls and on actions taken by the competent authorities in relation to PRM, in particular for laying down rules for the performance of official controls on PRM for verifying compliance with Union rules, for the import into, and marketing within, the Union of PRM, and on the activities of operators during the production of PRM.
- (64) Regulation (EU) 2018/848 should be amended to align the definitions of 'plant reproductive material' and 'heterogeneous material' with the definitions provided for by this Regulation. Moreover, the empowerment for the Commission to adopt specific provisions for the marketing of PRM of organic heterogeneous material should be excluded from Regulation (EU) 2018/848, as all rules concerning the production and marketing of PRM should be set out in this Regulation for reasons of legal clarity.
- (65) In order to adapt the list of genera and species of PRM, subject to the scope of this Regulation, to the developments related to the significance of area and value of production, food/feed security and number of Member States where it is cultivated, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of amending that list.
- (66) In order to adapt the rules on the production and marketing of PRM to the technical and scientific developments and the applicable international standards, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of amending the requirements of this Regulation concerning the production and marketing of pre-basic, basic, certified and standard material and seeds.
- (67) In order to adapt the rules on the production and marketing of PRM of heterogeneous material to the technical and scientific developments, and take into account the experience gained from the application of the rules of this Regulation, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the

¹⁹ 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).

²⁰ 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).

Commission in respect of amending the requirements concerning the production and marketing of heterogeneous material.

- (68) In order to adapt the content of variety registers to the technical developments and follow up to the experience gained from variety registration, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of amending the requirements concerning that content.
- (69) In order to adapt the cultivation of varieties to the development of technical and scientific knowledge, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of adopting conditions of cultivation of varieties that are herbicide-tolerant or have other characteristics that could lead to undesirable agronomic effects. Those conditions should include measures in the field, such as crop rotation; monitoring measures; the notification of those measures by Member States to the Commission and the other Member States; reporting by professional operators to the competent authorities concerning the application of those measures; and the indications of those conditions in the national variety registers.
- (70) In order to adapt testing and requirements for the sustainable value of cultivation and use requirements to the potential technical and scientific developments, and the possible development of international standards, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of supplementing this Regulation with certain elements. Those consist of the necessary methodologies for the growing trials to be carried out with a view to assessing, and adopting further requirements for, sustainable value of cultivation and use for certain genera or species.
- (71) In order to adapt the rules on variety denomination to the technical and scientific developments, and follow up on the experience gained from the application of those rules, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of supplementing this Regulation by setting out specific criteria concerning the suitability of variety denominations.
- (72) In order to adapt the provisions of this Regulation concerning technical examinations of varieties to the technical and scientific developments and the practical needs of competent authorities and professional operators, and follow up on the experience gained from the application of the respective rules, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of supplementing this Regulation by setting out the rules concerning the audit of the premises of professional operators to carry out technical examinations for the satisfactory value for sustainable cultivation and use.
- (73) In order to adapt the provisions of this Regulation concerning the examination for sustainable cultivation and use to the technical or scientific developments, and to any new Union policies or rules on sustainable agriculture, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of supplementing this Regulation by establishing the minimum requirements for carrying out this examination, establishing the methodologies for assessing the characteristics examined, establishing the standards for the evaluation and the reporting of the results of this examination and amending the characteristics examined.
- (74) It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, 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-Making²¹. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

- (75) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council²².
- (76) In order to ensure uniform conditions for the implementation of this Regulation, and to improve the performance of professional operators and the identity and quality of PRM produced and marketed by them, implementing powers should be conferred to the Commission with respect to specifying the requirements for the audits, training, examinations, inspections, sampling and testing, with regard to particular genera or species, for the official supervision of the professional operators by the competent authorities.
- (77) In order to ensure uniform conditions for the implementation of this Regulation concerning handling and marketing of PRM, and adapt the respective rules to the experience gained from the application of the provisions of this Regulation, implementing powers should be conferred to the Commission for adopting specific requirements for all or certain species of PRM, concerning the merging or splitting of lots in relation to the origin of PRM lots, their identification, records on that operation and labelling following the merging or splitting of PRM lots.
- (78) In order to ensure uniform conditions for the implementation of this Regulation, follow up on the practical experience gained by the application of its provisions, and improve the integrity of the marketed PRM, implementing powers should be conferred to the Commission for adopting specific requirements concerning the sealing, fastening, size and form of packages, bundles and containers of specific species of PRM.
- (79) In order to ensure uniform conditions for the implementation of this Regulation, and in particular concerning the legibility, recognisability and security of labels, implementing powers should be conferred to the Commission for adopting specific provisions concerning the official labels, labels used for certain derogations and, labels used for some specific types of PRM, and set out the content, size, colour and form of those labels for the respective categories or types of PRM.
- (80) In order to ensure uniform conditions for the implementation of this Regulation and follow up on any practical experience gained by the application of the respective rules, implementing powers should be conferred to the Commission for adopting specific provisions concerning mixtures of seeds.
- (81) In order to ensure uniform conditions for the implementation of this Regulation with respect to retail marketing of PRM, and make the marketing of PRM as practical and suitable for each species as possible, implementing powers should be conferred to the

²¹ OJ L 123, 12.5.2016, p. 1.

²² 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. 13–18.

Commission for adopting rules concerning the size, form, sealing and handling requirements of the small packages for seeds and the packages and bundles for other PRM marketed to final users.

- (82) In order to ensure uniform conditions for the implementation of this Regulation and to address urgent supply difficulties of PRM, implementing powers should be conferred to the Commission for authorising, in the case of temporary difficulties in the supply of PRM, for a maximum period of 1 year, the marketing of PRM of the categories of pre-basic, basic or certified material or seed subject to less stringent requirements, or to derogate from the requirement to belong to a variety, and with respect to repealing and amending that authorisation.
- (83) In order to ensure uniform conditions for the implementation of this Regulation, and ensure some flexibility to Member States to adopt national measures adapted to their agro-climatic conditions and higher quality standards, implementing powers should be conferred to the Commission for authorising the Member States to adopt, with regards to production and marketing of PRM, more stringent production or marketing requirements, in all or part of the territory of the Member State concerned, and with respect to repealing or amending such measures adopted pursuant to the PRM marketing Directives.
- (84) In order to ensure uniform conditions for the implementation of this Regulation, and ensure a swift response to sudden risks, implementing powers should be conferred to the Commission for taking emergency measures, where the production or marketing of PRM is likely to constitute a serious risk to human, animal or plant health, the environment or cultivation of other species, and such risk cannot be contained satisfactorily by measures taken by the Member State concerned, and with respect to repealing or amending any such measure taken by a Member State.
- (85) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred to the Commission for deciding on the organisation of temporary experiments to seek improved alternatives to the scope and certain provisions of this Regulation.
- (86) In order to ensure uniform conditions for the implementation of this Regulation with regard to the import of PRM, and ensure compliance of the third country requirements with the equivalent Union requirements, implementing powers should be conferred to the Commission with respect to recognising whether PRM of specific genera, species or categories produced in a third country, or particular areas of a third country, fulfils requirements equivalent to those applicable to PRM produced and marketed in the Union, in order to be imported.
- (87) In order to ensure uniform conditions for the implementation of this Regulation and to ensure appropriate maintenance of the registered varieties in third countries too, implementing powers should be conferred to the Commission with respect to recognising that the controls on variety maintenance carried out in the third country afford the same guarantees as those set out in the Union.
- (88) In order to ensure uniform conditions for the implementation of this Regulation, and to adapt its provisions to the evolving applicable protocols of the International Union for the Protection of new Varieties of Plants (UPOV) or protocols established by the CPVO, and the relevant technical and scientific developments, implementing powers should be conferred to the Commission for adopting specific requirements concerning distinctness, uniformity and stability per genera or species of varieties.

- (89) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred to the Commission for adopting specific rules as regards the size of the standard sample of registered varieties used for the official post controls of PRM, the rules for the renewal of those samples and the provision of those samples to other Member States.
- (90) Since the objective of this Regulation, namely to ensure a harmonised approach with regard to the production and marketing of PRM, 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 PRM and professional operators.
- (91) This Regulation should apply from 3 years after its entry into force, in order to allow the competent authorities and the professional operators to adapt to its provisions and also to provide the necessary time for the adoption of the respective delegated and implementing acts. The rules concerning the satisfactory value for sustainable cultivation and use of varieties of vegetables and fruit plants should however apply from 5 years after its entry into force. That additional time period is needed for the competent authorities and professional operators to make the necessary preparations and carry out the first tests in the fields complying with those new rules.

HAVE ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter

This Regulation lays down rules for the production and marketing in the Union of plant reproductive material ('PRM'), and in particular requirements for the production of PRM in the field and other sites, categories of material, identity and quality requirements, certification, labelling, packaging, imports, professional operators and the registration of varieties.

This Regulation also lays down rules concerning the conditions of cultivation of certain varieties that could have undesirable agronomic effects, including the cultivation for purposes beyond the production and marketing of PRM, for the production of food, feed and other products.

Article 2

Scope and objectives

1. This Regulation applies to the genera and species listed for the respective uses referred to in Parts A to E of Annex I.
Its requirements concern, respectively, all types of PRM, only seeds, or only material other than seeds.

The requirements concerning production of PRM shall apply only to production with a view to its marketing.

2. The objectives of this Regulation are the following:
 - (a) to ensure quality and diversity of choice for PRM, and its availability for professional operators and final users;
 - (b) to ensure a equal conditions for the competition of the professional operators across the Union and the functioning of the internal market in PRM;
 - (c) to support innovation and competitiveness of the PRM sector in the Union;
 - (d) to contribute to conservation and sustainable use of plant genetic resources and agro-biodiversity;
 - (e) to contribute to sustainable agricultural production, adapted to current and future projected climatic conditions;
 - (f) to contribute to food security
3. The Commission is empowered in accordance with Article 75 to adopt delegated acts, amend Annex I, in order to adapt it to the developments of technical and scientific knowledge, and the economic data concerning production and marketing of genera and species, by adding genera and species to or removing them from the list that Annex.

The delegated act referred to in the first subparagraph shall add genera or species to the list in Annex I if they fulfil at least two of the following elements:

 - (a) represent a significant area of production of PRM and a significant value of marketed PRM in the Union
 - (b) are of substantial importance for security of food and feed production in the Union, compared to other genera and species not listed in that Annex; and
 - (c) are marketed in at least two Member States.

The delegated act referred to in the first subparagraph shall remove genera or species from the list in Annex I if they no longer fulfil at least two of the elements set out in the second subparagraph.
4. This Regulation does not apply to:
 - (a) propagating material of ornamental plants as defined in Article 2 of Directive 98/56/EC;
 - (b) forest reproductive material as defined in Article 3 of Regulation (EU) .../... of the European Parliament and of the Council²³+
 - (c) PRM produced for export to third countries;
 - (d) PRM sold or transferred in any way, whether free of charge or not, between final users for their own private use and outside their commercial activities;
 - (e) PRM used solely for official testing, breeding, inspections, exhibitions or scientific purposes.

²³ Regulation (EU) .../... of the European Parliament and of the Council (OJ..., p....).

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OJ: Please insert in the text the number of the Regulation contained in document (... (COD)) and insert the number, date, title and OJ reference of that Regulation in the footnote.

Article 3

Definitions

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

- (1) ‘plant reproductive material’ (‘PRM’) means plants as defined in Article 2(1) of Regulation (EU) 2016/2031, capable of, and intended for, producing entire plants;
- (2) ‘professional operator’ means any natural or legal person, involved professionally in one or more of the following activities in the Union concerning PRM:
 - (a) production;
 - (b) marketing;
 - (c) maintenance of varieties;
 - (d) provision of services for identity and quality;
 - (e) preservation, storage, drying, processing, treating, packaging, sealing, labelling, sampling or testing;
- (3) ‘marketing’ means the following actions conducted by a professional operator: sale, holding, transfer for free, or offering for sale or any other way of transferring or distribution within, or import into, the Union
- (4) ‘variety’ means a variety as defined in Article 5(2) of Regulation (EC) No 2100/94;
- (5) ‘clone’ means an individual plant progeny, originally derived from another single plant by vegetative reproduction, remaining genetically identical to that plant;
- (6) ‘selected clone’ means a clone that has been selected and chosen for some special intravarietal phenotypic traits and its phytosanitary status that give the selected clone a better performance, is true to the description of the variety to which it belongs and, in the case of selected clones not belonging to a variety, it is true to the description of the species to which it belongs;
- (7) ‘polyclonal plant reproductive material’ means a group of several distinct individual plant progenies derived from different genotypes, each of which is true to the description of the variety to which it belongs;
- (8) ‘multiclonal mixture’ means a mixture of selected clones, all belonging to the same variety or species, as appropriate, whereby each of them has been obtained through independent selection;
- (9) ‘competent authority’ means the 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, certification and other official activities concerning the production and marketing of PRM, or any other authority to which that responsibility has been conferred in accordance with Union law;
- (10) ‘official description’ means a description that has been established by a competent authority, includes the relevant characteristics of the variety and makes the variety identifiable as a result of the examination on its distinctness, uniformity and stability;
- (11) ‘officially recognised description’ means a written description of a conservation variety, which has been recognised by a competent authority, includes the specific characteristics of the variety, and has been obtained by other means than the examination of its distinctness, uniformity and stability;

- (12) 'variety maintenance' means the actions taken for controlling varietal purity and identity with the aim to ensure that a variety remains in accordance with its description over subsequent cycles of reproduction;
- (13) 'seeds' means seeds in the botanical sense;
- (14) 'pre-basic seed' means seed that belongs to a generation preceeding the generation of the basic seed, is intended for the production and certification of basic or certified seed, and has been found by means of official certification, or certification under official supervision, to satisfy the respective conditions laid down in Part A of Annex II;
- (15) 'basic seed' means seed that has been produced from pre-basic seed or preceding generations of basic seed, is intended for the production of further generations of basic seed or certified seed, and which has been found by means of official certification, or certification under official supervision, to satisfy the respective conditions laid down in Part A of Annex II;
- (16) 'certified seed' means seed that has been produced from pre-basic, basic or preceding generations of certified seed, and which has been found by means of official certification, or certification under official supervision, to satisfy the respective conditions laid down in Part A of Annex II;
- (17) 'standard seed' means seed, other than pre-basic, basic or certified seed, that is not intended for further multiplication, and satisfies the respective conditions laid down in Part A of Annex III;
- (18) 'pre-basic material' means PRM, other than seeds, that belongs to a generation preceeding the generation of basic material, is intended for the production and certification of basic or certified material, and has been found by means of official certification or certification under official supervision to satisfy the respective conditions laid down in Part B of Annex II;
- (19) 'basic material' means PRM, other than seed, that has been produced from pre-basic material or preceding generations of basic material, is intended for the production and certification of further generations of basic material or certified material, and has been found by means of official certification or certification under official supervision to satisfy the respective conditions laid down in Part B of Annex II;
- (20) 'certified material' means PRM, other than seed, that has been produced from pre-basic, basic or preceding generations of certified material, and has been found by means of official certification or certification under official supervision to satisfy the respective conditions laid down in Part B of Annex II;
- (21) 'standard material' means PRM other than seed, and other than pre-basic, basic or certified material, that is not intended for further multiplication, and satisfies the respective conditions laid down in Part B of Annex III;
- (22) 'official certification' means official attestation by the competent authority of the compliance of pre-basic, basic or certified seed or material with the respective requirements of this Regulation, where all relevant inspections on site, sampling and testing including where appropriate control plot testing have been carried out by that authority, and if it has concluded that the seed or material concerned meets those requirements;
- (23) 'certification under official supervision' means attestation by a specifically authorised professional operator that pre-basic, basic or certified seed or material

complies with the applicable requirements, and where at least one or more of the relevant inspections, sampling, testing or label printing have been carried out by that professional operator, under the official supervision of the competent authority, and if it has concluded that the seed or material concerned meets those requirements;

- (24) ‘category’ of PRM means a group or an individual unit of PRM that qualifies as pre-basic, basic, certified or standard seed or material and is identifiable by complying with specific identity and quality requirements;
- (25) ‘genetically modified organism’ means a genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC of the European Parliament and of the Council (²⁴), excluding organisms obtained through the techniques of genetic modification listed in Annex I B to Directive 2001/18/EC;
- (26) ‘lot’ means a unit of PRM, identifiable by its homogeneity of composition and origin;
- (27) ‘heterogeneous material’ means a plant grouping within a single botanical taxon of the lowest known rank which:
 - (a) presents common phenotypic characteristics;
 - (b) is characterised by a high level of genetic and phenotypic diversity between individual reproductive units, so that that plant grouping is represented by the material as a whole, and not by a small number of units;
 - (c) is not a variety; and
 - (d) is not a mixture of varieties;
- (28) ‘final user’ means any person acquiring, transferring and using PRM for purposes which are outside that person’s professional activities;
- (29) ‘conservation variety’ means a variety that is:
 - (a) traditionally grown or locally newly bred under specific local conditions in the Union, and adapted to those conditions; and
 - (b) characterised by a high level of genetic and phenotypical diversity between individual reproductive units;
- (30) ‘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 PRM production or storage; and
 - (c) their presence has an unacceptable adverse impact on the quality of the PRM, and an unacceptable economic impact as regards the use of that PRM in the Union;

²⁴ 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, 17.4.2011, p. 1).

- (31) 'practically free from pests' means completely free from pests, or a situation where the presence of quality pests on the respective PRM is so low that those pests do not affect adversely the quality of that PRM;
- (32) 'seed potatoes' means tubers of *Solanum tuberosum* L., used for the reproduction of other potatoes;
- (33) 'farmer' means farmer as defined in Article 3(1) of Regulation (EU) 2021/2115 of the European Parliament and of the Council ²⁵;
- (34) 'off-type' means, in relation with seed or other plants, a seed or other PRM not corresponding to the description of the variety or species to which it is supposed to belong pursuant to this Regulation
- (35) 'hybrid variety' means a variety produced as a result from the crossbreeding of two or more other varieties.

Article 4

Compliance with Regulation (EU) 2016/2031

This Regulation shall apply without prejudice to Regulation (EU) 2016/2031.

Any PRM lot produced and marketed in accordance with this Regulation, shall also comply with the rules set out in, or pursuant to, Articles 36, 37, 40, 41, 42, 49, 53 and 54 of Regulation (EU) 2016/2031 concerning Union quarantine pests, protected zone quarantine pests and RNQPs, and with the measures adopted pursuant to Article 30(1) of that Regulation.

CHAPTER II

REQUIREMENTS CONCERNING VARIETIES, CATEGORIES OF PRM, LABELLING, AUTHORISATIONS, HANDLING, IMPORTS AND DEROGATIONS

SECTION 1

General requirements for the production and marketing of PRM

Article 5

Belonging to a registered variety

Only PRM belonging to a variety registered in a national variety register referred to in Article 44 may be produced and marketed within the Union, except the following cases:

- (a) as rootstocks, if produced and marketed with a reference, contained in an appropriate labelling, to the species to which they belong;
- (b) as heterogeneous material in accordance with Article 27.
- (c) as PRM marketed to final users in accordance with Article 28;

²⁵ Regulation (EU) 2021/2115 of the European Parliament and of the Council of 2 December 2021 establishing rules on support for strategic plans to be drawn up by Member States under the common agricultural policy (CAP Strategic Plans) and financed by the European Agricultural Guarantee Fund (EAGF) and by the European Agricultural Fund for Rural Development (EAFRD) and repealing Regulations (EU) No 1305/2013 and (EU) No 1307/2013 (OJ L 435, 6.12.2021, p. 1).

- (d) as PRM produced and marketed for the purposes of conservation of genetic resources in accordance with Article 29;
- (e) as seed exchanged in kind between farmers in accordance with Article 30;
- (f) as breeder's seed, in accordance with Article 31;
- (g) as PRM of not yet registered varieties in accordance with Article 32;
- (h) in the event of supply difficulties of PRM in accordance with Article 33;

Article 6

Belonging to certain categories of PRM

1. Only PRM belonging to one of the following categories may be produced and marketed within the Union, except in the cases provided for in paragraph 2:
 - (a) pre-basic material or seed;
 - (b) basic material or seed;
 - (c) certified material or seed;
 - (d) standard material or seed.

Where a reference is made in this Regulation to lower or higher categories concerning identity and quality of PRM, that determination shall be based on the ranking the order of points (a) - (d), with point (a) indicating the highest rank and point (d) the lowest one.
2. By way of derogation from paragraph 1, PRM may be produced and marketed without belonging to a category listed in (a) - (d) in the following cases:
 - (a) marketing of PRM of heterogeneous material in accordance with Article 27;
 - (b) marketing to a final user in accordance to Article 28;
 - (c) marketing to and between conservation networks as referred to in Article 29;
 - (d) as seed exchanged in kind between farmers in accordance with Article 30;
 - (e) breeder's seed as referred to in Article 31.

SECTION 2

Requirements for the production and marketing of pre-basic, basic, certified and standard material and seed

Article 7

Requirements for the production and marketing of pre-basic, basic and certified seed and material

1. Pre-basic, basic and certified seed may only be produced and marketed within the Union, if all the following conditions are fulfilled:
 - (a) the pre-basic, basic or certified seed is practically free from quality pests;
 - (b) it is produced and marketed:
 - (i) following official certification by the competent authorities, or certification by the professional operator under official supervision;

- (ii) in accordance with the requirements set out in Part A of Annex II, and its compliance with those requirements is attested by the official label referred to in Article 15(1).
- 2. Pre-basic, basic and certified material may only be produced and marketed within the Union, if all the following conditions are fulfilled:
 - (a) the pre-basic, basic or certified material is practically free from quality pests;
 - (b) it is produced and marketed:
 - (i) following official certification by the competent authorities, or certification by the professional operator under official supervision;
 - (ii) in accordance with the requirements set out in Part B of Annex II, and its compliance with those requirements is attested by the official label referred to in Article 15(1).
- 3. The Commission is empowered to adopt delegated acts in accordance with Article 75, in order to amend Annex II. Those amendments shall adapt to the developments of international technical and scientific standards and may concern the requirements for the following:
 - (a) sowing and planting, and production in the field, of pre-basic, basic and certified seed;
 - (b) harvesting and post-harvesting of pre-basic, basic and certified seed;
 - (c) marketing of seeds;
 - (d) sowing and planting, and production in the field, of pre-basic, basic and certified material;
 - (e) harvesting and post-harvesting of pre-basic, basic and certified material;
 - (f) marketing of pre-basic, basic and certified material;
 - (g) pre-basic, basic and certified material of clones, selected clones, multiclonal mixtures and polyclonal PRM;
 - (h) production of pre-basic, basic and certified material produced by in vitro propagation;
 - (i) marketing of pre-basic, basic and certified material produced by in vitro propagation.
- 4. The Commission may adopt implementing acts specifying the production and marketing requirements referred to in Part A and Part B of Annex II for certain genera, species or categories of PRM, and, where appropriate, for certain grades, classes, generations or other sub-divisions of the category concerned. Those requirements shall concern one or more of the following elements
 - (a) specific uses of the genera, species or the types of the PRM concerned;
 - (b) production methods of PRM, including sexual and asexual reproduction and in vitro propagation;
 - (c) conditions for sowing or planting;
 - (d) field cultivation;
 - (e) harvesting and post-harvesting;

- (c) germination rates, purity and content of other PRM, moisture, vigour, presence of earth or extraneous matter;
- (c) certification methods of PRM, including the application of bio-molecular or other technical methods, as well as their approval and use, and the listing of approved methods in the Union;
- (d) the conditions for rootstocks and other parts of plants of genera or species other than those listed in Annex I, or their hybrids, if propagating material of the genus or species listed in Annex I or their hybrids is grafted onto them;
- (e) conditions for the production of seeds from fruit plants or vine;
- (f) conditions for the production of fruit plants, vine or seed potatoes from seeds.

Those implementing acts shall be adopted in accordance with the examination procedure set out in Article 76(2), in order to adapt to the developments of the relevant international technical and scientific standards.

Article 8

Requirements for the production and marketing of standard seed and material

1. Standard seed may only be produced and marketed within the Union, if all the following conditions are fulfilled:
 - (a) it is practically free from quality pests;
 - (b) it is produced and marketed:
 - (i) under the responsibility of the professional operator;
 - (ii) in accordance with the requirements set out in Part A of Annex III, and its compliance with those requirements is attested by the operator's label referred to in Article 16.
2. Standard material may only be produced and marketed within the Union, if all the following conditions are fulfilled:
 - (a) it is practically free from quality pests;
 - (b) it is produced and marketed:
 - (i) under the responsibility of the professional operator;
 - (ii) in accordance with the requirements set out in Part B of Annex III, and its compliance with those requirements is attested by the operator's label referred to in Article 16.
3. Once a year, professional operators shall submit to the competent authority a declaration concerning the quantities per species of standard seed and material they produced.
4. The Commission is empowered to adopt delegated acts, in accordance with Article 75, in order to amend Annex III, to adapt the requirements referred to in paragraphs 1 and 2 to the scientific and technical developments and to the applicable international standards. Those amendments shall concern the following:
 - (a) requirements for sowing and planting, and production in the field, of standard seeds;
 - (b) requirements for harvesting and post-harvesting of standard seeds;

- (c) requirements for marketing of standard seeds;
 - (d) requirements for sowing and planting, and production in the field, of standard material;
 - (e) requirements for harvesting and post-harvesting of standard material;
 - (f) requirements for the marketing of standard material;
 - (g) requirements for clones, selected clones, multiclonal mixtures and polyclonal PRM of standard material;
 - (h) requirements for the production of standard material produced by in vitro propagation;
 - (i) requirements for the marketing of standard material produced by in vitro propagation.
5. The Commission may adopt implementing acts specifying the production and marketing requirements referred to in Part A and Part B of Annex III for certain genera or species of standard seed or material. Those requirements shall concern one or more of the following elements:
- (a) specific uses of the genera, species or the types of the PRM concerned;
 - (b) production methods of PRM, including sexual and asexual reproduction and in vitro propagation;
 - (c) conditions for sowing or planting;
 - (d) field cultivation;
 - (e) harvesting and post-harvesting;
 - (f) germination rates, purity and content of other PRM, moisture, vigour, presence of earth or extraneous matter;
 - (g) the application of bio-molecular or other technical methods, as well as their approval and use, and the listing of approved methods in the Union;
 - (h) the conditions for rootstocks and other parts of plants of genera or species other than those listed in Annex I, or their hybrids, if propagating material of the genus or species listed in Annex I or their hybrids is grafted onto them;
 - (i) conditions for the production of seeds from fruit plants or vine;
 - (j) conditions for the production of fruit plants, vine or seed potatoes from seeds.

Those implementing acts shall be adopted in accordance with the examination procedure set out in Article 76(2), in order to adapt to the developments of the relevant international technical and scientific standards.

Article 9

Production, marketing and registration of clones, selected clones, multiclonal mixtures and polyclonal PRM

1. In addition to the requirements referred to in Articles 4 to 43, pre-basic, basic, certified and standard material of clones, selected clones, multiclonal mixtures and polyclonal PRM shall be produced and marketed in accordance with paragraphs 2 and 3 and the requirements set out respectively in Annex II, Part C, and Annex III, Part C.

2. Clones, selected clones, multiclonal mixtures and polyclonal PRM may only be produced and marketed if they are registered by a competent authority in at least one official register for clones established by a Member State.

That register shall include all elements referred to in the application for the registration of a clone, selected clone, multiclonal mixture and polyclonal PRM, as set out in Annex II, Part B, Part C point 2.

3. Clones, selected clones, multiclonal mixtures and polyclonal PRM shall be maintained for the purpose of preserving their identity. The persons responsible for maintenance of the clones, selected clones, multiclonal mixtures and polyclonal PRM shall take all measures to be able to make them verifiable by the competent authorities or any other person, on the basis of kept records.

SECTION 3

Authorisation of professional operators and official supervision of the competent authorities

Article 10

Authorisation of professional operators to carry out certification under official supervision

1. A professional operator may, upon application, be authorised by the competent authority to perform all or certain activities required for certification of PRM under official supervision of the competent authority for pre-basic, basic and certified material or seeds, and to issue an official label for them.

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 7;
 - (b) be qualified to carry out the inspections referred to in Annex II or employ personnel qualified for such inspections;
 - (c) employ qualified personnel for carrying out the sampling referred to in Annex II, or conclude contracts with companies employing qualified personnel for those activities;
 - (d) employ specialised personnel and equipment to carry out the testing referred to in Annex II, or use laboratories employing qualified personnel for those activities;
 - (e) have identified, and have the capability to monitor, the critical points of the production process which may influence the quality and identity of the PRM, and keep records of the results of that monitoring;
 - (f) have in place systems to ensure the fulfilment of the requirements concerning the identification of lots pursuant to Article 13;
 - (g) have in place systems to ensure the fulfilment of the traceability requirements set out in Article 42.
2. The Commission is empowered to adopt delegated acts in accordance with Article 75, supplementing paragraph 1 as regards one or more of the following elements:

- (a) 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 (g).

Article 11

Withdrawal or modification of the authorisation of a professional operator

Where an authorised professional operator no longer fulfils the requirements set out in Article 10(1), the competent authority shall request that operator to take corrective actions within a specified period of time.

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 the first subparagraph 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 sanctions to the professional operator.

Article 12

Official supervision by the competent authorities

1. For the purposes of the certification under official supervision, the competent authorities shall, at least once per year, conduct audits to ensure that the professional operator fulfils the requirements referred to in Article 10(1).

They shall also organise training and examinations of the personnel carrying out field inspections, sampling and testing provided for in this Regulation.

2. For the purposes of the certification under official supervision, the competent authorities shall carry out official inspections, sampling and testing on a portion of the crops on the site of production and on lots of the PRM in order to confirm compliance of that material with the requirements referred to in Article 7.

That portion shall be determined on the basis of the assessment of the potential risk of non-compliance of the PRM with those requirements.

3. The Commission may, by means of implementing acts, specify the requirements for the audits, training, examinations, inspections, sampling and testing, as referred to in paragraphs 1 and 2, with regard to particular genera or species.

Those implementing acts may specify one or more of the following elements:

- (a) the risk criteria as referred to in paragraph 2 and minimum portion of the crops and the lots of PRM, to be subject to inspections, sampling and testing, as referred to in paragraph 2;
- (b) monitoring activities to be carried out by the competent authorities;
- (c) use of particular accreditation schemes by the professional operator, and the possibility for the competent authorities to reduce the inspections, sampling and testing, and monitoring activities referred to in this Article due to the use of those schemes.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).

SECTION 4

HANDLING REQUIREMENTS

Article 13

Lots

1. PRM shall be marketed in lots. The content of the varieties and species of each lot shall be sufficiently homogeneous regarding and identifiable by its users as distinct from other lots of PRM.
2. During processing, packaging, storage, or at delivery, lots of PRM may be merged into a new lot only if they belong to the same variety and harvest year.

Where lots consisting of different certification categories are merged, the new lot shall belong to the category of the component of the lowest category. The merging operation may only be undertaken in a facility and by persons authorised by the competent authority for this specific purpose.

3. During processing, packaging, storage, or at delivery, lots of PRM may be split into two or more lots.
4. In cases of merging or splitting of the lots of PRM, as referred to in paragraphs 2 and 3, the professional operator shall keep records concerning the origin of the new lots.
5. The Commission may, by means of implementing acts, adopt specific requirements for all or certain species of PRM, concerning the maximum size of lots, their identification and labelling, the merging or splitting of lots in relation to the origin of the PRM lots, recording of those operations and labelling following the merging or splitting. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).

Article 14

Packages, bundles and containers

1. PRM shall be marketed in fastened packages, bundles or containers, bearing a sealing device and marking. In the case of PRM other than seeds, it may also be marketed in the form of individual plants.
2. The packages, bundles and containers referred to in paragraph 1 shall be fastened in such a way, that they cannot be opened without destroying that fastening or leaving traces demonstrating that the package, bundle or container has been opened. The effectiveness of the fastening device shall be ensured, either by incorporating the labels provided for in Articles 15 and 16 in the device or by use of a seal. Packages and containers shall be exempted from this requirement if the fastening cannot be reused.
3. In the case of pre-basic, basic or certified PRM, those packages, bundles and containers shall be fastened by the competent authority, or by the professional operator under the official supervision of the competent authority. Those packages and containers shall not be refastened unless this is done by the competent authority or by the professional operator under the official supervision of the competent authority. If a package, bundle or a container is refastened, the date of refastening and the details of the responsible competent authority shall be stated on the label referred to in Article 15.

4. Lots of pre-basic, basic or certified PRM may be repackaged, re-labelled, and re-sealed only under official control or under the official supervision of the competent authority.
5. By way of derogation from paragraph 1, seeds may be marketed from a professional operator directly to a farmer in bulk.

That professional operator shall be authorized for that purpose by the competent authority. It shall inform the competent authority in advance of such activity and of the lot from which such seed comes.

Where seed is loaded directly into the farmer's machinery or trailer, the professional operator and the farmer concerned shall ensure traceability of that seed by issuing and retaining documents indicating the species and variety, quantity, the time of transfer and lot identification.
6. The Commission may, by means of implementing acts, adopt specific requirements concerning sealing, fastening, size and form of packages, bundles and containers of specific species of PRM, and specify conditions for the marketing of seeds in bulk. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).

SECTION 5

LABELLING REQUIREMENTS

Article 15

Official label

1. Pre-basic, basic and certified material and seeds shall be identified, and their compliance with this Regulation shall be attested, through an official label, issued after the conclusion by the competent authority that the requirements referred to in Article 7 have been fulfilled.
2. The official label shall be issued by the competent authority and bear a serial number given by the competent authority.

It shall be printed by:

 - (a) the competent authority, if so requested by the professional operator, or if the professional operator is not authorised to carry out certification under official supervision, by the competent authority in accordance with Article 10; or
 - (b) the professional operator, under the official supervision of the competent authority, where the professional operator is authorised to carry out certification under official supervision in accordance with Article 10.
3. The official label shall be affixed to the outside of the bundle, package or container by the professional operator under the official supervision of the competent authority, or by a person acting under the responsibility of the professional operator.
4. The official label shall be newly issued. Adhesive official labels may be used, if so authorised by the competent authority where there is no risk that they can be re-used.
5. The Commission is empowered to adopt delegated acts in accordance with Article 75, supplementing this Article by establishing the following rules on:

- (a) the digital recording of all actions taken by the professional operators and the competent authorities in order to issue the official label;
- (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;
- (c) the technical arrangements for the issuance of electronic official labels.

Following the adoption of such delegated act, the official label may also be issued in an electronic form ('electronic official label').

- 6. By way of derogation from paragraphs 1 to 5, pre-basic, basic material and seed basic material and seed and certified material and seed, imported from third countries pursuant to Article 39, shall be marketed in the Union with the respective OECD label that was accompanying them at import.

Article 16

Operator's label

Standard material and standard seed shall be identified through an operator's label. That label shall attest that standard material or standard seed complies with the relevant production and marketing requirements, referred to in Article 8, on the basis of inspections, sampling and testing carried out by the professional operator.

The operator's label shall be issued, printed and affixed by the professional operator, or by a person acting under the responsibility of the professional operator, on the outside of a bundle, package or container.

Article 17

Content of labels

- 1. The official label and the operator's label, shall be written in at least one of the official Union languages.
- 2. The official label and the operator's label shall be legible, indelible, not modifiable if tampered with, printed on one side, not having been used previously, and easily visible.
- 3. Any space of the official label or the operator's label apart from the elements mentioned in paragraph 4, may be used for additional information by the competent authority. Such information shall be presented in letters not larger than those used for the content of the official label or the operator's label as referred to in paragraph 4. That additional information shall be strictly factual, it shall not represent advertising material, and shall be related only to the production and marketing requirements or to labelling requirements for genetically modified organisms or category 1 NGT plants as defined in Article 3(7) of Regulation (EU) .../... (Office of Publications, please insert reference to NGT Regulation ...). .
- 4. The Commission shall, by means of implementing acts, specify the content, size, colour and form of the official or operator's label, as applicable, in relation to the respective categories or types of PRM, for:
 - (a) the official label referred to in Article 15(1);
 - (b) the operator's label referred to in Article 16;

- (c) the label for mixtures referred to in Article 21(1);
- (d) the label for preservation mixtures referred to in Article 22(1);
- (e) the label for repackaged and relabelled seeds referred to in Article 23(5);
- (f) the label for PRM belonging to conservation varieties referred to in Article 26(2);
- (g) the label for PRM marketed to final users referred to in Article 28(1), point (a);
- (h) the label for the PRM marketed by certain gene banks, organisations and networks referred to in Article 29;
- (i) the label for breeder's material referred to in Article 31(2);
- (j) the label for PRM of not yet registered varieties referred to in Article 32(5);
- (k) the label for PRM authorised in cases of temporary difficulties in the supply referred to in Article 33(2); and
- (l) the label for seeds with a provisional authorisation for marketing referred to in Article 34(3);
- (m) the label for seeds which are not finally certified referred to in Article 35(3);
- (n) the label for PRM imported from third countries referred to in Article 40(1) and (2).

That implementing act shall be adopted in accordance with the examination procedure referred to in Article 76(2).

5. The competent authority may authorise the professional operator to indicate information other than the content referred to in paragraph 4, and other than advertising material, placed at the periphery of the official label, in an area of a size not larger than 20 % of the total area of the official label, bearing the title 'Non official information'. Such information shall be in letters not larger than those used for the content of the official label as referred to in paragraph 4.

Article 18

Reference to lots

The official label and the operator's label shall be issued for each lot.

If a lot of the same variety is split into two or more lots, a new official label or operator's label shall be issued for each lot.

If several lots of the same variety are merged into a new lot, a new official label or operator's label shall be issued for that new lot.

Article 19

Non-compliance of PRM with production and marketing requirements

In the case where official controls carried out during the marketing of PRM show that pre-basic, basic, certified seeds or material, or standard seeds or material, have not been produced or marketed within the Union in compliance with the respective requirements referred to in Articles 7 or 8, or in the case where the varietal identity and purity of the PRM were not confirmed in the control plot testing in accordance with Article 24, the competent authorities shall ensure that the professional operator concerned takes the necessary corrective actions

concerning the PRM concerned and its premises and production methods, as appropriate. Those actions shall aim at achieving one or more of the following elements:

- (a) the PRM concerned complies with the respective requirements;
- (b) the PRM concerned is withdrawn from the market or is used as material other than PRM;
- (c) with the exception of standard seed or standard material, the PRM concerned is produced or marketed under a lower category, in accordance with the requirements applicable for that category;
- (d) the professional operator is sanctioned by additional means to the withdrawal or modification of the authorisation referred to in Article 11.

Article 20

PRM to be only produced and marketed as pre-basic, basic or certified seeds or material

1. PRM belonging to the genera or species as listed in Annex IV may only be produced and marketed as pre-basic, basic or certified seeds or material.
2. The Commission is empowered to adopt a delegated act in accordance with Article 75 in order to amend Annex IV.

The delegated act referred to in the first subparagraph shall add a genus or a species to Annex IV, if both the following conditions are fulfilled:

- (a) there is a need for higher guarantees for the quality of seeds belonging to that genus or species; and
- (b) the costs of the certification activities, necessary to produce and market the respective seed as pre-basic, basic and certified seed are proportionate:
 - (i) to the purpose of ensuring food and feed security, or ensuring high value of industrial processing; and
 - (ii) to the economic benefits deriving from the highest standards concerning identity and quality of the seed, resulting from the compliance with the requirements for pre-basic, basic and certified seed compared to those for standard seed.

That proportionality shall be based on an overall assessment of the following elements in combination: the importance of the respective genus or species for the Union food and feed security; the volume of its production in the Union; its demand by the professional operators and operators of the food/feed industry; the costs of the production of pre-basic, basic and certified seed compared to the cost of production of other seed of the same genus or species; and the economic benefits derived from the production and marketing of pre-basic, basic and certified seed compared to other seed of the same genus or species.

The delegated act referred to in the first subparagraph shall remove a genus or a species from Annex IV, if one of the conditions set out in the second subparagraph, point (b), points (i) and (ii), is no longer fulfilled.

SECTION 6

SPECIFIC REQUIREMENTS FOR MIXTURES OF SEEDS, RE-PACKAGING OF SEEDS AND CONTROL PLOT TESTS FOR SEEDS

Article 21

Mixtures of seeds

1. Mixtures of certified seed or mixtures of standard seed of various genera or species listed in Part A of Annex I and complying with the requirements of Articles 5 to 8, as well as of different varieties of those genera or species, may be produced and marketed in the Union, if they fulfill the requirements of this Article.

The seeds included in those mixtures shall be accompanied by:

- (a) an official label, where the mixture consists only of certified seeds; or
- (b) an operator's label, in the case where the mixture consists only of standard seed, or of certified and standard seed.

For the purposes of the second subparagraph, point (a), the professional operators shall submit to the competent authority the list of constituent varieties of the mixture and their ratios, for verification of eligibility of those varieties.

2. Mixtures of seeds referred to in paragraph 1 may only be produced by professional operators, which are authorised for that purpose by the competent authority. In order to receive an authorisation for the production of such mixtures, professional operators shall fulfil the following requirements:

- (a) having installed suitable mixing equipment and appropriate procedures ensuring that the finished mixture is uniform and the stated ratio between the component varieties in each container can be achieved;
- (b) having a person in charge who has direct responsibility for the mixing and packaging operation; and
- (c) maintaining a register of seed mixtures and their intended use.

3. The mixing and packaging operation of the seeds referred to in paragraph 1, point (a), shall be carried out under the supervision of the competent authority.

The mixing operation shall be carried in a manner to ensure that there is no risk of presence of seeds not intended for inclusion and that the resulting mixture is as homogeneous as possible.

The weight of the seed in a single container, which consists of a mixture of both small-seeded species and species of which the seed is larger than the size of wheat, shall not exceed 40 kg.

4. The Commission may, by means of implementing acts, specify, on the basis of technical and scientific developments and the experience gained from the application of this Article, rules concerning:

- (a) the mixing equipment and procedure;
- (b) maximum lot sizes for particular species and varieties.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).

Article 22

Preservation mixtures

1. By way of derogation from Article 21(1), Member States may authorise the production and marketing of a mixture of seeds of various genera or species listed in Part A of Annex I, as well as of different varieties of those genera or species, together with seeds of genera or species of other Parts of that Annex, or of genera or species not listed in that Annex, if such a mixture fulfils all of the following conditions:
 - (a) it contributes to the conservation of genetic resources, or the restoration of the natural environment; and
 - (b) it is naturally associated with a particular area ('source area') contributing to the conservation of genetic resources or the restoration of the natural environment;
 - (c) it complies with the requirements of Annex V.

Such mixture constitutes a 'preservation mixture' and this shall be mentioned on its label.

2. The Commission is empowered to adopt a delegated act, in accordance with Article 75, amending Annex V concerning the following elements:
 - (a) authorisation requirements for mixtures of seeds collected directly from a natural place belonging to a defined source area, for the conservation and restoration of the natural environment (directly harvested preservation mixtures);
 - (b) authorisation requirements for crop-grown preservation mixtures;
 - (c) use and content of certain species;
 - (d) requirements on sealing and packaging;
 - (e) requirements for the authorisation of the professional operators.

Those amendments shall be based on the experience gathered by the implementation of this Article, and any technical and scientific developments and the improvement of the quality and identification of preservation mixtures. They may concern particular genera or species only.

3. Professional operators shall report to the respective competent authorities, for each production season, the amount of preservation mixtures produced and marketed by them.

The Member States shall report on request to the Commission and to the other Member States the amount of preservation mixtures produced and marketed in their territory and, where applicable, the names of competent authorities responsible for plant genetic resources or of organisations recognised for this purpose.

Article 23

Re-packaging and re-labelling of seed lots

1. Seed lots of pre-basic, basic and certified seed shall be repackaged and relabeled in accordance with this Article, Articles 14 and 15, where this is necessary for splitting or merging of lots.
2. The re-packaging and re-labelling of a seed lot shall be conducted by:

- (a) the professional operator under the official supervision of the competent authority; or
- (b) a seed sampler, who is authorised and supervised for that purpose by, and reports to, the competent authority.

In the case of point (b), the professional operator shall be notified in advance by the competent authority so as to organise its co-operation with the seed sampler.

- 3. The professional operator and the seed sampler carrying out re-packaging and re-labelling of seed lots, shall take all steps to ensure that during the operation of re-packaging, the identity and varietal purity of the seed lot is maintained, no contamination occurs, and the resulting seed lot is as homogeneous as possible.
- 4. The professional operators and the seed sampler shall keep records, when re-packaging and re-labelling seed lots, for 3 years after the respective re-labelling and re-packaging. The information contained in the records shall include:
 - (a) the reference number of the original seed lot;
 - (b) the reference number of the repackaged or relabeled seed lot;
 - (c) the weight of the original seed lot;
 - (d) the weight of the re-packaged or relabeled seed lot;
 - (e) the date of final disposal of the lot.

Those records shall be kept in a form allowing to identify and verify the authenticity of the original seed lot, which is subject to re-packaging and re-labelling. They shall be made available to the competent authority on request.

- 5. The original seals and labels shall be removed from the seed lot. The professional operators or the seed sampler shall also keep the label, which was replaced, of each component seed lot.

The new labels shall either state the original seed lot reference number or a new seed lot reference number assigned by the competent authority.

- 6. Where the competent authority assigns a new seed lot reference number, it shall either keep a record of the former seed lot reference number or ensure that this former number is included on the new labels.
- 7. Repackaging of mixtures of certified seed may only be carried out where the professional operator or the seed sampler has established that the ratio of the different components within a mixture will be maintained during the repackaging process.

Article 24

Control plot tests for pre-basic, basic and certified seeds

- 1. After the production of pre-basic, basic and certified seeds, the competent authorities shall carry out annual field tests, immediately after, or during, the season following the drawing of the samples, additionally to field inspection, in plots where the variety is compared to an officially validated sample of seed of the variety to ascertain that the characteristics of varieties have remained unchanged in the process of production and to verify the varietal identity and purity of individual seed lots.

Those tests shall be used for assessing:

- a) whether the requirements for the next categories or generations are fulfilled. When, as a result of such tests of the immediately descending category or generation, it is established that the varietal identity or purity of the seeds has not been maintained, the competent authority shall not certify seed derived from the lot concerned;
 - b) that such seed complies with the respective identity, quality and other certification requirements. When, as a result of such test, it is established that the requirements of Article 7 have not been fulfilled, the competent authority shall withdraw the lot concerned from the market or ensure that it complies with the applicable requirements.
2. The proportion of these control plot tests for pre-basic, basic and certified seed shall be determined on the basis of a risk analysis concerning possible non-compliance of the seeds with the respective requirements.
3. On the basis of the risk analysis referred to in paragraph 2, control plot tests shall be carried out through samples taken by the competent authority from the harvested seed.
4. The Commission is empowered to adopt delegated acts in accordance with Article 75, supplementing this Regulation by setting out rules for the control plot tests of seeds per genera or species. Those rules shall adapt to the development of scientific and technical knowledge and international standards, and may be established per particular genera, species or categories. They may concern the following:
 - (a) criteria for the conduct of the risk analysis referred to in paragraph 2;
 - (b) the testing procedure;
 - (c) evaluation of results of the tests.
5. In the case of control of varietal identity and purity, the use of bio-molecular techniques may be used as a supplementary tool where the results of the control plot tests referred to in paragraph 1 are non conclusive

Article 25

Control plot tests for standard seeds

1. After the marketing of standard seeds, the competent authorities shall carry out control plot tests to check whether the seeds comply with the respective varietal identity and varietal purity requirements, and with other requirements, as appropriate.
2. The proportion of the control plot tests shall be determined on the basis of a risk analysis concerning possible non-compliance of the respective seeds with those requirements.
3. Based on the risk analysis of non-compliance with the respective rules, the control plot tests referred to in paragraph 1 shall be carried out annually, by using samples taken by the competent authority from homogeneous seed lots. Those tests shall assess identity and varietal purity of the seed concerned, and its germination rate and analytical purity.
4. In the case of control of varietal identity and purity, the use of bio-molecular techniques may be use as a supplementary tool where the results of the control plot tests referred to in paragraph 1 are non conclusive.

SECTION 7

DEROGATIONS FROM THE REQUIREMENTS OF ARTICLES 5 TO 25

Article 26

PRM belonging to conservation varieties

1. By way of derogation from Article 20, PRM belonging to a conservation variety registered in a national variety register referred to in Article 44(1), point (b), may be produced and marketed in the Union as standard seed or material, if it complies with all the requirements concerning standard seed and material for the respective species, as referred to in Article 8.
2. PRM referred to in paragraph 1 shall be accompanied by an operator's label with the indication 'Conservation variety'.
3. A professional operator who uses this derogation shall annually notify to the competent authority this activity, with regard to the species and quantities concerned.

Article 27

PRM of heterogeneous material

1. By way of derogation from Article 5, PRM of heterogeneous material may be produced and marketed within the Union without belonging to a variety. The heterogeneous material shall be notified to and register by the competent authority prior to its production and/or marketing, in accordance with the requirements set out in Annex VI.
2. By way of derogation from Articles 7(1), (3) and Article 8(1), (3), the PRM of heterogeneous material referred to in paragraph 1 shall be produced and marketed in accordance with the requirements set out in Annex VI.
3. The Commission is empowered to adopt a delegated act in accordance with Article 75, amending Annex VI. Those amendments may concern all, or particular genera or species only, and shall:
 - (a) improve the provision of information in notifications, description and identification of heterogeneous PRM, on the basis of experience gained by the application of the respective rules;
 - (b) improve the rules concerning packaging and labelling of heterogeneous PRM, on the basis of the experience gained from the checks carried out by the competent authorities;
 - (c) improve the rules on maintenance of heterogeneous PRM, on the basis of the emergence of best practices.

Those amendments shall be adopted in order to adapt to the development of the respective technical and scientific evidence, and the international standards, and to follow up on the experience gained by the application of this Article concerning all or certain genera or species only.

4. Any professional operator producing and/or intending to market PRM of heterogeneous material shall submit a notification to the competent authority prior to marketing. If no further information is requested by the national competent authority

within a time determined by the competent authority, the PRM of heterogeneous material may be marketed.

5. The professional operator shall ensure the traceability of the PRM of heterogeneous material by keeping information allowing to identify the professional operators which have supplied them with the initial material used for the production (parental material) of heterogeneous material.

The professional operator shall keep that information for 5 years.

The professional operator producing PRM of heterogeneous material intended for marketing shall also record and keep the following information:

- (a) the name of the species and denomination used for each notified heterogeneous material;
- (b) the type of technique used for the production of heterogeneous material as referred to in paragraph 1;
- (c) the characterisation of the notified heterogeneous material;
- (d) the breeding location of the PRM of heterogeneous material and production location;
- (e) the surface area for the production of PRM of heterogeneous material and quantity produced.

The competent authorities shall have access to the information referred to in this paragraph.

6. Article 54 shall apply accordingly for the suitability of the denomination of heterogeneous material.
7. Heterogeneous material as notified pursuant to paragraph 1, shall be registered by the competent authorities in a dedicated register ('heterogeneous material register').

The competent authorities shall keep, update and publish that register, and notify immediately its content and updates to the Commission.

Article 28

PRM marketed to final users

1. By way of derogation from Articles 5 - 12, 14, 15 and 20, PRM may be marketed to final users, if it complies with all of the following requirements:
 - (a) to bear an operator's label with the denomination of the PRM and the indication 'Plant reproductive material for final users – not officially certified' or, in the case of seeds, 'Seeds for final users – not officially certified';
 - (b) in case not belonging to a variety registered in a national variety register referred to in Article 44, to have a description made publicly available, on the basis of a private documentation, in a commercial catalogue kept by the professional operator. This private documentation shall be made available by the professional operator upon request to the competent authority;
 - (c) to be practically free from quality pests and any defects likely to impair its quality as reproductive material, and shall have satisfactory vigour and dimensions in respect of its usefulness as PRM, and, in the case of seeds, shall have satisfactory germination capacity; and

- (d) to be marketed as individual plants, or, in the case of seeds and tubers, in small packages.

A professional operator who uses this derogation shall annually notify this activity to the competent authority, with regard to the species and quantities concerned

2. The Commission shall, by means of implementing acts, adopt rules concerning the size, form, sealing and handling requirements concerning the small packages referred to in paragraph 1 point (d).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).

Article 29

PRM marketed to and between gene banks, organisations and networks

1. By way of derogation from Articles 5 to 25, PRM may be marketed to, or between, gene banks, organisations and networks with a statutory objective, or an objective official notified to the competent authority, to conserve plant genetic resources, whereby any of the activities are carried out for non-profit purposes.

It can be marketed as well from those gene banks, organisations and networks to persons who carry out conservation of that PRM as final consumers, for non-profit purposes.

In the cases provided for in the first and the second subparagraphs, PRM shall fulfil the following requirements:

- (a) be listed in a register kept by those gene banks, organisations and networks with an appropriate description of that PRM;
 - (b) be conserved by those gene banks, organisations and networks, and samples of that PRM be made available by them to the competent authorities upon request; and
 - (c) be practically free from quality pests and any defects likely to impair its quality as a reproductive material, and have satisfactory vigour and dimensions in respect of its usefulness as PRM, and, in the case of seeds, have satisfactory germination capacity.
2. The gene banks, organisations and networks shall notify the competent authority of the use of the derogation referred to in paragraph 1 and the species concerned.

Article 30

Seed exchanged in kind between farmers

1. By way of derogation from Articles 5 - 25, farmers may exchange seeds in kind, if such seeds fulfill all of the following conditions:
 - (1) are produced in the respective farmer's own premises;
 - (2) are derived from the respective farmer's own harvest;
 - (3) are not subject to a service contract conducted by the respective farmer with a professional operator performing seed production; and
 - (4) the seed is used for dynamic management of farmer's own seed for the purpose of contributing to agro-diversity.

2. Such seeds shall fulfil all of the following requirements:
 - (a) not to belong to a variety for which plant variety rights have been granted in accordance with Regulation (EU) 2100/94;
 - (b) to be limited to small quantities, defined by the competent authorities for specific species per year and per farmer, without using commercial intermediaries or public offer of marketing; and
 - (c) to be practically free from quality pests and any defects likely to impact their quality as seeds, and shall have satisfactory germination capacity.
3. Member States shall annually notify to the Commission and the other Member States the amounts per species defined in accordance with paragraph 2, point (b).

Article 31

Breeder's seed

1. By way of derogation from Articles 5 -25, a competent authority may authorise operators to market seed of generations preceeding the pre-basic category to another operator, for the purpose of breeding new varieties (breeders' seed).

The competent authority shall determine the duration of the authorisation and quantities per species, when granting that authorisation.
2. The PRM referred to in paragraph 1 shall be accompanied by a label issued by the professional operator, with the indication 'breeder's seed', that shall be affixed, as applicable, on the container, bundle or package of that material.

It shall be sealed and bear a lot number to be used for identification purposes and control plot testing before it is used as pre-basic seed.

Article 32

PRM of not yet registered varieties

1. By way of derogation from Article 5, a competent authority may authorise professional operators to produce and market, for the purposes of multiplication, pre-basic seeds, pre-basic material, basic seeds and basic material belonging to a variety not yet registered in a national variety register, referred to in Article 44, if all of the following requirements are fulfilled:
 - (a) the respective marketing sectors need to acquire that material or seeds in advance, so as to have sufficient stocks available, when the respective variety will be registered; and
 - (b) there is no risk that such an authorisation will lead to insufficient identification or quality of the marketed PRM; and
 - (c) the respective PRM belongs to a variety for which an application has been submitted for registration in a national variety register pursuant to Article 55.

Such authorisation may be granted for a maximum period of 3 years in the case of seeds, and 5 years in the case of PRM other than seeds, and for small quantities per species as specified by the competent authority.
2. By way of derogation from Articles 5, 7, 10 -12, 15, 20, 23 and 24, a competent authority may authorise professional operators for a maximum period of 3 years in

the case of seeds, and 5 years in the case of PRM other than seeds, and for small quantities per species as determined by the competent authority, to produce and market PRM belonging to a variety not yet registered in a national variety register referred to in Article 44, if all of the following requirements are fulfilled:

- (a) the authorised PRM is only used for tests or trials carried out by professional operators, in order to gather information on the cultivation or use of the variety concerned on farms;
 - (b) the marketing is made to those professional operators only, with no further marketing thereafter, who produces a report on results of the tests or trials, in relation to the information on the cultivation or use of that variety;
 - (c) there is no risk that such an authorisation will lead to insufficient identification or quality of the marketed PRM; and
 - (d) the authorised PRM complies with the requirements of standard PRM for the respective species.
3. In order to obtain the authorisation referred to in paragraphs 1 and 2, the professional operator shall submit to the competent authorities a request, indicating the information about the following:
- (a) the production of the stock of pre-basic seeds and material, and basic seeds and material, and certified seeds and material available before the variety registration and the envisaged tests and trials for the standard seeds and material;
 - (b) the breeder's reference of the variety indicated in the application for registration;
 - (c) the procedure for the variety maintenance, where applicable;
 - (d) the authority before which the application for the registration of the variety is pending, and the reference assigned to that application;
 - (e) the site where production will take place; and
 - (f) the quantities of the material to be made available on the market.
4. The Member States whose competent authorities have granted the authorisation referred to in paragraphs 1 and 2 shall annually inform the other Member States and the Commission thereof.
5. PRM referred to in paragraphs 1 and 2 shall be accompanied by a label, issued by the professional operator, with the indication 'Not yet listed variety'.

Article 33

Authorisation in cases of temporary difficulties in the supply

1. In order to remove temporary difficulties in the general supply of PRM that may occur in the Union due to adverse climatic conditions or other unforeseen circumstances, the Commission, by means of an implementing act, may authorise Member States for a maximum period of 1 year, to allow the marketing of the categories of pre-basic, basic or certified material or seed, which fulfils one of the following conditions:
- (a) belongs to a variety not included in a national variety register; or

- (b) complies with less stringent requirements than the requirements referred to in Article 7(1).

Point (a) shall apply by way of derogation from Articles 5, and point (b) shall apply by way of derogation from Articles 7(1).

That implementing act may set out the maximum quantities, which may be marketed per genera or species.

That implementing act shall be adopted in accordance with the examination procedure referred to in Article 76(2).

2. PRM referred to in paragraph 1 shall be accompanied by a label that states, as applicable, that the PRM in question belongs to a non-registered variety or fulfils less stringent quality requirements than the ones referred to in Article 7(1).
3. The Commission may decide, by means of an implementing act, that the authorisation concerned has to be repealed or amended, if it concludes that is no longer necessary or proportionate to the objective of removing the temporary difficulties in the general supply of the PRM concerned. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 76(2).
4. Member States may, without obtaining the authorisation of the Commission referred to in paragraph 1, allow, for a maximum period of 1 year, and for a limited amount of quantities per genera or species as necessary for supply difficulties in question, the production and marketing of seeds that fulfill germination rates reduced up to 15 percentage points compared to the ones set out pursuant to the implementing act referred to in Article 7(3).

Article 34

Provisional authorisation in urgency cases for marketing of seeds not certified as complying with applicable quality requirements

1. Competent authorities may authorise, for a maximum period of 1 month, the marketing of seeds as pre-basic, basic or certified seeds, before they have been certified to comply with the requirements referred to in Article 7 concerning germination, maximum content of other species or purity, if it is necessary to make that seed rapidly available on the market to address urgent needs of supply.
2. The authorisation referred to in paragraph 1 shall be granted on the basis of a an analytical report on the seed, issued by the professional operator, attesting its compliance with the requirements concerning germination, content of other species or purity, adopted pursuant to Article 7(1).

The name and address of the first recipient of the seeds shall be submitted to the competent authority by the professional operator. The professional operator shall keep the information on the provisional analytical report at the disposition of the competent authority.

3. The seeds referred to in paragraph 1 shall bear a label indicating ‘Provisional authorisation for marketing’marketing’.

Article 35

PRM which is not yet certified

1. PRM which has been produced in the Union, but has not yet been certified as pre-basic, basic or certified seed pursuant to Article 7, may be marketed with a reference to any of those categories, if all of the following requirements are fulfilled:
 - (a) prior to the harvesting, a field inspection has been carried out by the competent authority, or the professional operator under the official supervision of the competent authority, and that inspection has confirmed compliance of that PRM with the production requirements referred to in Article 7(1);
 - (b) it is in the process of being certified by the competent authority, or by the professional operator under the official supervision of the competent authority; and
 - (c) the requirements set out in paragraphs 2 to 5 are fulfilled.
2. PRM referred to in paragraph 1 may be marketed only by the professional operator who has produced that PRM to the professional operator who is to carry out the certification. Such PRM may not be further transferred to any other person before its final certification.
3. PRM referred to in paragraph 1, shall be accompanied by a label, issued by the professional operator, with the indication ‘Seeds/Material not yet finally certified’.
4. If the competent authority, where the PRM has been harvested (‘competent authority of production’), and the competent authority where the PRM is certified pursuant to Article 7 (‘competent authority of certification’) are different, they shall exchange the relevant information concerning the production and marketing of that PRM.
5. PRM which has been harvested in a third country, but has not yet been certified as pre-basic, basic or certified material pursuant to Article 7, may be marketed in the Union by reference to any of those categories, if:
 - (a) a decision on equivalence has been adopted pursuant to Article 39 concerning that third country;
 - (b) the requirements set out in paragraph 1, points (a) and (b), paragraphs 2 and 3, are fulfilled, and the professional operators of the third country concerned have been subject to the official supervision of their competent authorities;
 - (c) the competent authorities of the Member State and the third country concerned exchange between themselves the relevant information concerning the marketing of that material; and
 - (d) on request, the competent authorities of the third country concerned provide all relevant production information to the competent authority of the Member State of certification.

For the purposes of this paragraph, references made in paragraphs 1 - 5 to the competent authority of production shall be construed as references made to the competent authority of the third country concerned, and references made therein to the requirements set out pursuant to Article 7(1) shall be construed as references made to equivalent requirements of the third country, as recognised pursuant to Article 39(2).

Article 36

More stringent production and requirements

1. The Commission, by means of implementing acts, may authorise the Member States to impose, with regards to production and marketing of PRM, more stringent production or marketing requirements than those referred to in Articles 7 and 8, in all or part of the territory of the Member State concerned, provided that those more stringent requirements correspond to specific production conditions in, and agro-climatic needs, of that Member State in regard to the respective PRM.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).

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

- (a) the draft provisions containing the proposed requirements; and
- (b) a justification on the necessity and proportionality of such requirements.

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

- (a) the implementation of the draft provisions, as referred to in paragraph 2, point (a), ensures the improvement of the identity and quality of the PRM concerned, and it is justified by the specific agricultural or climatic conditions of the Member State concerned; and
- (b) the draft provisions are necessary and proportionate to the objective of the measure referred to in paragraph 2, point (a).

4. Where applicable, each Member State shall, by ... [one year after date of application of this Regulation], review the measures it has adopted pursuant to Article 5 of Directive 66/401/EEC, Article 5 of Directive 66/402/EEC, Article 7 of Directive 2002/54/EC, Article 24 of Directive 2002/55/EC, Article 5 of Directive 2002/56/EC and Article 7 of Directive 2002/57/EC, and either repeal those measures or amend them to comply with the production and marketing requirements set out in, and adopted pursuant to, Articles 7 and 8.

The Member State concerned shall inform the Commission and the other Member States of those actions.

The Commission may, by means of implementing acts, decide that the measures, as referred to in the first subparagraph, are to be repealed or amended, in case they are considered to be unnecessary and/or disproportionate to their objective. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).

Article 37

Emergency measures

1. Where the production or marketing of PRM is likely to constitute a serious risk to human, animal or plant health, environment or cultivation of other species, and such risk cannot be contained satisfactorily by means of measures taken by the Member State concerned, the Commission shall take, without delay, by means of implementing acts, any appropriate interim emergency measures. Such measures shall be limited in time. They may include provisions restricting or prohibiting the marketing of the PRM concerned or laying down appropriate conditions for its production or marketing, depending on the gravity of the situation.

Such measures may be taken on the Commission's own initiative or at the request of a Member State. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).

On duly justified imperative grounds of urgency to address a serious risk to human health, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 76(3).

2. Where a Member State officially informs the Commission of the need to take emergency measures and the Commission has not acted in accordance with paragraph 1, that Member State may adopt the appropriate interim emergency measures. Those measures may include provisions restricting, prohibiting or laying down appropriate conditions for the production or marketing of PRM within the territory of that Member State, depending on the gravity of the situation. The Member State concerned shall immediately inform the other Member States and the Commission of the measures adopted, stating the grounds for its decision.
3. The Commission may decide, by means of implementing acts, that the national interim emergency measures referred to in paragraph 2 are to be repealed or amended, if it considers that those measures are not justified in view of the respective risk as referred to in paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2). The Member State concerned may maintain its national interim emergency measures until the date of application of the implementing act(s) referred to in this paragraph.

Article 38

Temporary experiments to seek improved alternatives to provisions of this Regulation

1. By way of derogation from Articles 2, 5, 6, 7, 8 and 20, the Commission may, by means of implementing acts, decide on the organisation of temporary experiments to seek improved alternatives to provisions of this Regulation concerning the genera and species it applies to, the requirements for belonging to a registered variety, the production and marketing requirements for pre-basic, basic, certified and standard material or seed, and the obligation to belong to pre-basic, basic and certified material or seed.

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 2, 5, 6, 7, 8 and 20 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 76(2) and shall specify one or more of the following elements:
 - (a) the genera or species concerned;
 - (b) the conditions of the experiments per genera or species;
 - (c) the duration of the experiment;
 - (d) the monitoring and reporting obligations of the participating Member States.

Those acts shall adapt to the evolution of techniques for production of the PRM concerned, as shall be based on any comparative trials 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 2, 5, 6, 7, 8 or 20.

SECTION 8

IMPORTS FROM THIRD COUNTRIES

Article 39

Imports on the basis of Union equivalence

1. PRM may only be imported from third countries, if it is established, pursuant to paragraph 2, that it fulfils requirements equivalent to those applicable to PRM produced and marketed in the Union.

However, no such import shall be allowed, and no such equivalence shall be recognised pursuant to paragraph 2, for the preservation mixtures such as those referred to in Article 22, and for PRM such as that subject to the derogations of Articles 26 - 30.

2. The Commission may recognise, by means of implementing acts, that PRM of specific genera, species or categories produced in a third country, or particular areas of a third country, fulfils requirements equivalent to those applicable to PRM 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;
 - (b) an audit carried out by the Commission in the third country concerned, showing that the PRM concerned fulfils requirements equivalent to those applicable to PRM produced and marketed in the Union, where that audit has been considered necessary by the Commission; and
 - (c) in the case of seeds, the fact that this the country concerned participates in the OECD Schemes for the Varietal Certification of Seed moving in International Trade and implements the methods of the International Seed Testing Association (ISTA), or, where applicable, complies with the rules of the Association of Official Seed Analysts (AOSA).

For that purpose, the Commission shall examine:

- (a) the third country's legislation on the species concerned;
- (b) the structure of the competent authorities of the third country and its control services, the powers available to them, the guarantees that can be provided with regard to the application and enforcement of the legislation of the third country applicable to the sector concerned, and the reliability of the official certification procedures;
- (c) the performance by the competent authorities of the third country of adequate official controls concerning the identification and quality of the PRM of the species concerned;
- (d) the guarantees given by the third country that:
 - (i) the conditions applied to the production sites from which PRM are exported to the Union comply with requirements that are equivalent to those referred to in this Article; and

- (ii) those production sites are subject to regular and effective controls by the competent authorities of the third country.

The Commission may also carry out audits to verify the compliance with points (b) to (d) of the second subparagraph.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).

3. The implementing act referred to in paragraph 2 may provide for one or more of the following elements, as appropriate for the respective PRM:
 - (a) conditions relating to inspections in the production site, carried out in third countries;
 - (b) in the case of seeds, conditions relating to the issuance by the third country of a certificate provided by the International Seed Testing Association;
 - (c) conditions relating to seed not yet finally certified;
 - (d) conditions relating to packaging, sealing and marking of PRM;
 - (e) conditions relating to the production, identity and marketing of PRM, in addition to the ones provided for by the third country's legislation, if so needed to address particular aspects concerning the identity and quality of that PRM;
 - (f) requirements to be fulfilled by the professional operators producing and marketing that PRM.
4. The Commission may, by means of implementing acts, recognise that the controls on variety maintenance carried out in the third country afford the same guarantees as those provided for in Article 72(1), (2) and (4), if varieties registered in a national variety register or in the Union variety register are to be maintained in the third country concerned.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).

Article 40

Labelling and information to be provided for the PRM imported from third countries

1. Pre-basic, basic and certified seeds referred to in Article 39 may only be imported from third countries, if they are accompanied by an OECD label.

Pre-basic, basic and certified material referred to in Article 39 may only be imported from third countries if it is accompanied by an official label issued by the competent authority of the third country concerned.

Those labels shall contain all of the following information:

- (a) the indication 'meets EU rules and standards';
- (b) the species, variety, category and lot number of the PRM concerned;
- (c) the date of closure, in case of marketing in containers or packages;
- (d) the third country of production and the respective competent authority;
- (e) where applicable, the last third country from which the PRM is imported and the last third country where the PRM has been produced;

- (f) in the case of seeds, the declared net or gross weight of the imported seeds or declared number of imported lots of seeds;
 - (g) the name of the person importing the PRM.
- 2. Standard seed and material referred to in Article 39 may only be imported from third countries, if it is accompanied by an operator's label containing all of the following information:
 - (a) the indication 'meets EU rules and standards';
 - (b) the species, variety, category and lot number of the PRM concerned;
 - (c) the date of closure, in case of marketing in containers or packages;
 - (d) the third country of production;
 - (e) where applicable, the last third country from which the PRM is imported and the last third country where the PRM has been produced;
 - (f) in the case of seeds, the declared net or gross weight of the imported seeds or declared number of imported lots of seeds;
 - (g) the name of the person importing the PRM.
- 3. PRM may only be imported into the Union after the electronic submission of the information referred to in paragraph 1 or 2 by the importer to the competent authority of the Member State of import.
- 4. Member States shall immediately notify the Information management system for official controls (IMSOC), referred to in Article 131 of Regulation (EU) 2017/625, of all established non-compliances of the imported PRM concerning the requirements of paragraphs 1 and 2.

CHAPTER III

REQUIREMENTS FOR PROFESSIONAL OPERATORS

Article 41

Obligations of professional operators producing PRM

Professional operators, which produce PRM, shall:

- (a) be established in the Union;
- (b) be registered in the register referred to Article 65 of Regulation (EU) 2016/2031, in accordance with Article 66 of that Regulation;
- (c) be available personally, or designate another person, to liaise with the competent authorities for facilitating the official controls;
- (d) identify and monitor the critical points of the production process, or of the marketing, which may influence the identity and quality of PRM;
- (e) keep records of the monitoring of the critical points referred to in point (b) and provide them for examination when requested by the competent authorities;
- (f) ensure that lots of PRM remain separately identifiable;
- (g) keep updated information on the address of the premises and other locations used for the production of PRM;

- (h) make sure that competent authorities have access to the premises and other locations of production, including premises and fields of third contracting parties, and to the records of the monitoring and all related documents;
- (i) take measures, where appropriate, for the maintenance of the identity of the PRM in accordance with the requirements of this Regulation;
- (j) make available on request of the competent authorities any contracts with third parties.

Article 42

Traceability

1. Professional operators shall ensure that PRM is traceable at all stages of production and marketing.
2. For the purposes of paragraph 1, professional operators shall keep information allowing them to identify:
 - (a) the professional operators, which have supplied them with the seeds and the material concerned;
 - (b) the persons to whom they have supplied PRM and the PRM concerned, except in case of final users.

On request, they shall make such information available to the competent authorities.
3. Professional operators shall keep records of the PRM and the professional operators and persons referred to in paragraph 2 for 3 years after that material has been respectively supplied to or by them.

Article 43

Annual notification of the intended production and certification of pre-basic, basic and certified seed and material

Every year, professional operators shall notify the competent authorities about:

- (a) their intention to produce pre-basic, basic and certified material or pre-basic, basic and certified seed, at least one month before the beginning of that production; and
- (b) the production of pre-basic, basic and certified material that started in previous years and continues in the year concerned.

That notification shall state the plant species, varieties and categories concerned and the exact location of production.

CHAPTER IV VARIETY REGISTRATION

SECTION 1

VARIETY REGISTERS

Article 44

Establishment of national variety registers

1. Each Member State shall establish and publish, in electronic format, and shall keep updated a single national register of varieties ('national variety register') containing:
 - (a) all varieties registered pursuant to the procedure set out in Articles 55 - 68;
 - (b) the conservation varieties referred to in Article 26 and registered pursuant to Article 53.
2. PRM belonging to a variety registered in at least one national variety register may be produced and marketed in the Union, in accordance with this Regulation.
3. Following the establishment of their national variety registers, as well as following any of their updates, Member States shall immediately notify them to the Commission for inclusion in the Union variety register referred to in Article 45.
4. This Article, and Articles 45 to 74, may not apply to varieties which are bred solely as components of hybrid varieties.

Article 45

Establishment of a Union variety register

1. The Commission shall establish, publish, in an electronic format, and keep updated a single register of varieties ('the Union variety register').
2. The Union variety register shall include the varieties, registered in national variety registers and notified in accordance with Article 44.

The Union variety register may be accessible by an electronic portal containing other registers of plant variety rights, forest reproductive material or other plants.

Article 46

Contents of the national and Union variety registers

1. The national variety registers and Union variety register shall contain all the elements set out in Annex VII, concerning the varieties referred to in Article 44(1), point (a).

In the case of the conservation varieties referred to in Article 44(1), point (b), those registers shall indicate at least a brief summary of the officially recognised description, the initial region of their origin, their denomination and the person that maintains them.
2. The Commission is empowered to adopt a delegated act in accordance with Article 75, in order to amend Annex VII, taking into account the technical and scientific developments, and on the basis of gained experience indicating the need of competent authorities or professional operators to obtain more precise information about the registered varieties.

SECTION 2

REQUIREMENTS FOR REGISTRATION OF VARIETIES

Article 47

Requirements for registration in national variety registers

1. Varieties shall be registered in a national variety register in accordance with Articles 55 to 68, only if:
 - (a) they have:
 - (i) an official description showing compliance with the requirements of distinctness, uniformity and stability set out in Articles 48, 49 and 50, and fulfil the requirements for satisfactory value for sustainable cultivation and use, as set out in Article 52; or
 - (ii) an officially recognised description pursuant to Article 53, if they are conservation varieties;
 - (b) they bear a denomination deemed suitable pursuant to Article 54;
 - (c) where the varieties contain or consist of genetically modified organisms, the organism is authorised 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;
 - (d) where the varieties 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 ...), that plant has obtained a declaration of category 1 NGT plant status pursuant to Article 6 or 7 of that Regulation or is progeny of such plants;
 - (e) where the varieties contain or consist of a category 2 NGT plant as defined in Article 3(8) of Regulation (EU) .../... (Office of Publications, please insert reference to NGT Regulation), that plant has been authorised pursuant to Chapter III of that Regulation;
 - (f) where the varieties are tolerant to herbicides, they are subject to cultivation conditions for the production of PRM and for any other purpose, adopted pursuant to paragraph 3 or, in the case they have not been adopted, as adopted by the competent authorities responsible for registration, to avoid the development of herbicide resistance in weeds due to their use;
 - (g) where the varieties have particular characteristics other than the ones referred to in point (f) that may lead to undesirable agronomic effects, they are subject to cultivation conditions for the production of PRM and any other purpose, adopted pursuant to paragraph 3 or, in the case they have not been adopted, as adopted by the competent authorities responsible for their registration, to avoid those particular undesirable agronomic effects, such as the development of resistance of pests to the respective varieties or undesirable effects on pollinators.

A variety may not be registered with both an official description and an officially recognised description.

2. The Commission shall adopt, by means of implementing acts, specific requirements concerning:
 - (a) distinctness, uniformity and stability per genera or species of varieties, as referred to in paragraph 1, point (a), based on the applicable protocols of the International Union for the Protection of new Varieties of Plants (UPOV),

protocols established by the CPVO, or other relevant technical and scientific evidence; and

- (b) specific requirements concerning the distinctness, uniformity and stability per genera and species, as referred to in point (a), for organic varieties suitable for organic production, as defined in Article 3 of Regulation (EU) 2018/848, based on the applicable protocols established by UPOV or the CPVO, and in particular by adjusting the requirements concerning uniformity;

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).

They shall adapt the respective requirements to the development, where applicable, of international standards, and the new scientific and technical knowledge.

Until the requirements referred to in point 2(b) are established, the assessment of uniformity of varieties suitable for organic production, other than the varieties referred to in Article 68(1), shall be carried out on the basis of off-types. For self-pollinating species, a population standard of 10% and an acceptance probability of at least 90 % shall be applied. For open pollinated out-crossing species, a population standard of 20% shall be applied and an acceptance probability of at least 80 % shall be applied.

- 3. The Commission is empowered to adopt delegated acts in accordance with Article 75, supplementing this Regulation with the minimum cultivation conditions to be adopted by the competent authorities pursuant to paragraphs 1(f) and (g), concerning:
 - (i) measures in the field, including crop rotation;
 - (ii) monitoring measures;
 - (iii) the mode of notification of the conditions referred to in point (i) to the Commission and the other Member States;
 - (iv) rules for reporting from professional operators to the competent authorities concerning the application of the conditions referred to in point (i);
 - (v) the indication of the conditions referred to in point (i) in the national variety registers.

Those conditions shall be based on the latest scientific and technical knowledge.

- 4. For the purpose of registering a variety in its national variety register, a competent authority shall accept, without any further examination, an official description or an official examination of the requirements for value for sustainable cultivation and use, as referred to in paragraph 1, point (a)(i), which has been produced by a competent authority of another Member State.

Article 48

Distinctness

- 1. For the purposes of the official description, referred to in Article 47(1), point (a), a variety shall be deemed to be distinct, if it is clearly distinguishable, by reference to the expression of the characteristics that results from a particular genotype or combination of genotypes, from any other variety whose existence is commonly

known on the date of the submission of the application established in accordance with Article 58.

2. The existence of another variety, as referred to in paragraph 1, shall be deemed to be commonly known, if one or more of the following conditions are complied with:
 - (a) the variety is included in a national variety register;
 - (b) an application for registration of the variety, or an application for granting a plant variety right in respect of that variety, has been filed in the Union; or
 - (c) an official description of that variety exists in the Union, it is commonly known worldwide, or the technical examination has been conducted pursuant to Article 59.
3. Where paragraph 2, point (c) applies, the person(s) responsible for the technical examinations shall make available to the competent authorities the official description of the variety examined by them.

Article 49

Uniformity

For the purposes of the official description, a variety shall be deemed to be uniform if, subject to the variation that may be expected from the particular features of its reproduction and type, it is sufficiently uniform in the expression of the characteristics included in the examination for distinctness, as well as in the expression of any other characteristics used for its official description.

Article 50

Stability

For the purposes of the official description, a variety shall be deemed to be stable if the expression of the characteristics included in the examination for distinctness, as well as of any other characteristics used for the variety description, remains unchanged after repeated reproduction or, in the case of cycles of reproduction, at the end of each such cycle.

Article 51

Granted plant variety rights

If a variety has been granted a plant variety right pursuant to Article 62 of Regulation (EC) No 2100/1994 or pursuant to the legislation of a Member State, that variety shall be deemed to be distinct, uniform and stable for the purposes of the official description and to have a suitable denomination for the purposes of Article 47(1), point (b).

Article 52

Value for sustainable cultivation and use

1. For the purposes of Article 47(1), point (c), the value of a variety for sustainable cultivation and use of a variety shall be considered as satisfactory if, compared to other varieties of the same species registered in the national variety register of the respective Member State, its characteristics, taken as a whole, offer a clear improvement for the sustainable cultivation and the uses which can be made of the crops, other plants or the products derived therefrom.

The characteristics referred to in the first subparagraph are the following, as appropriate for the species, regions, agro-ecological conditions and uses concerned:

- (a) yield, including yield stability and yield under low-input conditions;
 - (b) tolerance/resistance to biotic stresses, including plant diseases caused by nematodes, fungi, bacteria, viruses, insects and other pests;
 - (c) tolerance/resistance to abiotic stresses, including adaptation to climate change conditions;
 - (d) more efficient use of natural resources, such as water and nutrients;
 - (e) reduced need for external inputs, such as plant protection products and fertilisers;
 - (f) characteristics that enhance the sustainability of storage, processing and distribution;
 - (g) quality or nutritional characteristics.
2. For the purpose of paragraph 1, Member States may collaborate with other Member States with similar agro-ecological conditions. Those Member States may establish shared facilities for carrying out the examination for value for sustainable cultivation and use.
3. The Commission is empowered to adopt delegated acts in accordance with Article 75, supplementing this Regulation by:
- (a) establishing the minimum requirements for carrying out the examination referred to under paragraph 1;
 - (b) establishing the methodologies for assessing the characteristics listed under paragraph 1, points (a) to (g);
 - (c) establishing the standards for the evaluation and the reporting of the results of the examination of the value for sustainable cultivation and use.

Those delegated acts shall adapt the requirements, methodologies and standards of points (a) to (c) to the applicable technical or scientific developments, and to any new Union policies or rules on sustainable agriculture.

Where those rules are not yet established, Member States may adopt such rules for their respective territories. They shall notify them to the Commission and to the other Member States.

The Commission may adopt, by means of implementing acts, a decision requesting a Member State to repeal or modify those rules, if they are deemed, on the basis of the available scientific and technical evidence, to be inappropriate for the examination of value for sustainable cultivation and use of a variety. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).

4. For the purposes of registration of organic varieties suitable for organic production as defined in Article 3(19) of Regulation (EU) 2018/848, the examination of the value for sustainable cultivation and use shall be conducted under organic conditions, in accordance with that Regulation, and in particular Article 5, points (d), (e), (f) and (g), and Article 12 thereof and Part I of Annex II to that Regulation.

Where competent authorities are not able to carry out an examination under organic conditions, or the examination of certain characteristics, including disease

susceptibility, testing may be carried out under low-input conditions and with only the absolutely necessary for the completion of the testing treatments with pesticides and other external inputs.

Article 53

Registration of conservation varieties

1. By way of derogation from Articles 48, 49, 50, 52, 55(2), 56, 57, and 59 to 65, a conservation variety shall be registered in a national variety register if it complies with the following conditions:
 - (a) it has an officially recognised description, specifying the characteristics that qualify it as a conservation variety, in accordance with the definition in Article 3, point (29);
 - (b) it has an indication of its initial region of origin;
 - (c) it bears a denomination complying with Article 54;
 - (d) it is maintained in the Union.
2. A conservation variety shall be registered in the national variety register upon application by a professional operator established in the Union. That application shall include all the elements referred to in paragraph 1, points (a) to (d).

The competent authority shall accept or reject the registration of a conservation variety, after checking its compliance with paragraph 1.
3. A variety shall not be listed in the national variety register as conservation variety, if:
 - (a) it is already listed in the Union variety register with an official description, pursuant to Article 44(1), point (a), or it was deleted from the Union variety register as a variety with an official description within the last 2 years, or within 2 years from the expiry of the period granted pursuant to Article 71(2), or
 - (b) it is protected by a Community plant variety right as provided for in Regulation (EC) No 2100/94, or by a national plant variety right, or an application for such a right is pending.
4. The officially recognised description referred to in paragraph 1, point (a), shall be based on results of unofficial tests, knowledge gained from practical experience during cultivation, reproduction and use, or other information, in particular from the plant genetic resource authorities or from organisations recognised for this purpose by Member States.

The Commission may, by means of implementing acts, specify the characteristics and information that that description should cover if appropriate for specific species. Such implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).
5. The person responsible for the maintenance of a conservation variety shall keep samples of it and, upon request, make them available to the competent authorities.

Article 54

Suitability of variety denominations

1. For the purposes of Article 47(1), point (b), the denomination of a variety shall not be deemed suitable if:
 - (a) its use in the territory of the Union is precluded by the prior right of a third party;
 - (b) it may commonly cause its users difficulties as regards recognition or reproduction;
 - (c) it is identical to, or may be confused with, a variety denomination:
 - (i) under which another variety of the same or of a closely related species is entered in a national variety register or in the Union variety register; or
 - (ii) under which material of another variety has been made available on the market in a Member State or in a Member of the International Union for the Protection of New Varieties of Plants,unless variety referred to in point (i) or (ii) no longer remains in existence and its denomination has acquired no special significance;
 - (d) it is identical to, or may be confused with, other designations which are commonly used for making available on the market goods or which have to be kept free pursuant to Union legislation;
 - (e) it is liable to give offence in one of the Member States or is contrary to the public order;
 - (f) it is liable to mislead or to cause confusion concerning the characteristics, the value or the identity of the variety, or the identity of the breeder.
2. Without prejudice to paragraph 1, if a variety is already registered in other national variety registers, the denomination shall be deemed suitable, only if it is identical to that appearing in those registers.

This paragraph shall not apply if:

 - (a) the denomination is likely to mislead or cause confusion concerning the relevant variety in one or more Member States; or
 - (b) the rights of third parties impede the free use of that denomination in connection with the variety in question.
3. Where, after the registration of a variety, it is established by the competent authority that at the time of the registration the denomination of the variety was not suitable within the meaning of paragraphs 1 and 2, the applicant shall submit an application for a new denomination. The competent authority shall decide on that application upon consultation with CPVO.

The competent authority may permit the previous denomination to be used temporarily.
4. The Commission is empowered to adopt delegated acts in accordance with Article 75, supplementing this Regulation by setting out specific criteria concerning the suitability of variety denominations as regards:
 - (a) their relation to trade marks;
 - (b) their relation to geographical indications or designations of origin for agricultural products;

- (c) written consents of holders of prior rights to remove impediments to the suitability of a denomination;
- (d) determination of whether a denomination is misleading or confusing as referred to in paragraph 1, point (f); and
- (e) the use of a denomination in the form of a code.

SECTION 3

PROCEDURE FOR REGISTRATION OF VARIETIES IN THE NATIONAL VARIETY REGISTERS

Article 55

Submission of application

Any professional operator established in the Union may electronically submit to the competent authority an application for registration of a variety in the national variety register.

The submission of that application may be subject to a fee paid by the applicant, as established by the competent authority.

Article 56

Contents of the application for registration of a variety

1. The application for registration of a variety in a national variety register shall consist of the following:
 - (a) a request for registration;
 - (b) the identification of the botanical taxon to which the variety belongs;
 - (c) where applicable, the registration number of the applicant, its name and address or, where appropriate, the names and addresses of the joint applicants, and the credentials of any procedural representative;
 - (d) a proposed denomination;
 - (e) the name and address of the person responsible for the variety maintenance, and, where applicable, the registration number of that person;
 - (f) a description of the main characteristics of the variety, information on whether it is adapted only for particular seasons of the year, and, if available, a completed technical questionnaire;
 - (g) a description of the procedure of variety maintenance;
 - (h) the place of breeding of the variety and, if applicable, its particular region of origin;
 - (i) information on whether the variety is registered in another national variety register and on whether it is known to the applicant that an application for registration in one of those registers is pending;
 - (j) where the variety contains or consists of a genetically modified organism, evidence that the genetically modified organism in question is authorised for cultivation in the Union, in accordance with Directive 2001/18/EC or Regulation (EC) No 1829/2003, or, where applicable, in the respective Member State in accordance with Article 26b of Directive 2001/18/EC;;

- (k) where the application concerns conservation varieties, information related to the production of an officially recognised description of the variety, a proof of that description and any document or publication supporting it;
 - (l) in the case of an application concerning varieties with a granted plant variety right pursuant to Regulation (EC) No 2100/94 or the legislation of a Member State, the proof that the variety is protected by such right, with the corresponding official description;
 - (m) in case the variety contains or consists of a category 1 NGT as defined in Article 3(7) of Regulation (EU) .../... of the European Parliament and of the Council²⁶ (Office of Publications, please insert reference to NGT Regulation), evidence that the plant has obtained a declaration of category 1 NGT plant status pursuant to Article 6 or 7 of that Regulation or is progeny of such plant(s);
 - (n) in case the variety 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), indication of that fact;
 - (o) the intended use or conditions of cultivation, if applicable pursuant to Article 47(2), of the variety.
2. The application for registration of a variety in a national variety register shall be accompanied by a sample to be used for the examination of that variety. The competent authority of the respective Member State shall set a deadline for the submission of that sample and specify its quality and quantity.

Article 57

Formal examination of application

1. The competent authority of the respective Member State shall register and examine each application referred to in Article 55 in order to establish whether it complies with the requirements laid down in Article 56.
2. If the application does not comply with the requirements laid down in Article 56, the competent authority shall give the applicant a possibility to rectify the application accordingly within a given time. If the application does not meet these requirements by the expiry of that given time, the competent authority shall reject the application and terminate the variety registration.

Article 58

Date of application for registration

The date of the submission of the application for registration shall be the date on which the application, fully complying with the requirements laid down in Article 56, is received by the competent authority of the respective Member State.

The competent authorities shall immediately send to the applicant a confirmation of the successful submission of the application, including information on the date of that submission.

²⁶ Regulation (EU) .../... of the European Parliament and of the Council of ... (....., p.....).

Article 59

Technical examination of the variety

1. Where, as a result of the formal examination, the application is found to comply with the requirements laid down in Article 56, a technical examination of the variety shall be carried out.

The technical examination shall be carried out by growing the variety, taking into account the intended use and conditions for cultivation of the variety. Other means, including the use of bio-molecular techniques, may be used as a supplementary tool, as appropriate for the purposes of the technical examination, the species concerned or the characteristics to be checked, as established pursuant to the implementing act referred to in Article 47(2) concerning distinctness, uniformity and stability.

The technical examination referred shall verify:

- (a) the compliance with the requirements for distinctness, uniformity and stability of the variety, as laid down in Articles 48 to 50;
 - (b) whether the variety has value for sustainable cultivation and use, in accordance with Article 52, in the case of the varieties referred to in Article 47(1), point (a)(ii).
2. The technical examination referred to in paragraph 1 shall be carried out by the competent authorities in accordance with Article 60, unless the derogation referred to in Article 61(1) applies.
 3. In case a formal report on the distinctness, uniformity and stability of the variety, produced by CPVO or another competent authority, is already available, the competent authority shall take into consideration the conclusions of that report for the purposes of concluding the technical examination.
 4. The conduct of the technical examination referred to in paragraph 1 may be subject to a fee paid by the applicant, as established by the competent authority.

Article 60

Audit of the competent authority's premises

The competent authority of the respective Member State may carry out the technical examination as regards compliance with the requirements for distinctness, uniformity and stability referred to in Articles 48 to 50 only after its premises and working arrangements, dedicated to this purpose, have been found suitable for carrying out this examination pursuant to an audit conducted by the CPVO or the Commission.

On the basis of the audit referred to in the first subparagraph, the Commission may recommend to the competent authority, if appropriate, actions to ensure the suitability of the premises and organisation of the competent authorities. The Commission may carry out additional audits and, where applicable, recommend to the competent authorities corrective actions to ensure the suitability of their premises and organisation.

Article 61

Authorisation of the applicant to carry out technical examination for value for sustainable cultivation and use

1. By way of derogation from Article 59(2), the technical examination of whether the variety has a sustainable value for cultivation and use, in accordance with Article 52, or part of it, may be carried out by the applicant if:
 - (a) that applicant has been authorised by the competent authority of the respective Member State;
 - (b) the examination is carried out under the official supervision and guidance of the competent authority concerned; and
 - (c) the examination is carried out in the premises dedicated to that purpose.
2. Prior to granting the authorisation to carry out the technical examination on breeders' premises, the competent authority shall audit the premises, the resources and the organisational capacities of the applicant. That audit shall verify whether the premises, the laboratory facilities, the organisation and the carrying out of the growing trials are suitable for realising the technical examination on breeders' premises as regards compliance with the requirements of a value for sustainable cultivation and use referred to in Article 52.
3. The Commission is empowered to adopt delegated acts in accordance with Article 75, supplementing this Regulation by setting out the rules concerning the audit referred to in paragraph 2.
4. On the basis of the audit referred to in paragraph 2, the competent authority may recommend to the applicant, if appropriate, actions to ensure the suitability of the applicant's premises and organisation of the examination.
5. The competent authority may carry out additional audits to the one referred to in paragraph 2 and, where applicable, recommend to the applicant to perform, within a specific period of time, corrective actions concerning the its premises and the working arrangements. In case the competent authority concludes, following that period, that the applicant's premises and working arrangements are not suitable, it may withdraw or modify the authorisation referred to in paragraph 1.

Article 62

Additional rules on technical examination

1. The Commission is empowered to adopt delegated acts in accordance with Article 75, supplementing the requirements on the technical examination laid down in Article 59. Those delegated acts may concern:
 - (a) qualification, training and activities of staff of the competent authority or of the applicant, for the purposes of the technical examination referred to in Article 61;
 - (b) the necessary equipment, including laboratories for testing, necessary to carry out the technical examination;
 - (c) the establishment of a variety reference collection to compare the examined variety with other varieties to assess distinctness, and the storage management of such reference collection;
 - (d) the establishment of quality management systems, including record of activities and protocols or guidelines, to be used for the technical examination;

- (e) the carrying out of growing trials and laboratory tests for particular genera or species, including bio-molecular techniques.

Those delegated acts adapt to the available international technical and scientific protocols.

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

Article 63

Confidentiality

- 1. Where, during the technical examination provided for in Article 59, an examination of the genealogical components appears to be necessary, the results of that examination and the description of the genealogical components shall be treated as confidential, if the applicant requests so.
- 2. In the case of varieties of PRM intended exclusively for the production of agricultural raw materials for industrial purposes, certain elements of the technical examination and the intended uses of those varieties, whose public disclosure may affect the competitive position of the applicant, shall be treated as confidential, if that applicant requests so.
- 3. This Article shall apply without prejudice to Article 8 of Regulation (EU) 2017/625.

Article 64

Provisional examination report and provisional official description

- 1. Following the technical examination provided for in Article 59, the competent authority shall produce a provisional examination report, as to the compliance with the distinctness, uniformity and stability requirements, and the characteristics of value for sustainable cultivation and use, as applicable, as referred to in Articles 48, 49, 50 and 52, and shall issue a provisional official description of the variety on the basis of that report.
- 2. The provisional examination report may refer to findings of other examination reports, produced on the relevant variety, by the competent authority concerned, other competent authorities or the CPVO.
- 3. The competent authority shall communicate the provisional examination report and the provisional official description of the variety to the applicant. The applicant may comment on these documents within 15 calendar days.
- 4. Where the competent authority does not consider that the provisional examination report constitutes a sufficient basis for a decision on the registration of the variety, it shall request from the applicant additional information, examinations or other actions, as appropriate, to ensure compliance of the variety with the requirements concerning distinctness, uniformity, stability and value for sustainable cultivation and/or use, as set out respectively in Articles 48, 49, 50 and 52.

Article 65

Examination report and final official description

After taking into account any comments on the provisional examination report and the provisional official description provided by the applicant, the competent authority shall issue a final examination report and a final official description on the distinctness, uniformity and stability of the variety and including a summary of the examination results on value for sustainable cultivation and use.

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

Article 66

Examination of the denomination of a variety

After the formal examination of the application provided for in Article 57, and prior to the registration of a variety in a national variety register pursuant to Article 67, the competent authority shall consult the CPVO on the variety denomination proposed by the applicant.

The CPVO shall submit to the competent authority a recommendation on the suitability of the variety denomination proposed by the applicant, in accordance with Article 54. The competent authority shall inform the applicant on that recommendation.

Article 67

Decision on the registration of a variety in the national variety register

1. If, on the basis of the procedure set out in Articles 55 to 66, it is concluded that the variety complies with the requirements set out in Article 47(1), the competent authority of the respective Member State shall decide to register the variety in the national variety register.
2. The competent authority shall adopt a decision refusing registration in the national variety register, if:
 - (a) it establishes that the respective requirements set out in Article 47(1) are not fulfilled; or
 - (b) the applicant has failed to comply with any of the obligations set out for it in Articles 55 to 64.
3. Decisions refusing the registration of a variety in the national variety register shall state the reasons justifying such refusal.
4. The competent authority shall communicate to the applicant the decision referred to in paragraphs 1 and 2.
5. The decisions referred to in paragraph 1 and 2 may be appealed, in accordance with the administrative rules of the Member State concerned. Any appeal against a decision referred to in paragraph 1 shall have a suspensory effect on the registration of the respective variety.
6. The adoption of the decision referred to in paragraph 1 may be subject to a fee paid by the applicant, as established by the competent authority.

Article 68

Varieties registered pursuant to Directives 68/193/EEC, 2002/53/EC, 2002/55/EC and 2008/90/EC

1. By way of derogation from Articles 54 to 67, the competent authorities shall immediately register in their national variety registers all varieties officially accepted or registered before ... [*the date of the entry into force of this Regulation*], in the catalogues, lists or registers established by their Member States pursuant to Article 5 of Directive 68/193/EEC, Article 3 of Directive 2002/53/EC, Article 3(2) of Directive 2002/55/EC and Article 7(4) of Directive 2008/90/EC, without applying the registration procedure set out by those Articles.
2. By way of derogation from Article 53, varieties accepted in accordance with Article 3 of Directive 2008/62/EC and Article 3(1) of Directive 2009/145/EC before... [*OJ, please, insert the date of the entry into force of this Regulation*] shall be immediately registered in the national variety registers as conservation varieties provided with an officially recognised description without applying the registration procedure set out by that Article.

SECTION 4

REGISTRATION PERIOD AND VARIETY MAINTENANCE

Article 69

Period of registration

1. The period of registration of a variety in a national variety register ('period of registration') shall be 10 years.

However, that period of registration shall be 30 years for varieties of species of fruit plants and vine propagating material, as listed respectively in Parts C and D of Annex I.

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

In the case of varieties consisting of, or containing, a category 2 NGT plant as defined in Article 3(8), of Regulation (EU) .../... (Office of Publications, please insert reference to NGT Regulation ...), the period of registration shall be limited to the period for which that plant is authorised pursuant to that Regulation.

2. The period of registration of a variety in a national variety register may be renewed for a further period of 10 years, or respectively 30 years, in accordance with the procedure and the conditions laid down in Article 70.

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

3. The registration of a variety may be subject to an annual fee paid by the applicant, as established by the competent authority.

Article 70

Procedure and conditions for registration renewal

1. Any person intending to renew the registration of a variety shall submit an application, no earlier than 12 months, and no later than 6 months, before the expiration of the period of registration as referred to in Article 69(1).
2. The application shall be submitted electronically. It shall be accompanied by evidence showing that the conditions set out in paragraph 3 are fulfilled.
3. The renewal of the registration of a variety in a national variety register may only be granted, if:
 - (a) the applicant has submitted sufficient evidence that the variety continues to comply with the respective requirements of Article 47(1); and
 - (b) the competent authority of the respective Member State has established that there is a person responsible for the variety maintenance in accordance with Article 72.
4. The competent authority may, on its own initiative, renew the registration of a variety, if it is still in large demand by the professional operators and farmers concerned, or it should be retained in the interest of conserving plant genetic resources.

Article 71

Removal from national variety registers

1. The competent authority of the respective Member State shall remove a variety from the national variety register, if:
 - (a) it concludes, on the basis of any new evidence, that the requirements for registration, as set out in Article 47(1) are no longer fulfilled;
 - (b) the applicant does not pay the fee that the competent authority has established in accordance with Articles 55, 59(4), 67(6) and 69(3);
 - (c) the person responsible for the variety maintenance, as referred to in Article 72, so requests, or that person has ceased to maintain the variety and no other person has become responsible for its maintenance;
 - (d) the variety is no longer maintained pursuant to requirements of Article 72;
 - (e) the variety is maintained in a third country, which has not provided assistance on the controls of that maintenance pursuant to Article 72(7);
 - (f) at the time of the application, false or fraudulent data were supplied on the basis of which the registration was decided;
 - (g) no application for renewal has been submitted by the deadline referred to in Article 70(1) and the validity period of registration referred to in Article 69(1) has expired.
2. On request by the applicant, the competent authority may allow that a variety removed from the national variety register in accordance with paragraph 1, point (g), continues to be made available on the market until 30 June of the third year following the removal from the register.

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

3. Following its removal from a national variety register, as referred to in paragraph 1, the variety concerned shall be immediately removed from the Union variety register, if it is not registered in any other national variety register.

Article 72

Variety maintenance

1. Varieties registered in a national variety register shall be maintained by the applicant, or by any other person notified by the applicant to the competent authority. The competent authority shall authorise that other person to carry out the maintenance of the variety, if that person proves its capacity for that task, and the competent authority shall withdraw that authorisation if that person is no longer capable for that. The name and registration number of that person shall be notified by the applicant to the competent authority of the Member State.
2. Variety maintenance shall take place in accordance with accepted practices concerning, as appropriate, genera, species or particular types of varieties.
3. The persons referred to in paragraph 1 shall keep records concerning the variety maintenance. It shall at all times be possible for the competent authority to check the variety maintenance from those records. Those records shall also cover the production of pre-basic, basic, certified and standard material, and the stages of production prior to pre-basic material.

A standard sample of the variety concerned shall be provided to the competent authority on request.
4. The competent authority shall carry out controls on the manner in which the variety maintenance is carried out and may, to this purpose, take samples of the varieties concerned. The frequency of those controls shall be based on the likelihood of non-compliance with paragraphs 1 to 3.
5. Where a competent authority finds that the person responsible for variety maintenance does not comply with paragraphs 1 to 3, it shall give that person appropriate time to take corrective action or request another person to carry out the variety maintenance. If no such action is taken within that time limit, the competent authority shall remove the variety from the national variety register in accordance with Article 71.
6. Where variety maintenance takes place in a Member State other than the Member State in whose national variety register the variety has been registered, the competent authorities of the two Member States concerned shall assist each other in the controls on variety maintenance. If no such assistance is provided within a reasonable period of time, or if it is concluded that the variety maintenance is not carried out in accordance with this Article, the respective competent authority shall remove the variety from the national variety register in accordance with Article 71.
7. Where variety maintenance takes place in a third country, the competent authorities of the Member State, in whose national variety register the variety has been registered, shall request the third country's authorities assistance in the controls on variety maintenance, if such a maintenance has been subject to the recognition of equivalence referred to in Article 39(5). If no such assistance is provided within a reasonable period of time, or if it is concluded that the variety maintenance is not

carried out in accordance with this Article, the respective competent authority shall remove the variety from the national variety register in accordance with Article 71.

SECTION 5

KEEPING OF DOCUMENTATION AND SAMPLES

Article 73

Documentation on the national variety registers

The competent authority of the respective Member State shall keep a file on each variety registered in the national variety register, containing:

- (a) the official description or the officially recognised description of the variety;
- (b) the examination report; and
- (c) any complementary examination report pursuant to Article 64(4).

In the case of an officially recognised description, the file shall only contain that description and the documents supporting it.

Article 74

Samples of the registered varieties

The competent authorities shall keep samples of the varieties registered in the national variety registers and make them accessible to any third party upon request.

The Commission may, by means of implementing acts, specify the size of those samples, the rules for their replacement, in the case where the quantity of the original sample is too limited or it is no longer adequate due to its use in other examinations, and their submission to other competent authorities. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 76(2).

CHAPTER V

PROCEDURAL PROVISIONS

Article 75

Exercise of delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The delegation of power referred to in Articles 2(3), 7(3), 8(4), 10(2), 15(5), 20(2), 22(2), 24(4), 27(3), 46(2), 47(3), 52(3), 54(4), 61(3), and 62(1) shall be conferred on the Commission for 5 years from the date of the entry into force of this Regulation.

The delegation of power shall be tacitly extended for periods of 5 years, unless the European Parliament or the Council opposed such extension not later than three months before the end of each period. The Commission shall draw up a report in respect of the delegation of power no later than nine months before the end of the first 5-year period.
3. The delegation of power referred to in Articles 2(3), 7(3), 8(4), 10(2), 15(5), 20(2), 22(2), 24(4), 27(3), 46(2), 47(3), 52(3), 54(4), 61(3), and 62(1) may be revoked at any time by the European Parliament or by the Council. A decision of revocation

shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. 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 on Better Law-Making of 13 April 2016.
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 Articles 2(3), 7(3), 8(4), 10(2), 15(5), 20(2), 22(2), 24(4), 27(3), 46(2), 47(3), 52(3), 54(4), 61(3), and 62(1) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of 2 months of the 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 the Council.

Article 76

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 Council²⁷. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
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 decides so or a simple majority of committee members requests it.
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 VI

REPORTING, PENALTIES AND AMENDMENTS OF REGULATIONS (EU) 2016/2031, 2017/625 AND 2018/848

Article 77

Reporting

²⁷ 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).

1. By ... [5 years after the date of application of this Regulation], and every five 5 years there after, Member States shall transmit to the Commission a report on the following:
 - (a) quantities of certified and standard PRM and areas used for their production per year and species with a specification of the quantities used for organic varieties suitable for organic production;
 - (b) quantities of marketed PRM of heterogeneous material and areas used for their production per year and species;
 - (c) quantities of marketed PRM of conservation varieties per year and species;
 - (d) number of professional operators using the derogations for marketing to final users in accordance with Article 28, the species concerned and total quantities of PRM per species;
 - (e) number of gene banks, organisations and networks with a statutory or other declared objective to conserve plant genetic resources, in accordance with Article 29 and the species concerned;
 - (f) the quantities as defined per species for the seeds exchanged in kind between farmers, in accordance with Article 30;
 - (g) the quantities authorised per species for PRM intended for tests and trials for the breeding of new varieties, in accordance with Article 31;
 - (h) quantities of PRM per genera and species for which Article 33(4) has been applied;
 - (i) quantities of PRM per genera and species imported from third countries, in accordance with Article 39;
 - (j) penalties imposed in accordance with Article 78;
 - (k) number of professional operators established in their territory.
2. The Commission shall, by means of implementing acts, specify the technical formats for reporting made pursuant to paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 76(2).

Article 78

Penalties

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

Article 79

Amendments of Regulation (EU) 2016/2031

In Article 37 of Regulation (EU) 2016/2031, 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). Those measures shall, where appropriate, concern the introduction into, and the movement within, the Union of those plants.’.

Article 80

Amendments of Regulation (EU) 2017/625

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

- (1) in Article 1, paragraph 2, the following point is added:
‘(k) production and marketing of plant reproductive material.’;
 - (2) in Article 3, the following point is added:
‘(52) ‘plant reproductive material’ means plant reproductive material as defined in Article 3(1) of Regulation (EU) .../... of the European Parliament and the Council(*)+’;
-
- (*) Regulation (EU) .../... of the European Parliament and of the Council (OJ ..., p...). [*footnote that will be in that regulation goes here*]
- [+ OJ: Please insert in the text the number of this Regulation and insert the number, date, title and OJ reference of this Regulation in the footnote.]
- (3) the following article is inserted after Article 22:

‘Article 22a

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

1. Official controls to verify compliance with the rules referred to in Article 1(2), point (k), shall include official controls on plant reproductive material, operators and other persons 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 plant reproductive material in order to verify compliance with Union rules referred to in Article 1(2), point (k), 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 specific requirements for the performance of such official controls on:

- (a) the import into, and marketing within, the Union of particular plant reproductive material subject to the rules referred to in Article 1(2), point (k), concerning its identification and quality, and
- (b) specific requirements for the performance of such official controls on the activities of operators during the production of particular plant

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

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 (k), 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 plant reproductive material of a particular origin or provenance;
 - (b) uniform frequency of official controls performed by competent authorities on operators authorised to carry out certification under official supervision in accordance with Article 12(1) of Regulation (EU) .../...++Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

++ OJ: Please insert in the text the number of this Regulation.

4. For the purposes of Article 30, the delegation of certain official control tasks, referred to in this Article, to one or more natural persons shall be allowed.’;
- (4) in Article 40(1), the following point is added:
- ‘(c) laboratories which are accredited by the International Seed Testing Association to carry out analyses, tests and diagnoses on seed samples’samples’.

Article 81

Amendment of Regulation (EU) 2018/848

Regulation (EU) 2018/848 is amended as follows:

- (1) Article 3 is amended as follows:
 - (a) point (17) is replaced by the following:

‘(17) ‘plant reproductive material’ means plant reproductive material as defined in Article 3(1) of Regulation (EU) .../... of the European Parliament and Council(*)+;’;
-
- (*) Regulation (EU) .../... of the European Parliament and of the Council (OJ ..., p...). [*footnote that will be in that regulation goes here*]
- [+ OJ: Please insert in the text the number of this Regulation and insert the number, date, title and OJ reference of this Regulation in the footnote.]
- (b) point (18) is replaced by the following:

‘(18) ‘organic heterogeneous material’ means heterogeneous material as defined in Article 3(27) of Regulation (EU) .../...(*)++ , produced in accordance with this Regulation;’

(*) Regulation (EU) .../... of the European Parliament and of the Council
.... (OJ ..., p...). [*footnote that will be in that regulation goes here*]

[++ OJ: Please insert in the text the number of this Regulation.]

(2) Article 13 is deleted.

(3) The second paragraph of Point 1.8.4. of Part I of Annex II to Regulation (EU) 2018/848 is replaced by the following: “ All multiplication practices, except plant tissue cultures, cell cultures, germplasm, meristems, chimaeric clones, micro-propagated material, shall be carried out under certified organic management”.

CHAPTER VII

FINAL PROVISIONS

Article 82

Repeals

Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 2002/53/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90/EC are repealed.

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

Article 83

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 ... [*36 months from the date of the entry into force of this Regulation*].

However,

- (a) Article 40(4) shall apply from three days after the entry into force of this Regulation;
- (b) Article 52 shall apply from ... [*60 months from the date of the entry into force of this Regulation*] for the species listed in Parts B and C of Annex I. 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