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Delegations will find attached document SWD(2023) 414 final.

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EUROPEAN
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COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT REPORT

Accompanying the documents

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 (Regulation on plant reproductive material)

and

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

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Glossary

Term or acronym	Meaning or definition
BMT	Bio-molecular techniques
CPVO	Community plant variety office
CPVR	Community plant variety rights
DG SANTE	Directorate-General for Health and Food Safety
DUS	Distinctness, Uniformity and Stability
EGD	European Green Deal
EU	European Union
F2F	Farm to Fork Strategy
FRM	Forest reproductive material
FSFS	Framework for sustainable food system
GMO	Genetically modified organism
IMSOC	Information management system for official controls
MS	Member State(s)
NCA	National Competent Authority
NGT	New genomic techniques
OC	Official control
OCR	Official Controls Regulation
OECD	Organization for Economic Co-operation and Development
PHL	Plant health legislation
PRM	Plant reproductive material
QP	Quarantine pest
RNQP	Regulated non-quarantine pest
SDG	Sustainable Development Goal
SME	Small and medium-sized enterprise
SUR	Proposal for a Regulation on the sustainable use of plant protection products
TFEU	Treaty on the Functioning of the European Union
UPOV	International union for the protection of new varieties of plants
VCU	Value for cultivation and use
VSCU	Value for sustainable cultivation and use

1. INTRODUCTION: POLITICAL AND LEGAL CONTEXT

Plant reproductive material (PRM) is any plant material (for example seeds, tubers, cuttings, rootstocks, seedlings, young plants, fully grown trees) that is used for the reproduction of other plants. **Forest reproductive material (FRM)** is the PRM of tree species that is used for the creation of new forests, the reforestation of existing ones and other tree planting activities (for example, in rural areas for the purpose of climate adaptation). Thus, PRM and FRM form the starting point of agricultural and food production and forestry, respectively. In particular, the availability of, and access to, high-quality PRM are key contributors to food security. They link to the four main pillars on which food security is based: availability, access, utilisation and stability[1]. The actions taken under the Farm to Fork Strategy (F2F) including those under this initiative will help enable and contribute to the transition to sustainability, which will strengthen resilience and in turn enhance short- and long-term food security. The availability of and access to high-quality and genetically diverse FRM will contribute to more sustainable afforestation and reforestation which will in turn strengthen the resilience of forest ecosystems and ensure that forests can adapt to climate change.

The EU legislation on PRM and FRM currently includes 12 basic Directives, collectively known as 'marketing Directives': 10 specific for each type of crop (seed of cereals, seed of fodder plants, seed of oil and fibre plants, seed of beet, seed potatoes, vegetable seed, vegetable reproductive material other than seed, fruit plants, vine, ornamental plants), one Directive establishing the Common Catalogue of varieties of agricultural species and one on FRM (for a detailed overview see Annex 5, Section 1). The oldest of these Directives date back to 1966[2]. The legislation applies to the economically most important plant species. The aim of this legislation is to ensure the identity, quality and health of the marketed PRM and FRM for its users.

The **PRM legislation** has two main pillars: registration of varieties[3] and certification of PRM (Annex 5, Section 2). For the purposes of **variety registration**, the candidate varieties are tested in field trials for their **distinctness, uniformity and stability (DUS)[4]** by the National Competent Authority (NCA) of the MS where the application is submitted. DUS tests take two to three years in the case of varieties of agricultural plant species[5] and vegetable species and five to six years in the case of varieties of fruit plants and vine. For agricultural plant species the candidate varieties are also assessed by comparative field trials carried out by the NCAs for their **value for cultivation and use (VCU)**, i.e. whether they offer a clear improvement in performance compared to reference varieties. Upon satisfactory completion of the DUS, and where applicable of the VCU examination,

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[1] FAO (2022).

[2] A compilation of the legislation can be found at https://food.ec.europa.eu/plants/plant-reproductive-material/legislation/specific-legislation_en. See also Section 1 of Annex 5.

[3] A plant variety represents a group of plants of a given species with a common set of characteristics, while a plant species can include from a few to thousands of different plant varieties. PRM (seed, cuttings etc.) is marketed with reference to a registered variety.

[4] New varieties need to be different from other known (reference) varieties (distinctness requirement). The characteristics of different plants within the same variety should be similar (uniformity requirement). The characteristics of the plants of a new variety should not change over time (stability requirement).

[5] The term 'agricultural plant species' is referring collectively to cereals, fodder plants, beet, potato, oil and fibre plants.

varieties are registered in the national catalogue of the MS and subsequently notified to the corresponding EU Common Catalogue for marketing throughout the EU. Each registered plant variety is designated a unique denomination, i.e. a name that serves to identify that variety.

Certification of PRM consists of checks (both in the field where PRM is produced, by sampling and testing the PRM lots produced and control plot testing of the varietal identity) to verify its **identity, quality and health**. As regards identity, it is verified that the PRM has the same characteristics as the registered plant variety to which that PRM belongs (i.e. it is true to variety description). Different marketing categories of PRM are defined depending on the quality and technical requirements (e.g. analytical purity, germination rate, absence of weeds). As regards health, it is verified that the PRM does not contain any plant pests or diseases. Certain aspects of the certification procedures can be carried out by authorised operators under the **official supervision** of the NCAs. For PRM that meets the certification requirements the NCAs issue an official label with which the PRM can be marketed throughout the EU[6]. The PRM legislation furthermore includes rules for marketing of PRM in homogeneous lots with reference to a lot number to assure traceability, as well as rules for packaging, sealing, labelling and documentation. The PRM legislation also sets the rules for imports of PRM into the EU. Such PRM can only be marketed in the Union if it satisfies the same requirements as the material produced and certified within the Union (EU equivalence regime). Exports are not covered by the legislation. Finally, to ensure the quality of PRM marketed throughout the EU, NCAs should carry out **official controls** (OCs) in order to verify compliance with the rules on the production, marketing and imports of PRM.

The **FRM legislation** is based on principles quite different from those of the PRM legislation, as FRM differs significantly from PRM (Annex 5, Section 3). While seeds of agricultural crops are harvested in annual cycles, for certain forestry species it takes 50-100 years before FRM can be harvested. FRM is marketed in relation to basic material (i.e. approved trees from which seed is harvested) and provenance (the place in which trees are growing). NCAs approve basic material through an official inspection following which basic material is registered in the national catalogue of the MS and subsequently in the EU Common Catalogue FOREMATIS[7]. Upon harvesting seeds and other FRM from basic material, NCAs issue a master certificate. FRM has to meet the relevant requirements (age, development, health and resistance of trees in stands to adverse climatic conditions) before the operator can issue a supplier's document or supplier's label. The registration of basic material, the master certificate and the supplier's document/label are prerequisites for the marketing of FRM throughout the EU. Similar to the PRM legislation, the FRM legislation also includes rules for marketing of FRM, imports (equivalence), derogations aiming to facilitate the conservation and sustainable use of forest genetic resources, and OCs for verifying compliance with the rules on the production, marketing and imports of FRM.

The **EU PRM and FRM market** has an estimated annual value of over EUR 13 billion[8]. As regards the seed sector in particular, the EU is in the top three of globally exporting regions. The EU seed market covers agricultural species (e.g. wheat, maize, rice), vegetable species (e.g. tomato,

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[6] Ornamental plants are an exception to the general approach described above. There is no obligation for registration of varieties and the PRM is subject only to basic requirements as regards health, vigour and germination.
[7] Forest Reproductive Material Information system (http://ec.europa.eu/forematis).
[8] Eurostat, see Annex 4 Section 1.

carrot, lettuce). It is the third largest seed market after the USA and China and accounts for around 20% of the global market, estimated at EUR 7-10 billion (revenues from commercial seed sales, not including farm-saved seeds). There is little information available on the structure of the seed sector in the EU. The number of companies in the seed sector is about 7 000. They are very diverse in terms of size (turnover, employees), crops or geographical area covered. They may be active in one or several stages of the seed industry: plant breeding, seed production, seed conditioning, and seed marketing and distribution. The number of small and medium-sized enterprises (SMEs) is assumed to be high, but no information is available on their market share. Furthermore, it is not known how many are independent (a single company may own a large number of brands), while cross-licensing and cooperation agreements have created a network of relationships between seed companies that make the mapping of the sector extremely difficult[9]. The EU plant breeding sector is highly innovative and new varieties are constantly developed to meet the demands of farmers, industry and consumers. It spends around 15% of its annual turnover on research and development[10]. Farmers also play an important role in the seed sector as they multiply the seed of agricultural plant species in their fields on behalf of the seed companies. In 2021 the area used for production of certified seed (vegetable and ornamental seeds not included) in EU amounted to slightly more than 2 million ha[11]. As regards PRM of fruit plants, there are over 20 000 suppliers in the EU, almost all of which are SMEs[12]. As regards FRM, there are over 4 000 suppliers in the EU, almost all of which are SMEs[13]. The overwhelming majority of FRM (tree seeds and plants) are marketed within the EU and only a minority is traded with non-EU countries[14].

Relationship with other EU policies and instruments

The PRM/FRM legislation interacts with a number of **EU policies and instruments** (Annex 5, Section 4). There is a close link with the European Green Deal (EGD)[15] and its related strategies:

- F2F[16] recognises that sustainable food systems rely on seed security and diversity and that farmers need to have access to a range of quality seeds for plant varieties adapted to the pressures of climate change. The initiative for the PRM/FRM revision will introduce relevant considerations in the criteria for acceptance of new varieties. It will also contribute to reaching the F2F objective of at least 25% of the EU's agricultural land under organic farming by 2030 by introducing rules on registration of organic varieties suitable for organic production adapted to the needs of organic production.
- The initiative for the PRM/FRM revision will contribute to the objective of the EU Biodiversity Strategy for 2030[17] to reverse the decline of genetic diversity by facilitating the market access

[9] Ragonnaud G. (2013).
[10] Bakker T. *et al.* (2012).
[11] European Seed Certification Agencies Association (ESCAA) Seed production in EU - 2021 (escaa.org). This area corresponds to about 1% of the total utilised agricultural area in EU. The number of farmers involved is unknown, indicatively in France about 17 900 farmers are involved in seed multiplication (semae.fr).
[12] Data collected from the NCAs. The existence of in total 20 137 suppliers of PRM of fruit plants were reported by the NCAs from 10 MS.
[13] Data collected from the NCAs. The existence of in total 4 129 suppliers of FRM were reported by the NCAs from 8 MS.
[14] Information from the NCAs.
[15] COM(2019) 640 final.
[16] COM(2020) 381 final.
[17] COM(2020) 380 final.

for traditional and locally adapted varieties, thus contributing to the conservation and sustainable use of plant genetic resources.

- It will also contribute to the objective of the EU Strategy on Adaptation to Climate Change[18] to help farmers and land managers tackle climate risks. Relevant criteria will be introduced in the rules for the registration of new varieties and of FRM with a view to facilitate the broadening of the supply of suitable high-quality plant reproductive material to support adaptation in agriculture, forestry, and land ecosystem management.
- It will furthermore contribute to the objectives of the EU Forest Strategy[19] for adapting forests to climate change and restoring forests following climate damages by introducing measures promoting the production of FRM suitable for future climatic conditions. It will finally contribute to meeting the target of planting at least 3 billion additional trees in the EU by 2030, by revising the scope of the FRM legislation, in order to ensure that FRM of high quality will be used for this.

There are also links and interplays with other EU legislation, notably the Plant Health Legislation (PHL)[20], the Official Controls Regulation (OCR)[21], the Organic Regulation[22], the Community Plant Variety Rights (CPVR) legislation[23] and the genetically modified organisms (GMO) legislation[24] as well as the EU Digital Strategy[25]. The PRM/FRM legislation also has to be aligned or interrelates with a number of international standards or agreements[26].

Relationship with other ongoing initiatives

The initiative for the revision of the PRM/FRM legislation is linked to the following ongoing initiatives (for details see Annex 5, Section 5):

- The **Framework for Sustainable Food System (FSFS) initiative[27]** aims to introduce an overarching, horizontal legal framework ('*lex generalis*') establishing common sustainability principles and objectives for all food system related policies. The initiative for the PRM/FRM revision, which is underpinned by sustainability as an objective, will include specific rules for the PRM/FRM sectors ('*lex specialis*'). FSFS will ensure the benefits of an integrated policy

[18] COM(2021) 82 final.
[19] COM(2021) 572 final.
[20] Regulation (EU) 2016/2031. OJ L 317, 23.11.2016, p.4.
[21] Regulation (EU) 2017/625. OJ L 95, 7.4.2017, p. 1.
[22] Regulation (EU) 2018/848. OJ L 150, 14.11.2020, p.1.
[23] Council Regulation (EC) No 2100/94. OJ L 227, 1.9.1994, p. 1.
[24] Directive 2001/18/EC. OJ L 106, 17.4.2001, p. 1. Regulation (EC) No 1829/2003. OJ L 268, 18.10.2003, p. 1.
[25] COM(2021)118 final - The EU's digital strategy aims to make the transformation to digital technologies work for people and businesses, while helping to achieve its target of a climate-neutral Europe by 2050. Allowing the use of digital technologies will help creating future proof PRM and FRM sectors.
[26] Notably the OECD Seed Schemes for the Varietal Certification of Seed (https://www.oecd.org/agriculture/seeds/), OECD Scheme for the Certification of Forest Reproductive Material (https://www.oecd.org/agriculture/forest/), the International Convention for the Protection of New Varieties of Plants (UPOV), the International Rules for Seed Testing of the International Seed Testing Association (ISTA), the United Nations Economic Commission for Europe (UNECE) Standard for Seed Potatoes, the International Treaty on plant genetic resources for Food and Agriculture (ITPGRFA).
[27] https://food.ec.europa.eu/horizontal-topics/farm-fork-strategy/legislative-framework_en

perspective and approach, while specific requirements introduced by the PRM/FRM initiative will accelerate the transition towards more sustainable practices in the PRM/FRM sectors.

- The **New Genomic Techniques (NGT) initiative**[28] concerns plants produced by genetic modification, in particular targeted mutagenesis[29] and cisgenesis[30]. These plants may contribute to the innovation and sustainability objectives of the EGD and of the F2F and Biodiversity strategies. The initiative aims at a proportionate regulatory oversight better adapted to NGTs that combines high levels of safety with clear benefits to society and the environment. Coherence will be ensured between the PRM/FRM and NGT initiatives, in particular as regards any sustainability aspects (see Annex 5, Section 6). The plant variety registration system of the PRM legislation applies to all varieties irrespective of the breeding technique. A variety obtained by genetic modification and subject to the provisions of the GMO legislation can only be registered and PRM of such variety can only be marketed if this variety complies with the requirements of the GMO legislation[31]. The same applies for FRM consisting of GMOs. Varieties and FRM with NGT traits[32] will be treated under PRM and FRM legislation in the same way as all other varieties and FRM regardless of the breeding methodology (conventional breeding, NGTs, established genetic modification techniques).
- The **sustainable use of plant protection products (SUR)**[33] **initiative** aims to reduce the use and risk of chemical pesticides. Current VCU rules (examination for resistance to plant pests and diseases) and the envisaged measures to extend these (Section 5) contribute to this objective of the SUR, as new varieties with increased resistance to plant pests may require less pesticides.

Legislative context

The PRM and FRM legislation was first evaluated in 2008[34]. In 2013, the Commission adopted a proposal for its revision[35] ('2013 PRM proposal') accompanied by an impact assessment[36]. That proposal was rejected by the European Parliament in 2014[37] as according to the European Parliament, one Regulation could not address the requirements of the broad range of PRM and cover FRM. The European Parliament also had concerns regarding the marketing to amateur gardeners, the unnecessary burden on operators and NCAs and insufficient biodiversity provisions. Subsequently, the proposal was withdrawn by the Commission in 2015[38].

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[28] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques_en

[29] Targeted mutagenesis is an umbrella term used to describe newer techniques of mutagenesis that induce mutation(s) in selected target locations of the genome without insertion of foreign genetic material.

[30] Cisgenesis means the insertion of genetic material (e.g. a gene) into a recipient organism from a donor that is sexually compatible (crossable).

[31] Directive 2001/18/EC and Regulation (EC) No 1829/2003.

[32] In genetics a trait is a specific characteristic. NGT traits are modified traits obtained by targeted mutagenesis and cisgenesis.

[33] COM(2022) 305 final.

[34] FCEC (2008).

[35] COM(2013) 262 final.

[36] SWD(2013)162 final.

[37] European Parliament legislative resolution of 11 March 2014 (COM(2013)0262 — C7-0121/2013 — 2013/0137(COD)). OJ C 378, 9.11.2017, p. 303–303.

[38] Withdrawal of Commission proposals (2015/C 80/08). OJ C 80, 7.3.2015, p. 17–23.

Following a request by the Council[39], the Commission presented in 2021 a study on the Union's options to update the existing legislation on the production and marketing of plant reproductive material ('PRM study')[40], which was supported by an external data gathering study[41]. In 2022 another external study[42] was undertaken in support of this impact assessment.

All concerns expressed by the European Parliament on the 2013 PRM proposal are addressed by this initiative (Table 1). The context has changed to the degree that the issues identified in 2013 are even more actual, e.g. need to modernise the legislation to allow for new technical developments, increasing demand for sustainability in agriculture, adaptation to climate change and conservation of agro-biodiversity. These issues are also relevant in view of the new political objectives.

Concerns expressed by the European Parliament on the 2013 PRM proposal	**Approach taken in this initiative**
"One size fits all" approach does not meet the different requirements of different PRM, operators, consumers and authorities.	Two different proposals will be adopted, one on PRM and the other on FRM. The PRM proposal addresses crop-specific issues with separate sections and annexes for seeds and for other plant reproductive material. The PRM of ornamental plants will remain separately regulated by the current Directive 98/56/EC that will be kept in place.
Significant number of delegated and implementing acts make it difficult to properly assess the future impact of the regulation.	Empowerments are considered only where there is the need to maintain flexibility to adapt the technical requirements to scientific and technological developments.
FRM is a specific sector that should not be covered by the same legislation as with other PRM.	Measures on PRM and FRM have been considered separately. There will be two different proposals, one on PRM and one on FRM.
Concerns in relation to PRM for ornamental purposes.	The PRM of ornamental plants will remain separately regulated by the current Directive 98/56/EC that will be kept in place.
Concerns in relation to PRM intended for sale to home gardeners.	Lighter requirements for marketing to amateur gardeners have been considered, on the basis on the results of the consultation while ensuring quality of PRM.
Concerns regarding poor quality of the impact assessment.	The Better Regulation guidelines for the preparation of the impact assessment have been respected.
Concerns in relation to extended remit for the CPVO.	CPVO's role is limited to the extent necessary (audits of NCAs on DUS and denomination checks).
Vague definitions and unnecessary administrative burden placed on the Member States.	Improved legal drafting and simplification of procedures.

[39] Council Decision (EU) 2019/1905.
[40] SWD(2021)90 final.
[41] ICF (2021).
[42] ICF (2023).

Need to facilitate and encourage the maintenance of biodiversity in agriculture and horticulture.	A number of new approaches (lighter rules on conservation varieties, new locally adapted varieties and heterogeneous material, rules for organic varieties adjusted to the needs of organic production) will contribute to the conservation and sustainable use of plant genetic resources and the increase of the genetic diversity of cultivated crops.

Table 1. Overview of concerns expressed by the European Parliament in 2014 and approach taken in this initiative to address them.

2. PROBLEM DEFINITION

2.1. What are the problems?

The PRM/FRM legislation has gradually evolved over several decades since the introduction of the first marketing Directives in the 1960s. The long history of amendments has led to a complex, incoherent and fragmented legal framework that is not up to date with the current scientific and technical developments. For certain aspects, such as the implementation of derogations and OCs, it leaves too much room for interpretation, resulting in divergent implementation across MS, thus hindering the internal market. Furthermore, the complexity and rigidity of the procedures puts a high burden on NCAs and operators alike. The basic legislation includes detailed technical requirements, making it difficult to adapt the system to new policy priorities, as well as to new developments in science and technology and demands for more sustainable agri-food production and forestry.

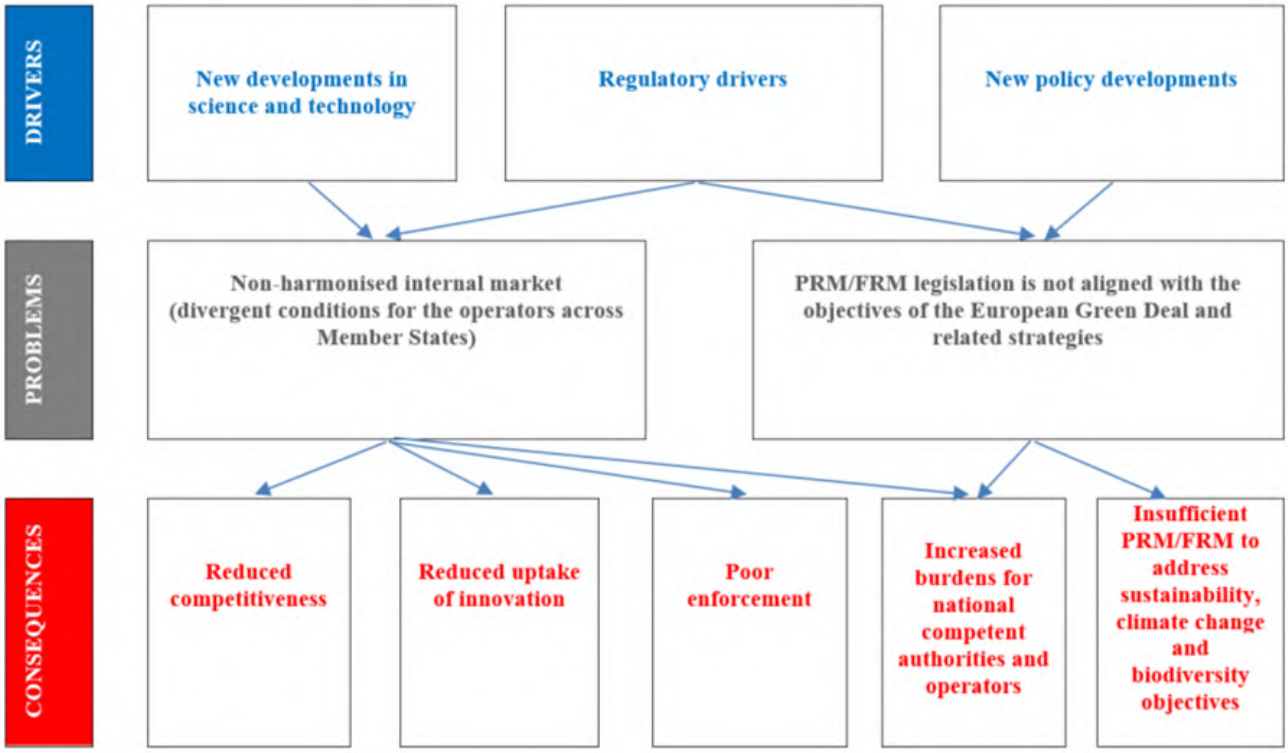

Figure 1. Problem tree

Development of the problems since 2013:

The 2008 evaluation and the 2013 impact assessment already identified most of these problems. Although no full-fledged evaluation of the PRM legislation was carried out after 2008, two evaluative studies were carried out. In 2021, there was an external data gathering study[43] supporting the PRM study that was requested by the Council and in 2022 another external study[44] supporting this impact assessment. The analysis and evidence of the existing problems was considered comprehensive, and the problems remain valid. The results of the feedback received on the inception impact assessment in 2021, and of extensive consultations activities have confirmed the problems and provided further elements to substantiate them.

However, in comparison to 2008 and 2013 the overall context has changed significantly as the EGD and its related strategies have put a stronger focus on sustainability, climate change adaptation and biodiversity. Other related legislation (PHL[45], OCR, Organic Regulation[46]) has evolved and there have been new scientific and technological developments. Individual Directives have undergone a high number of targeted amendments in certain articles to address specific issues and to keep pace with these developments[47]. Furthermore, seven out of 11 Directives have been recast (Annex 5, Section 1). However, the majority of the provisions in the Directives have never been revised in a coherent and systematic way. Additionally, MS have adopted their own solutions in relation to new developments not covered by the legislation[48]. These scattered approaches have exacerbated the problems of incoherence between the different Directives and further increased their overall complexity.

2.1.1. Problem 1: Non-harmonised internal market (divergent conditions for the operators across Member States)

Implementation of various aspects of the legislation and therefore **conditions for operators and marketed PRM and FRM differ between Member States (MS)**, either because the legislation is unclear and leaves room for interpretation, or MS tried to find practical solutions to overcome rigid provisions and provisions that have not followed in a timely manner new developments in science and technology.

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[43] ICF (2021).
[44] ICF (2023).
[45] For example, under the new PHL the plant passport covers compliance with the requirements for RNQPs. It is therefore no longer possible to regulate RNQPs only in the framework of the PRM/FRM certification, a solution considered in the 2013 IA.
[46] The Organic Regulation has introduced new categories of "organic varieties suitable for organic production" and "organic heterogeneous material" (Annex 5, Section 2.5).
[47] For example, Commission Implementing Directive (EU) 2021/971 introduced the use of BMTs in certification but only for agricultural plant species. Other uses (e.g. DUS, marketing controls) and other species are not covered by the legislation. Commission Implementing Directive (EU) 2022/1647 and 2022/1648 introduced derogations as regards DUS for the acceptance of "organic varieties suitable for organic production" for a few vegetable and agricultural plant species but the PRM legislation does not include a comprehensive approach for such varieties
[48] For example, the use of BMTs.

The provisions in the marketing Directives on OCs[49] for verification of compliance with the requirements of the legislation are quite vague and do not specify minimum requirements[50]. PRM imported from third countries needs to fulfil the same requirements as PRM produced in the Union pursuant to Union rules, but there is no harmonised framework for OCs establishing the place of those OCs (at the border control post[51] or the final point of destination) and the approach (random or risk-based OCs). MS have implemented import controls in a different way and as a consequence it is easier to import PRM in some MS compared to others. There are also differences between MS as regards **OCs and enforcement** related to marketed PRM and FRM[52]. All operators are affected by those inconsistent and unsystematic controls and enforcement that undermine the functioning of a competitive market and increase the likelihood of lower quality PRM and FRM on the market.

Differences in controls and enforcement regarding Union regulated non-quarantine pests (RNQPs)[53] have an impact on all operators[54] producing and marketing PRM. Those difference arise because RNQPs are regulated both under the PHL[55] and under the marketing Directives as part of the certification requirements (Annex 5, Section 7). Those two frameworks are not fully coherent, as any amendments of PHL and the marketing Directives are not simultaneous. Furthermore, the PHL falls under the scope of the OCR[56] while the marketing Directives do not. Where measures on RNQPs of fruit plants and vine are regulated under the marketing Directives[57] while the RNQPs are listed in the PHL[58], there is uncertainty as to whether RNQPs fall under the scope of the OCR (Annex 5, Section 7). The OCs on the deliberate release into the environment of Genetically Modified Organisms (GMOs) for the purpose of food and feed production falls under the scope of OCR and includes the presence of GMOs in PRM. OCs on PRM containing GMOs fall under the scope of the OCR while the identity and quality controls on that PRM in the frame of the PRM legislation are not under the OCR. This results in the doubling of OCs on the same material and subject to different approaches. This situation leads to uncertainty for all MS and operators about which legislation to adhere to[59] and consequently to differences in implementation and conditions for the operators, that could eventually undermine enforcement and the quality of controls.

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[49] OCs are carried out during the production and marketing of PRM in the EU and the import of PRM/FRM from third countries.
[50] See for example Article 19(1) of Council Directive 66/402/EEC.
[51] Border control posts are the places designated by MS for the performance of OCs at first arrival into the Union and on each consignment of certain categories of goods (i.e. in contrast to OCs performed at the place of destination).
[52] ICF (2021) Section 4.1.6 and ICF (2023) Section 2.1. For example, while documentary checks form the largest proportion of OCs in all MS, there is a huge variation between MS as regards the proportion of the inspected PRM/FRM subjected to visual inspections and to sampling and testing (ranging from 0% to 100%). In relation to import controls there are big differences between MS in relation to the percentage of consignments subjected to official controls (ranging from less than 10% to more than 75%).
[53] RNQPs are defined in Article 36 to Regulation (EU) 2016/2031. The definition of RNQP includes the following elements: It has a taxonomic identity. It is present in the Union territory. PRM/FRM is the main pathway for spreading of RNQPs. The presence of an RNQP on PRM/FRM has an unacceptable economic impact on the intended use of that PRM/FRM.
[54] About 7 000 operators in seed sector and over 20 000 suppliers of PRM of fruit plants across the EU.
[55] Commission Implementing Regulation (EU) 2019/2072.
[56] Article 2, point (g) of Regulation (EU) 2017/625.
[57] This is the case for fruit plants under Commission Implementing Directive 2014/98/EU and Implementing Directive 2008/90/EC and for vines under Council Directive 68/193/EEC.
[58] Additionally, PHL includes requirements on Quarantine Pests (QPs).
[59] ICF (2021) Section 4.1.5 and targeted survey of NCAs in the context of ICF (2023).

The VCU examination for variety registration can only be carried out officially, but in order to overcome the limitations in resources[60] a few NCAs have introduced their own practices for taking into account breeders' data[61], leading to a divergence in the conditions for operators across MS[62].

Absence of common rules on **recent scientific and technical developments**, namely innovative production processes, bio-molecular techniques (BMTs)[63] and digitalisation[64], has resulted in operators not being able to market certain PRM/FRM produced by innovative processes (e.g. true potato seed[65], the fruit plants and vine marketing Directives do not include rules for the certification of selected clones). For FRM, clones produced by *in vitro* propagation the current rules do not ensure traceability, because the legislation does not require reference to the production place of the clones. As regards BMTs, MS increasingly adopt national approaches (Annex 5, Section 8). For example, in Spain the use of BMTs is allowed as a self-standing tool for the identification of varieties during marketing controls without the need for observing the phenotypic characteristics of the varieties during control plot testing[66,67]. This leads to divergent conditions for operators across MS as well as to missed opportunities to increase the efficiency of processes and competitiveness of the PRM/FRM sectors[68] Furthermore, the absence of such rules at EU level leads to the divergence of the EU legislation from international standards where such advances are already catered for (e.g. International Union for the Protection of New Varieties of Plants (UPOV)[69], Organization for Economic Co-operation and Development (OECD) Seed Schemes).

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[60] The examination for variety registration (DUS and VCU where applicable, with DUS and VCU done in parallel) depending on the species last at least two years. This period cannot be reduced as these examinations require growing the plants in the field. Implementation of DUS is standardised across the MS (based on the application of CPVO protocols for CPVR) while for VCU only four general characteristics are laid down. There are also differences between the MS as regards VCU costs (attributed mostly to differences in wages) and duration of VCU (for a given species some NCAs may perform VCU 1 year longer than others, difference attributed mostly to the relative importance of the species in the given MS), FCEC(2010) and ICF (2021).

[61] Before submitting an application for official registration of a new variety, breeders already test that variety for a number of desirable characteristics.

[62] Outcome of targeted survey of NCAs in the context of ICF (2023).

[63] BMTs have the potential to increase efficiency by shortening variety registration (PRM) and provenance trials (FRM). BMTs also have the potential to support marketing controls to check the identity of varieties, by supplementing visual inspection and control plot testing in the field.

[64] Currently the legislation implies that labels are physical. Digitalisation has the potential to improve the efficiency and integrity of the certification and labelling system and to address the increased risk of fraud in the seed sector caused by increasing volumes of seed lots being traded internationally.

[65] The marketing Directive on seed potatoes is restricted to vegetative propagation with potato tubers (= asexual reproduction), therefore it does not cover the use of true potato seeds, i.e. botanical seed (= sexual reproduction). The legislation on fruit plants and FRM lacks specific provisions for the use of *in vitro* propagation (process whereby PRM and FRM are produced in the laboratory under sterile conditions).

[66] Article 30 to Real Decreto 929/1995, de 9 de junio, por el que se aprueba el Reglamento técnico de control y certificación de plantas de vivero de frutales. «BOE» núm. 141, de 14/06/1995.

[67] PLAN NACIONAL DE CONTROL Y CERTIFICACIÓN DE PLANTAS DE VIVERO DE FRUTALES PARA EL AÑO 2017. MINISTERIO DE AGRICULTURA, ALIMENTACIÓN Y MEDIO AMBIENTE. https://www.mapa.gob.es/es/agricultura/temas/medios-de-produccion/plannacionaldecontrolycertificaciondeplantasdevivero2017_tcm30-552931.pdf

[68] ICF (2021) Section 4.2.

[69] UPOV (2020).

2.1.2. *Problem 2: PRM/FRM legislation is not aligned with the objectives of the European Green Deal and related strategies*

This problem concerns restrictions in relation to genetic diversity of PRM/FRM, insufficient sustainability considerations and incomplete scope of the FRM legislation. In the case of PRM, more genetically diverse varieties (e.g. conservation and organic varieties) cannot meet the existing legal requirements for variety registration. The activities of seed conservation networks and exchange in kind of seed are subject to the current rules on variety registration. There is an insufficient supply of high-quality certified FRM due to the increasing demand for FRM for non-forestry purposes[70]. The increasing occurrence of extreme weather and disasters in combination with an insufficient assessment of sustainability characteristics in the registration of new varieties and of FRM put pressure on the stability of yield in the PRM sector and on the supply of suitable FRM and thus on the resilience of agri-food production and forestry.

First, the current variety registration system based on DUS limits the acceptance and therefore the access to the market of less uniform and more genetically diverse varieties. Such varieties are desirable for **organic production**[71] and other low input agricultural systems. They could contribute to more diverse agri-food systems, in particular at local level and broaden the genetic reservoir of cultivated crops[72] but are currently restricted due to the DUS requirements. The demand for organic seed in the EU vastly exceeds the supply (though with variations between the different regions and crops), resulting in a high use of derogations for untreated conventional seeds despite that these derogations are phased out by 2036 under the Organic Regulation. In the absence of sufficient quantities of certified organic seed, the use of untreated conventional seed in organic farming ranges between 18% in Central Europe and 48% in Eastern Europe[73]. The problem concerns all breeders active in the breeding of organic varieties, since those varieties have difficulties to access the market[74] as well as the organic farms across the EU. There are about 244 000 farms in the EU that have some organic area, two-thirds of which are fully organic. In 2018 the total area under organic production in the EU was 13 million hectares or 8% of the total utilised agricultural area[75]. The problem also undermines the effort to reach the objective under F2F of at least 25% of the EU's agricultural land under organic farming by 2030.

The variety registration system has a restrictive impact on activities that are important for the **conservation and sustainable use of plant genetic resources** and help in addressing the biodiversity and climate change challenges. Seed conservation networks[76] aim to conserve

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[70] Non-forestry purposes comprise agroforestry, plantations for biomass production and the EU target of planting 3 billion additional trees by 2030.

[71] According to the principles of the Organic Regulation, for the production of organic varieties suitable for organic production, the organic breeding activities shall be conducted under organic conditions and shall focus on enhancement of genetic diversity, reliance on natural reproductive ability, as well as agronomic performance, disease resistance and adaptation to diverse local soil and climate conditions. However, currently the biggest share of PRM for organic varieties marketed in the EU are varieties accepted under the DUS rules (Euroseeds (2019)), i.e. they are characterised by high uniformity contrary to the abovementioned principles.

[72] FAO (1997).

[73] Solfanelli F. *et al.* (2022).

[74] The number of those breeders in EU is unknown.

[75] Eurostat (2020).

[76] There is no accurate information on the number of such networks in EU, nor on the number of varieties or accessions that they maintain. Indicatively, DIVERSIFOOD (2017a) collected via a survey information on 80 such initiatives

threatened varieties[77] and prevent genetic erosion[78], while for addressing particular local needs new **locally adapted varieties**[79] are bred[80]. However, most often conservation and new locally adapted varieties either do not meet the variety registration requirements (DUS) or the quantities of PRM are so low that it is unfeasible to benefit from the existing derogations for conservation varieties[81]. Due to these restrictions the availability of such varieties in the public domain often relies on **exchange in kind of seed**[82,83], which is currently not possible as it is covered by the definition of "marketing" within the Directives[84] and therefore requires the fulfilment of variety registration and certification requirements (Annex 5, Section 2.2). Exchange in kind of seeds between farmers is currently also restricted by these requirements, although an important number of small farmers across EU save and exchange seed from their harvest, because such seed is better adapted to their local environment conditions following ongoing on-farm selection over many years. Indicatively, one of the organisations advocating for a framework for seed exchange between farmers counts over 80 000 members across EU. These restrictions also affect all operators **marketing to amateur gardeners** (Annex 5, Section 2.4) with the vast majority of PRM marketed to amateur gardeners belonging to registered varieties, leaving the demand for locally adapted varieties unsatisfied[85]. The derogations to the rules for acceptance of varieties and certification of seeds for agricultural and vegetable conservation varieties[86] have had some results[87] but the requirements are still considered too burdensome[88]. Furthermore, these derogations do not cater for new locally adapted varieties. MS currently have the possibility to accept conservation varieties on the basis of an official DUS examination, or an official DUS examination with increased tolerance for reduced uniformity or on the basis of other information such as historical knowledge. This leads to different conditions for operators between the MS. For example, Czechia carries out DUS, Spain carries out DUS but

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across the EU. Most of them manage between 100 to 1 000 samples each. Number of members varies from a few to hundreds. The survey also identified that there are probably many more initiatives across the EU than those that responded.

[77] Conservation can be done *in situ* at the existing location (i.e. in the farmed environment in the case of cultivated plant species and forest genetic resources in forests) or *ex situ* in gene banks.

[78] Genetic erosion is the loss of genetic diversity between and within populations or varieties of the same species over time, or reduction of the genetic basis of a species due to human intervention or environmental change (Article 2(b) of Commission Directive 2008/62/EC).

[79] Lack of improved varieties suitable for marginal areas led to breeding of such varieties, which are typically quite heterogeneous in order to withstand particular conditions. Usually bred under participatory plant breeding, whereby breeders, researchers, farmers and other stakeholders work together.

[80] This is reflected also in the eligible types of intervention in CAP Strategic Plans under Regulation (EU) 2021/2115

[81] Exemption from DUS and certification requirements under Directives 2008/62/EC and 2009/145/EC. See also Annex 5, Section 2.6.

[82] DIVERSIFOOD (2017b).

[83] Exchange in kind of seed means the transfer of seed from one farmer to another farmer. See also Annex 10 of ICF (2023).

[84] Marketing is defined in the Directives as '*the sale, holding with a view to sale, offer for sale and any disposal, supply or transfer aimed at commercial exploitation of seed to third parties, whether or not for consideration*.'

[85] ICF (2021) Section 4.5.

[86] Conservation varieties according to Commission Directives 2008/62/EC and 2009/145/EC are landraces and varieties which have been traditionally grown in particular localities and regions and threatened by genetic erosion. Landrace means a set of populations or clones of a plant species which are naturally adapted to the environmental conditions of their region.

[87] At the end of 2021, there were 396 conservation varieties of agricultural plant species and 177 of vegetable species registered in the Common Catalogues (representing around 1% of the total number of registered varieties).

[88] ICF (2021) Section 4.6.

accepts uniformity levels of 90%, Germany accepts a variety description by applicant but carries out a DUS examination in case of doubt[89].

Second, the current PRM/FRM rules have only a **limited contribution to sustainable production**. Those provisions are restricted to varieties of agricultural species (VCU)[90] in the case of PRM and the higher FRM categories[91]. Similar requirements to VCU are in place for vine under the DUS examination[92]. Currently no such provisions exist for vegetable species and fruit plants. The PRM legislation prescribes four broad criteria that must be examined in VCU testing leaving the degree to which sustainability is addressed at the discretion of the MS, thus implying that new varieties can be registered without improved performance regarding sustainability characteristics[93].

Likewise, the FRM legislation prescribes two broad sustainability characteristics (adaptability of basic material to ecological conditions, and health and resistance of basic material to adverse climatic conditions), leaving room for manoeuvre to MS for their implementation[94]. Some MS (e.g. Estonia, France, Finland, France and Germany) have invested in tree breeding programmes to ultimately improve the sustainability of the resulting FRM. Others have paid little attention to this aspect[95] despite forests being under pressure because of climate change. This situation is inadequate for rapidly changing conditions.

Potentially all farmers and foresters in the EU (over 5 million specialist crop farms and over 500 000 persons employed in the forestry and logging sector[96]) are at risk of not having PRM and FRM suitable for future challenges and subsequently of facing increased losses of production. The consequences will be equally detrimental for the wider society in terms of reduced food security and other indirect impacts on sectors relying on agriculture and forestry. The magnitude of the problem is already very significant. Over the period 1981-2010, the average annual crop losses caused by drought in the EU have been estimated at EUR 4.8 billion/year[97]. However, in 2018 and 2019 in Germany alone extreme drought and heat events have caused losses in agriculture of EUR 7.8 billion, including direct losses of EUR 4.4 billion across all crops (especially wheat and potato) and indirect losses of EUR 3.4 billion. Losses in forestry were EUR 17.8 billion, including losses of forestry companies of EUR 8.5 billion, indirect costs of EUR 2.8 billion from CO_2 release from

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[89] Information collected by the survey under ICF(2019).
[90] Some sustainability aspects are included in the VCU examination of candidate varieties of agricultural plant species.
[91] Qualified and tested material.
[92] For the purpose of simplicity, the field trials carried out to meet these VCU-like requirements for vine will also be referred to as VCU.
[93] Those criteria are currently defined as "1. Yield; 2. Resistance to harmful organisms; 3. Behaviour with respect to factors in the physical environment; 4. Quality characteristics" without any further specification. France has elaborated multi-criteria indexes for each plant species with weighting factors for each of the criteria and therefore already cater for sustainability in a holistic manner. Most MS (e.g. Germany and The Netherlands) have simpler systems in place, based on yield and pest resistance and include abiotic factors only for certain specific cases.
[94] The targeted survey undertaken by ICF (2023) could only collect indicative data due to a low response rate. About 55% of forest nurseries assess basic material for sustainability characteristics and more than 55% out of those conduct this assessment on a voluntary basis.
[95] 72% of basic material available in FOREMATIS is intended for the production of the lower quality FRM categories (source-identified and selected material) whereby a minimal effort is undertaken to demonstrate the superiority of the FRM in comparison with the efforts undertaken for the qualified and tested categories.
[96] EUROSTAT (2020)
[97] PESETA IV https://joint-research-centre.ec.europa.eu/peseta-projects/jrc-peseta-iv_en

damaged wood (at EUR 201 per tonne of CO_2) and additional indirect damages of EUR 6.5 billion along various value chains[98].

Third, the **scope of the FRM legislation is incomplete** as it is restricted to the production of FRM for forestry purposes despite an increasing demand for FRM for non-forestry purposes under the EGD[99]. Moreover, temporary difficulties in the supply of FRM are increasing because of a higher incidence of adverse weather, drought and disasters caused by changing climatic conditions. This results in the need for reforestation of damaged parts of the forests. Because of the restricted scope of the legislation, the current FRM production levels are insufficient to address the higher demand for FRM. In addition, MS have interpreted in a different way the activities[100] that are considered as forestry purposes[101] causing a difference in scope between the national legislations. This problem affects all operators active in the production and marketing of FRM because an activity that is within the scope in one MS may be out of the scope of the legislation in another MS. Finally, the legislation does not contain clear rules on the information to be provided to users of FRM by the nurseries[102], while such information is necessary for sound decision making in relation to tree planting[103]. Without prior access to this information, users of FRM may plant trees that are not suited for the regional climatic and ecological conditions in the worst-case scenario. This is likely to result in forests that are more vulnerable to drought, pest attacks and other disturbances and could in turn have a huge environmental, economic and social impact[104].

2.2. What are the problem drivers?

2.2.1. Regulatory drivers

The long history of amendments of the legislation has led to a complex, incoherent and fragmented legal framework that is not up to date with the current scientific and technical developments. Certain provisions, as on OCs, are vague, therefore leaving significant margin for interpretation to the MS and resulting in different conditions for operators. Furthermore, there are no legal means of ensuring more coherent OCs and enforcement of the rules across MS[105]. The PRM and FRM legislation has not been fully adjusted to the evolution of closely related policies (PHL, Organic Regulation, OCR and SUR). Overlaps between the different policies create uncertainty about how to implement the respective provisions, exacerbating the possibilities for different interpretations by the MS and subsequently different conditions for operators.

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[98] Trenczec J. *et al.* (2022)
[99] FRM production for non-forestry purposes makes up about 10% of FRM in most Member States (Section 3.8.6 to Analytical summary report targeted survey by ICF (2023)).
[100] Certain MS consider restoration of ecosystems and biodiversity conservation to be forestry purposes while others do not.
[101] Position paper submitted by EUFORGEN in reply to public consultation.
[102] ICF (2021) Section 4.7.2.
[103] Mauri *et al.* (2023)
[104] Schuldt *et al*. (2020), Hlásny *et al.* (2021)
[105] With the exception of fruit plants and FRM, the marketing Directives do not contain any provisions for audits of the OC systems in MS.

2.2.2. New policy developments

At the time of its introduction, the PRM legislation focussed on productivity and good quality of the PRM in order to ensure food security[106], while the FRM legislation prioritised the origin of the basic material and its characteristics suitable for forestry purposes. The legislation however has limited means to address the new challenges in relation to sustainability, climate change adaptation and biodiversity. This alignment is inadequate, as it does not provide the appropriate tools for meeting the commitments made under EGD strategies. Rules for variety registration are not adapted to the needs for less uniform varieties (such as the "organic varieties suitable for organic production" under the Organic Regulation) and new locally adapted varieties. The comprehensive scope of the current marketing rules restricts the activities related to conservation and sustainable use of plant and forest genetic resources. The scope of the FRM legislation is unfit for the increased demand for FRM due to climate change and the objectives of the Biodiversity Strategy. The PRM/FRM legislation has also diverged from other related legislation (PHL, Organic Regulation, OCR) that has significantly evolved over the last years.

2.2.3. New developments in science and technology

Developments in technology and new scientific knowledge lead to new processes of production of PRM/FRM. New solutions are being developed with the use of BMTs and digital tools that have the potential to simplify and render more efficient variety registration, certification of PRM and FRM and marketing controls. The PRM and FRM legislation has not kept pace with these advances, therefore leading to non-harmonised application of such techniques as MS increasingly adopt national approaches (Annex 5, Section 8).

2.3. How likely is the problem to persist?

In the absence of EU action, the differences between MS as regards the interpretation and implementation of the existing marketing Directives will persist and are likely to further increase. The lack of coherence of the PRM/FRM legislation with the PHL and OCR and resulting burdens for NCAs and stakeholders will remain, such as the duplication of RNQPs in the marketing Directives and the PHL and the uncertainty as regards the OCs on RNQPs. MS will likely continue to deploy different solutions, further aggravating the differences of conditions for operators.

Technical innovations such as digital technologies and BMTs are more likely to be taken up by big companies while there is a risk that SMEs would not invest in such technologies if there is no legal certainty around the acceptance of their use (Annex 5, Section 8) thus impacting the competitiveness of the EU industry in relation to other major international players (US, China) and in lost opportunities in related innovation and marketing.

Disproportionate burdens for activities, such as seed conservation networks and breeding for organic production and locally adapted varieties are likely to be aggravated. Without clarifying the rules, such activities will depend on MS decisions to support them, leading to increased uncertainty for the stakeholders concerned and a non-level playing field for operators. This situation is likely to lead to further loss of cultivated diversity. Differences between MS related to sustainability

[106] See for example the recitals of Directive Council Directive 66/402/EEC.

characteristics in the examination of new varieties and the approach for registering "organic varieties suitable for organic production" are also likely to further increase.

Activities, such as agroforestry, plantations for biomass production and the EU target of planting 3 billion additional trees by 2030 are gaining importance under the EGD. Those activities generate an increasing demand in supply of FRM. Problems in supply of appropriate FRM are likely if the scope of the FRM legislation is not adjusted accordingly.

Efforts to address the challenges around sustainability, climate change and biodiversity will be undermined. In the medium or long term there could likely be insufficient incentives to produce PRM and FRM that is adapted to new climatic conditions and could contribute to sustainable production. More frequent extreme weather events (e.g. drought, heavy winds, and flooding) may cause more regular difficulties in supply of PRM and FRM. This may in turn jeopardise the availability of crops to ensure seed and food security as well as of tree seedlings for multifunctional forestry purposes.

3. WHY SHOULD THE EU ACT?

3.1. Legal basis

The PRM legislative framework is based on Article 43(2) of the Treaty on the Functioning of the European Union (TFEU) implementing the Common Agricultural Policy. The TFEU qualifies agriculture as shared competence between the EU and its MS. All sectors of agricultural activity, as well as ancillary activities upstream and downstream, have been largely regulated at EU level. This means that in accordance with Article 2(2) TFEU, legislation in the area of agriculture is predominantly a role for the institutions of the EU. The same legal basis should also be used for the new act(s) that might be adopted as a result of this initiative.

3.2. Subsidiarity: Necessity of EU action

The introduction of the EU Directives on the marketing of PRM/FRM has been a major contributor to the creation of the internal market. The EU rules on marketing of PRM/FRM have had a generally positive impact on free movement, availability and quality of PRM/FRM[107]. If there had been no action at EU level, 27 systems instead of one would be in place today thus hindering the movement within the internal market, distorting competition and increasing the financial burden associated with registration of varieties and the necessary controls on the identity, health and quality of PRM/FRM.

3.3. Subsidiarity: Added value of EU action

Variety registration and certification and marketing of PRM and FRM rely on examinations, assessments and inspections performed by NCAs. Their results are valid in all 27 MS and follow the 'one key, several doors' principle. This ensures the quality of EU PRM and FRM while safeguarding open and fair competition on the single market. However, the different interpretation and implementation of the EU rules at national level has caused unequal conditions for operators

[107] FCEC(2008), ICF(2021).

across MS. This requires a greater harmonisation of the legislation but at the same time MS need flexibility to adapt the production process and the examination of the characteristics of the plants to local agro-ecological conditions and in the case of FRM to environmental and climatic conditions.

The unrestricted marketing of PRM and FRM throughout the EU territory is imperative to address transboundary issues such as the climate and biodiversity crises, the need for sustainable production to ensure food security and sustainable afforestation/reforestation to secure multi-functional forests for future generations. The current geopolitical situation and energy crisis have elevated the importance of securing agricultural and food production. Under the F2F, EU Adaptation and Biodiversity Strategies several commitments were made that necessitate the amendment of the PRM and FRM legislation. Those commitments mirror the demand from society for increased food security, more sustainable food production, locally produced food, diversification of production methods and multi-functional forests (e.g. timber production, biodiversity conservation, leisure activities).

4. OBJECTIVES: WHAT IS TO BE ACHIEVED?

4.1. General objectives

The general objective of this initiative is to ensure, for all types of users, PRM and FRM 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.

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

4.2. Specific objectives

- 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 (in particular, innovative production processes, BMTs and digital solutions);
- To ensure availability of PRM/FRM suitable for future challenges;
- To support the conservation and sustainable use of plant and forest genetic resources.
- To harmonise the framework for OCs on PRM/FRM;
- To improve coherence of PRM/FRM legislation with the PHL.

4.3. Intervention logic

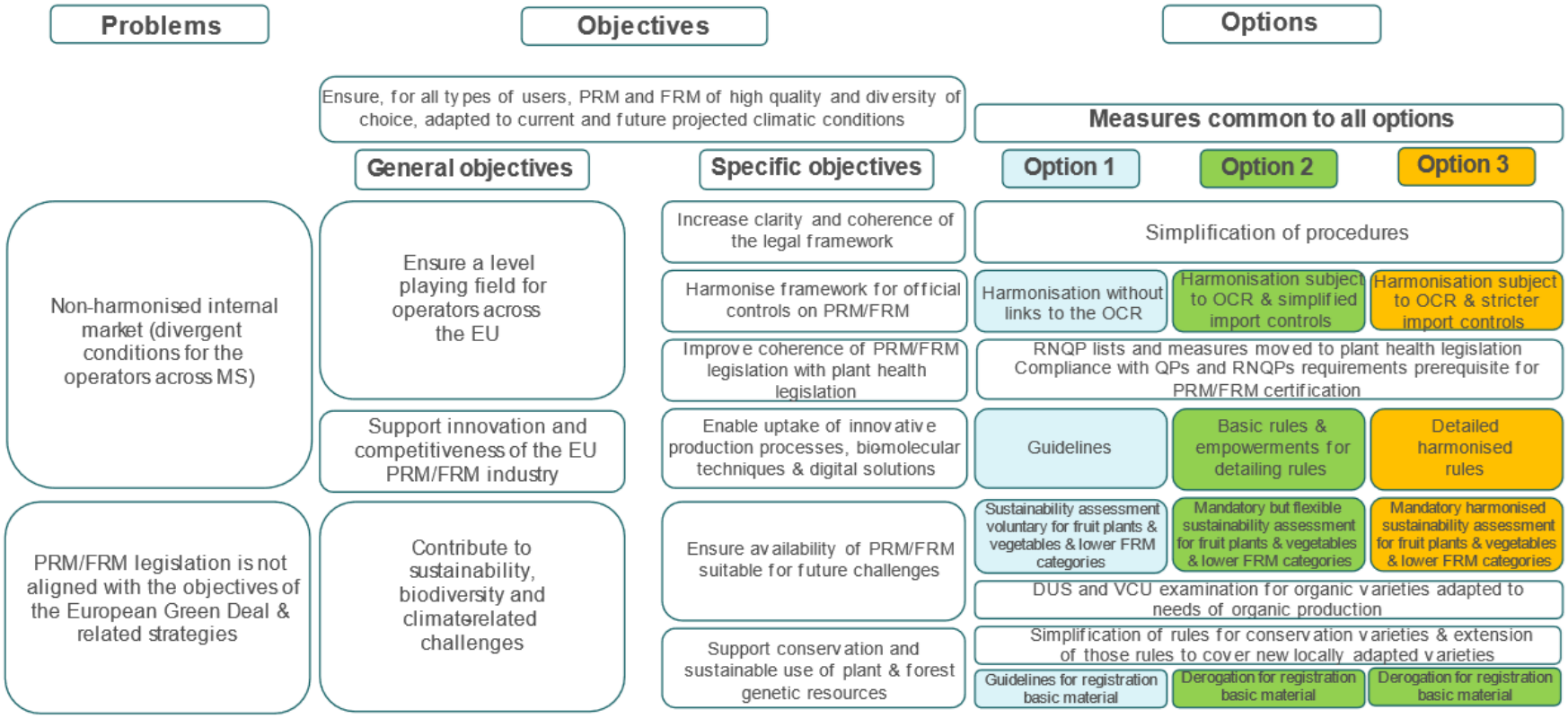

Figure 2. Intervention logic

5. WHAT ARE THE AVAILABLE POLICY OPTIONS?

5.1. What is the baseline from which options are assessed?

The baseline is a "no policy change" scenario, in which the current EU legislation on PRM and FRM remains in force as it currently stands, while other policy initiatives (SUR and NGTs) will be adopted. As regards PRM, the current VCU requirements provide a basic common framework for the sustainability assessment of new varieties of agricultural plant species. For species not subject to VCU assessment for variety registration (vegetables and fruit plants), the breeding of new varieties depends only on the priorities set by the breeders and the degree to which they respond to market demands. Increased yield, tolerance to pests and abiotic factors and other desirable characteristics are in increasingly high demand by farmers, however present only to a certain extent in the breeding efforts of new varieties[108]. As regards FRM, some elements of sustainability assessment are in place only for the highest categories of FRM. Political priorities set by the EGD Strategies (i.e. F2F, Biodiversity, Forest and Adaptation) and regulatory developments (e.g. the initiative for a new regulation on the sustainable use of plant protection products, SUR) for reduced use of fertilisers and pesticides also provide an incentive for breeders to develop new varieties that are less dependent on such inputs and are, therefore, contributing to sustainability of agri-food systems. The F2F, EU Forest Strategy[109] and SUR[110] recognise the necessity of introducing relevant measures in the PRM/FRM legislation. Breeding of new varieties take on average over 10 years depending on the species, while the timeframe for FRM can be much longer[111]. Over the same timeframe, challenges as climate change are projected to have significant impacts on agriculture and forestry[112].

Efforts are made to compensate impacts of climate change by moving from south to north agronomic practices (e.g. introduction or increase of irrigation in areas where it was previously not necessary), varieties and species (e.g. cultivation of sorghum instead of maize to compensate for reduced availability of water). However, these solutions are constrained by the new agro-ecological conditions (e.g. precipitation rates, daylight, soil). In forestry there are longer cycles (several decades) than in agriculture. It is therefore not likely that foresters will change the tree species used in the mid-term period. Foresters could consider using the same tree species but from a different provenance (origin). Moving of varieties and species from south to north is not a sufficient solution in itself as there will not be enough area as soils are not always suitable for agricultural production (e.g. tundra). Targeted breeding efforts for new varieties, new species and selection for FRM are needed to overcome these constraints in order to be able to successfully move varieties and species from south to north, but also for developing new varieties adapted to new conditions in the south.

The time frame assumed for the dynamic baseline is 10 years and assumes that other relevant EU policies (SUR, NGTs and FSFS) would be implemented. Even if other initiatives would be

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[108] For example, https://www.kws.com/corp/en/media-innovation/innovation/breeding-objectives/

[109] F2F recognises that farmers need to have access to a range of quality seeds for plant varieties adapted to the pressures of climate change. The EU Forest Strategy recognises that adapting forests to climate change and restoring forests following climate damages will require large quantities of appropriate FRM.

[110] SUR identifies new varieties with increased resistance to pests as one of the means to achieve its objectives.

[111] Some tree species set seed only every decade. Trees can reach 100s of years depending on the species and as such are likely to face unpredictable conditions over their lifetime.

[112] Changes in temperature and precipitation as well as weather and climate extremes are already influencing crop yields and forest productivity in Europe. The number of extreme events negatively affecting agriculture in Europe is projected to increase. Other climate change effects are increase in plant pests, changing patterns in water availability for irrigation, changes in species range and forest composition. EEA (2016) and EEA (2019).

successful in halting/limiting greenhouse gas emissions, the impacts of climate change would persist. Adaptation of new varieties and species and of FRM to those impacts would still be needed. In absence of regulatory changes for steering the breeding of new varieties for characteristics necessary to face those challenges, new varieties and FRM would gradually become unsuitable for the current and future challenges. A recent assessment suggests that current breeding programmes and variety selection practices do not sufficiently prepare for climatic uncertainty and variability[113]. The opportunity to mitigate the impacts of climate change that are already occurring would be lost (e.g. on average EUR 4.8 billion/year of crop losses caused by drought in the EU, 4.9% of canopy cover loss in Germany in 2018-2020[114]). Similarly, opportunities would be missed to introduce varieties with improved disease resistance that could help reduce the use of pesticides.

The problems resulting from the limitation of activities that can be carried out under official supervision, incoherence and/or duplications between PRM/FRM legislation and PHL, OCR and the Organic Regulation, the use of innovative production processes, BMTs, and digital solutions will remain. They are expected to persist and gradually aggravate, as MS will continue to adopt divergent national practices.

Under the baseline there are no provisions in the EU legislation for the use of innovative production processes, BMTs and digital solutions. For this reason, an effort to resolve these issues by EU guidelines would be impossible without any revision of the EU legislation. The absence of a common EU framework will lead to further divergence of conditions for operators across the Union. In turn, the burdens for NCAs and operators are expected to increase, leading to reduced competitiveness of the EU PRM and FRM sectors. Likewise, the clarification and streamlining of existing administrative procedures cannot be resolved without changing the legislation. That clarification in most cases concerns the streamlining and/or simplification of procedures across crop groups such as the decision-making procedure for regulation/deregulation of species. In Directive 2008/90/EC on fruit plants, the decision to regulate/deregulate species is based on the Comitology procedure while in the Directives on agricultural species the co-decision procedure applies[115].

Experience gained by temporary experiments has shown that certain aspects of the legislation can be simplified. For example, the extension of the possibility for operators to carry out certification activities for pre-basic and basic seed of agricultural species has been shown to be equally reliable as official certification but with reduced costs for the operators. However, permanent implementation of such changes is not possible under the baseline without a revision of the legislation. The legislative framework will furthermore remain cumbersome for activities linked to the conservation and sustainable use of plant and forest genetic resources. Currently the Common Catalogues contain a small number of conservation varieties[116] and no forest genetic resources[117]. The number of conservation varieties of agricultural plant species and vegetable species added to the Common Catalogues every year is negligible. There is no indication that this trend will change over the next years under the baseline.

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[113] Kahiluoto *et al.* (2019)

[114] Thonfeld *et al.* (2022) In the period 2018-2020 4.9% of canopy cover was lost in German forests because of extreme drought and tree species unsuitable for the environmental and climatic conditions.

[115] The list of species can be amended by comitology but at the same time the technical requirements for the new species must be introduced in the basic act by co-decision.

[116] Conservation varieties constitute less than 1% of the varieties of agricultural and vegetable species.

[117] The FRM Common Catalogue (https://ec.europa.eu/forematis) does not contain any forest genetic resources due to the cumbersome process for the registration of basic material fit for use as forest genetic resources.

Breeding of varieties for organic production and low-input agriculture and of varieties adapted to local agro-ecological conditions will remain under the baseline marginal activities because such varieties are often too heterogeneous to meet the uniformity requirements under DUS examination, while they are not covered by the current derogations for conservation varieties. Provisions on organic heterogeneous material recently introduced by the Organic Regulation offer a partial solution as the production of this type of material is restricted to certified organic production (Annex 5, Section 2.5).

5.2. Description of the policy options

The options were designed based on the PRM study, the supporting studies and by reassessing elements of the 2013 impact assessment. The options constitute the best options to address the problems, albeit to a different extent. Alternative measures have been reviewed but discarded at an early stage due to lack of stakeholder support (Section 5.3). There was no reason to design options that deregulate the sector as no stakeholder supported it.

The options share a common set of measures which are the same for all options (Figure 3). Some of those common measures are only for PRM and others are only for FRM. There is overall support in the PRM/FRM sector for maintaining the current regulatory system and its two basic pillars of registration of varieties/basic material and PRM/FRM certification. The policy options have therefore been designed from a spectrum of highest flexibility for MS and operators (option 1) to one of highest harmonisation with little to no room for individual flexibility (option 3) with option 2 presenting a balanced approach. The current presentation of the 3 options graded as described in terms of flexibility/harmonisation seemed to be the most coherent approach, especially given the number of issues to be addressed and taking into account their actual feasibility in relation to the interaction with various stakeholders. The design of the policy options considered the priority of the F2F to address sustainability challenges. Hence, under all options the sustainability requirements for the approval of new varieties are strengthened.

The flexibility which the MS need relates in the first place to their national agro-ecological conditions. The MS will continue to be exempted from the scope of the legislation for certain crops (e.g. vine not growing in Nordic MS). Variety testing including relevant variety characteristics needs to be adapted to the climatic conditions (e.g. cold tolerance in the North and drought tolerance in the South) or the certification requirement to combat noxious weeds (*Avena fatua* in certain MS).

Under all options, a transitional period will be foreseen to allow the reorientation of breeding efforts towards varieties with improved sustainability characteristics. The defining elements of the options for both PRM and FRM are:

- Strengthened sustainability requirements;
- Conservation and sustainable use of plant and forest genetic resources;
- Official controls;
- Enable uptake of BMTs, innovative production processes and digital solutions.

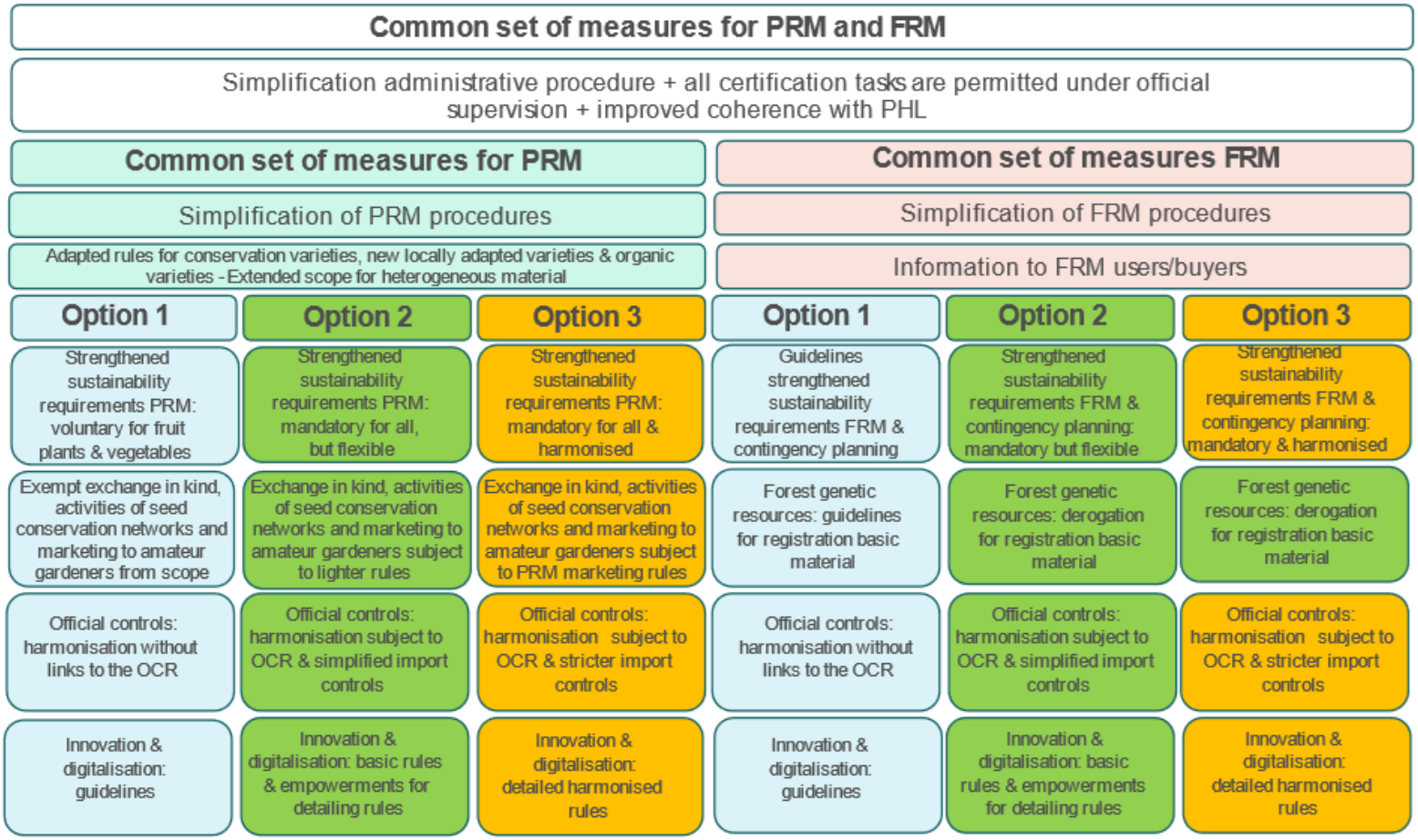

Figure 3. Design of options

5.2.1. Measures common to all options

Apart from the no policy change scenario all 3 options share **a core of several common measures** aimed at simplifying administrative procedures and a more flexible decision-making process, as this is a problem which affects the efficiency of processes.

For PRM and FRM legislation:

- All professional operators to be registered in a single register under the PHL[118].
- All certification tasks are permitted under **official supervision** except the issuing of the official label (PRM) and the Master certificate (FRM).
- To avoid overlaps with PHL, PRM/FRM legislation will directly refer to PHL for the list of RNPQs and specific measures. Compliance with requirements for QPs and RNQPs will remain a prerequisite for the certification of PRM/FRM.

For PRM legislation:

- **Simplification of existing administrative procedures**:
  - Decisions for addition of new species in, or removal of species from, the scope of the PRM legislation and Decisions on the equivalence to EU rules for third countries will be taken by means of tertiary legislation[119].
  - The transfer/notification of new varieties from national to the EU Plant Variety Portal will be managed by the MS without the need for a Commission Decision[120].
  - Allow MS to decide themselves on permitting temporarily the marketing of seed that does not satisfy the requirements in respect of minimum germination, if germination is not lower than 15 % than the required germination rate[121].
- The requirements for the registration of **organic varieties suitable for organic production** (Annex 5, Section 2.5) will be adapted to the specific needs of organic production, by providing the possibility to deviate from certain DUS requirements as regards uniformity.
- The rules for **conservation varieties** are lighter and extended to cover **new locally adapted varieties** (Annex 5, Section 2.6.).

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[118] Currently professional operators in the sectors of fruit plants and FRM are obliged to be registered both under the marketing Directives and the PHL.

[119] Currently this is already the case for some marketing Directives for both the addition of new species and equivalence. However, some Directives require that for such decisions the ordinary legislative procedure is followed, which is cumbersome and disproportionate compared to the technical nature of the matter.

[120] On the basis of notifications received from MS, the Commission publishes in the Official Journal of the European Communities under the titles 'Common Catalogue of Varieties of Agricultural Plant Species' and 'Common Catalogue of Varieties of Vegetables Species' lists of all the varieties of which the seed and propagating material can be marketed throughout the EU. The publication of the supplements to the Common Catalogues requires a Commission Decision. This procedure creates unnecessary waiting time until a variety is included in the Common Catalogues and gets access to the common market.

[121] Currently MS wishing to use this derogation have to inform the Commission and the other MS who can make an offer to cover the missing supply. If no offers are received, the MS are authorised to allow the marketing of seed with lower germination rate by a Commission Decision. The procedure is disproportionate as most often there are no suitable offers. Over the last five years only 5 to 12% of the requested amounts could be covered by seed offered by other MS. Around 85% of the requests concern germination 15% or less below the minimum germination as laid down in the seed marketing Directives.

- The scope for heterogeneous material is broadened beyond organic production (Annex 5, Section 2.5.).

For FRM legislation:

- The decisions on the equivalence to EU rules for third countries will be taken by means of tertiary legislation.
- The existing empowerment to define the **information to be made available to users/buyers of FRM** is extended to explicitly cover suitability of FRM for climatic and ecological conditions.

5.2.2. Option 1 - Highest flexibility

Option 1 gives the highest level of flexibility to MS in relation to enabling the uptake of innovative production processes, BMTs and digital solutions, the sustainability considerations in the assessment of new varieties/FRM, OCs and the activities of seed conservation networks, marketing to amateur gardeners and exchange in kind of PRM between farmers.

Common elements for PRM and FRM:

- The uptake of **innovative production processes, BMTs and digital solutions** will be enabled by introducing in the PRM/FRM legal framework provisions allowing their use. Under option 1, these new possibilities will be implemented by the adoption of guidelines based on existing international standards but adjusted to the specificities of the EU legislation (Annex 5, Section 8).

  - The use of BMTs will be clarified by allowing the use in variety registration process to speed up DUS testing and as a supplementary test in PRM/FRM certification and marketing controls, in those cases where the field inspection and control plot testing are inconclusive about the identity of the variety under investigation.
  - The PRM/FRM legal framework will allow the certification of PRM/FRM produced by innovative production processes such as *in vitro* propagation of clones, true potato seeds and seed for the production of PRM of fruit plants and vines.
  - The PRM/FRM legal framework will allow the use of digital technologies (e.g. digital certificates and digital labels) and digitalisation of the PRM/FRM certification system.

- Option 1 lays down minimum requirements for PRM/FRM OCs. Risk based OCs aligned with the OCR provisions will be introduced and MS will be required to prepare a multi-annual control plan, aligned with the principles of the OCR. However, all rules on OCs remain in the PRM/FRM legislation. More specifically, requirements for OCs on production, marketing and imports of PRM/FRM are introduced in the PRM/FRM legislation (e.g. delegation of OC tasks and multi-annual national control plans) but without linking these to the OCR.

For PRM legislation only:

- **Sustainability considerations** in the examination of new varieties are strengthened.

- The current VCU examination for agricultural plant species and vine is extended to include characteristics that contribute to sustainable production in order to better steer breeding efforts in this direction. The new examination will be called 'Value for sustainable cultivation and use' ('VSCU'). For organic varieties suitable for organic production, it will be required that the VSCU examination is carried out under conditions adapted to the specific needs of organic production.
- A new voluntary approach is adopted for the assessment of new varieties of other crop groups (i.e. fruit plants and vegetables) for characteristics that contribute to sustainable production. Applicants may submit along with their application for the registration of a new variety the results of trials that they have carried out themselves. A link to this information is published in the Common Catalogues[122]. Submission of any information is not linked to the acceptance of the varieties.

- The activities of **seed conservation networks, marketing to amateur gardeners and exchange in kind of seed between farmers** are exempted from the scope of the legislation to stimulate the increase in genetic diversity of PRM.

For FRM legislation only:

- "Forestry"/"non-forestry" purposes are defined but the **scope of the legislation** remains limited to the production of FRM for "forestry" purposes. The FRM legislation only covers the production for "forestry purposes" to ensure the availability of high-quality FRM for afforestation/reforestation.
- The **sustainability requirements** are extended to cover lower FRM categories (source-identified and selected material) and guidelines are adopted on sustainability requirements for all FRM categories.
- Empowerment to authorise MS to use FRM not fulfilling all requirements when there are temporary **difficulties in supply** is maintained and supplemented by adoption of guidelines on **contingency planning** in the MS to better prepare for major shortages in supply of FRM caused by extreme weather, disasters or any other event.
- Adoption of guidelines for the registration of basic material for the purposes of **conservation and sustainable use of forest genetic resources**.

5.2.3. Option 2 - Balancing flexibility and harmonisation

Option 2 balances the need for flexibility with a higher degree of harmonisation to overcome the problems stemming from differences in interpretation.

Common elements for PRM and FRM:

- The uptake of **innovative production processes, BMTs and digital solutions** will be enabled by introducing in the PRM/FRM legal framework provisions allowing their use. Under option 2, these new possibilities will be implemented by the introduction of basic

[122] As of beginning of 2023 the Common Catalogues are accessible through a new EU Plant Variety Portal. This will allow in the future to include links to MS's sites where variety descriptions are published.

principles for the use of **innovative production processes, BMTs and digital solutions** in the legislation (Annex 5, Section 8).

- The use of BMTs will be clarified by allowing the use in variety registration process to speed up DUS testing and as a supplementary test in PRM/FRM certification and marketing controls, in those cases where the field inspection and control plot testing are inconclusive about the identity of the variety under investigation.
- The PRM/FRM legal framework will allow the certification of PRM/FRM produced by innovative production processes such as *in vitro* propagation of clones, true potato seeds and seed for the production of PRM of fruit plants and vines.
- The PRM/FRM legal framework will contain rules on the use of digital technologies (e.g. digital certificates and digital labels) and foresee the possibility for digitalisation of the PRM/FRM certification system.

- Risk based OCs aligned with the OCR provisions will be introduced and MS will be required to prepare a multi-annual control plan. The OCs for PRM/FRM will be brought under the scope of the OCR, but with simplified import controls at appropriate places within the EU to ensure a more targeted and efficient enforcement of existing rules[123]. Specific rules for production, marketing and imports will be established through tertiary legislation under the OCR. OCR will apply to all OCs in the sector. Article 44(1) to Regulation (EU) 2017/625 will apply for PRM/FRM import controls, which will be performed at appropriate places within the EU[124]. The operator responsible for the PRM/FRM consignment must provide the relevant information about that consignment (e.g. quantity of PRM/FRM, type of material, category of material,…). OCs in relation to PRM/FRM certification remain in the sectoral PRM/FRM legislation.

For PRM legislation only:

- **Sustainability considerations** in the examination of new varieties are strengthened.

  The current VCU examination for agricultural plant species and vine is extended to include additional characteristics that contribute to sustainable production in order to better steer breeding efforts in this direction. The new examination will be called Value for sustainable cultivation and use (VSCU). It will also be extended to new varieties of the other crop groups (fruit plants and vegetables).

  - MS will have the flexibility to implement VSCU according to their agro-ecological conditions.
  - It will be possible for operators to conduct the VSCU examination under official supervision.
  - MS will be able to collaborate and accept results from MS with similar agro-ecological conditions, and/or create shared testing networks.

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[123] This approach is in line with Article 44(1) to Regulation (EU) 2017/625 for OCs on animals and goods other than those subject to OCs at border control posts.
[124] OJ L 95, 7.4.2017, p. 1

- An empowerment will be created to determine the minimum requirements for carrying out the VSCU examination and the accepted methodologies for assessing the individual VSCU characteristics.
- For organic varieties suitable for organic production, it will be required that the VSCU examination is carried out under conditions adapted to the specific needs of organic production.

- The activities of **seed conservation networks, marketing to amateur gardeners and exchange in kind of seed between farmers** are subject to lighter rules to stimulate the increase in genetic diversity of PRM but also retain traceability and guarantee a minimum level of PRM quality.

For FRM legislation only:

- The "forestry" and "non-forestry" purposes are defined and the current **scope of legislation** is extended to increase the FRM quality beyond afforestation/reforestation uses and include the production of FRM for specific "non-forestry" purposes.
- The **sustainability requirements** are extended to cover lower FRM categories (source-identified and selected material). General principles on the sustainability requirements are introduced in the legislation for all FRM categories, with flexibility for MS to implement according to their environmental conditions.
- The existing empowerment to authorise MS to use FRM not fulfilling all requirements when there are temporary **difficulties in supply** is supplemented by the introduction in the legislation of a general requirement for **contingency planning** by the MS to better prepare for major shortages in the supply of FRM caused by extreme weather, disasters or any other event.
- A derogation is introduced in the legislation for the registration of basic material for the purposes of **conservation and sustainable use of forest genetic resources**.

5.2.4. Option 3 - Highest harmonisation

Option 3 would entail the highest harmonisation in order to minimise differences in the implementation of the legislation.

Common elements for PRM and FRM:

- The uptake of **innovative production processes, BMTs and digital solutions** will be enabled by introducing in the PRM/FRM legal framework provisions allowing their use. Under option 3, these new possibilities will be implemented by the introduction of detailed and binding rules for the use of **innovative production processes, BMTs and digital solutions** in the legislation (Annex 5, Section 8).

  - The use of BMTs will be clarified by allowing the use in variety registration process to speed up DUS testing and as a supplementary test in PRM/FRM certification and marketing controls, in those cases where the field inspection and control plot testing are inconclusive about the identity of the variety under investigation.
  - The PRM/FRM legal framework will allow the certification of PRM/FRM produced by innovative production processes such as *in vitro* propagation of clones, true potato seeds and seed for the production of PRM of fruit plants and vines.

- The PRM/FRM legal framework will contain detailed rules on the use of digital technologies (e.g. digital certificates and digital labels) and the conditions for digitalisation of the PRM/FRM certification system.

- Risk based OCs aligned with the OCR provisions will be introduced and MS will be required to prepare a multi-annual control plan. The OCs for PRM/FRM will be brought under the scope of the OCR, with stricter import controls at border control posts requiring special import documentation pursuant to Article 47(1) to Regulation (EU) 2017/625[125] to strengthen and fully harmonise enforcement. Specific rules for production, marketing and imports will be established through tertiary legislation under the OCR. OCR will apply to all OCs in the sector. For each consignment of PRM/FRM subject to OCs at border control posts, the operator responsible for the consignment must complete the relevant part of the Common Health Entry Document (CHED), providing the information necessary for the immediate and complete identification of the consignment and its destination. Rules on fees will be laid down by MS pursuant to Article 79 of the OCR.

For PRM legislation only:

- **Sustainability considerations** in the examination of new varieties are strengthened.

  The current VCU examination for agricultural plant species and vine is extended to include additional characteristics that contribute to sustainable production in order to better steer breeding efforts in this direction. The new examination will be called Value for sustainable cultivation and use (VSCU). It will also apply to new varieties of the other crop groups (fruit plants and vegetables).

  In contrast to option 2:

  - Implementation of the VSCU will be harmonised between the MS.
  - Detailed rules on accepted methodologies for assessing the individual VSCU characteristics will be introduced and harmonised across MS. The VSCU examination would still be conducted in different locations that reflect the different agro-ecological conditions in each MS. However, this could result in a MS having to test for tolerance/resistance to plant pests that do not occur in their territory. This on the one hand would lead to the highest assurance regarding the variety characteristics but would on the other hand also lead to unnecessary costs.

  As under option 2:

  - It will be possible for operators to conduct the VSCU examination under official supervision.
  - MS will be able to collaborate and accept results from MS with similar agro-ecological conditions, and/or create shared testing networks.

[125] OJ L 95, 7.4.2017, p. 1

- For organic varieties suitable for organic production, it will be required that the VSCU examination is carried out under conditions adapted to the specific needs of organic production.

- The activities of **seed conservation networks, marketing to amateur gardeners and exchange in kind of seed between farmers** are subject to the general requirements of the legislation (See Annex 5, Sections 2.3. and 2.4.) to achieve homogenous rules for all market segments.

For FRM legislation only:

- The "forestry" and "non-forestry" purposes are defined and the current **scope of legislation** is extended to increase the FRM quality beyond afforestation/reforestation uses and include the production of FRM for specific "non-forestry" purposes.
- The **sustainability requirements** are extended to cover lower FRM categories (source-identified and selected material). Detailed and harmonised rules on sustainability requirements for all FRM categories are introduced in the legislation.
- The existing empowerment to authorise MS to use FRM not fulfilling all requirements when there are temporary **difficulties in supply** is supplemented by the introduction in the legislation of common rules for **contingency planning** by the MS to better prepare for major shortages in supply of FRM caused by extreme weather, disasters or any other event. A derogation is introduced in the legislation for the registration of basic material for the purposes of **conservation and sustainable use of forest genetic resources**.

Policy issue addressed	Option 1	Option 2	Option 3
Simplification of procedures	• A number of existing administrative procedures are clarified and simplified • Permit under official supervision all certification tasks except the issuing of the official label (PRM) and the issuing of the master certificate (FRM) [measures common to all options]	• A number of existing administrative procedures are clarified and simplified • Permit under official supervision all certification tasks except the issuing of the official label (PRM) and the issuing of the master certificate (FRM) [measures common to all options]	• A number of existing administrative procedures are clarified and simplified • Permit under official supervision all certification tasks except the issuing of the official label (PRM) and the issuing of the master certificate (FRM) [measures common to all options]
Innovative production processes, BMTs and digitalisation	• The uptake on the use of innovative production processes, BMTs and digital solutions will be enabled by introducing in the PRM/FRM legal framework provisions allowing their use. • Adoption of guidelines on innovative production processes, BMTs and digitalisation	• The uptake on the use of innovative production processes, BMTs and digital solutions will be enabled by introducing in the PRM/FRM legal framework provisions allowing their use. • Introduction of basic rules on innovative production processes, BMTs and digitalisation and creation of empowerments for detailing rules according to new developments	• The uptake on the use of innovative production processes, BMTs and digital solutions will be enabled by introducing in the PRM/FRM legal framework provisions allowing their use. • Introduction of detailed rules on innovative production processes, BMTs and digitalisation
Official controls	• Harmonisation of OCs on production, marketing and imports of PRM/FRM without links to OCR	• Harmonisation of OCs on production, marketing and imports of PRM/FRM subject to the OCR • Simplified import controls at appropriate places	• Harmonisation of OCs on production, marketing and imports of PRM/FRM subject to the OCR • Stricter import controls at border control posts requiring special import documentation

Policy issue addressed	Option 1	Option 2	Option 3
Plant health requirements	• The lists of RNQPs and specific measures are moved to the PHL and PRM/FRM legislation refer to them instead of duplicating them • Compliance with requirements for QPs and RNQPs remains a prerequisite for the certification of PRM/FRM through the continuation of the current robust certification regime [measures common to all options]	• The lists of RNQPs and specific measures are moved to the PHL and PRM/FRM legislation refer to them instead of duplicating them • Compliance with requirements for QPs and RNQPs remains a prerequisite for the certification of PRM/FRM through the continuation of the current robust certification regime [measures common to all options]	• The lists of RNQPs and specific measures are moved to the PHL and PRM/FRM legislation refer to them instead of duplicating them • Compliance with requirements for QPs and RNQPs remains a prerequisite for the certification of PRM/FRM through the continuation of the current robust certification regime [measures common to all options]
Assessment of new varieties for characteristics contributing to sustainable production	• Extension of the current VCU requirements for agricultural plant species and vine to better address sustainability • For all other species, reliance on information that applicants voluntarily submit along with the application for registration of a new variety	• Extension of the current VCU requirements for agricultural plant species and vine to better address sustainability • Introduction of these requirements for all other crop groups (vegetables and fruit plants) • Flexibility for MS to implement these requirements according to their agro-ecological conditions • Permit examination of these requirements under official supervision • Creation of empowerment to adopt rules on accepted methodologies for assessing the different characteristics	• Extension of the current VCU requirements for agricultural plant species and vine to better address sustainability • Introduction of these requirements for all other crop groups (vegetables and fruit plants) • Harmonised implementation of these requirements. • Permit examination of these requirements under official supervision • Introduction of detailed rules on accepted methodologies for assessing the different characteristics
Organic production	• For the examination of organic varieties DUS and VCU requirements are adapted to the specific needs of organic production [measure common to all options]	• For the examination of organic varieties DUS and VCU requirements are adapted to the specific needs of organic production [measure common to all options]	• For the examination of organic varieties DUS and VCU requirements are adapted to the specific needs of organic production [measure common to all options]
Conservation and sustainable use of plant genetic resources	• Exemption from the scope of the legislation of activities of seed conservation networks, marketing to amateur gardeners and exchange in kind of seed between farmers	• Subject activities of seed conservation networks, marketing to amateur gardeners and exchange in kind of seed between farmers to lighter rules	• Subject activities of seed conservation networks, marketing to amateur gardeners and exchange in kind of seed between farmers to the general requirements of the legislation
	• Simplification of current rules for conservation varieties and extension of those rules to cover new locally adapted varieties • Broadened scope for heterogeneous material beyond organic production [measure common to all options]	• Simplification of current rules for conservation varieties and extension of those rules to cover new locally adapted varieties • Broadened scope for heterogeneous material beyond organic production [measure common to all options]	• Simplification of current rules for conservation varieties extension of those rules to cover coverage by the same rules of new locally adapted varieties • Broadened scope for heterogeneous material beyond organic production [measure common to all options]
Scope of the FRM legislation	• Define forestry and non-forestry purposes but maintain current scope of FRM legislation	• Define forestry and non-forestry purposes and extend scope of FRM legislation to include the production of FRM for specific non-forestry purposes	• Define forestry and non-forestry purposes and extend scope of FRM legislation to include the production of FRM for specific non-forestry purposes
Assessment of	• Extend sustainability requirements to cover lower FRM	• Extend sustainability requirements to cover lower FRM	• Extend sustainability requirements to cover lower FRM

Policy issue addressed	Option 1	Option 2	Option 3
FRM for characteristics contributing to sustainable production	categories • Adopt guidelines on sustainability requirements for all FRM categories	categories • Introduce general principles on sustainability requirements for all FRM categories with flexibility for MS to implement according to their environmental conditions	categories • Introduce detailed and harmonised rules on sustainability requirements for all FRM categories
Address difficulties in supply of suitable FRM	• Maintain the existing empowerment to authorise MS to use FRM not fulfilling all requirements when there are difficulties in supply • Adopt guidelines on contingency planning to ensure availability of FRM	• Maintain the existing empowerment to authorise MS to use FRM not fulfilling all requirements when there are difficulties in supply • Introduce a general requirement for contingency planning in the MS to ensure availability of FRM	• Maintain the existing empowerment to authorise MS to use FRM not fulfilling all requirements when there are difficulties in supply • Introduce common rules on contingency planning in the MS to ensure availability of FRM
Information to FRM users/buyers	• Extend existing empowerment to define the information to be made available to users/buyers of FRM to explicitly cover suitability of FRM for climatic and ecological conditions [measure common to all options]	• Extend existing empowerment to define the information to be made available to users/buyers of FRM to explicitly cover suitability of FRM for climatic and ecological conditions [measure common to all options]	• Extend existing empowerment to define the information to be made available to users/buyers of FRM to explicitly cover suitability of FRM for climatic and ecological conditions [measure common to all options]
Conservation and sustainable use of forest genetic resources	• Adoption of guidelines for the registration of basic material for the purposes of conservation of forest genetic resources	• Introduction of a derogation for the registration of basic material for the purposes of conservation of forest genetic resources	• Introduction of a derogation for the registration of basic material for the purposes of conservation of forest genetic resources

Table 2. Overview of policy options

5.2.5. Stakeholders' views on policy options

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 DUS and where applicable VCU) and PRM certification. NCAs and stakeholders, in particular the seed industry, highlighted that the current system works well and that the EU PRM industry receives international recognition for the high quality of the certified seed. Likewise, in the FRM sector there is overall support for keeping the existing regulatory system of registration of basic material and FRM certification. The majority of NCAs, a business association and an EU trade union called for maintaining the current alignment of the EU FRM legislation with the Rules and Regulations of the OECD Forest Seed and Planting Scheme. All NCAs and stakeholders emphasised that the FRM legislation should remain separate from the PRM legislation. They argued that as forest trees often have a life span of over 100 years, some rules that apply to PRM might neither be needed for FRM, nor be reasonable to implement due to the difficulty of ensuring consistency over such long periods of time.

As regards PRM, the majority of NCAs and stakeholders is in favour of option 2 with the exception of the extension of the assessment of sustainability characteristics to all crop groups including fruit plants and vegetables. A few NCAs and stakeholders express a preference for option 3. A number of stakeholder groups is in favour of option 1 as regards e.g. the exemption from the scope of certain activities. As regards FRM, most NCAs and regional forest authorities, a regional union of forest nurseries and an NGO emphasised that MS should have the flexibility to decide which FRM is best adapted to their regional climatic and ecological conditions. For this reason, several stakeholders expressed preference for maintaining a Directive (option 1). Some business associations and a trade union expressed preference for a full harmonisation of the legislation.

NCAs and stakeholders strongly agree with the set of common measures proposed (Section 5.2.1.), with the exception of permitting certification tasks to be carried out by operators under official supervision instead of being carried out directly by the NCAs. Certain stakeholders are concerned that this will be disadvantageous for SMEs that do not have sufficient resources to carry out certification tasks under official supervision. The new legislation will however oblige MS to maintain official certification in order to respond to the needs of SMEs. No other alternative solutions that would allow simplification of administrative procedures have been identified.

One main objective of the revision is to extend the assessment of characteristics contributing to sustainable agri-food production. With the exception respondents from business associations, a majority of NCAs and stakeholders agreed with the need for a set of general sustainability criteria that MS can apply taking into account their agro-ecological conditions. Several stakeholders highlighted the difficulties of harmonising VCU across MS (option 3), the need for, and implications of, new sustainability criteria as well as suggested approaches for sustainability criteria.

The seed sector's position as regards agricultural plant species is that the sustainability assessment of new varieties can be addressed with slight modifications of the current VCU, while available information should be used before new obligations and costs are introduced for species other than agricultural plant species. The sector argues that such information is already available as other legislation and targets (organic production, reduction of pesticides and fertilisers), climate change conditions and market demand have been steering breeding towards the examination of more sustainable characteristics.

Some stakeholders call to abolish the current VCU requirement (and not to introduce a sustainability assessment) for:

- seed potatoes, using arguments similar to the vegetable sector mentioned above;
- crops for which there are very few applications for registering new varieties and where the current VCU makes it even more difficult for those varieties to reach the market. Moreover, they state that NCAs are not in a position to organise the relevant examinations every year.

The organic sector calls for a specific VCU examination adapted to organic varieties suitable for organic production. Moreover, they are of the opinion that all new plant varieties should be examined under organic and/or low input conditions. This opinion is shared by some seed saver organisations.

Several NGOs and small farmers' organisations overall reject the principle of VCU assessment of new varieties. In their view, this examination guarantees the adaptation of new varieties to certain local and regional agro-ecological conditions but not the adaptability of the varieties to different agro-ecological conditions. In their view, the adaptability of varieties is key for the resilience of agriculture to climate change. This approach is dealt with in the options by establishing the conditions for heterogeneous material, organic varieties suitable for organic conditions and the exchange in kind of seed between farmers.

Stakeholders' views differ regarding the measures proposed under the options to facilitate the conservation and sustainable use of plant genetic resources. NCAs and most stakeholders agree with the common measure under all options to adapt the DUS and VCU requirements for the examination of organic varieties to the specific needs of organic production. The seed sector on the

contrary states that organic varieties should comply with the current DUS requirements. NCAs and stakeholders agree with lighter rules for conservation varieties and new locally adapted varieties, but the seed sector would like to maintain the current restriction related to the local marketing of those varieties in their region of origin. Stakeholders' views are mixed as regards the activities of seed conservation networks and exchange in kind of seed between farmers. NGOs and certain academia favour an exemption of these activities from the scope of the legislation. They refer to UNDROP and the rights of peasants to freely exchange, multiply and sell seed In relation to exchange in kind of seed, the seed sector is concerned that a total exemption could be misused by farmers and calls for a quantitative restriction. As regards the activities of seed conservation networks, the seed sector is of the opinion that PRM marketed for the purposes of conserving plant genetic resources should be subject to the same rules as organic heterogeneous material. All NCAs and stakeholders agree with the broadening of the scope of heterogeneous material beyond organic production.

The majority of NCAs and stakeholders fear an increase in administrative burden upon the inclusion of OCs into the scope of the OCR (options 2 and 3). Several NCAs and businesses recognise the divergent conditions for operators and marketed PRM and FRM across MS. They prefer for OCs to be included into the scope of the OCR, albeit with simplified import controls (option 2). They see the advantages of using common IT applications for OCs such as IMSOC. Only a few stakeholders are in favour of a full inclusion into the scope of the OCR with stricter import controls at border control posts (option 3).

Most NCAs and stakeholders including SMEs want to have the possibility of using BMTs and digital solutions. Some SMEs highlight a lack of resources for being able to invest in BMTs and digitalisation. As regards the use of BMTs some stakeholders agree if their use remains optional in addition to the observation of the phenotypic characteristics. Others ask for the use of BMTs as self-standing tools for the characterisation of new plant varieties. Most NCAs call for allowing the use of innovative production processes such as the production of hybrid seed in the fruit plant sector and the use of *in vitro* propagation methods including somatic embryogenesis to produce PRM and FRM.

As regards FRM, stakeholders' views were mixed regarding the extension of the scope of the legislation to include certain specific non-forestry purposes. About 50% of stakeholders from across stakeholder categories believed that the definition of FRM should be clarified in relation to the purposes for which it is produced. Most stakeholders felt that FRM production should cover wood production, afforestation, reforestation, and conservation and sustainable use of forest genetic resources. In contrast, 52% believed that tree planting in urban and peri-urban areas and plantations for protection purposes (shelter belts against the wind) should not be covered.

Most stakeholders were favourable towards the assessment of sustainability characteristics with over half of the operators stating that they already assess, either on a voluntary or mandatory basis, basic material and FRM for characteristics that contribute to sustainable afforestation and reforestation. In relation to difficulties in supply, about half of stakeholders from across stakeholder groups recognise the need for more long-term planning across the FRM supply chain. They identified potential risks in the form of using lower quality FRM, economic losses and the increasing need of import. They expect that the demand for FRM will likely increase in the next 20 years further underlying the importance of security of supply and climatic suitability of FRM. This justifies the proposed measures on national contingency plans and better informing FRM users/buyers about the FRM characteristics.

Stakeholders active in the conservation and sustainable use of forest genetic resources declared that the current FRM legislation cannot address the needs of this type of FRM. They agree with the introduction of a derogation from the requirements for the registration of basic material (option 2).

5.3. Options discarded at an early stage and alternative measures

No full policy options were discarded at an early stage. Some specific measures however have been considered and discarded as unfeasible. Total deregulation is not supported by any stakeholder. To a lesser or greater extent all agree that the current system is functional and relevant. Abolishing the legislation would lead to different regulatory approaches at MS level with the possibility to threaten the principle of the internal market and leading to a lack of transparency of the EU market.

Different fees may cause different conditions for operators in different MS. An effort was made to harmonise fees for variety registration and PRM/FRM certification was proposed in the 2013 PRM proposal. It was based on the principle of cost recovery and the exemption of microenterprises but did not receive any support. The overall opinion was that the PRM/FRM legislation should not cover fees, even by the principle of cost recovery, because the cost structures differ between MS, the level of salaries being the main difference.

In relation to FRM, the creation of a voluntary coordination group for collaborative production, pooling and exchange of FRM was considered as an alternative measure to better address potential major shortages in the supply of FRM caused by extreme weather, disasters or any other event. Stakeholder consultations revealed that the situation differs between MS with some being largely self-sufficient and not yet having experienced any events that have led to shortages. A number of respondents from across stakeholder categories informed that difficulties in FRM supply may partly be due to a lack of planning and communication across the supply chain. It was therefore decided to require that MS prepare national contingency plans.

Likewise, the creation of a voluntary inventory was considered an alternative measure for providing information to FRM users/buyers about the suitability of FRM for climatic and ecological conditions. Most respondents from across stakeholder categories were in favour of such a measure, but opinions were evenly split on whether this voluntary inventory should be organised at EU or national level. As most stakeholders fear that an EU inventory would increase the administrative burden for NCAs and operators, it was opted to make such information available through websites, planters' guides and other appropriate means.

6. WHAT ARE THE IMPACTS OF THE POLICY OPTIONS?

Due to the complex nature of the options, the assessment of the impacts will be guided by the defining elements of the options[126] and a further distinction between PRM and FRM before assessing the total combined impact of each policy option. The assessment is mainly based on the data which was collected for the PRM study[127] and through two external supporting studies[128]. This was supplemented by feedback and consultation with the stakeholders as well as further in-house

[126] Strengthened sustainability requirements, OCs, conservation and sustainable use of plant and forest genetic resources and innovation and digitalisation
[127] SWD(2021)90.
[128] ICF(2021) and ICF(2023).

calculations. While the outmost effort was undertaken to collect as much as possible quantitative data e.g. by targeted questionnaires, it must be noted that a quantitative assessment of the potential economic, environmental and social impacts of each of the retained options was not always possible. This section summarises the main impacts. Details on the methodology, the limitations of the available data as well as a detailed assessment of all elements and their economic impacts are available in Section 8 of Annex 4.

6.1. Economic impacts

6.1.1. Common measures to policy options 1-3

For the common measures of policy options 1-3, the **simplification of existing administrative procedures** will result in a reduction of administrative burdens for NCAs and operators (same impacts for options 1-3):

- Professional operators will be required to be registered in a single register under the PHL. This measure will not result in new costs as currently professional operators are registered either under the marketing Directives, or PHL, or both. Over 20 000 duplicate registrations will be avoided and over EUR 800 000 annual savings in registration costs for operators supplying PRM of fruit plants. Over 4 000 duplicate registrations will be avoided and there will be over EUR 237 000 annual savings in registration costs for operators supplying FRM.
- Electronic notification by MS to the EU Plant Variety Portal of on average 4 000 new varieties per year will avoid the handling of those notifications (Commission Decision and publication in the Official Journal) and speed up access of those varieties to the EU market by 1 to 4 months[129]. In turn, faster market access will have a positive impact on the competitiveness of the EU PRM sector.
- Allowing MS to authorise the temporary marketing of seed that does not satisfy the requirements as regards the minimum germination rate, will avoid the handling by on average 30 notifications per year. The waiting time for operators to use this seed will be reduced by at least 15 days. Such notifications concern 50 000 tonnes of seed or 0.01% of the quantity of seed certified annually.
- Extending the possibilities for operators to carry out activities under official supervision (PRM and FRM) is not expected to have significant impacts on enforcement costs for NCAs[130] (Annex 4, Section 3). There will be no effect on the administrative burdens for operators as regards certification and variety registration, as the administrative steps remain the same. The measure is already applied by 10 MS under temporary experiments since 2012[131]. A permanent implementation would bring potential annual cost savings for operators of around EUR 1.7 million across the EU (Annex 4, Section 3).
- The possibility to deviate from certain DUS requirements as regards uniformity will be provided for the DUS examination of organic varieties suitable for organic production. The breeding period of varieties compliant with reduced uniformity requirements can be in average 2 years shorter than for varieties fully meeting the uniformity requirements.

[129] There are no data allowing the monetisation of these benefits.
[130] This will require a reallocation of resources of NCAs from official examinations to official supervision and training activities. The overall impact is neutral.
[131] Commission Implementing Decisions 2012/340/EU and 2020/1106.

Operators making use of this possibility will therefore access the market faster, with reduced breeding costs and with varieties that up to now were restricted from the market since it was not possible to register varieties not meeting the DUS requirements. A few dozen operators across EU are likely to use this option. The number of varieties registered under these rules could be in average 100 annually. Assuming EUR 50 000 savings in breeding costs per variety, concerned operators may see savings of EUR 5 million annually.

- The scope for heterogeneous material is broadened beyond organic production. This measure creates a new market segment. Potentially a large number of operators may benefit but the quantities of PRM concerned are expected to be very limited and of insignificant market value[132].
- The rules for conservation varieties are lighter and extended to cover new locally adapted varieties. This measure creates a new market segment. Operators would benefit from lighter procedures for access to market (no DUS/VSCU requirements for variety registration and no certification of PRM). The number of operators concerned could be in the range of several hundreds. The number of varieties marketed under these rules could be a few hundred annually. However, the quantities of PRM concerned are expected to remain limited and below 2% of the market[133]. The potential market value could be up to EUR 13.3 billion /year * 2%= EUR 266 million/year.

6.1.2. Strengthened sustainability requirements

This section examines the potential additional costs and benefits for operators, NCAs and users of PRM/FRM due to the inclusion of requirements for assessment of sustainability characteristics in the registration of new plant varieties (PRM) and basic material (FRM).

Operators

For the PRM sector, the envisaged measures for strengthening sustainability requirements in VCU for agricultural plant species and vine and for introducing sustainability requirements in the examination of new varieties of other crops (vegetables and fruit plants) will result in additional testing costs for operators due to increased fees paid to NCAs for the examination of new varieties (Table 3). The additional possibilities under options 2 and 3 for conducting the VSCU examination under official supervision and for collaboration between NCAs on these will mitigate the additional testing costs for operators. It is assumed, on the basis of a trend observed for certification under official supervision, that 44% of all VSCU examinations will be carried out under official supervision. Costs for operators are assumed to be 12% less for carrying out activities under official supervision in comparison to the costs they have under official examinations[134]. The savings will partly compensate the expected increase in the testing costs due to strengthened sustainability requirements (Table 3).

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[132] Based on the experience gained by the implementation of the provisions on organic heterogeneous material under Regulation (EU) 2018/848.

[133] Based on the experience gained by the temporary experiment providing for certain derogations for the marketing of populations of the plant species wheat, barley, oats and maize. Final report available at https://food.ec.europa.eu/system/files/2022-04/prm_temp-exp_pop-exp_en.pdf

[134] Calculated by ICF (2023) on the basis of survey results.

Increase in variety registration cost for operators	Baseline	Option 1	Option 2	Option 3
Agricultural species	0	6%	6%	9%
Vegetable species	0	11%	92%	115%
Vine	0	9%	9%	14%
Fruit plants	0	9%	101%	110%
Total annual increase in variety registration costs for operators EU27 (million EUR)	**0**	**2.45**	**6.75**	**8.39**
Total annual increase in variety registration costs for operators EU27 (million EUR) if 44% of VSCU examinations are carried out under official supervision	**0**	**N/A**	**6.40**	**7.95**

Table 3. Cost increases for operators for registration of new varieties due to the assessment of sustainability characteristics (for detailed calculations see Annex 4 Section 4).

It is important to note that these testing costs including strengthened sustainability considerations are negligible as they represent only about 1% of the total cost for developing a new plant variety[135]. The increased requirements for characteristics contributing to sustainable production could however lead to a reduction of the number of varieties being accepted. For agricultural and vegetable species up to about 4 000 varieties less could be made available in the EU market over a period of 10 years because of the strengthened sustainability requirements (Table 4), but this system will be necessary to avoid that varieties without improved characteristics contributing to sustainable production will enter the market. The position of SMEs with a small number of applications for new varieties per year could nevertheless be negatively affected in the short term, with the need to re-orient investments in varieties with improved sustainability characteristics[136].

Average number of new plant varieties registered per year	Baseline	Option 1 Additional withdrawal and/or rejection rate 3%	Option 2 Additional withdrawal and/or rejection rate 5%	Option 3 Additional withdrawal and/or rejection rate 10%
Agricultural plant species	2 564	2 487	2 435	2 308
Vegetable species	1 384	1 342	1 315	1 246
Vine	41	40	39	37
Fruit plants	39	38	37	35

Table 4. Average number of new plant varieties registered per year. The baseline is the average number of new plant varieties registered annually over the period 2012-2021 as retrieved from the Common Catalogues. Details on the assumptions on which the calculations are based can be found in Annex 4 Section 2.

In the FRM sector, the extension of the assessment of sustainability characteristics is expected to lead to a negligible increase of costs for operators under all options 1-3 (Table 5)[137]. New basic

[135] Total testing costs in the range of EUR 10 000 and total costs for developing a new variety in the range of 1 000 000 EUR. This value represents all costs (labour, infrastructure, land etc.) over the 10-12 years needed for the development of a new variety.

[136] There is no data available on allowing estimating the magnitude of this impact, in particular because several varieties are being registered without actually being made available on the market by the applicants.

[137] Increased testing (inspection) costs arise because of the need to assess more characteristics under all categories. Inspection of the lowest FRM category currently does not include sustainability characteristics. More characteristics will be included in the assessment of higher categories. For all categories it will also be required to indicate for which area the FRM is suited/adapted.

material is on average registered every 5 years and the budget spent by operators on the registration of basic material is estimated to be less than 1% of their total revenue[138].

Total annual cost increase for operators for registration of basic material in EU27	Baseline	Option 1	Option 2	Option 3
EUR	0	3 280	6 560	9 841

Table 5. Estimated annual cost increase in EU27 for the registration of new basic material due to the extension of assessment of sustainability characteristics of basic material to the lower FRM categories, based on an average of 44 applications per year. Detailed calculations are available in Annex 4, Section 6.

Under option 1 **non-forestry purposes** will be defined in the legislation, however these would not be included in the scope of the legislation. It would be up to MS which non-forestry purposes would be included, thus increasing or decreasing the FRM covered by the scope of the legislation with a potential increase of testing costs in some MS[139]. Under options 2 and 3 the extension of the scope of FRM legislation to include the production of FRM for specific non-forestry purposes (common measure), will result in an increase in **testing costs** (for certification) **for operators.** This increase would be more pronounced in those MS where the non-forestry purposes to be added in the scope of the FRM legislation are currently not within the scope of the current national legislation[140]. While there is insufficient data and evidence to allow an estimation, it is expected that the impacts on all options will be limited[141].

The measures contributing to sustainable production will not have an impact on administrative burden for operators, as the administrative requirements for the registration of varieties under the PRM legislation and for registration of basic material under the FRM legislation remain the same under all options in relation to the baseline.

NCAs

The measures will result in additional **enforcement costs for the NCAs**. In options 1-3 due to the introduction of strengthened sustainability characteristics there will be additional costs for carrying out the examination of new varieties For **agricultural species and vine**, there will be no need for additional testing stations for VSCU examinations. It will only be necessary to increase the number of characteristics assessed during the VSCU examination in comparison to the current VCU examination[142]. For new varieties **of fruit plants and vegetables**, under **options 2 and 3**, NCAs

[138] Based on the data provided by 2 respondents in the targeted survey by ICF (2023).
[139] By explicitly defining what is a non-forestry purpose, some MS may take out certain non-forestry purposes that are currently included in the scope of their legislation. This could even decrease costs but also risks reducing quality.
[140] Indicatively in 7 out of 11 MS that provided data non-forestry purposes are currently not within the scope of the FRM legislation.
[141] Information collected by the targeted survey under ICF (2023) indicates that only 10% of FRM produced corresponds to non-forestry purposes.
[142] It has not been possible to collect an overview of the situation in all MS as regards the assessment of sustainability characteristics under the current VCU provisions. For example, France has already included several sustainability

will have to increase up to 50% their capacity in areas and staff, including the need for additional testing stations. The total annual cost for the NCAs would be in the range of EUR 43 to 98 million in options 2 and 3 depending on the percentage of operators that will opt for official supervision. The cost for NCAs under option 1 will be insignificant because it does not require an increase in the capacity of the existing VCU testing stations (Annex 4, Section 5).

In the FRM sector, the extension of the assessment of sustainability characteristics is expected to lead to higher **enforcement costs for NCAs**. These will however be negligible for options 1-3 because the measure concerns on average only 44 applications per year in EU27 for the registration of basic material.

The extension of the scope of the FRM legislation to cover non-forestry purposes (not included under option 1, but under options 2 and 3) may result in some increase of costs for NCAs (up to 10%-increase in number of applications for certification of FRM[143]).

The requirement for MS to prepare **national contingency plans** aims to ensure the availability of FRM in case of major losses due to extreme weather or disasters. MS will have to set up such plan once and update it as appropriate in view of evolving conditions. The resulting costs are expected to be highest under option 3, whereby there will be common requirements on contingency planning for all MS, therefore risking that NCAs will also have to address issues that are not relevant for their MS. The additional costs would be lowest under option 1, as it will depend on the MS decision to prepare a contingency plan (voluntary approach). The costs in all options are however not considered significant as the MS already take similar measures[144].

Users of PRM and FRM

The increased costs for operators (breeders) caused by extension of the **sustainability requirements** in variety registration (leading to less varieties reaching the market) is expected to result in increased prices of PRM for their users (mainly farmers). This is assumed to result in an additional increase of the prices of PRM by 1% for option 1, 3% for option 2 and 5% for option 3. Assuming other factors influencing the costs of inputs do not change, these additional costs would correspond to an increase of overall costs of inputs for farmers[145] below 0.3% every year in all options, but would gradually reduce over the years as breeding programmes would adjust to the new requirements. Therefore, cascading impacts on the competitiveness of farmers and food prices due to the above-mentioned increases in price of PRM are estimated to be marginal. Furthermore, the resulting varieties with improved characteristics should result in a more stable agricultural output under fluctuating conditions and thus contribute to food security and the competitiveness of farmers. The avoided losses of production would compensate for the increased costs of PRM, with **option 2 resulting in a net benefit for farmers ranging between EUR 221 million and 2.1**

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characteristics in the VCU examination. Other MS (e.g. Germany and The Netherlands) focus on yield and disease resistance/tolerance but are already working towards a more comprehensive assessment of sustainability characteristics.

[143] ICF(2023) survey data showed that in MS producing FRM for non-forestry purposes (e.g. France, Germany and Poland) this covers on average up to 10% of all FRM produced.

[144] According to information collected through the interviews by ICF (2023), Finland and Sweden already have contingency plans in place, while Slovenia and Spain are undertaking efforts to improve contingency planning.

[145] Referred to in Eurostat as 'Intermediate consumption in agriculture'. It includes fertilisers, pesticides, seeds and other inputs.

billion annually, option 1 resulting in a net benefit for farmers ranging between EUR 177 and 1 110 million annually and option 3 resulting likely in benefits under an "optimistic" scenario (EUR 1 198 million annually) and in negative balance (EUR -201 million annually) under a more "conservative" scenario (Table 6 and Annex 4, Section 5).

	Million EUR (current 2021 price)	Impact on farms of strengthened sustainability requirements for the acceptance of new varieties of PRM	Option 1	Option 2	Option 3
INCREASE IN COSTS					
Total annual PRM cost in agriculture	13,346	Increase in total **PRM cost** in agriculture (%)	1%	3%	5%
		(million EUR)	133	400	667
Total annual PRM cost in relation to cost of all inputs in agriculture	260,168	Increase in **global cost of inputs** in agriculture due to increase in PRM cost(%)	0.05%	0.15%	0.26%
BENEFITS					
Total annual crop output	248,657	Avoided loss in crop output annually (%)	0.50%	1.00%	0.75%
		(million EU)	1,243	2,487	1,865
Balance / optimistic scenario		**million EUR**	**1,110**	**2,086**	**1,198**
Total annual crop output	248,657	Avoided loss in crop output annually (%)	0.125%	0.250%	0.188%
		(million EU)	311	622	466
Balance / conservative scenario		**million EUR**	**177**	**221**	**-201**

Table 6. Costs and benefits for farmers due to strengthened sustainability requirements for the acceptance of new varieties of PRM. Detailed calculations are presented in Annex 4 Section 5.

As the extension of the assessment of sustainability characteristics and the extension of the scope of FRM legislation to include the production of FRM for specific non-forestry purposes is expected to lead to a marginal increase of costs for operators and NCAs in the FRM sector, the impacts on FRM users in terms of price will be negligible. FRM may however experience reduced economic losses by using more suitable FRM, but these benefits cannot be quantified[146].

6.1.3. Official controls

Currently there are significant differences between MS as regards the total number and type of OCs carried out[147]. The impact of the harmonisation of OCs will differ between MS depending on their current implementation of OCs.

Operators

Under options 1 and 2, the harmonisation of the current requirements[148] will not introduce new obligations for operators.

Under options 1 to 3, passing from a combination of random checks and risk-based controls to risk-based controls will allow OCs to be carried out in a more focussed and efficient way. This will be a fairer system in comparison to the baseline, because operators will be subject to OCs depending on their risk profile. As a result, individual operators could either be subject to a lower or higher

[146] ICF(2023).
[147] Described in section 2.1.1.
[148] Import controls, marketing controls and production controls on operators carrying out certification under official supervision.

number of OCs in comparison to the baseline situation, especially when currently OCs are carried out only randomly. Consequently, the overall impact on operators will be neutral.

Under option 3, operators that are importing PRM/FRM into the Union will in addition be required to submit special import documentation and be subject to OCs at border control posts. NCAs will also have increased costs under option 3 for carrying out these OCs, which most likely will be transferred to operators in the form of fees. Therefore, those operators who import PRM/FRM into the Union will face increased administrative burden and costs (fees). These cannot be calculated as there is no information available on the number of operators and transactions concerned. The overall impact under option 3 on operators is considered as moderate negative as not all operators are concerned by the OCs on imports.

NCAs

Depending on the baseline situation per MS, under options 1 to 3 the harmonisation of the requirements for OC**s** may lead to **increased enforcement costs and administrative burden for NCAs**. Such costs will be due to the obligations to draft multi-annual control plans and report annually on OCs. There can also be one-off costs linked to potential need for reallocation of resources in order to adjust to the new requirements for risk-based OCs. NCAs may also need to increase or decrease the frequencies of OCs. These impacts overall are considered to be neutral for the NCAs in total.

Option 3 however entails additional costs for the NCAs in comparison to options 1 and 2 because under option 3 OCs on imports will be carried out at border control posts. This requirement would mean that NCAs would have to equip the border control posts with additional staff to carry out the sampling of imported PRM/FRM. There are about 500 border control posts across the EU designated for phytosanitary controls under the PHL. Assuming that these would also be designated for PRM/FRM, they would need to be equipped by staff to carry out sampling of imported PRM/FRM. With 1 person in average by border control post at EUR 30 000 for salary, the total annual cost under option 3 for NCAs amounts to EUR 15 million (not occurring under options 1 and 2).

As regards benefits, under options 1 to 3, the introduction of the risk-based approach will lead to better focus the OC activities of the NCAs on where most needed, therefore there will be overall **efficiency gains**. Moreover, options 2 and 3 will provide additional efficiency gains in comparison to option 1 due to the inclusion the OCs on PRM/FRM in the scope of the OCR. This will allow the use of common IT applications for reporting on OC[149] and for exchanging on fraud matters[150], as well as opportunities for training (Better Training for Safer Food programme). It will also allow to align the OCs on PRM/FRM with those under other legislative frameworks already within the

[149] IMSOC is the information management system for official controls under the OCR. In COM(2021)786 final on the experience with the implementation of PHL, it is reported that the use of TRACES-NT (part of IMSOC) can be considered an important improvement brought by the OCR. The functionality offered to notify non-compliances at import was declared as effective by 80% of the respondents. The interconnection with other systems, the user-friendliness and the availability of information was also rated positively.

[150] A secure IT system that would allow the exchange between MS of confidential information on fraud matters related to PRM/FRM is currently not in place. Inclusion in the scope of OCR would allow for these purposes the use of iRASSF, that allows secure exchanges on food and feed safety alerts.

scope of the OCR which might be applicable also to PRM/FRM, as the case may be (PHL, Organic Regulation and GMOs)[151]. Such efficiency gains are not possible under option 1.

Finally, measures aiming to increase the **coherence between the PRM/FRM legislation and the PHL** is expected to lead to a reduction of **administrative burden for operators** and **enforcement costs for NCAs to carry out OCs** (Annex 5, Section 7) depending on how the MS distribute the competences for PRM/FRM and PHL[152].

6.1.4. Conservation and sustainable use of plant and forest genetic resources

To contribute to biodiversity and increase the genetic diversity of PRM and FRM, there will be adapted rules for activities of seed conservation networks, exchange in kind of seed and marketing to amateur gardeners in the PRM sector and for the registration of basic material in the FRM sector.

Operators and NCAs

There will be a reduction of administrative burdens under options 1 and 2 for operators involved in seed conservation networks, marketing to amateur gardeners and exchange in kind of seed between farmers due to the exemption from the scope of the legislation, but given the limited volume of seed involved[153], the absolute magnitude of such reduction in relation to the whole seed sector is not significant. Under option 2 lighter rules still present a reduced administrative burden in comparison to the baseline. Those rules ensure a minimum level of quality and traceability which would in particular be important for marketing to amateur gardeners. They would allow for the documentation and characterisation of plant genetic resources, thus maximising their contribution to more resilient agri-food systems. Under option 3 the administrative burden remains unchanged in comparison to the baseline. Finally, it is assumed that mostly SMEs and, in particular small-scale local operators, are involved in such activities. They benefit from the exemptions and derogations to be introduced for varieties marketed exclusively to amateur gardeners, conservation varieties

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[151] A report on the experience with the implementation of PHL (COM(2021) 786 final) sought to collect data on the savings caused by simultaneous controls on QPs and RNQPs upon import but the low response rate did not allow monetising those savings.

[152] In 12 out of 27 MS the inspections for RNQPs have been delegated to the NCA responsible for PRM certification.

[153] Though the total numbers across the EU are not known, there is no indication that the volumes of PRM distributed by seed conservation networks and farmers engaged in exchange in kind of seed or of PRM marketed exclusively to amateur gardeners have a significant share of the EU PRM market. Furthermore, most of the PRM marketed to amateur gardeners belongs to varieties that are also available for professional operators. Marketing to amateur gardeners can be ascertained only if seed is marketed in small packages, which are relatively too expensive in comparison to larger packages and therefore not used by professional operators. Currently only "vegetable varieties developed for growing under particular conditions" are subject to such limitations to the size of packages and can be considered as marketed exclusively to amateur gardeners. Such varieties represent less than 5% of the varieties in the Common Catalogue for vegetables. Operators marketing varieties addressed to both professional users and amateur gardeners (i.e. the vast majority of varieties in the market) will not be able to benefit from the reduction of administrative burden under options 1 and 2 as regards marketing exclusively to amateur gardeners. It is considered unrealistic that for the same variety operators would start having separate production lines for PRM to be sold to amateur gardeners and for PRM to be sold to professional operators (ICF(2023) Section 5.1.2).

including locally adapted varieties, organic varieties suitable for organic production and heterogeneous material.

Exempting the marketing of PRM to amateur gardeners from the scope of the legislation could result in a lower PRM quality and lead to an increase of fraudulent practices if that PRM is marketed to professional users (**option 1**). Even though exchange in kind of seed between farmers is considered to be a marginal activity (see above), there could be a potential negative economic impact on seed companies if this activity is exempted from the scope of the PRM legislation (**option 1**). Such exemption would also allow in particular large farms and farmers' cooperatives currently operating as seed multipliers to place on the market big quantities of seed without the obligation to meet the certification requirements and thus have an unfair competitive advantage over the companies marketing seed. There would be a negative impact on those companies, and particularly on SMEs that are most likely to work with non-hybrid varieties that can be easily multiplied. Under option 2, an overall positive economic impact is expected because lighter rules will prevent fraudulent practices, enhance traceability and ensure a minimum PRM quality. Under option 3, benefits are minimal because activities of seed conservation networks, exchange in kind of seed and marketing to amateur gardeners would be subject to variety registration and PRM certification.

In the FRM sector there will be **no additional costs and administrative burden for operators and NCAs** as regards the measures for the purposes of conservation and sustainable use of forest genetic resources under option 1. Options 2 and 3 will **reduce the administrative burden for operators and NCAs** because there will be a notification for the purposes of the conservation of forest genetic resources instead of a fully-fledged registration process.

6.1.5. Innovation and digitalisation

Operators and NCAs

BMTs can be used to speed up the characterisation of new varieties and facilitate identification in PRM placed on the market. Digitalisation will improve the efficiency, integrity and traceability of the PRM/FRM certification and labelling system, making the certification process more efficient. Setting out a framework (implemented either by guidelines in option 1, or common rules in options 2 and 3) on the use of innovative production processes, BMTs and digital solutions will create legal clarity for operators and NCAs. It is expected to encourage NCAs and operators to invest in these[154], with a **positive impact on innovation and research** (Annex 5, Section 8). The measures under options 1-3 will provide new opportunities but not new obligations. Therefore, there are no costs imposed. Use of these new options however may require investments in equipment and/or staff. Any investment is expected to be recovered within few years due to efficiency gains and lower costs of operations (Annex 4, Section 7).

[154] Absence of such framework has been evoked in replies to the targeted survey by ICF(2023) as creating legal uncertainty for NCAs that prevents them from using BMTs. Other NCAs reported that they already use BMTs for variety identification and official inspections. Operators reported that BMTs are already used for plant breeding purposes (though this aspect is out of the scope of the PRM legislation), while in the FRM sector some companies have specialised in innovative production processes.

It is likely that initially not all SMEs would be able to benefit to the same degree as larger companies from the new opportunities given for the use of innovative production processes, BMTs and digital solutions[155]. Gradual reduction in investment costs and increase in the use of BMTs[156] and digital technologies is expected to quickly reduce this gap. The **long-term benefits** would anyway outweigh the initial investments. In turn, such investments are expected to **reduce costs for both NCAs and operators** for examinations for variety registration, PRM/FRM certification and marketing controls. Depending on the activity they specialise in and their current research and development intensity, some SMEs could be able to benefit from the new options more easily.

6.1.6. SMEs

Most of the 7 000 enterprises active in the seed sector in the EU are assumed to be SMEs. As regards PRM of fruit plants, there are over 20 000 suppliers in the EU, almost all of which are SMEs. As regards FRM, there are over 4 000 suppliers in the EU, almost all of which are SMEs. SMEs in the PRM/FRM sectors are very diverse in their activities and the degree of R&D intensity, but there is no comprehensive information available on the breakdown between the different activities. Some are highly specialised e.g. in breeding vegetable hybrids for only a few (or even one) species, in organic varieties, or in rapidly producing FRM clones through somatic embryogenesis. Others are just multiplying seed. The evidence available for the different activities of the SMEs is insufficient for a detailed assessment of the impact of the policy options on those SMEs.

An SME survey was carried out as part of the consultation activities. This confirmed the diversity of SMEs' activities and the variable impact that proposed measures may have on SMEs. The replies however did not indicate that SMEs could be disproportionately affected in relation to larger companies by the envisaged measures under the different options. Depending on the activity they specialise in and their current R&D intensity, some SMEs could be able to adjust more easily to the new obligations and benefit from the new opportunities. It would be however mostly SMEs that would benefit from the exemptions and derogations to be introduced for varieties marketed exclusively to amateur gardeners, conservation varieties including locally adapted varieties, organic varieties suitable for organic production and heterogeneous material, as it is mostly SMEs that are involved in such activities. Therefore option 3 that is most restrictive in these aspects can be assumed that it provides the least benefits for SMEs.

6.1.7. Competitiveness

All options are expected to improve the ***functioning of the internal market*** by increasing harmonisation and therefore more uniform application of requirements for operators across the EU, for both the PRM and FRM sectors. The highest harmonisation would be achieved in option 3 but possibly to a counter-productive degree as in option 3 most flexibility for Member States to adjust implementation to specific conditions would be lost. The policy options considered are not

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[155] Replies to the SME questionnaire indicate that the majority of SMEs considers that digital solutions and use of BMTs would bring advantages for them but would require additional investments in terms of access to third-party services, additional staff, training and/or infrastructure. A quantification of these investments is not possible.

[156] Costs are diminishing quickly and related technology becomes more accessible, but also improves. E.g. cost of genome sequencing from 1980s to today has diminished 1 000 fold, while the potential applications are multiple since then.

expected to have any significant impact on ***imports and exports*** of PRM and FRM. PRM and FRM imported from third countries is treated in the same way as the material produced in the EU. The principle remains that equivalence with EU requirements is given to third countries and imports are allowed if PRM/FRM produced in third countries meet the requirements of the EU legislation. Particularly for imported seeds, these must be of a variety already accepted in the EU Common catalogues. To be accepted, the variety has to be examined successfully by a MS according to the EU variety registration requirements. FRM can be imported from member countries of the OECD Forest Seed and Plant Scheme if the seed and planting stock fulfil the conditions set out by the EU legislation. PRM and FRM intended for export to third countries are not subject to the EU rules, while in all options the EU rules remain compatible to relevant international standards as OECD Seed Schemes, ISTA and WTO/SPS. Overall, efficiency gains from the various measures (increased coherence with PHL, OCR, a clearer framework for BMTs, innovative production processes, digitalisation) will have a positive impact on competitiveness of operators, that will be maximised under option 2.

6.2. Environmental impacts

Environmental impacts	Baseline	Policy Option 1	Policy Option 2	Policy Option 3
Availability of PRM/FRM suitable to address sustainability, climate change and biodiversity objectives	0	+/-	++	+
Conservation and sustainable use of plant and forest genetic resources	0	+	++	+/-

Table 7. Environmental impact of PRM/FRM measures
The scale corresponds to the following scheme: ++ positive impact, + moderately positive impact, +/- inconclusive/uncertain impact, = no significant impact, - moderate negative impact, --significant negative impact.

6.2.1. Strengthened sustainability requirements

The significant impact of rapidly changing conditions highlights the importance of varieties with improved sustainability characteristics. The positive **environmental impact** of such varieties may also contribute to the objectives of other policy initiatives (F2F, Biodiversity Strategy and Adaptation Strategy). Over the period 1981-2010, the average annual crop losses caused by drought in the EU have been estimated at EUR 4.8 billion/year[157]. Drought projections show that the maize sector may collapse at 2ºC of global warming if there would not be enough water available for irrigation. In Europe grain maize is projected to be the crop that is most affected by climate change[158]. Agro-climatic zones are moving northward and it is expected that this will further accelerate under climate change[159]. As a consequence, crops may no longer be suitable for the changing agro-climatic conditions[160]. Varieties with improved sustainability characteristics (e.g. drought tolerance[161]) would contribute to a more sustainable yield that would in turn contribute to

[157] https://joint-research-centre.ec.europa.eu/peseta-projects/jrc-peseta-iv
[158] Hristov *et al.* (2020), Toreti *et al.* (2022).
[159] Ceglar *et al.* (2019).
[160] Ceglar *et al.* (2021).
[161] Luo *et al.* (2019).

food security. Under option 1, the voluntary approach for the assessment of sustainability characteristics in vegetables and fruit plants, may result in PRM that is not suited for the local agro-ecological conditions. Under options 2 and 3, the mandatory assessment of sustainability characteristics in vegetables and fruit plants and the strengthened sustainability requirements of agricultural species and vine will have a positive **environmental impact**. The international organisation for vine and wine recommends the development of a specific examination of vine varieties present in different geographic zones with the aim to improve the knowledge about the adaptation potential of vine varieties[162]. They recognise the importance of the conservation and recuperation of genetic resources to develop new vine varieties that may contribute to adaptation to climate change.

Apart from the migration of climate zones, climate change also has an impact on the host range and geographical distribution of certain plant pests[163]. Certain pests may pose a danger for agricultural crop protection (e.g. *Meloidogyne graminicola* on rice) necessitating the EU to impose emergency measures[164]. Varieties with disease resistance / tolerance as a sustainability characteristic will have a positive **environmental impact** and may reduce the need for plant protection products. Varieties with strengthened sustainability characteristics may also contribute to the availability of PRM that is more suitable for the current and future projected climatic conditions.

The **environmental impact** of the strengthened sustainability considerations for FRM is interlinked with the impacts of other policy initiatives (Biodiversity Strategy, new Forest Strategy and Adaptation Strategy). By the end of the century, climate change will substantially alter the current distribution of climatically suitable areas for the majority of European trees[165]. FRM with improved sustainability characteristics can contribute to adaptation and mitigation of the already visible impact of climate change on forests such as drought, wildfires, increased vulnerability to climate-driven disturbances[166]. Strengthened sustainability requirements under options 2 and 3 will increase to the availability of FRM contributing to **sustainable forest management and restoration of healthy forest ecosystems**.

Option 2 overall performs very well in terms of the positive environmental impacts of strengthened sustainability requirements in the PRM and FRM sectors. Option 3 shows weaknesses because the creation of fully harmonised conditions for MS will limit possibilities for adjustments by MS to their own agro-ecological and environmental conditions, which is a key aspect in terms of contribution to sustainable agri-food production and forestry.

The extension of the scope of the FRM legislation to cover **non-forestry purposes** (options 2 and 3) will have a positive **environmental impact** especially in those MS where non-forestry purposes are significant[167] and currently not within the scope of the legislation. The long-term losses caused

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[162] OIV (2021).
[163] IPPC Secretariat. 2021.
[164] Commission Implementing Regulation (EU) 2022/1372.
[165] Mauri *et al*. (2022).
[166] Schuldt *et al.* (2020), Büntgen *et al*. (2021), Müller et al. (2020), Choat B. *et al*. (2012), Forzieri G. *et al*. (2020), Forzieri G. *et al*. (2021).
[167] Spain, Greece, France and Italy have a significant agroforestry cover.

by the planting of lower quality FRM would be reduced[168]. Even when FRM for non-forestry purposes is planted close to certified FRM there will no longer be any risk that it will lower the quality of the certified FRM, thus resulting long-run impacts on the resilience of forests are avoided. For all of the above, evidence is insufficient to allow a quantification of the described impacts.

National contingency plans (options 2 and 3) should address difficulties in supply of FRM in a more comprehensive way. National contingency plans will reduce the need for authorising the use of lower quality FRM, which would in turn help reduce canopy cover loss and contribute to the creation of resilient forests supporting biodiversity and mitigating climate change. In the absence of a requirement for contingency planning (option 1), it is less likely that MS will develop national contingency plans, but some MS have already done so or are in the process of doing so. Therefore, under option 1 the reduction of canopy cover loss would be low, while under options 2 and 3 it would be high. Difficulties in supply of FRM combined with the use of lower quality FRM can result in delayed planting and have a negative impact on the resilience of forests and could ultimately result in a loss of 5% of the total canopy cover[169].

More and better information on the suitability of FRM for current and future climatic conditions under all policy options will have a positive **environmental impact** through the selection of the right tree for the right place and thus support the resilience of future forests. It would also benefit users of FRM. Access to information about FRM characteristics would allow users to select the most appropriate FRM and reduce economic damage caused by the use of unsuitable FRM. Indicatively, incidences of entire forests disappearing due to bark beetle infestations caused by the planting of monocultures of unsuitable tree species susceptible to bark beetles could be reduced[170].

In the PRM and FRM sectors innovative production processes also offer big potential for addressing new demands as regards **sustainability and environmental objectives**[171]. Positive impacts are expected to be maximised in option 2, under which general legal provisions will provide a common framework that is on the one hand reliable and on the other hand flexible enough. Under option 1 (guidelines) there is a risk that the rules will be fragmented and requirements for operators will continue to differ across MS, with less environmental benefits. Under option 3 (more detailed rules) there is a risk that the legislation will be too prescriptive and become outdated very soon in light of new technical and scientific developments, thus nullifying initial benefits.

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[168] In the 9 MS that provided data in the targeted survey, on average 10% of the FRM produced is used for non-forestry purposes.

[169] Thonfeld *et al.* (2022) In the period 2018-2020 4.9% of canopy cover was lost in German forests because of extreme drought and tree species unsuitable for the environmental and climatic conditions.

[170] Hlásny *et al.* (2021).

[171] For example, true potato seed has great potential for genetic gains in potato breeding. *In vitro* propagation can contribute to increasing the production capacity and therefore meet the increasing demand for FRM. Some MS are exploring the use of new production processes to produce large quantities of FRM in a fast way. See for example Wu (2019) and Rosvall (2019).

6.2.2. Conservation and sustainable use of plant and forest genetic resources

Measures to conserve the genetic diversity of plant and forest genetic resources will alleviate the pressure on agricultural production and forests caused by increased exposure to biotic and abiotic factors. Genetically diverse PRM and FRM will have a positive environmental impact on the resilience against extreme weather conditions and disasters.

For PRM, lighter rules for the activities of seed conservation networks, marketing to amateur gardeners and exchange in kind of seed will also lead to **increased genetic diversity of cultivated crops** and contribute to the **conservation and sustainable use of plant genetic resources**. Genetic diversity of cultivated crops in turn can have benefits for **resilience** to a number of pressures (e.g. climate change, plant pests). Genetic diversity is also essential for future breeding efforts to develop new improved varieties[172]. A total exemption from the scope of the legislation (option 1) may cause loss of genetic diversity due to a lack of identification and traceability of the PRM concerned while the procedures in option 3 would be too cumbersome. Option 2 offers the best solution for safeguarding genetic diversity as it introduces light rules ensuring the identification and traceability of the PRM concerned.

In the FRM sector the environmental benefits regarding lighter rules for the registration of basic material will be marginal under option 1 since the effect of guidelines will be limited without changes in the requirements for the registration. By enabling the diversity of forest genetic resources, policy options 2 and 3 will have a **positive environmental impact** on **biodiversity** and **adaptation to climate change**. Policy option 2 will provide the strongest incentive as it allows operators to notify basic material instead of going through the official registration procedure requiring verification by the NCAs. EU forests are fragile because currently, 32.8% of EU forests have a single tree species, 49.5% have 2 to 3 tree species, 13.1% have 4-5 species and only 4.6% of forests have more than 6 tree species[173]. The measures under option 2 will ensure and conserve greater genetic diversity within a single tree species. It is estimated that the loss of canopy cover caused by the planting of a single tree species could be reduced by 5%.

6.2.3. Common measures for PRM to contribute to sustainability, biodiversity and climate-related challenges

A number of common measures under all options will have a positive environmental impact. Adapted rules on organic varieties suitable for organic production will contribute to the target of having 25% of agricultural production under organic conditions pursuant to the **goals of F2F**, therefore indirectly contributing to reduced use of inputs in agriculture. Simplified requirements for marketing of conservation varieties, extension of these requirements to cover new locally adapted varieties and broadening the scope of heterogeneous material beyond organic production will also reduce the administrative burdens for the operators concerned, but again not significantly in relation

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[172] Genetic diversity is crucial as it allows for the adaptability and resilience of the cultivated plants to climate change and other pressures. It is also necessary for breeding new varieties, as it provides for a pool of genes out of which breeders select according to new needs and challenges.

[173] https://foresteurope.org/wp-content/uploads/2016/08/SoEF_2020.pdf

to the whole sector[174] . Finally, it would be mostly SMEs that would benefit from such derogations, as it is assumed that mostly SMEs and small local actors are involved in such activities.

6.3. Social impacts

Under all options, lighter rules for conservation varieties and their extension to cover new locally adapted varieties have the potential to create a new market segment. Several hundreds of operators in rural areas could benefit from employment opportunities and a market that could reach an annual value of EUR 266 million annually. Also the exemption from the scope (option 1) or lighter rules (option 2) for activities of seed conservation networks, marketing exclusively to amateur gardeners and exchange in kind of seed between farmers are expected to have a positive impact on employment in rural areas, both in relation to SMEs in the PRM sector marketing these varieties and to the development of local value chains[175]. Under all options, the harmonisation of OCs, measures to improve the coherence with the PHL and extension of the activities that can be carried out under official supervision will have marginal/neutral impacts on employment. This would be restricted to reallocation of staff within the NCAs.

6.4. Sustainability

The introduction of strengthened **sustainability considerations** in the **examination of new varieties** will support **food security**[176], since better adapted varieties – future proof varieties - will result in more stable yields. Similar contributions are expected due to the availability of organic varieties suitable for organic production and new locally adapted varieties. Availability of seed of such varieties will result in more stable agricultural production and ultimately food availability. Finally, measures to support the conservation and sustainable use of plant genetic resources also contribute to sustainability by maintaining a broad genetic pool that is necessary for the breeding of improved varieties in the future. Currently food security in the short term is not an issue. However, the sustainability and resilience of the food system should be reinforced to ensure food security in the long term. The increasing frequency of extreme weather events will have a negative impact on agricultural production and risks increasing the number of pest outbreaks while all these events will potentially have an impact on food affordability[177].

Under option 1, the reinforcement of sustainability requirements would be restricted to agricultural crops and vine and would not contribute comprehensively to sustainability of food systems. Even though this would have low economic costs in the short term, there will be a potential negative economic impact in the long term. The environmental benefits would be limited because other crop groups (vegetable species and fruit plants) would not be addressed. In the mid to long term this would lead to increased crop losses and a negative impact on society because of expected fluctuations in food availability and food prices. Option 2 would reinforce sustainability requirements also in vegetable species and fruit plants. The overall benefits in terms of

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[174] Indicatively, in France locally adapted varieties of wheat represent 1% of volume.
[175] Conservation and locally adapted varieties are often linked to local food chains, e.g. wheat for local bakeries. See for example the final report on the Temporary experiment providing for certain derogations for the marketing of populations of the plant species wheat, barley, oats and maize (Decision 2014/150/EU) https://food.ec.europa.eu/system/files/2022-04/prm_temp-exp_pop-exp_en.pdf
[176] FAO recognises the role of improved varieties for food security globally.
[177] SWD(2023) 4 final.

sustainability would be positive. In the mid to long term crop yields would remain more stable and have a positive impact on society because of more stable food availability and food prices. Under option 3, the overall benefits in terms of sustainability would still be positive but limited by the reduced possibilities to adapt to local agro-ecological conditions.

The impact of climate change is already visible in the forest sector. Extreme weather events and disasters are becoming more frequent. Vegetation zones are moving fast and without a policy change, forests will not be able to cope with this[178]. As a result, forests will increasingly become poorly adapted to the changing climatic conditions. Large parts of forests will be increasingly destroyed by drought, storms, floodings, forest fires and heat while insufficient and poorly adapted FRM will be available for reforestation of the damaged forests. In the FRM sector, the measures to assess **sustainability characteristics** of basic material and the establishment of **national contingency plans** (options 2 and 3) will contribute to sustainable afforestation and reforestation. This will in turn result in more resilient forest ecosystems and contribute to forests that are better adapted to climate change. Similar positive contributions are expected from the obligation to provide information on FRM to users/buyers. Extending the scope of the legislation to non-forestry purposes will have a long-term positive environmental impact by avoiding failure of forest ecosystems (options 2 and 3). Measures on forest genetic resources will increase the genetic diversity of FRM and therefore also contribute to more resilient forest ecosystems (options 2 and 3). Given the uncertainty around the future projected climatic conditions and the time needed for the creation of new forests, it is important to ensure sustainable afforestation and reforestation by planting high-quality climate-adapted and genetically diverse FRM. This will ultimately result in resilient forest ecosystems that may withstand the pressures of climate change.

Under option 1, voluntary guidelines on the assessment of sustainability characteristics may result in improperly assessed FRM reaching the market. If non-forestry purposes would not be included in the scope of the legislation low-quality FRM may be planted close to high-quality certified FRM. In spite of their low economic impact in the short term, there would be a significant negative environmental impact in the long term (e.g. forests susceptible to pests or other environmental pressures). Under options 2 and 3, measures on the assessment of sustainability characteristics and the extension of the legislation to cover non-forestry purposes would have a slightly higher economic impact. Already in the mid-term the benefits would outweigh the initial costs by avoiding forest losses caused by the planting of low-quality and improperly assessed FRM. In the long-term forest ecosystems would become more resilient and less vulnerable to climate-driven disturbances. Under option 2 the benefit in terms of sustainability and contribution to genetic diversity would be positive while under option 3 those benefits, while still positive, would be more limited by the reduced possibilities for MS to adapt to their specific environmental conditions.

6.5. Global combined impact of the policy options

Option 1 presents low economic costs for operators and NCAs but also low benefits due to strengthened sustainability requirements. The increase in costs would be insignificant as few adjustments would be required both for operators and NCAs. However, the voluntary nature of the additional assessment of sustainability characteristics gives too much leeway, risking that varieties without improved sustainability characteristics enter the market. This would in turn reduce the

[178] Ceglar *et al.* (2019).

contribution to more sustainable agri-food production and food security. Annual agricultural losses already reach up to EUR 4.8 billion because of drought only. Without additional effort for varieties better adapted to such extreme conditions this situation is expected to deteriorate even further. In the FRM sector, the voluntary approach towards contingency plans may cause major shortages of FRM in case of extreme weather and disasters. Leaving non-forestry purposes out of the scope of the FRM legislation may result in the planting of low-quality FRM in proximity of high-quality FRM, and in long-term impacts on the resilience of forests. Finally, option 1 is expected to have positive impacts on the conservation and sustainable use of plant and forest genetic resources though limited by the absence of tools for traceability and quality assurance for plant and the voluntary nature of rules for forest genetic resources.

Option 2 presents considerable economic costs for operators and NCAs due to the need for additional investments to conduct additional sustainability assessments. On the other hand, benefits due to strengthened sustainability requirements are high as the mandatory nature of the additional assessment is combined with flexibility to adapt to local agro-ecological conditions. This would in turn increase the contribution to more sustainable agri-food production and food security. In the FRM sector, the obligation for MS to establish contingency plans is expected to increase preparedness for major shortages of FRM in case of extreme weather and disasters. The inclusion of non-forestry purposes in the scope of the FRM legislation would reduce the risk of planting low-quality PRM in proximity of high-quality FRM, and negative long-term impacts on the resilience of forests. Finally, option 2 is expected to have high positive impacts on the conservation and sustainable use of plant and forest genetic resources through tools for traceability and quality assurance for plant and adapted rules for forest genetic resources.

Option 3 presents considerable economic costs for operators and NCAs due to the need for additional investments to conduct additional sustainability assessments. Benefits due to strengthened sustainability requirements are positive though limited by the lack of flexibility to adapt to local agro-ecological conditions. This would in turn limit the contribution to more sustainable agri-food production and food security. In the FRM sector, harmonised contingency plans with lack of flexibility to adapt to local climatic and ecological conditions will limit the benefits regarding increased preparedness for major shortages of FRM in case of extreme weather and disasters. The inclusion of non-forestry purposes in the scope of the FRM legislation would reduce the risk of planting low-quality PRM in proximity of high-quality FRM, and negative long-term impacts on the resilience of forests. Finally, option 3 is expected to have negative impacts on the conservation and sustainable use of plant genetic resources as measures concentrate on increased traceability and quality assurance without fully accommodating the specific needs of plant genetic resources. Harmonised rules adapted for forest genetic resources will have a positive impact on the conservation and sustainable use of forest genetic resources.

The major cost and benefit elements of each option are summarised in Table 8.

Costs	Policy Option 1	Policy Option 2	Policy Option 3
Increased costs for PRM operators due to strengthened sustainability assessment	2	6	8
Increased costs for NCAs due to strengthened sustainability assessment	=	43 to 98	43 to 98
Increased costs of PRM for farmers due to strengthened sustainability assessment	133	400	667
Increased costs for NCAs due to measures on official controls	=	=	15
Increased costs for operators and NCAs due to measures for FRM (definition of purposes, assessment for sustainability characteristics, national contingency plans)	=	=	=
Benefits	**Policy Option 1**	**Policy Option 2**	**Policy Option 3**
Avoided loss in crop output due to increased sustainability requirements	310 to 1 243	621 to 2 486	466 to 1 864
Reduction in costs of registration of operators due to single registration under plant health legislation	1	1	1
Reduction in PRM certification costs due to extended scope of activities under official supervision	2	2	2
Market opportunities due to lighter rules for conservation varieties and new locally adapted varieties	266	266	266
Reduction of breeding costs due to adjusted uniformity requirements for organic varieties	5	5	5
Efficiency gains due to measures on official controls	+	++	++
Efficiency gains due to measures on innovation and digitalisation	+	++	+
Sustainability of agri-food production, forestry and food security	+/-	++	+
Benefits for the conservation and sustainable use of plant and forest genetic resources	+	++	+/-

Table 8. Overview of major cost and benefit elements of each option
The amounts are for EU27 in million EUR/year. For cost and benefit elements for which monetisation is not feasible, a qualitative score is used. The scale corresponds to the following scheme: ++ positive impact, + moderately positive impact, +/- inconclusive/uncertain impact, = no significant impact, - moderate negative impact, -- significant negative impact.

6.6. Stakeholders' views on impact of policy options

Policy option 1 would be acceptable to a majority of stakeholders and MS as the impacts/additional costs and required changes would be minimal. There would be benefits of the extension of the current VCU examination for agricultural plant species and vine to include characteristics that contribute to sustainable production (VSCU). For the other crop groups currently not subject to VCU (vegetables and fruit plants), the voluntary communication of the information coming from the pre-registration trials (before application) could enable the farmers to choose the right varieties according to their needs.

The majority of NCAs and stakeholders are of the opinion that the harmonisation of the framework for OCs outside the scope of the OCR (option 1) would have the lowest impact on the increase in cost and administrative burden. According to NGOs and certain academia the total exemption of the activities of seed conservation networks, exchange in kind of seed between farmers and marketing to amateur gardeners from the scope of the legislation would have the biggest positive impact on the conservation and sustainable use of plant genetic resources. The seed sector and some NCAs are concerned that a total exemption could be misused by farmers multiplying seed under a service contract. As regards the possibility of using BMTs and digital solutions, some stakeholders prefer that the use of BMTs and digital solutions remain optional because of a lack of resources to invest in such technologies.

Stakeholders and NCAs are concerned about the increased costs and the reduced number of varieties coming to the market under policy option 2 extending the VSCU examination to all crop groups. NCAs state that the need for, and costs of, additional testing areas would be an important limiting factor, highlighting that even official supervision may not be an adequate solution. Smaller MS have reported that there would not be enough areas for field trials. MS have already identified the lack of areas for field trials as a limiting factor for carrying out the VSCU under organic conditions. Likewise, the seed sector is concerned that the VSCU examination under option 2 would lead to disproportionate costs especially for SMEs and to the decrease of new varieties entering the market. While the main farmers' association considers it important to assess new varieties for those criteria and have the relevant information at hand, they are concerned about the increased cost and the reduced availability of new varieties because of the compulsory VSCU assessment[179].

The majority of NCAs and stakeholders fear an increase in administrative burden upon the inclusion of OCs into the scope of the OCR. Several NCAs and businesses are of the opinion that option 2 including OCs into the scope of the OCR with simplified import controls would contribute to more harmonised conditions for the operators and the marketing of PRM and FRM across MS. NGOs are of the opinion that the introduction of lighter rules for the activities of seed conservation networks, exchange in kind of seed between farmers and marketing to amateur gardeners would hamper those activities and have a negative impact on the conservation and sustainable use of plant genetic resources. According to the seed sector, the introduction of at least lighter rules for such

[179] This position however reflects a compromise between their different members.

activities would offer a minimum guarantee for compliance with the plant health requirements and for the traceability of such activities. Most NCAs and stakeholders including SMEs are of the opinion that the introduction of basic rules on innovative production processes, BMTs and digital solutions would have a positive impact on the uptake and advancement of such technologies.

Most stakeholders and MS are of the opinion that harmonisation of the VSCU examination under option 3 would be disproportionate and counterproductive. The majority of NCAs and stakeholders fear an increase in administrative burden upon the inclusion of OCs into the scope of the OCR. Only a few stakeholders are of the opinion that a full inclusion into the scope of the OCR with stricter import controls at border control posts (option 3) would have the highest positive impact on the creation of equal conditions for operators and marketed PRM and FRM across MS. NGOs and certain academia strongly oppose to subjecting the activities of seed conservation networks, exchange in kind of seed between farmers and marketing to amateur gardeners to the requirements of the legislation. In their view, this would undermine all efforts undertaken for the conservation and sustainable use of plant genetic resources. Most stakeholders and NCAs in favour of the use of BMTs and digital solutions are of the opinion that the introduction of detailed rules would have a negative impact on the use of such technologies and restrict scientific and technological developments.

As regards FRM, the majority of NCAs and regional forest authorities who participated in the targeted survey on FRM believe that the inclusion of the purposes for which the FRM is produced will increase the administrative burdens for NCAs and operators, increase the costs for inspections and require and additional investment by the operators. Respondents agreed that it is essential to guarantee traceability of the genetic origin for the FRM users without increasing the administrative burden and the costs.

7. HOW DO THE OPTIONS COMPARE?

This section compares the expected impacts of the policy options in relation to the baseline scenario in terms of their overall effectiveness, efficiency, coherence, subsidiarity and proportionality. It considers the effects of no policy change in the long term.

Criteria		No policy change	Policy Option 1	Policy Option 2	Policy Option 3
Effectiveness: contribution to achieving the policy specific objectives (SO)		0	+	++	+
SO1: Simplified, clarified and harmonised basic rules		0	+	+	+
SO2: Enabling the uptake of new scientific and technical developments		0	+/-	++	+
SO3: Ensure availability of PRM/FRM suitable to address future challenges		0	+/-	++	+
SO4: Support the conservation and sustainable use of plant and forest genetic resources		0	+	++	+/-
SO5: Harmonisation of the framework for official controls		0	+	++	++
SO6: Coherence with PHL		0	+	+	+
Effectiveness: other economic, social and environmental impacts		0	+/-	++	+
Economic impacts	SMEs	0	++	++	+

Criteria		No policy change	Policy Option 1	Policy Option 2	Policy Option 3
	Competitiveness	0	+	+	+
	Innovation and research	0	+	++	+
Environmental impacts	Climate change resilience	0	+/-	++	+
	Sustainable use of resources	0	+/-	++	+
Social impacts	Food security	0	+/-	++	+
	Employment	0	+	+	=
Efficiency		**0**	++	+/++	+/-
Coherence		**0**	+	++	+
Subsidiarity		**0**	+	+	+
Proportionality		**0**	+	++	-

Table 9: Global comparison of the options. The scale of the score given to impacts and assessment of efficiency, coherence, subsidiarity and proportionality is based on the following scheme: ++ positive, + moderately positive, +/- inconclusive/uncertain, = not significant, - moderate negative, --significantly negative.

7.1. Effectiveness

The evaluation of effectiveness looks at the extent to which the option would achieve the objectives. Option 2 overall outranks the other policy options. Option 3 ranks second, slightly better than option 1, which however performs better than the no policy change scenario.

The common measures for **simplification** of administrative procedures are expected to accelerate market access of PRM/FRM produced within the EU and of imported PRM/FRM.

For **innovative production processes, BMTs and the use of digital solutions**, options were assessed in relation to the initial investment and the gradual reduction of costs for NCAs and operators. Option 2 performed the best on these criteria while options 1 and 3 performed equally well. Laying down a reliable framework under option 2 will create legal certainty and encourage operators and NCAs to invest in these technologies and the **long-term benefits** would anyway outweigh the initial investments. With option 1 (implementation by guidelines) there is a risk that the rules will be fragmented and that operators may not be inclined to invest in such technologies due to the absence of a reliable framework that will give them a perspective of a return on their initial investment. More consistent rules on innovative production processes, BMTs and digital solutions under option 3 come at the expense of the frequency for updating those rules due the rapid pace of new technical and scientific developments.

To **ensure availability of PRM suitable for future challenges**, options were assessed in relation to the scope of the sustainability assessment of new varieties and the level of harmonisation of that assessment. The enlarged scope of the sustainability assessment under options 2 and 3 addresses the objective of PRM contributing to more sustainable agri-food production and increased resilience to climate change conditions in the most comprehensive way. With the voluntary extension of the scope of the sustainability assessment (option 1) the increase in varieties with improved sustainability characteristics of non-regulated crop groups may be lower. An approach balancing harmonisation of the sustainability assessment with flexibility (option 2) allows for adaptation to

local agro-ecological conditions. For example, the relevance of pests and climatic conditions (e.g. drought, frost) differs per region. Such adaptation would not be possible under a harmonised sustainability assessment (option 3). The risk of option 1 (most flexible approach for sustainability assessment) is that MS will diverge in relation to the approach for this sustainability assessment and that varieties without improved sustainability characteristics will reach the market.

Common measures creating a legal framework to **ensure the availability of PRM suitable for the needs of organic agriculture** will ensure a consistent approach for variety registration and certification of 'organic varieties suitable for organic production' and contribute to the target of having 25% of agricultural production under organic conditions (F2F).

To **ensure availability of FRM suitable for future challenges**, options were assessed in relation to the sustainability assessment of basic material, inclusion of non-forestry purposes into the scope of the legislation and contingency planning. The enlarged scope of the sustainability assessment under options 2 and 3 addresses the objective of FRM contributing to more sustainable forest management and restoration of healthy forest ecosystems and increased resilience to climate change conditions in the most comprehensive way. It cannot be guaranteed that the voluntary guidelines on the assessment of sustainability characteristics under option 1 will be taken up to the same degree as mandatory principles under options 2 and 3. Under option 1, there is the possibility that improperly assessed FRM would reach the market and this could have a significant negative environmental impact in the long term (e.g. forests susceptible to pests or other environmental pressures). An approach balancing harmonisation of the sustainability assessment with flexibility (option 2) allows MS to adapt to environmental and climatic conditions which may show quite substantial regional differences. Option 3 would not allow such adaptation. The inclusion of specific non-forestry purposes in the scope of the legislation (options 2 and 3) will avoid long-run negative impacts on the resilience of forests and perform better than keeping the current scope (option 1). In addressing temporary difficulties in supply of suitable FRM through contingency planning, option 2 is expected to be the most effective. Under option 2 the requirement to establish national contingency plans is coupled with the flexibility for MS to adapt contingency plans to their environmental and climatic conditions. The voluntary approach under option 1 risks that MS will ignore the need for such plans, while the highly harmonised approach under option 3 can prove counterproductive as needs and priorities can differ significantly across the EU. A common measure providing more and better information by nurseries to FRM users/buyers on the suitability of FRM for current and future climatic conditions will allow FRM users/buyers to buy the right tree for the right place and thus support the resilience of future forests. Overall option 2 would be more effective in securing the availability of FRM suitable for future challenges.

To support the **conservation and sustainable use of plant genetic resources**, options were assessed in relation to the approach towards seed conservation networks, exchange in kind of seed, and marketing exclusively to amateur gardeners. A total exemption of these activities from the scope of the legislation (option 1) will not fully meet the objective due to a lack of identification and traceability of the PRM concerned. The procedures in option 3 (general requirements of the legislation for variety registration and PRM certification) would be too cumbersome and counterproductive towards meeting the objective. Option 2 offers the best solution for safeguarding genetic diversity as it introduces lighter rules ensuring the identification and traceability of the PRM concerned. To support the **conservation and sustainable use of forest genetic resources**, dedicated measures under options 2 and 3 would be most effective in comparison to the adoption of guidelines that risk not to be followed by the MS (option 1). Overall, in supporting the conservation and sustainable use of plant and forest genetic resources, option 2 would be most effective,

followed by option 1. Option 3 would have uncertain results as the highest harmonisation foreseen under option 3 would be effective for securing the quality of the PRM/FRM concerned but not suitable for its specific needs due to its higher genetic diversity.

For the **harmonisation of the framework for OCs**, common measures on OCs across MS and minimum requirements as regards the frequency and scope of OCs will provide a clear regulatory framework and contribute to a level playing field for operators. Options 2 and 3 perform equally well and better than option 1. Alignment of the OC rules outside the scope of the OCR (option 1) would have the drawback of not making use of the advantages of the OCR (existing IT applications and training). Options 2 and 3 will make use of the existing IT applications for OCs such as the Information Management System for Official Controls (IMSOC). Moreover, it will be possible to report suspected cases of PRM/FRM fraud through a secure IT portal. Training activities will be organised to train MS official inspectors. As under option 1 the PRM/FRM legislation is outside the scope of the OCR as regards risk-based OCs, it will not be possible for MS to use the aforementioned IT applications and follow training courses.

Common measures for **coherence between the PRM/FRM legislation and the PHL** will create clarity for NCAs and operators as regards the legal framework for OCs on PHL through the removal of the duplication of RNQP requirements in both legal frameworks and the regulation of all plant pests (QPs and RNQPs) only under the PHL.

7.2. Efficiency

The evaluation of efficiency considers the extent to which the options result in costs and benefits for NCAs, operators and other stakeholders (in the case of this initiative the users of PRM and FRM). The net benefit as well as the Benefit Cost Ratio of each option have been calculated (detailed presentation in Annex 4). Due to high uncertainty, calculations have been done for an optimistic scenario (under which the highest benefits and the lowest costs are realised) and for a conservative scenario (under which the lowest benefits and the highest costs are realised).

Global costs and benefits per option (excluding common measures)									
	Option 1			**Option 2**			**Option 3**		
	PRM/FRM users	**Operators**	**NCAs**	**PRM/FRM users**	**Operators**	**NCAs**	**PRM/FRM users**	**Operators**	**NCAs**
Costs per stakeholder category (million EUR/year)	133	2	0	400	6	from 43 to 98	667	8	from 58 to 113
Global costs (million EUR/year)	**135**			**from 449 to 504**			**from 733 to 788**		
Benefits per stakeholder category (million EUR/year)	from 310 to 1 243	0	0	from 621 to 2 486	0	0	from 466 to 1 864	0	0
Global benefits (million EUR/year)	**from 310 to 1 243**			**from 621 to 2 486**			**from 466 to 1 864**		
Cost benefit analysis of options under an optimistic scenario (highest benefits and lowest costs)									
Net benefit (million EUR/year)	1 243 – 135 = 1 108			2 486 – 449 = 2 037			1 864 - 733= 1 131		
Benefit Cost Ratio	1 243 / 135 = 9.20			2 486 / 449 = 5.53			1 864 / 733 = 2.54		
Cost benefit analysis of options under a conservative scenario (lowest benefits and highest costs)									
Net benefit (million	310 – 135 = 175			621 – 504 = 117			466 - 788 = - 322		

EUR / year)			
Benefit Cost Ratio	310 / 135 = 2.29	621 / 504 = 1.23	466 / 788 = 0.59

Table 10: Net benefit and Benefit Cost Ratio of the options

In terms of net benefits, under the optimistic scenario option 2 ranks first, followed by option 3 that only marginally outranks option 1. Under the conservative scenario option 1 ranks first, followed by option 2, while option 3 presents higher costs than benefits. In terms of Benefit Cost Ratio, under both scenarios option 1 ranks better than option 2, while option 3 is always the worst option.

These calculations cannot capture a number of non-monetised benefits described in section 6. For these, option 2 is performing better than options 1 and 3, especially as regards long-term environmental and sustainability benefits (see an overview in Table 8). As a result, the comparison of the options in terms of net benefit and benefit cost ratio is distorted in favour of option 1 against option 2.

7.3. Coherence

The initiative relates to several EU policy objectives, policy initiatives and instruments. The evaluation of coherence looks at how consistent each option is with these and identifies the extent to which they promote horizontal objectives and facilitate delivery of relevant key targets.

EU initiatives / regulatory framework	Key considerations
PHL	Under all options (same measure) coherence with PHL is maximised. All requirements for PRM/FRM as regards plant health will be moved to PHL. The PRM/FRM certification rules will require compliance with PHL.
OCR	Option 1 does not introduce any links between the PRM/FRM legislation and the OCR. Options 2 and 3 harmonise OCs for PRM/FRM under the OCR thus allowing alignment with OCs for other legislative frameworks under the OCR (PHL, Organic Regulation and GMOs).
CPVR system	The DUS protocols used for granting CPVR (intellectual protection) are applied also for the purposes of variety registration (authorisation for marketing). While the two systems are independent, that is a variety can be registered regardless of CPVR protection, the use of common DUS protocols results in significant efficiency gains. Measures to facilitate organic production and to support the conservation and sustainable use of plant genetic resources will result in varieties (conservation, new locally adapted and organic varieties) and heterogeneous material becoming available to the market without meeting the DUS requirements, therefore also not eligible for CPVR. However, this trade-off is considered necessary to achieve the respective objectives for organic production and plant genetic resources.
NGTs	The variety registration system of the PRM legislation (including the assessment for characteristics contributing to sustainable production) applies to all varieties irrespective of the breeding technique. The same applies for

	acceptance of basic material under the FRM legislation. Varieties and FRM with NGT traits will be treated in the same way as all other varieties independently of the breeding methodology (conventional breeding, GM technology, NGT technology). This initiative and the NGT initiative in preparation contribute to the goals of the EFD and F2F.
F2F	The increased efficiency and efficacy of the variety registration and certification systems will support innovation in plant breeding and thus seed and food security. The envisaged measures for organic production, conservation varieties, new locally adapted varieties and heterogeneous material will increase coherence with F2F as regards the genetic diversity of PRM/FRM. Option 2 would be most coherent with the sustainability targets of F2F through a sustainability assessment covering all crop groups (improved varieties can help reduce use of fertilisers and pesticides) with an implementation adjusted to the agro-ecological conditions of the MS.
The initiative for a new regulation on the sustainable use of plant protection products (SUR)	In comparison to option 1, options 2 and 3 present increased coherence with the SUR targets on reduced pesticide use through the extension of the current VCU requirements for agricultural species and the introduction of sustainability characteristics for the other crop groups which include examination for resistance to plant pests. New varieties with increased resistance to plant pests may require less pesticides. As option 2 is considered more effective in this aspect than option 3, coherence with SUR would be highest under option 2.
FSFS	The PRM/FRM initiative includes specific sustainability considerations ('*lex specialis*'), while respecting the general sustainability principles and objectives of FSFS ('*lex generalis*').
Biodiversity Strategy	Measures supporting the conservation and sustainable use of plant and forest genetic resources contribute to the Biodiversity Strategy objective to reverse the decline of genetic diversity. Highest coherence is achieved under option 2, whereby lighter rules will enable the characterisation and documentation of plant and forest genetic resources (in contrast to the absence of any traceability under option 1) and provide more flexibility to operators (in contrast to being subject to the general rules on variety registration and certification under option 3).
EU Forest Strategy	Option 2 offers more coherence with the EU Forest Strategy target of ensuring resilient and multifunctional forest ecosystems as it will be most effective in enabling availability of climate-adapted FRM, by the inclusion in the scope of the legislation of non-forestry purposes such as biodiversity conservation and the requirement for national contingency plans.
Climate adaptation	The initiative will facilitate the broadening of the supply of suitable high-quality PRM/FRM to support adaptation in agriculture and forestry through the requirements for more information to end users of FRM on the suitability of FRM for future climatic and ecological conditions; the establishment of national contingency plans and strengthened sustainability requirements for FRM; a strengthened assessment of new plant varieties (including as regards abiotic factors such as drought); enabling the registration of locally adapted

	varieties. Highest coherence is achieved under option 2 that provides for flexibility to MS for implementation according to their agro-ecological and environmental conditions).
Digital Strategy	All options improve coherence with the general requirement for digital transformation by enabling digitalisation to improve the efficiency, integrity and traceability of the certification and labelling system. Options 2 and 3 support digitalisation of OCs through IMSOC and on-line applications for notifying non-compliances and combatting fraud.
SDGs	By strengthened sustainability requirements for all crop groups, measures for organic production, plant and forest genetic resources, FRM national contingency plans the initiative contributes to SDG 2 on zero hunger, SDG 12 as regards responsible production, SDG 13 on climate action and SDG 15 on life on land. As described above, the most coherent approach is provided by option 2.

Table 11. Key considerations on coherence

7.4. Subsidiarity and proportionality

All three options are consistent with the EU's right to act under the Treaty of the Functioning of the EU (agricultural production, the single market and the free movement of products within the EU).

In line with the principle of **subsidiarity**, the initiative is limited to aspects that can be better achieved at Union level than if they were addressed individually by MS. Without common rules for PRM (variety registration and certification), FRM (approval of basic material and certification) and OCs, there would be 27 different systems instead of one common system in place. This situation would result in obstacles to the movement of PRM/FRM in the internal market and increased costs for controls to ensure equivalence between the different systems. A common EU framework is also most appropriate in order to implement in a harmonised way the various international standards in relation to PRM/FRM quality and plant health[180].

In line with the principle of **proportionality**, the envisaged measures do not exceed what is necessary for achieving the set objectives. A number of existing administrative procedures and requirements will be simplified. The options reflect a trade-off between flexibility and harmonisation. Their comparison shows that a fully harmonised system (option 3) does not perform better and that the most proportionate solution is to retain some flexibility for MS (option 2). The latter balances the need for harmonised rules for variety registration and PRM certification with the flexibility for MS to implement those rules to adapt to their local agro-ecological conditions and measures to strengthen sustainability (F2F) and respond to the call for adaptation to climate change (EU Strategy on Adaptation to Climate Change) and restoring biodiversity (Biodiversity Strategy). Likewise, in the FRM sector option 2 creates a balance between the general principles of registration and FRM certification with flexibility for MS to respond to the biodiversity and climate challenges. To achieve these needs and take account of the important differences between the PRM

[180] OECD, International Seed Testing Association (ISTA), United Nations Economic Commission for Europe (UNECE), International Plant Protection Convention (IPPC), World Trade Organization/Sanitary and phytosanitary measures (WTO/SPS).

and FRM sectors, the current 11 basic Directives[181] will be replaced by a Regulation on PRM and a Regulation on FRM.

8. PREFERRED OPTION

The assessment indicates that policy option 2 is the strongest option to effectively address all the objectives of the revision of the PRM and FRM legislation in an efficient and consistent manner. Option 1 presents the best Benefit Cost Ratio as it presents the lowest costs, but it is not the most effective option in terms of achieving the objectives. Actually, option 1 presents the risk that it will lead in the long term to increased losses due to its reduced ambition in addressing comprehensively the sustainability and climate adaptation challenges.

Stakeholder consultations showed that preferences were split between option 1 (most flexible system but also with lowest costs) and option 2 (balancing harmonisation with flexibility). A majority of stakeholders highlighted the need for some degree of flexibility for MS to adapt to their local agro-ecological (PRM) and climatic and ecological conditions (FRM). All stakeholders were in favour of a separate legal framework for FRM.

There are different stakeholders in the sector. Most stakeholders produce PRM and FRM for commercial purposes while a segment does so for non-profit purposes. Although these stakeholders have different activities and objectives, they all recognise the need to preserve and increase the genetic diversity of PRM and FRM. In fact, the work done by seed conservation networks as regards the conservation of plant genetic resources is invaluable as it gives the seed industry a wider choice of PRM from which they can develop new varieties. Currently, the activities of actors involved in conservation and sustainable use of plant and forest genetic resources, such as activities of seed conservation networks and exchange in kind of seed are restricted. A future regulatory framework needs to respond to the needs of the different stakeholders. The impact assessment investigated what would be the best approach to do so. NCAs and the seed industry value the well-functioning certification system and its importance at global level with the EU in the top three of globally exporting regions. However, they recognise that the current system has its flaws, in particular as regards the non-level playing field for operators, marketed PRM and FRM, OCs and enforcement. Concerned operators and NGOs have highlighted that the existing derogations for conservation varieties have not been successful. The organic sector has expressed the need for adapted rules for organic varieties intended for organic production. Moreover, the existing system is currently quite restrictive as regards the activities that can be carried out by operators under the official supervision of the authorities. Since 2013, scientific and technical developments have swiftly moved forward while the legislation does not have adequate provisions on innovative production processes, BMTs and digitalisation.

The current legislation does not have sufficient means to respond to **sustainability and climate-related challenges** addressed by the EGD and its strategies. For agricultural species sustainability characteristics have been incorporated by certain MS in the VCU examination while there are no sustainability characteristics for the other crop groups. The current experience with agricultural species shows that a voluntary approach towards extending the sustainability assessment to other

[181] Council Directive 98/56/EC on the marketing of propagating material of ornamental plants will remain in place.

crop groups will not work. The preferred option will extend and strengthen **sustainability requirements**. This will come with a cost for businesses in terms of increased breeding costs while NCAs may need to increase their capacity in areas and staff. Mitigating measures can be taken such as a transition period in the application of the new legislation, reduction of the adjustment cost by permitting VSCU examination under official supervision and promote collaboration between MS by creating shared testing networks and allowing delegation of activities to other MS. Therefore, strengthened sustainability requirements applicable to all crop groups show the highest effectiveness in contributing to the increase in sustainable agri-food production under F2F and the availability of climate-adapted and more resilient PRM.

The regulatory framework should leave room for flexibility for MS to adapt to their local agro-ecological conditions. Furthermore, it should proportionally regulate activities related to **conservation and sustainable use of plant and forest genetic resources**. The choice of legal instrument, 2 Regulations (PRM and FRM) replacing 11 Directives, will reduce divergent implementation across MS caused by national transpositions.

Under option 2, the introduction of **lighter rules for registration** of conservation and locally adapted varieties and for conservation activities will introduce a proportionate approach for a small market segment. This will most likely have a positive impact on employment in rural areas, both on small operators marketing these varieties and on the development of local value chains. The preferred option will also result in increased genetic diversity and contribute to the objectives of the Biodiversity Strategy. Likewise, the introduction of variety registration rules adjusted to the principles of **organic production** will contribute to the target of having 25% of agricultural production under organic conditions pursuant to the goals of F2F.

As regards FRM stakeholder consultations also showed a split between options 1 (most flexible approach) and 2 (balancing flexibility with harmonisation). Stakeholders were very strong on separating the FRM legislation from the PRM legislation. In fact, the inclusion of FRM in the PRM proposal was one of the reasons for rejecting the PRM proposal. FRM stakeholders recognise the challenges brought about by climate change. They are confronted with increasing forest damages caused by insects, storms and drought. Furthermore, there is an increased demand for FRM for plantations for biomass production and for responding to the target of planting 3 billion additional trees by 2030. To respond to these challenges and the higher demand in FRM there is a need for a legal framework that includes a **sustainability assessment** of basic material, increasing the resilience of FRM by taking measures on the **conservation and sustainable use of forest genetic resources** and responds to the increased demand for FRM by extending to scope of the legislation to **non-forestry purposes**. The FRM proposal will contain updated rules for FRM and ensure that more information about the **suitability of FRM for future climatic conditions** is provided by the nurseries to FRM users/buyers. National contingency plans will prepare MS for difficulties in supply of suitable FRM. Altogether these measures will result in the planting of high-quality FRM in suitable areas and contribute to the creation of resilient forests and the restoration of forest ecosystems. The impact assessment showed that option 2 combining flexibility with harmonisation was the best approach to address the problems identified in the current legislation. Option 3 does not allow taking into account the differences between MS as regards the type of forests and the activities carried out.

In the PRM and FRM proposals, the measures on the **harmonisation of OCs**, the **coherence with the PHL**, **innovative production processes, BMTs and digital solutions** serve to increase the

efficacy and efficiency of the procedures and reduce the administrative burden for MS and businesses, overall contributing to the competitiveness of the PRM/FRM sectors.

8.1. REFIT (simplification and improved efficiency)

The revision of the PRM and FRM legislation offers the opportunity of savings for businesses as regards variety registration, certification and OCs. There will be lighter rules for the registration of conservation and locally adapted varieties as well as for the activities of seed conservation networks, the possibility of VSCU examination under official supervision (PRM), extension of certification activities possible under official supervision (PRM/FRM), increased efficiency of the registration and certification system (innovative production processes, BMTs and digital solutions) and more efficient OCs. The table below gives an overview of the main opportunities under the preferred option. Some of these serve to mitigate the increased burden caused by the extension of sustainability requirements in the PRM and FRM sectors.

REFIT cost savings – preferred option		
Description	**Qualitative assessment**	**Comments**
Replacing 11 Directives by 2 Regulations	+/-	Regulation is directly applicable and creates more harmonised approach for businesses.
Simplified registration and labelling requirements for conservation varieties and new locally adapted varieties	+	Reduction in administrative and compliance costs because there will be no official variety examination and certification requirements, and labelling requirements will be simplified.
Adapted variety registration requirements for organic varieties	+	Savings in compliance costs because variety registration will be adapted.
Notification of heterogeneous material/OHM (PRM)	+	Reduction in administrative and compliance costs because marketing of heterogeneous material will be subject to notification and simple labelling requirements.
Notification of basic material for the purposes of conservation and sustainable use of forest genetic resoures (FRM)	+	Reduction in administrative and compliance costs because basic material will be notified without the need for an official registration requiring an official inspection.
Extension of certification activities that are possible under official supervision	+	Reduction in compliance costs. Possible need for one-off investment in equipment and official training of inspectors by certification NCAs, but rather limited for those operators that already carry out certification activities under official supervision.

Digitalisation for more efficient processes in NCAs and businesses	+	The EU Plant Variety Portal will facilitate administration of variety registration and accelerate market access of new varieties by up to 4 months. Digital certification labels will decrease administrative burden. Exchanges between MS through digital systems will decrease administrative burden.
Innovative production processes and BMTs	+	Innovative production processes and BMTs will speed up PRM/FRM production. BMTs will render variety registration, PRM/FRM certification and OCs more efficient.
Inclusion in the scope of the OCR	+	Harmonised OCs for operators across MS. Increased efficiency of OCs. Use of common IT platforms for notifying information about PRM/FRM imports, reporting non-compliances and combatting fraud.

Table 12: Refit cost savings – preferred option

8.2. Simplification and burden reduction for businesses, supporting the one-in one-out approach

The activities that imply significant administrative costs for businesses are the following:

- Application for acceptance of new varieties (PRM);
- Application for registration of basic material (FRM);
- Certification of PRM;
- Certification of FRM;
- OCs.

For implementing the one-in-one-out requirement, for each of these activities all cost drivers were mapped but the analysis showed that these would undergo only marginal changes. There are no administrative costs for the citizens.

9. HOW WILL ACTUAL IMPACTS BE MONITORED AND EVALUATED?

Indicators for the preferred option, in relation to the core objectives of the PRM/FRM revision, with suggested data sources are presented in table below.

General objectives	Specific objectives	*Measures of success* and monitoring indicators
To ensure a level playing field for operators across the EU	Harmonise the framework for OCs on PRM/FRM	*Comparable level of OCs across MS*
		- Number of controls in proportion to risk from analysis of multi-annual national control plans (NCAs) and annual reporting on the number and outcome of OCs (NCAs) - Number of controls in proportion to risk from harmonised checking and reporting of PRM/FRM imports (IMSOC) - Findings of EU audits (Commission)
	To improve coherence of PRM/FRM legislation with PHL	*Implementation of RNQP rules under PHL*
		- Number of reporting and checking of RNQP-related non-compliances (IMSOC) and from findings of EU audits
To support innovation and competitiveness of the EU	Enable uptake of innovative production processes, BMTs and digital solutions	*Uptake of innovative production processes, BMTs and digital solutions*
		- Number of new certification schemes for PRM produced by innovative production processes - Number of BMTs accepted for registration and certification - Number of MS setting up a digital system - Number of FRM entries obtained through innovative production processes (FOREMATIS)
Contribute to sustainability, biodiversity and climate-related challenges	Ensure availability of PRM/FRM suitable (identity, quality and health) for future challenges	*Availability of PRM/FRM* *Rules on FRM contingency planning*
		- Number of new varieties per crop group accepted following the general rules on DUS and sustainability assessment (Common Catalogues) - Number of FRM entries containing information on suitability of FRM for climatic and ecological conditions (FOREMATIS) - Quantities of certified PRM/FRM (reporting by NCAs) - Number of MS requests to apply for derogations to address temporary difficulties in supply of seed (Commission) - Number of national contingency plans to address FRM supply difficulties (notification by NCAs at adoption) - Findings of EU audits (Commission)
	Ensure availability of PRM/FRM suitable to address future challenges	*Increased availability of PRM suitable for the needs of organic agriculture*
		- Number of accepted "organic varieties suitable for organic production" (Common Catalogues) - Quantities of certified PRM of "organic varieties suitable for organic production" marketed within the EU (NCAs)
	Support the conservation and sustainable use of plant and forest genetic resources	*Increased availability of PRM of conservation and locally adapted varieties* *Increased availability of FRM for purposes of conservation of forest genetic resources*

General objectives	Specific objectives	*Measures of success* and monitoring indicators
		- Number of conservation and new locally adapted varieties per crop group (Common Catalogues) - Quantities of PRM of conservation and new locally adapted varieties marketed (notifications by operators to NCAs and reporting by NCAs) - Number of notifications of heterogeneous material (notifications by operators to NCAs and reporting by NCAs) - Quantities of marketed PRM of heterogeneous material (notifications by operators to NCAs and reporting by NCAs) - Number of SCNs (notifications by operators to NCAs and reporting by NCAs) - Number of FRM notifications for the purposes of forest genetic resources' conservation (FOREMATIS)

Table 13. Measures of success and monitoring indicators

The legislation will be considered successful if there are sufficient quantities PRM and FRM available that are suitable to address future challenges and respond to the needs of the different types of PRM and FRM users. The design of indicators that are Specific, Measurable, Achievable, Realistic and anchored within a Time Frame (SMART) is not fully possible because the number and types of varieties available in the Common Catalogues is demand driven. Farmers will plant PRM of those varieties for which there is a demand. Moreover, there is no simple relationship between the number of varieties and the quantities of certified PRM. For example, a few wheat varieties could cover the demand for wheat if planted in a large agricultural area, while it would be required to plant 100 varieties of tomatoes to cover diverse consumer demands.

The PRM and FRM legislation regulates the access to the market and the revision addresses the identified bottlenecks. For example, current variety registration rules are too restrictive for organic and conservation varieties. Rules that are adjusted to the characteristics of such varieties will be introduced in order to enable their access to the market. Accordingly, success would mean that within 10 years more organic and conservation varieties are registered and their seed/PRM is made available in the market in sufficient quantities. It cannot be anticipated how many new varieties and which quantities of PRM/seed will be marketed, as this depends on the uptake of the new opportunities by the operators and the farmers presenting a sustained demand for such varieties.

Another example is that the current rules for examination of new varieties, PRM certification and OCs do not provide for the use of new methods (BMTs) that have the potential to increase the efficiency of these procedures. The revision will remove this obstacle. Success would mean that within 10 years BMTs are widely used and lead to a reduction of costs of examination of new varieties. The revision is expected to stimulate their development and use. Genetic markers are specific to each species and variety. It cannot be anticipated if suitable markers will be available for all.

The success of the legislation will therefore be measured through the number of varieties and basic material which are successfully registered in the Common Catalogues and the quantities of certified PRM and FRM produced thereof. The Common Catalogues (as of 2023 accessed through the new EU Plant Variety Portal) will be a key source for the indicators for monitoring progress as regards

the type of plant varieties (accepted under general rules on DUS and sustainability assessment or under rules for conservation/locally adapted varieties or organic varieties suitable for organic production). Other sources will be notifications and reports from MS as well as audits by the Commission.

Moreover, this approach has been chosen because it is difficult to assess the individual contributions of the PRM and FRM legislation to sustainable agri-food production and restoration of forest ecosystems, respectively. The impact of using improved varieties will be a combination of selecting the appropriate variety for the regional agro-ecological conditions and applying good agricultural practices. It will also depend on the weather conditions. Likewise, in the FRM sector the improvement is assessed through the indirect impact of using improved tree seeds on the per unit area productivity of regenerated forests. Improved tree seeds may better survive in a harsh climate or show better tolerance against damages through abiotic or biotic factors.

The number and quantities of PRM of conservation and locally adapted varieties, organic varieties suitable for organic production, heterogeneous material and FRM notifications for the purposes of forest genetic resources conservation will offer an indirect measure of contribution to increased genetic diversity.

The EU Plant Variety Portal will allow MS to fulfil their reporting obligations through online submission of the relevant data (in the long term, machine to machine). MS' reporting obligations under the OCR as well as EU audits will be important mechanisms to check the implementation of the new PRM/FRM legislation in MS. As regards the coherence with the PHL, the use of already existing IT applications for reporting RNQP non-compliances and the submission of PRM/FRM import documents (IMSOC) will lead to efficiency gains.

The Commission will review the indicators periodically. The implementation of the national contingency plans ensuring FRM supply will be regularly monitored and compared with the data obtained from the Forest Information System for Europe[182] as regards the forest areas lost because of extreme weather, forest fires and disasters.

The proposed reference period for the monitoring framework of the new PRM and FRM legislation is 10 years as it takes 10-12 years to develop a new plant variety. Based on the time needed to obtain meaningful data through annual monitoring, it is considered appropriate to supplement this monitoring with a formal evaluation of the initiative at the earliest 10 years after the planned legal proposal becomes applicable. It should be avoided that the evaluation takes place before the impact of the new requirements for variety acceptance, lighter system for registration of conservation varieties and new locally adapted varieties and the notification of heterogeneous material and basic material for the purposes of forest genetic resources conservation becomes visible. The same holds true for the other actions that need sufficient data and monitoring information on the implementation, application and enforcement of the expected legal provisions.

[182] Forest Information System for Europe https://forest.eea.europa.eu/

ANNEX 1: PROCEDURAL INFORMATION

1. LEAD DG, DECIDE PLANNING/CWP REFERENCES

The Directorate-General for Health and Food Safety (DG SANTE) is the lead DG on the initiative on Revision of the plant and forest reproductive material legislation. This initiative is in the European Commission's Work Programme for 2022, in Annex II: REFIT initiatives, under the heading "A European Green Deal". The initiative has received the validation in the Agenda Planning on 25 September 2020 (reference PLAN/2020/7576) and the Inception Impact Assessment was published on 15 June 2021.

2. ORGANISATION AND TIMING

An Inter-Service Steering Group (ISSG) was set up. The following Commission services were its members: SG (Secretariat-General), SJ (Legal Service), AGRI (Directorate-General for Agriculture and Rural Development), CLIMA (Directorate-General for Climate Action), ENV (Directorate-General for Environment), JRC (Joint Research Centre) and TRADE (Directorate-General for Trade). GROW (Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs) and RTD (Directorate-General for Research and Innovation) were also invited but did not join the ISSG. The ISSG met on the following dates:

Dates	Topics discussed
17 June 2021	• Consultation strategy • Terms of reference of the study supporting the impact assessment for the revision
6 October 2021	• State of play of the revision • Kick-off meeting with the contractor for the study supporting the impact assessment for the revision
19 May 2022	• State of play of the revision • Draft policy options • Outcome of consultations • Draft interim report of the study supporting the impact assessment for the revision
14 December 2022	• Final report of the study supporting the impact assessment for the revision • Draft Commission impact assessment report
12 January 2023	• Finalisation of the Commission impact assessment report
18 April 2023	• Presentation of revisions following the RSB opinion

	• Presentation of the legal proposals

Table 14. Meetings of the ISSG.

In addition to the above meetings, the members of the ISSG were regularly informed on the progress of the initiative and consulted in written on the questionnaire of the open public consultation and the draft final report of the study supporting the impact assessment for the revision. In addition, DG SANTE consulted the Community Plant Variety Office (CPVO) on aspects of this initiative relevant to CPVO's mandate.

3. CONSULTATION OF THE RSB

An upstream meeting with the Regulatory Scrutiny Board was held on 6 May 2022. A first version of this Impact Assessment Report was submitted to the RSB on 18 January 2023, the meeting took place on 15 February 2023 and the RSB written opinion was received on 17 February 2023. The Board concluded that the DG had to revise the report in accordance with the Board's findings before launching the interservice consultation.

RSB main findings	**Modification of the IA report**
The Board noted the additional information provided and commitments to make changes to the report. However, the report still contained significant shortcomings. The Board gave a positive opinion with reservations because it expected the DG to rectify the following aspects: (1) The report did not present a comprehensive analysis of costs and benefits. The analysis of impact on competitiveness of EU operators, including on SMEs, was not sufficiently developed. (2) The comparison of the options in terms efficiency was flawed.	The recommendations of the Board have been implemented. (1) A comprehensive analysis of costs and benefits has been added in Section 8 of Annex 4. Aspects related to SMEs and competitiveness have been further detailed across Section 6 of the IA report and they are also summarised in the new Sections 6.1.6 and 6.1.7. (2) The Section 7.2 on the comparison of the options in terms of efficiency has been revised.
RSB adjustment requests	**Modification of the IA report**
(1) The report should explain how the concerns raised by the European Parliament in rejecting the Commission's '2013 PRM proposal' have been addressed by this initiative. The description of the dynamic baseline should	(1) In Section 1 of the IA report Table 1 has been added, giving an overview of the concerns expressed by the European Parliament in 2014 and the measures addressing those concerns in this initiative.

be supplemented with quantitative assessment where feasible.	No additional information has been found to allow adding further quantitative elements in the description of the baseline. The relevance of moving from south to north of agronomic and forestry practices in order to compensate for climate change is described in Section 5.1 of the IA report.
(2) The intervention logic should be more clearly presented. The report should better link the specific objectives with the identified problems. The specific objectives should be expressed in more SMART terms.	(2) In Section 4.3 of the IA report the intervention logic has been added, linking the identified problems, the general objectives, specific objectives and the policy options. In Section 9 of the IA report, the measures of success and monitoring indicators have been revised and certain limitations in applying the SMART approach are explained.
(3) Based on a clearer intervention logic, the report should explain in more detail how the policy options were designed.	(3) The Section 5.2 of the IA report has been redrafted in order to explain in more details the design of the policy options. The previous Annex 6 has been integrated in Section 5.2 of the IA report, so that the main report presents in more details the content of each option. In Sections 5.1 and 5.2 the differences between the baseline and Option 1 are further clarified.
(4) The report should assess the impact on the EU operators, seed producers, foresters, and farmers, including on their international competitiveness. The report should elaborate on Member States' and other stakeholders' groups views on the impacts of the options under consideration.	(4) More details have been added on these aspects across Section 6. Aspects related to SMEs and competitiveness from across Section 6 are also collated in the new Sections 6.1.6 and 6.1.7. The different views on the impacts of the options under consideration are presented in the new Section 6.6.
(5) The report should present a clear and comprehensive overview of the costs and benefits of each of the three options. It should present the net benefit of each option, as well as the Benefit Cost Ratio.	(5) A comprehensive analysis of costs and benefits has been added in Section 8 of Annex 4. The major costs and benefits elements of each option are summarised in Section 6.5 of the IA report. The net benefit as well as the Benefit Cost Ratio of each option is presented in Section 7.2 of the IA report. Further details on underlying assumptions and uncertainties have been added in Annex 4.
(6) Throughout the report and in all comparison tables the scores of the baseline should be set at zero.	(6) The scores of the baseline have been set to zero throughout the report.
(7) The report should systematically refer to the	

views of different stakeholder categories, including diverging views, throughout the report.	(7) Further details on the views of different stakeholder categories have been added throughout the report. Sections 5.2.5 and 6.6 have been added, elaborating respectively on the views on policy options and on views on impacts of the options, including diverging views on these.

Table 15. Modifications of the IA report following the comments by the RSB.

4. EVIDENCE, SOURCES AND QUALITY

The current PRM and FRM legislation comprises 1 Directive on the Common Catalogue and 11 marketing Directives and covers diverse crop groups from annual crops in the case of agricultural species to perennial crops in the case of fruit trees. Each crop group has its specificities in relation to the two pillars variety registration (DUS examination) and PRM/FRM certification. The consultation activities have focussed on gathering quantitative and qualitative data in relation to those two pillars and on OCs. It must be highlighted that most of the available information concerns agricultural species as this is the most important market segment. A lot of effort was put in the collection of information on the activities of seed conservation networks, exchange in kind of seed between farmers and the reasons for the limited implementation of the Directives on conservation varieties and landraces. In general, it is to be noted that because of the diversity of crop groups and the multitude of technical aspects and some marginal activities, it was not feasible to assess each aspect of the envisaged amendment of the legislation in detail.

Evidence for this Impact Assessment has been collected by two external studies and a number of other sources.

A first study[183] aimed to update the state of play since the last evaluation of the PRM/FRM legislation in 2008[184] and the 2013 impact assessment[185], as well as to fill key knowledge gaps, in order to support the Commission to prepare the study on the Union's options to update the existing legislation on the production and marketing of PRM[186] following a request by the Council[187]. Evidence was collected by literature review, 40 interviews (with academics, civil society organisations, public authorities, industry representatives and farmers' organisations), a workshop with 6 FRM experts, and four targeted surveys. The targeted surveys were addressed to 1) NCAs (authorities from 25 MS responded), 2) amateur gardeners (with 6089 participants from 29 countries), 3) maintainers of registered varieties for the amateur market (81 participants) and 4) FRM stakeholders (80 participants, including both FRM users and NCAs). The limited publicly available information and the fact that it is rarely broken down per group of agricultural species (i.e. cereal seed, beet seed, etc.), the small sample size and self-selection bias (interviews and targeted

[183] ICF (2021).
[184] FCEC (2008).
[185] SWD (2013) 162 final.
[186] SWD (2021) 90 final.
[187] Council Decision (EU) 2019/1905 of 8 November 2019. OJ L 293, 14.11.2019, p. 105-106.

surveys) were identified by the contractor as limitations to the quality of the evidence collected by this study.

A second study[188] aimed to support the Commission in the preparation of this impact assessment. This study collected evidence by literature review, a targeted survey addressing NCAs, operators and other stakeholders in the PRM and FRM sectors (99 respondents in total), 43 interviews (30 on PRM and 13 on FRM), a focus group on the topic of marketing to amateur gardeners, a focus group on FRM topics, a case study on exchange in kind of seed (based on literature review and interviews) and an analysis of MS experiences on conservation varieties and varieties for amateurs of fruit plants and vine (based on a targeted survey to 17 NCAs). The low response rates to questions aiming to collect quantitative information to fill-in knowledge gaps as regards market size and costs for NCAs and operators were identified by the contractor as limitations to the quality of the evidence collected by this study.

Despite the aforementioned limitations, the data collected by these studies allows to make assumptions (e.g. range of minimum to maximum values) and even allows for higher certainty on certain aspects where the dataset is rather complete, as NCAs from most MS have responded to the relevant questions. DG SANTE has used this data for in-house calculations additional to those carried out by the external studies, as appropriate in combination with quantitative data extracted from the Common Catalogues[189] on the numbers of registered varieties, Eurostat[190] and the farm accountancy data network (FADN)[191] on the cost of PRM and its share of the total cost of inputs in agricultural production, and the portal of the European Seed Certification Agencies Association[192] on production of certified seed (see Annex 4 for details). These sources offer the best available data for the respective topics. DG SANTE also extracted evidence from published position papers of stakeholder organisations (either published online or submitted in the context of the consultations), online documents of NCAs, articles published in scientific journals and reports of EU co-financed research projects. In particular information from official sites and articles in scientific journals (having been subject to peer review) is considered to be evidence of higher quality. Remaining data gaps have been addressed by using assumptions and calculations done in older studies[193] but in such cases the uncertainty is higher. Finally, additional evidence on views and opinions of NCAs and stakeholders were collected by extensive consultation activities undertaken by DG SANTE in the form of online questionnaires and meetings with NCAs and stakeholders (see Annex 2 for details).

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[188] ICF (2023).
[189] https://food.ec.europa.eu/plants/plant-reproductive-material/plant-variety-catalogues-databases-information-systems_en.
[190] Economic accounts for agriculture: https://ec.europa.eu/eurostat/web/agriculture/data/database.
[191] https://agriculture.ec.europa.eu/data-and-analysis/farm-structures-and-economics/fadn_en.
[192] http://escaa.org/.
[193] FCEC (2008) and FCEC (2011).

ANNEX 2: STAKEHOLDER CONSULTATION (SYNOPSIS REPORT)

1. CONSULTATION STRATEGY

The objectives of the consultation activities were:

- to ensure that all relevant stakeholders are identified and given the opportunity to participate in the consultation;
- to provide the opportunity for stakeholders to inform the impact assessment, in particular, offering an opportunity for them to inform the development of policy options addressing the problems identified;
- to gather stakeholders' opinions on the potential policy options together with data and qualitative evidence concerning the relevant impacts of the policy options considered.

The consultation strategy combined different consultation methods in order to engage as much as possible all stakeholders identified:

- NCAs for variety registration, PRM certification (agriculture, horticulture, vine), FRM certification, plant and forest genetic resources
- The CPVO
- Plant breeding companies, seed and PRM multipliers and suppliers, seed and plant trading companies, nurseries, from the organic and non-organic sectors, both large and small operators, and their associations
- Professional farmers including organic farmers
- Amateur gardeners
- Foresters and forestry associations
- Scientific networks on plant and forest genetic resources
- Seed conservation networks.

1.1. Consultation activities undertaken by DG SANTE

DG SANTE consulted stakeholders by means of the publication of the inception impact assessment (IIA) for feedback, the open public consultation (OPC), targeted surveys, working groups with NCAs and stakeholders and bilateral meetings with stakeholder organisations.

The IIA was open for feedback between 15 June and 13 July 2021 on the 'Have your say' portal[194] and was addressed to any interested citizen or stakeholder. Feedback was provided in a free text format, while respondents also had the possibility to submit position papers. The feedback collected

[194] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13083-Plant-and-forest-reproductive-material-revised-rules-_en

was taken into account for adjusting the problem description and options, the design of further consultation activities, as well as for this impact assessment.

The OPC was carried out between 21 December 2021 and 27 March 2022 on the 'Have your say' portal[195] and was addressed to any interested citizen or stakeholder. It included two sets of closed multiple choice questions, one for PRM and one for FRM. Respondents could also provide additional information either by a short free text or by uploading a position paper. The feedback collected was taken into account for this impact assessment.

DG SANTE also organised two targeted online consultations on EUSurvey[196], one addressed to NCAs responsible for FRM, held from 5 April to 30 May 2022 and one addressed to SMEs, held from 2 May to 13 July 2022. The SME survey was anonymous. Furthermore, DG SANTE held meetings of working groups (online due to Covid-19 restrictions) with the NCAs and with stakeholders to discuss specific aspects of the revision. Summary reports of these meetings were published on the webpages of DG SANTE[197]. At the request of a number of stakeholders, DG SANTE held bilateral meetings with them and also attended relevant events of stakeholders. Finally, some stakeholders and NCAs submitted to DG SANTE opinions on specific matters outside the framework of the IIA and the OPC. All relevant information was taken into account for this impact assessment.

1.2. Consultation activities conducted in the framework of the study supporting the impact assessment

In the framework of the study a targeted survey, interviews and two focus groups were carried out. The targeted survey was held online between 9 March and 1 April 2022. It was open to NCAs, operators and other stakeholders in the PRM and FRM sectors, but those interested to participate had to pre-register. The interviews aimed to obtain more detailed and contextualised views. The first focus group addressed the topic of marketing to amateur gardeners and the second one the definitions of "forestry" and "non-forestry" purposes in relation to the scope of the FRM legislation and the potential measures to address temporary difficulties in supply of FRM.

2. STAKEHOLDER PARTICIPATION

The feedback to IIA received 66 responses from 16 countries (15 MS and a third country). Geographic distribution was uneven, as 47 responses came from 5 MS (5 to 15 responses by each of them) and 18 responses from 10 MS (1 to 4 responses per MS). As regards type of stakeholder, the submissions were from business associations (20), NGOs (13), companies/businesses (10), public authorities (5), EU citizens (4), academic/research institutions (3), trade unions (3) and other (8). The over-representation of one MS (15 respondents from Belgium) is explained by the fact that these respondents are EU-wide associations or NGOs based in Brussels. With the exception of

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[195] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13083-Revision-of-the-plant-and-forest-reproductive-material-legislation/public-consultation_en

[196] https://ec.europa.eu/eusurvey/home/welcome

[197] https://food.ec.europa.eu/plants/plant-reproductive-material/expert-groups-and-working-groups-legislation-plant-reproductive-material_en and https://food.ec.europa.eu/horizontal-topics/expert-groups/advisory-groups-action-platforms/advisory-group-fcaph/wg-2022_en

public authorities, the most relevant types of activities, plant breeders (conventional and organic), marketing of PRM, nurseries (FRM, ornamental), seed conservation networks and farmers, are represented in a balanced way.

The OPC received 2449 responses from 29 countries (24 MS and 5 third countries). Number of responses ranged from 1 to 1684 per MS when citizens are included and from 1 to 184 per MS when citizens are not included. There were no responses from Lithuania, Malta and Romania. All relevant types of activities as well as public authorities are represented in a balanced way. Furthermore, there were in total 15 responses from third countries. The majority of responses (78%, 1908 of 2449) were from EU Citizens. Of the 541 respondents who were not citizens, 37% (202 of 541) were from company/business organisations. By size, a majority of company/business organisations (59%, 120 of 202) were from 'Micro (1 to 9 employees)' enterprises. Over half of all public authority responses (54%, 29 of 54) were from national authorities. Amongst Public authorities, Germany had the highest number of responses (18 of 54), with responses from national, regional and local authorities. The first question of the OPC was targeted at the general public and was responded to by the whole sample. Subsequent questions were addressed to stakeholders with expert knowledge of the legislation and only 10% of citizen participants respond to these. In total, 488 participants responded only to expert questions on PRM, 61 only to expert questions on FRM, and 210 to expert questions on both PRM and FRM. Over three quarters (79%) of citizen respondents, and half (50%) of company/business organisation respondents were from Sweden. National press articles concerning the PRM legislation revision and public consultation may have stimulated the higher-than-average level of response from Sweden. However, these have not been identified as a campaign as there was a high level of variation in the replies to closed question responses. For Swedish citizens, only a small number of open question responses are identical (less than five in any one case) but they have a high tendency to focus on a few specific issues, in particular asking to facilitate the preservation of local and traditional varieties and not to impose any rules on the exchange of seed between hobby growers. In both categories "company/business organisations" and "public authorities" there were cases of submissions of identical additional documents, although less than 10 in each case. A campaign has been identified where 32 respondents, mostly citizens from Germany, submitted identical additional documents supporting that DUS criteria should not be a prerequisite for variety registration, calling for extended exemptions for conservation purposes and for the implementation of the farmers' rights defined in the International Treaty on Plant Genetic Resources for Food and Agriculture and the United Nations Declaration on the Rights of Peasants. As regards FRM 12 German stakeholders composed of regional authorities, citizens and a business association stated that; the legislation should not be substantially changed, an extension of the number of EU-regulated species is necessary, forestry and non-forestry purposes should be clearly defined, the origin of the FRM must be guaranteed in order for forests derived from that FRM to fulfil the various forest functions for the next decades and centuries, a stable and sustainable funding to minimise potential supply shortages should be prioritised through an EU regulation and that the financial impact on all forest stakeholders affected by the implementation of the legislation must be restricted to a minimum. There were 25 responses to the targeted survey addressed to NCAs responsible for FRM from 19 different MS. There were 251 responses to the targeted survey addressed to SMEs from 22 different MS (from 1 to 33 responses per MS).

The targeted survey conducted in the framework of the external study supporting the impact assessment received 99 responses from 27 countries (23 MS and 4 third countries). 8 respondents identified themselves as academic/research institute, 26 as business association, 21 as company/business, 4 as NGO, 31 as a public or NCA and 8 as "other". There were no responses

from Latvia, Lithuania, Malta and Romania. 74 respondents contributed only in relation to PRM, 18 only in relation to FRM and 7 in relation to both PRM and FRM aspects. Distribution as regards origin and type of activities is considered satisfactory.

3. RESULTS OF STAKEHOLDER CONSULTATION ACTIVITIES

As regards PRM, there is overall support for maintaining the **current regulatory system** and its two basic pillars of variety registration (based on DUS and where applicable VCU) and PRM certification. Some respondents called for maintaining the current "one-key one-door" approach (i.e. same DUS rules for the plant variety rights regime and the market access of varieties) while most NGOs called to maintain DUS only for plant variety rights, allowing the breeder to choose whether to use DUS or not for variety registration. Potato breeders in particular called for the abolishment of VCU for potato varieties and vegetable breeders called not to introduce VCU for vegetable varieties. The various actors involved in conservation activities, small-scale farmers interested in exchange in kind, the organic sector and most citizens, also called for **derogations from this basic system** in order to enable the availability of PRM belonging to varieties that cannot meet the DUS requirements and/or to heterogeneous material. The necessity of such derogations is agreed by all stakeholders for meeting objectives relevant to conservation and sustainable use of plant genetic resources, organic production and production in marginal areas. There is however important divergence of views in relation 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. In particular, 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. Main arguments against total exemption are the concerns about plant health i.e. spreading of diseases by PRM exempted from the legislation (opinion shared by conventional breeders, farmers other than small-scale ones and NCAs), the respect of plant variety rights and the avoidance of unequal competition (opinion mostly supported by conventional breeders), as well as the need to guarantee a minimum quality and traceability (opinion shared by farmers other than small-scale ones and most NCAs, also important for 50% of the citizens responded to the various consultations). As regards **marketing to amateur gardeners**, several stakeholders were of the view that it is not possible to separate marketing to professional users from marketing to amateur gardeners. Many operators market PRM to both professional users and amateur gardeners whereas others market exclusively to amateur gardeners. As regards **organic varieties**, organic breeders stressed the need for variety examination (DUS and VCU where applicable) adjusted to the needs and the principles of organic production. In contrast, conventional breeders questioned the need for such derogations for organic varieties, as currently in their view DUS varieties multiplied under organic conditions cover most of the needs of the organic sector with very good results.

In relation to **sustainability**, there is overall recognition of the importance of PRM as the starting point of agri-food production for achieving the relevant objectives. Conventional breeders and most NCAs supported that the current VCU requirements for agricultural plant species already contribute to these objectives, as they allow for the acceptance of varieties with characteristics that contribute to a more sustainable production as disease resistance, nutrient efficiency, drought tolerance and increased yield. Introduction of requirements of examination of new varieties of fruit plants and vegetables for such characteristics was supported, though not in the form of the current VCU for agricultural plant species, as the uses especially for vegetables are very diverse. The need for

flexibility to address the different conditions across Europe was stressed by almost all respondents. Actors involved in conservation activities and organic production stressed that the contribution to sustainability of material not meeting the DUS requirements is equally important, especially for production under low-input and organic conditions and in relation to short supply chains (locally adapted varieties for local markets). Some of these actors also put in question the usefulness of examination of varieties for specific characteristics, arguing that one should rather look into the sustainability of agricultural production practices.

In relation to links to **plant health requirements**, the need to remove duplications on RNQPs between PHL and PRM was recognised by most NCAs and operators. For the purposes of conservation and sustainable use of genetic resources some stakeholders called for exempting operators and PRM from all plant health requirements. On the contrary, the majority of NCAs and other operators explicitly opposed to exemptions from plant health requirements, even if exemptions would be granted from the PRM rules for variety registration and PRM certification.

As regards **OCs**, most operators agreed that a harmonisation of requirements is desirable, noting that this however should not lead to increased administrative burdens for them. Views were also split as regards the inclusion of the PRM and FRM legislation in the scope of the OCR, due to concerns for potential increase in administrative burdens. In particular for PRM, almost all NCAs and operators were against including the certification system as such under the OCR. The majority saw benefits as regards more efficient marketing and import controls. As regards FRM, most respondents opposed to the inclusion of the FRM legislation into the scope of the OCR because of the specificity of OCs in this sector and called for OCs to remain under the control of the respective forest competent authority. Most stakeholders of all categories called for maintaining some flexibility in the organisation of OCs and keeping the costs as low as possible.

In relation to the use of **BMTs** and **digital solutions,** most PRM and FRM stakeholders agreed that these could bring benefits and called for the legal framework to allow the latest technologies to be applied, in line also with developments of international standards. There is overall agreement that the phenotype-based system of registration of varieties should be maintained. Some stakeholders even called to limit BMTs use only when these are linked to phenotypic expression. Almost all however could agree to introduce the options for use of BMTs and digital solutions, without making these an obligation.

There is overall support for extending PRM certification activities under **official supervision**. Above 50% of FRM stakeholders were favourable of allowing certain certification tasks to be conducted under official supervision except for the issuing of the master certificate. Some PRM and FRM stakeholders declared that SMEs might not have sufficient human and financial resources for carrying out certification under official supervision. They stressed that it should always be possible for the operators to opt for certification by the NCAs. However, views on whether VCU should become possible under official examination were split, as fears were expressed by different stakeholders that the reliability of results would be undermined and/or that it could be difficult to have comparable results. The majority of forest NCAs and regional authorities opposed to the assessment for the approval of basic material intended to produce FRM of the source-identified and tested categories by operators under the official supervision of the NCAs.

All respondents that provided comments in relation to **ornamental propagating material** emphasised that there is no need to change the current simple rules. There should not be any DUS tests for variety registration of ornamental crops as such tests would seriously increase costs and

decrease the number of varieties on the market without having any benefits. In their opinion, the market regulates itself with a private registration system for determining the identity of varieties.

As regards **FRM**, there is overall support for keeping the FRM legislation separated from the legislation on other PRM. All respondents called for keeping the existing pillars of registration of basic material and FRM certification. The majority of respondents highlighted the necessity to retain flexibility allowing MS to decide which FRM is adapted to the local and regional climatic and ecological conditions. Respondents expressed mixed views on the extension of the scope of the FRM legislation to the production and marketing of FRM for certain non-forestry purposes.

4. CONCLUSIONS

The different consultation activities complemented each other to achieve a balanced evidence base covering different stakeholder categories. From all the stakeholder consultation activities organised, it emerges that option 2 would best address the concerns of all actors.

ANNEX 3: WHO IS AFFECTED AND HOW?

1. PRACTICAL IMPLICATIONS OF THE INITIATIVE

This proposal will have practical implications for all those in the private, public and non-governmental sectors who are active in the marketing of PRM and FRM. This includes operators (breeders of new varieties, seed multipliers, companies marketing PRM and FRM, organisations engaged in conservation and sustainable use of plant and forest genetic resources), NCAs responsible for the acceptance of new varieties and the certification of PRM and FRM and the relevant OCs.

1.1. Operators

Breeders and/or applicants for the registration of new varieties of the regulated species will have to meet more elaborated criteria as regards the contribution of these varieties to a more sustainable agri-food production. This may result in increased breeding costs and lower numbers of new varieties being authorised for marketing, at least in the first years after entry into force of the new requirements until breeding programmes can be adjusted to the new requirements.

Producers of FRM will have to assess FRM for characteristics contributing to sustainable production and make available to buyers/users of FRM information on the suitability of FRM for climatic and ecological conditions. Producers of FRM for specific non-forestry purposes will have to meet the requirements of the FRM legislation (approval of basic material, rules on provenance, certification of FRM).

All other measures do not result into new obligations for operators but provide them with new options (additional certification tasks possible under official supervision, VSCU examination under official supervision, digitalisation of documents, use of BMTs, use of innovative production methods). In order to make use of some of these new options, operators may have to reallocate their resources and/or carry out some investment. The extent of such investments will largely depend on the current situation, e.g. using the option for additional certification tasks will be much easier and will probably require no significant investments for operators already carrying out certification tasks under official supervision. Other measures will provide lighter conditions for accessing the market (organic varieties suitable for organic production, conservation and locally adapted varieties, heterogeneous material), without resulting into new obligations.

1.2. National competent authorities

Extension of the certification tasks that may be carried out under official supervision is expected to require that NCAs will have to reallocate staff from official certification activities to training and supervision activities. The impact of this will depend on the demand by operators to carry out additional tasks under official supervision.

Extension of the current VCU requirements for agricultural plant species and vine to better address sustainability and introduction of sustainability requirements for all other crop groups (vegetables

and fruit plants) in the procedure of acceptance of new varieties will require that NCAs increase their capacity in terms of staff and testing stations. This impact will be mitigated by a transition period before these requirements enter into force, permitting these examinations to take place under official supervision at the premises of the operators and allowing the cooperation between the MS.

Harmonisation of OCs on production, marketing and imports of PRM/FRM and subjecting them to the OCR, as well as moving the lists of RNQPs and specific measures to the PHL with PRM/FRM legislation referring to them instead of duplicating them, will also require NCAs to reallocate some of their resources (depending on current allocation between PHL and PRM/FRM certification) or increase their resources in case they don't already meet the minimum rates of OCs to be introduced. OCs subject to OCR will also mean that NCAs will have to include OCs on PRM and FRM in the multi-annual national control plan and to publish an annual report on the number of OCs carried out and the outcome of those controls, but several NCAs already follow these practices despite not being an obligation currently.

Adapted DUS and VCU requirements for the examination of organic varieties suitable for organic production will require that NCAs allocate staff and testing stations to test these.

Lighter rules for seed conservation networks, marketing to amateur gardeners and exchange in kind of seed, simplification of current rules for conservation varieties and extension of those rules to cover new locally adapted varieties and broadened scope for heterogeneous material beyond organic production on the one hand will require dedicated staff for their implementation. On the other hand, removal of some of the current requirements (variety registration and PRM certification) will mitigate this impact.

Extension of the scope of FRM legislation to include the production of FRM for specific non-forestry purposes, extension of sustainability requirements to cover lower FRM categories, and introduction of a requirement for contingency planning to ensure availability of FRM may also require an increase in the resources of the NCAs.

1.3. Users of PRM and FRM

There are no new obligations for the users of PRM and FRM resulting from this initiative as the scope of the legislation does not cover the use and the users of PRM and FRM. However, the increased sustainability assessment may lead to a marginal increase of price of inputs (seed and other PRM) for farmers, but the initiative is expected to lead to increased availability of PRM and FRM for all types of users, and to PRM and FRM being more suitable for meeting future challenges. Consequently, users of PRM and FRM will benefit from a higher stability of their income under adverse conditions.

2. SUMMARY OF COSTS AND BENEFITS

The estimates of costs and benefits refer to the preferred option in relation to the baseline. The main recipient of the benefit is indicated in the comments' column.

I. Overview of Benefits (total for all provisions) – Preferred Option		
Description	***Amount***	***Comments***
Direct and indirect benefits		
All certification tasks are permitted under official supervision except the issuing of the official label.	• EUR 1.7 million per year in reduced certification costs[198] (direct benefit) • Efficiency gains and flexibility, not monetised (indirect benefits)	• Operators
Strengthened sustainability requirements	• Avoided loss in crop output ranging from EUR 621 to 2 486 million annually (indirect benefit) • Reduced losses in forestry (indirect benefit, not monetised)	• Farmers • Foresters
Harmonisation of official controls subject to OCR	• Efficiency gains (direct benefit, not monetised)	• NCAs
Decisions for addition of new species in (or removal of species from) the scope of the PRM legislation and on the equivalence to EU rules for third countries will be taken by means of tertiary legislation.	• Shorter time to reach such decisions but the benefits are rather limited as only a small number of decisions every year (0-4) are concerned. Not monetised.	• Commission • NCAs • Operators
Lighter rules for seed conservation networks, marketing to amateur gardeners and exchange in kind of seed, simplification of current rules for conservation varieties and extension of those rules to cover new locally adapted varieties and broadened scope for heterogeneous material.	• Operators would benefit from lighter procedures for access to market. Number of operators and quantities of PRM concerned are unknown. Though number of operators could be in the range of several thousands, the quantities of PRM concerned are considered to be limited. New market opportunities could have a value of up to EUR 266 million annually.	• Operators: Several hundred varieties or heterogeneous material to be brought in the market over the next ten years.
The possibility to deviate from certain DUS requirements as regards uniformity will be provided for the DUS examination of organic varieties suitable for organic production.	The breeding period of varieties compliant with reduced uniformity requirements can be in average 2 years shorter than for varieties fully meeting those requirements. Operators making use of this possibility will therefore access the market faster, with reduced breeding costs and with varieties that up to now were restricted from the market since it was not possible to register varieties not meeting the DUS requirements. A few dozen operators across EU are likely to use this option. The number of varieties registered under these rules could be in average 100 annually. Assuming EUR 50 000 savings in breeding costs per variety, concerned operators may see savings of EUR 5 000 000/year.	• Operators
Administrative cost savings related to the 'one in, one out' approach		

[198] The certification costs are considered as *testing costs* and not as *administrative costs*.

The transfer/notification of new varieties from national to Common Catalogues will be managed by the MS without the need for a Commission Decision.	The period between acceptance in a national catalogue and access to the common market will be shortened by 1 to 4 months for about 4 000 new varieties every year. Not monetised.	• Commission: need for adoption of 24 Decisions every year and publication of the Common Catalogues in the Official Journal is removed • Operators: avoidance of unnecessary waiting time
Allow MS to decide themselves on permitting temporarily the marketing of seed that does not satisfy the requirements in respect of minimum germination, if germination is not lower than 15 % than the required germination rate.	In average 30 notifications annually (for a total of 50 000 tonnes of seed, or about 0.01% of the quantities of seed certified annually) become redundant. Not monetised.	• Commission and NCAs: avoiding the handling of on average 30 notifications per year and adoption of corresponding Commission Decisions. • Operators: Reduced waiting time by at least 15 days for each notification avoided.
All professional operators to be registered in a single register under the PHL.	Over 20 000 duplicate registrations will be avoided and over EUR 800 000 annual savings in registration costs for operators supplying PRM of fruit plants. Over 4 000 duplicate registrations will be avoided and there will be over EUR 237 000 annual savings in registration costs for operators supplying FRM	• Operators

II. Overview of costs – Preferred option							
		Citizens/Consumers		**Businesses**		**Administrations**	
		One-off	**Recurrent**	**One-off**	**Recurrent**	**One-off**	**Recurrent**
Strengthened sustainability requirements	Direct adjustment costs	N/A	N/A				
	Direct administrative costs	N/A	N/A				
	Direct regulatory fees and charges	N/A	N/A		Increased registration costs: EUR 6.4 million annually (PRM)		
	Direct enforcement costs	N/A	N/A				EUR 43 to 98 million annually
	Indirect costs	N/A	EUR 400 million annually in increased PRM costs for farmers, corresponding to 3% increase in cost of PRM or 0.15% increase in cost of global inputs		Up to 200 varieties less (or 5% less) registered every year (PRM)		
Harmonisation of OCs subject to OCR	Direct adjustment costs	N/A	N/A			Reallocation of resources, depending on current organisation Globally neutral impact.	

	Direct administrative costs	N/A	N/A		Modified rate of OCs (increase or decrease) depending on current situation per MS. Globally neutral impact.		• Multi-annual national control plan • Annual report on OCs
	Direct regulatory fees and charges	N/A	N/A				
	Direct enforcement costs	N/A	N/A				Depending on current implementation (not quantifiable). Globally neutral impact.
	Indirect costs	N/A	N/A				
Costs related to the 'one in, one out' approach							
Total	Direct adjustment costs	N/A	N/A	N/A	N/A		
	Indirect adjustment costs	N/A	N/A	N/A	N/A		
	Administrative costs (for offsetting)	N/A	N/A	N/A	N/A		

RELEVANT SUSTAINABLE DEVELOPMENT GOALS

III. Overview of relevant Sustainable Development Goals – Preferred Option(s)		
Relevant SDG	**Expected progress towards the Goal**	**Comments**
SDG 2 – End hunger, achieve food security and improved nutrition and promote sustainable agriculture SDG 12 – Ensure sustainable consumption and production patterns SDG 13 – Take urgent action to combat climate change and its impacts SDG 15 – Protect, restore and promote sustainable use of terrestrial ecosystems, sustainably manage forests, combat desertification, and halt and reverse land degradation and halt biodiversity loss	The simplification of the legal framework and its adjustment to recent scientific and technical developments will increase the efficiency of the system and support the competitiveness of the EU PRM sector. In turn, this will contribute in securing the availability and affordability of PRM in the EU. As PRM is the starting point and critical input for the agri-food production, this is also a direct contribution towards achievement of food security (SDG 2). The assessment of new varieties for sustainability characteristics will steer breeding efforts towards improved varieties with higher and more stable yields (SDG 2), improved water and nutrients efficiency and increased resistance to plant pests, contributing to reduced reliance of agri-food production on inputs like water, fertilisers and plant protection products (SDG 12), better performing under the climate change conditions, contributing to a strengthened resilience and adaptive capacity of agri-food production to climate-related hazards and natural disasters (SDG 13). Measures for facilitating the registration of organic varieties suitable for organic production will contribute to the further expansion of organic farming, which produces high quality food with low environmental impact (SDGs 2 and 12). Measures for facilitating the availability of conservation varieties and other locally adapted varieties, exchange in kind of seed and the use of heterogeneous material will contribute to the sustainability of agricultural production in marginal areas (SDGs 2 and 12). Furthermore, these measures will contribute to increased genetic diversity of cultivated plants (SDG 15), which again is a contribution to SDG 2, as the breeding of improved varieties relies on this genetic diversity. Measures for assessing FRM for characteristics contributing to sustainable production (resistance to pests, suitability for climatic conditions), making available information to users/buyers of FRM on the suitability of FRM for climatic and ecological conditions, contingency planning ensuring the availability of FRM will enable the availability and use of the most appropriate FRM for each location, therefore contributing to a more sustainable forest management and afforestation (SDGs 12, 13 and 15). Facilitation of the registration of basic material for the purposes of conservation of forest genetic resources will also contribute to the achievement of SDG 15.	

ANNEX 4: ANALYTICAL METHODS / CALCULATIONS

1. GLOBAL VALUE OF PRM/FRM AND COST OF PRM AS A SHARE OF TOTAL INPUT COSTS OF AGRICULTURAL PRODUCTION

According to information retrieved from Eurostat economic accounts for agriculture[199], **the total value in EU27 of seeds and planting stock used in agriculture as input in the production[200] in 2021 was 13.3 billion EUR.** This value covers the total consumption of bought-in domestic and imported seeds and planting stock for current production and maintaining stocks in vineyards, orchards, and Christmas tree plantations. It includes in particular direct purchases of seeds and planting stock from other farmers. However, it does not include seed produced and consumed within the same unit[201]. It also does not include seeds and planting stock sold to amateur gardeners. It includes PRM of species not subject to the PRM legislation and therefore provides the upper limit of the value of PRM covered by the PRM legislation. The overestimate is not considered excessive, as the PRM legislation covers the economically most important species.

The amount of EUR 13.3 billion represents in comparison to 2010 an increase of 24.77% (values at constant prices, 2010 = 100) and an increase of 27.84% in current values. The evolution in current prices is comparable to that of the total value of all inputs (total intermediate consumption) and to that of plant protection products. The cost of seeds and planting stocks as a percentage of the total intermediate consumption has remained stable at around 5.2% but this is only an indicative average, as seeds and planting stock are input mainly for crop production, while the total intermediate consumption includes all input for all sectors including the livestock sector.

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[199] https://ec.europa.eu/eurostat/web/agriculture/data/database

[200] See point 2.089 of Annex I of Regulation (EC) No 138/2004 on the economic accounts for agriculture in the Community.

[201] See point 2.097 of Annex I of Regulation (EC) No 138/2004 on the economic accounts for agriculture in the Community.

Constant prices (2010 = 100) in million EUR				
Year	**Total intermediate consumption**	**Seeds and planting stock**	**Fertilisers and improvers**	**Plant protection products**
2005	200.843,86	9.267,60	16.372,26	9.132,67
2006	200.340,25	9.537,09	16.004,65	8.939,98
2007	202.561,99	9.622,62	16.199,51	9.087,47
2008	202.725,39	9.973,34	14.484,88	9.790,25
2009	201.365,51	9.609,87	12.991,40	9.518,42
2010	**201.771,43**	**10.439,09**	**13.751,84**	**9.200,33**
2011	205.928,91	10.463,09	14.122,28	9.465,13
2012	202.797,05	10.071,73	13.905,10	9.664,09
2013	205.244,50	10.187,92	14.777,15	10.123,11
2014	208.589,48	10.491,53	15.177,37	10.531,11
2015	209.352,92	10.724,34	15.077,51	10.593,68
2016	210.845,06	10.872,46	15.289,65	10.682,33
2017	212.882,43	11.105,58	15.310,92	10.611,95
2018	215.706,45	11.342,27	15.535,67	10.584,32
2019	215.873,54	11.465,32	15.333,82	10.593,60
2020	218.111,87	11.442,48	15.405,23	10.538,50
2021	220.084,44	11.563,71	15.340,85	10.980,05
Evolution between 2010-2021 (constant prices, 2010 = 100)	**9.08%**	**24.77%**	**-6.29%**	**19.34%**
Current prices in million EUR				
Year	**Total intermediate consumption**	**Seeds and planting stocks**	**Fertilisers and improvers**	**Plant protection products**
2010	201.771,43	10.439,09	13.751,84	9.200,33
	Share of total intermediate consumption	5.17%	6.82%	4.56%
2021	260.167,89	13.345,85	19.599,82	11.828,69
	Share of total intermediate consumption	5.12%	7.53%	4.54%
Evolution between 2010-2021 (current prices)	**28.94%**	**27.84%**	**42.52%**	**28.56%**

Table 16. Value of PRM as input to agricultural production and its evolution (calculations based on data retrieved from Eurostat).

Data retrieved from the farm accountancy data network (FADN)[202] was used to estimate[203] the cost of seeds and plants (PRM) as a share of total intermediate consumption (total input costs) for the eight different types of farming defined in FADN. This is compared to the share of fertilisers and plant protection products. These estimates are considered indicative as they express only the FADN surveyed farm populations[204]. Furthermore, the FADN data structure does not allow calculating by extrapolation total values[205]. Nevertheless, the FADN data indicates that the cost of seeds and plants as share of the total intermediate consumption is more important in horticulture (largely corresponding to the vegetable species) and double than the share for field crops (largely corresponding to the agricultural plant species).

Cost of main input categories as share of the total intermediate consumption for the different types of farming Average for the period 2018-2020 for EU27			
Type of farming	**Seeds and plants**	**Fertilisers**	**Plant protection products**
Field crops	13.61%	16.37%	12.04%
Horticulture	26.97%	6.36%	5.15%
Wine	1.52%	6.53%	11.49%
Other permanent crops	2.39%	16.15%	14.19%
Milk	2.65%	4.40%	1.45%
Other grazing livestock	2.40%	4.37%	7.04%
Granivores	1.24%	1.37%	1.22%
Mixed farms	4.53%	6.36%	4.08%
Global average	**6.73%**	**9.83%**	**7.75%**

Table 17. Cost of main input categories as share of the total intermediate consumption for the different types of farming (average for the period 2018-2020 for EU27), calculations based on data retrieved from FADN.

The global average share of seeds and plants to the total intermediate consumption derived from the two datasets is comparable, therefore it is assumed that the share of "seeds and planting stocks" to "total intermediate consumption" according to Eurostat data can be used for further calculations.

No similar data are available in relation to FRM in Eurostat and FADN.

2. NUMBER OF NEW VARIETIES

The Common Catalogues were used to calculate the average number of new varieties registered annually over the period 2012-2021. It is assumed that due to the envisaged measures for increased sustainability requirements in the examination of candidate varieties, it will become more difficult to register new varieties. A number of varieties that would have been registered under the baseline will be either withdrawn by the applicants or rejected. This impact is expected to be lowest for agricultural plant species, where the VCU is already in place. For the other crop groups, the impact

[202] http://agridata.ec.europa.eu/extensions/FADNPublicDatabase/FADNPublicDatabase.htmlhttps://agridata.ec.europa.eu/extensions/FADNPublicDatabase/FADNPublicDatabase.html

[203] DG SANTE in-house calculations.

[204] The FADN survey does not cover all the agricultural holdings in the Union, but only those which are of a size allowing them to rank as commercial holdings. The FADN weighting system has been optimised with a view to providing good averages for groups rather than good total values for groups. Taken from the document "FADN definitions of variables in FADN standard rules".

[205] The FADN used a weighting system optimised for providing good averages for groups rather than good total values for groups. Taken from the document "FADN definitions of variables in FADN standard rules".

of sustainability assessment would be lowest in option 1 (reliance on information that applicants voluntarily submit along with the application for registration of a new variety). For all crop groups, the impact would be highest in option 3 as highly harmonised rules would be most difficult to comply with.

Average number of new plant varieties per year	Baseline[1]	Option 1 Additional withdrawal and/or rejection rate 3%	Option 2 Additional withdrawal and/or rejection rate 5%	Option 3 Additional withdrawal and/or rejection rate 10%
Agricultural plant species	2 564	2 487	2 435	2 308
Vegetable species	1 384	1 342	1 315	1 246
Vine	41	40	39	37
Fruit plants	39	38	37	35

Table 18. Average number of new plant varieties per year.

3. PRM CERTIFICATION AREAS / CERTIFIED QUANTITIES AND CERTIFICATION UNDER OFFICIAL SUPERVISION

ESCAA category	Certified seed quantities (in tons) in 2020 (EU27)
Cereals	3 988 386.90
Potatoes	2 443 652.30
Maize and sorghum	572 810.70
Forage and turfgrass	397 890.91
Oil crops	198 757.00
Pulses	191 373.30
Beets and chicory	179 725.80
Fibre crops	17 239.20
Vegetables	8 594.96
TOTAL	**7 998 431.07**

Table 19. Certified seed quantities per ESCAA crop categories (in tons) in 2020 (EU27) (calculated on basis of data retrieved from escaa.org).

CERTIFIED SEED QUANTITIES in EU in 2020 (tonnes)		
Common name	**Latin name**	**Total**
Seed potatoes	*Solanum tuberosum* L.	2.443.652,30
Wheat	*Triticum aestivum* L.	2.095.709,00
Barley	*Hordeum vulgare* L.	1.029.853,70
Maize (except popcorn and sweet corn)	*Zea mays* L.	568.833,20
Forage and turfgrass	Various species	397.890,91
Durum wheat	*Triticum durum* desf.	297.390,40
Triticale (hybrid of wheat and rye)	*Triticosecale* wittm.	251.942,20
Oat	*Avena sativa* L.	175.221,10
Rye	*Secale cereale* L.	151.386,40
Sugar beet	*Beta vulgaris* L.	99.347,20
Soja bean	*Glycine max* (L.)	92.943,20

Rice	*Oryza sativa* L.	60.607,80
Sunflower	*Helianthus annuus* L.	50.743,30
Spelt wheat	*Triticum spelta* L.	25.690,20
Flax for fibres	*Linum usitatissimum* L.	15.054,90
Bristle oat	*Avena strigosa* L. Schreb.	13.794,00
Cotton	*Gossypium* spp.	8.280,40
Flax for oil	*Linum usitatissimum* L.	6.086,50
Sorghum	*Sorghum bicolor* (L.) Moench subsp. bicolor	2.572,60
Hemp	*Cannabis sativa* L.	2.184,30
Fodder beet	*Beta vulgaris* L.	1.150,40
Sudan grass	*Sorghum x drummondii*	317,50
Groundnut (peanut)	*Arachis hypogaea* L.	226,40
Poppy	*Papaver somniferum* L.	211,70
Safflower	*Carthamus tinctorius* L.	159,20
Canary grass	*Phalaris canariensis* L.	113,30
Caraway	*Carum carvil* L.	50,40

Table 20. Certified seed quantities per species (in tons) in 2020 (EU27) (calculated on basis of data retrieved from escaa.org).

EU area for seed production (1000 ha, excluding vegetables)				
Member State	**2018**	**2019**	**2020**	**2021**
France	355	357	363	372
Italy	201	191	199	205
Germany	177	195	198	195
Spain	187	185	179	183
Poland	146	147	166	173
Denmark	152	162	163	164
Romania	140	138	161	139
Hungary	113	114	118	118
Czech Republic	100	102	103	111
Sweden	63	60	65	67
Rest of the MS (incl. UK for 2018 and 2019)	339	361	367	368
EU total	**1973**	**2012**	**2082**	**2095**
Top 10 MS share	82.82%	82.06%	82.37%	82.43%

Table 21. EU area for seed production per MS (1000 ha, excluding vegetables) (calculated on basis of data retrieved from escaa.org).

Area for seed production by species (1000 ha)									
Species	**2018**	**% of total area**	**2019**	**% of total area**	**2020**	**% of total area**	**2021**	**% of total area**	**Average 2018-2021**
Soft wheat	457	23%	470	23%	468	22%	440	21%	459
Forage and turf	485	25%	482	24%	508	24%	546	26%	505
Barley	248	13%	259	13%	263	13%	250	12%	255
Durum wheat	109	6%	96	5%	90	4%	101	5%	99

Corn	140	7%	152	8%	174	8%	190	9%	164
Potatoes	102	5%	106	5%	109	5%	109	5%	107
Sunflower, soja and rapeseed	113	6%	112	6%	108	5%	106	5%	110

Table 22. Species with highest areas for seed production in EU 2018-2021 (calculated on basis of data retrieved from escaa.org).

The possibility will be introduced to carry out under official supervision for the certification activities for which it is currently not possible:

Certification activity	**Agricultural plant species (except from seed potatoes)**	**Vegetable species**	**Seed potatoes**
Field inspections for bred seed of generations prior to basic seed (pre-basic seed)	Possibility to carry out under official supervision will be introduced	Possibility to carry out under official supervision will be introduced	Possibility to carry out under official supervision will be introduced
Field inspections for basic seed	Possibility to carry out under official supervision will be introduced	Possibility to carry out under official supervision will be introduced	Possibility to carry out under official supervision will be introduced
Field inspections for certified seed	Currently possible under official supervision	Currently possible under official supervision	Possibility to carry out under official supervision will be introduced
Seed sampling	Currently possible under official supervision	Currently possible under official supervision	Possibility to carry out under official supervision will be introduced
Seed testing	Currently possible under official supervision	Currently possible under official supervision	Possibility to carry out under official supervision will be introduced

Table 23. Scope of the measure of extension of certification activities permitted under official supervision.

The generations of pre-basic and basic seed constitute up to 2% of the quantities of certified seed and the areas of production[206].

In EU every year about 2 million hectares[207] are used in average for the production of certified seed, of which 1.9 million hectares for agricultural plant species other than seed potatoes and 0.1 million hectares are for seed potatoes. The areas used for the production of certified vegetable seed are in comparison insignificant (about 2 500 hectares).

Furthermore, in EU every year about 8 million tons of seed in average are certified, of which 5.54 million tons of agricultural plant species other than seed potatoes, 2.44 million tons of seed potatoes and 0.01 million tons of vegetable seed.

The measures therefore concern:

[206] Own estimation in absence of more accurate data, based on an average multiplication rate of 100 between subsequent generations.
[207] Average for the years 2018-2021, source: escaa.org.

- For agricultural plant species (except from seed potatoes) the certification of up to 2% * 1.9 = 0.04 million hectares and of 2% * 5.54 = 0.11 million tons of pre-basic and basic seed annually.
- For seed potatoes, the certification of up to 0.1 million hectares and 2.44 million tons of seed potatoes.
- Small areas and quantities as regards vegetable seed.

Potential annual savings for operators by extension of certification activities possible under official supervision		
a)	Area becoming eligible for certification under official supervision (ha)	140 000
b)	Average annual cost for official certification (EUR/ha)	10
c)	Total annual cost for official certification (EUR) (a*b)	1 400 000
d)	Potential annual savings for operators by switching to certification under official supervision (EUR) (c*12%)	180 000
e)	Seed quantities becoming eligible for certification under official supervision (tons)	2 550 000
f)	Average annual cost for under official supervision (EUR/ton)	5
g)	Total annual cost for official certification (EUR) (e*f)	12 750 000
h)	Potential annual savings for operators by switching to certification under official supervision (EUR) (g*12%)	1 530 000
Total potential annual savings for operators by switching to certification under official supervision (EUR) (d+h)		**1 710 000**

Table 24. Calculation of the potential annual savings for operators by extension of certification activities possible under official supervision.

Extending the possibilities for operators to carry out certification activities under official supervision is not expected to have significant impacts on enforcement costs for NCAs. On the basis of experience gained by a temporary experiment[208], it is expected that if there is high demand by operators, NCAs rather risk a reduction of the competence and the jobs for their official inspectors[209]. NCAs will also need to reallocate resources from carrying out official inspections to training, licensing and supervising the operators' inspectors. Overall, the impact on NCAs will largely depend on the demand by the operators but it is considered to be neutral and/or insignificant, as already certification under official supervision is possible for the certified categories (except seed potatoes) that are assumed to constitute 98% of areas and of quantities.

The demand by operators is expected to depend largely on the quantities to be certified, with lower willingness to invest in own inspectors when quantities are lower. The size of the company (small, medium or big) does not seem to affect the ability to use the option for official supervision. Operators opting for official supervision are likely to bear one-off (upfront) costs for setting up laboratories and recurrent costs for hiring and training staff in order to use this option, however the responses to the related survey did not provide data allowing to calculate the scale of such costs. However, survey results[210] indicate that around 50% of operators (valid also for SMEs) already use the existing options for official supervision and would make use of certification conducted by operators under official supervision for all steps of the seed certification process if this was made available. Survey data also indicate that obtaining a certification under official supervision is estimated to be around 12% less costly to operators than certification performed by MS

[208] Temporary experiment on field inspection under official supervision for pre-basic and basic seed 2012-2019 - final report, available at https://food.ec.europa.eu/system/files/2022-04/prm_temp-exp_field-inspec_en.pdf
[209] The impact assessment of 2013 (SWD(2013) 162 final) estimated that up to 700 public sector jobs might be lost if all fields and seed lots of pre-basic and basic seed were inspected by operators under official supervision. Part of this staff would be recruited in the private sector.
[210] ICF (2023) and SME targeted survey.

authorities[211]. If all operators opt to carry out certification activities under official supervision under the new possibilities introduced, the potential annual cost saving for operators would be around EUR 1.7 million (Table 24). These savings are rather insignificant, but survey responses indicate that operators appreciate the efficiency gains and flexibility resulting from carrying out certification under official supervision, expecting that in the long term there will be more significant savings. These impacts are most relevant for agricultural plant species, as 95% of the seed of vegetable species is not certified but marketed as standard seed. There are no data available to allow an estimation of cost and benefits from introducing the option to carry out certification under official supervision of PRM for fruit plants and of FRM.

4. VARIETY REGISTRATION COSTS

The costs for operators for variety registration currently consist of administrative costs (submission of an application), the cost of DUS examination and for the agricultural plant species the cost of the VCU examination. In the case of vine, there is an examination similar to the VCU examination, but this is carried out in the frame of the DUS examination. Under all options there will be no changes in the component of administrative costs and DUS examination. The envisaged measures for strengthening **sustainability requirements** in the VCU examination of agricultural plant species and vine and the introduction of an obligation for assessment for characteristics that contribute to sustainable agri-food production of new varieties of the other crop groups (i.e. vegetables and fruit plants) will result in **additional testing costs for operators** (increased fees paid to NCAs for the examination of new varieties).

The current average cost for VCU for agricultural plant species is EUR 3 200 per year and on average VCU examination is carried over two years. The assessment for characteristics that contribute to sustainable agri-food production of new varieties of the other crop groups is assumed that will last for 2 years on average for vegetables, and for 4 years for fruit plants and vine

[211] ICF (2023) Section 6.1.1.1.

	option 1			option 2			option 3		
Baseline: Average registration cost (administrative fee + DUS + VCU where applicable) for operatorsper variety (EUR)	**Assumption on additional costs for operators**	**Increase per variety in relation to baseline (EUR)**	**Total increase in variety registration costs in relation to baseline (EUR)**	**Assumption on additional costs for operators**	**Increase per variety in relation to baseline (EUR)**	**Total increase in variety registration costs in relation to baseline (EUR)**	**Assumption on additional costs for operators**	**Increase per variety in relation to baseline (EUR)**	**Total increase in variety registration costs in relation to baseline (EUR)**
Agricultural plant species	10% of current VCU * 2 years [2.364 varieties]			10% of current VCU * 2 years [1.859 varieties]			15% of current VCU * 2 years [1.795 varieties]		
10.915	EUR	640	1.512.960	EUR	640	1.189.760	EUR	960	1.723.200
	%	6%		%	6%		%	9%	
Vegetable species	10% of current VCU * 2 years [1.314 varieties]			80% of current VCU * 2 years [1.003 varieties]			100% of current VCU * 2 years [969 varieties]		
5.580	EUR	640	840.960	EUR	5.120	5.135.360	EUR	6.400	6.201.600
	%	11%		%	92%		%	115%	
Vine	10% of current VCU * 4 years [39 varieties]			10% of current VCU * 4 years [30 varieties]			15% of current VCU * 4 years [29 varieties]		
13.840	EUR	1.280	49.920	EUR	1.280	38.400	EUR	1.920	55.680
	%	9%		%	9%		%	14%	
Fruit plants	10% of current VCU * 4 years [37 varieties]			110% of current VCU * 4 years [28 varieties]			120% of current VCU * 4 years [27 varieties]		
14.000	EUR	1.280	47.360	EUR	14.080	394.240	EUR	15.360	414.720
	%	9%		%	101%		%	110%	
Grand total of increase in variety registration costs (upper limit) for operators in EU27	**EUR**		**2.451.200**			**6.757.760**			**8.395.200**
Grand total of increase in variety registration costs (lower limit) for operators in EU27, assuming 44% of VCU and sustainability assessments under official supervision with 12% reduced costs	**EUR**		**2.321.777**			**6.400.950**			**7.951.933**

Table 25. Calculation of the total increase of variety registration costs for operators due to increased sustainability requirements (VSCU).

The increase in variety registration costs relative to the baseline due to the new VSCU can reach to EUR 2.45 million in option 1, EUR 6.75 million in option 2 and EUR 8.39 million in option 3 in total for all operators in EU27 every year. This can be reduced to EUR 6.40 million and EUR 7.95 million under options 2 and 3 respectively following the application of mitigating measures (VSCU examination under official supervision and collaboration between NCAs). These savings are calculated by assuming that up to 44% operators will opt for official supervision and have 12% savings in their costs (i.e. assuming the same percentage and savings recorded for certification under official supervision).

5. IMPACT OF STRENGTHENED SUSTAINABILITY REQUIREMENTS IN VARIETY REGISTRATION

It is expected that the measures for strengthened sustainability requirements for the acceptance of new varieties (VSCU) will result in increase of cost of seeds and other PRM for farmers. The main driver of the increase of the costs is the reduced number of varieties that can be put on the market that will increase the cost of breeding of new varieties. The return of the costs of breeding programmes will depend on a smaller number of varieties. The assumed loss of new varieties will be highest in option 3 and lowest in option 1 (Table 18). A secondary driver is the increase of cost of examination of new varieties due to the strengthened sustainability requirements. The increase will be highest in option 3 and lowest in option 1 (Table 25). In absence of data allowing more accurate calculations, it is assumed that the total cost of PRM used in agriculture annually in EU27 will increase on average 1%, 3% and 5% under options 1, 2 and 3 respectively. This assumed increase in prices is lower than the reduced number of varieties coming to the market (additional rejection or withdrawal rate of varieties is assumed at 3%, 5%, 10% under options 1, 2 and 3 respectively) because it is observed that the returns on breeding investments come from only a part of the varieties marketed, while some varieties are registered without being actually put in the market.

On the other hand, farmers will benefit from the improved characteristics of the new varieties in terms of improved use of inputs, reduction of loss of yield due to extreme conditions etc. Such gains are being realised over the years due to a number of different factors, including genetic gains by plant breeding, improved agronomic practices etc. The impact of these factors cannot be disentangled. The strengthened sustainability requirements will contribute to the abovementioned gains. The requirements will steer breeding to aspects as increased resistance to plant pests that will lead to reduced pesticide use, increased drought tolerance and more efficient use of nutrients that will lead to more stable yields in extreme conditions etc. Gains are expected to be lowest under option 1 (voluntary approach for species other than agricultural plant species) and highest in option 2 (leaving flexibility to MS to adjust to local agro-ecological conditions). Option 3 is expected to result in intermediate gains, as the level of flexibility for MS to adjust to local agro-ecological conditions is limited. In absence of data allowing more accurate calculations, it is assumed that the avoided loss of total crop output on top of the progress made anyway in the baseline can be used as a proxy for all the benefits for farmers that derive from the improved characteristics of the new varieties. This avoided loss of total crop output is assumed to be 0.5%, 1% and 0.75% under options 1, 2 and 3 respectively. These assumptions are based on the average genetic progress that has been recorded for various species over the last decades[212]. With these assumptions option 2

[212] E.g. Rijk B. *et al.* (2013); Voss-Fels K.P *et al.* (2019).

clearly outperforms, with option 1 delivering the least benefits. The uncertainty of these assumptions is rather high. Therefore, in place of a sensitivity analysis, a conservative scenario where the avoided loss of total crop output is assumed to be 4 times lower (0.13%, 0.25% and 0.19% under options 1, 2 and 3 respectively) is also examined. In this conservative scenario, option 2 also performs best, while for option 3 the costs are higher than the benefits.

	Million EUR (current 2021 price)	Impact on farms of strengthened sustainability requirements for the acceptance of new varieties of PRM	Option 1	Option 2	Option 3
INCREASE IN COSTS					
Total annual PRM cost in agriculture	13.345,85	Increase in total PRM cost in agriculture (%)	1%	3%	5%
		(million EUR)	133,46	400,38	667,29
Total annual intermediate consumption in agriculture	260.167,89	Increase in global intermediate consumption due to increase in total PRM cost in agriculture (%)	0,05%	0,15%	0,26%
BENEFITS					
Total annual crop output	248.656,89	Avoided loss in crop output annually (%)	0,50%	1,00%	0,75%
		(million EU)	1.243,28	2.486,57	1.864,93
Balance / optimistic scenario		**million EUR**	**1.109,83**	**2.086,19**	**1.197,63**
Total annual crop output	248.656,89	Avoided loss in crop output annually (%)	0,125%	0,250%	0,188%
		(million EU)	310,82	621,64	466,23
Balance / conservative scenario		**million EUR**	**177,36**	**221,27**	**-201,06**

Table 26. Impact on farms of strengthened sustainability requirements for the acceptance of new varieties of PRM

Impact on NCAs:

Currently 16 MS receive the bulk of the applications for new varieties of agricultural plant species (corresponding to annual acceptance of 2 564 varieties on average every year). For meeting the annual needs for implementing the VSCU for vegetable species and fruit plants (respectively 1 384 and 39 varieties on average accepted annually) the capacity of testing stations and staff would need to be increased by up to 50% if all were to be carried out by the NCAs and by up to 22% if 44% were done under official supervision (i.e. assuming the same rate as that for certification under official supervision). Indicatively the annual budget of the French NCA responsible for variety registration is EUR 30.6 million, of which approximately 60% corresponds to DUS activities and 40% to VCU (GEVES, n.d.). Assuming a similar budget for each of the 16 NCAs that receive the bulk of the applications and that an increase in capacity by 22% to 50% would result in equal increase in their budget, the total annual cost for the NCAs could be in the range of EUR 43 to 98 million in options 2 and 3 depending on the percentage of operators that will opt for official supervision.

Total additional costs per NCA (16 largest ones):

- EUR 30.6 million * 40% = EUR 12.24 million annual costs for VCU per NCA (baseline)
- EUR 12.24 million * 50% = EUR 6.12 million additional annual costs per NCA without official supervision (options 2 and 3)
- EUR 12.24 million * 50% * 44% = EUR 2.69 million additional annual costs per NCA if 44% of operators opt for official supervision (options 2 and 3)

Total additional costs for NCAs (sum for 16 largest ones that cover the bulk of applications for EU27):

- 16 * EUR 6.12 million = EUR 97.92 million without official supervision (options 2 and 3)

- 16 * EUR 2.69 million = EUR 43.04 million if 44% of operators opt for official supervision (options 2 and 3).

The costs for NCAs under option 1 are considered insignificant, as under that option NCAs are not required to increase significantly their capacity.

6. IMPACT OF ASSESSMENT OF SUSTAINABILITY CHARACTERISTICS OF BASIC MATERIAL

The average annual fee for registration of new basic material is estimated to be EUR 1 491 based on data provided by 4 MS[213]. Both the targeted survey and the data available in the Common Catalogue (FOREMATIS) show that new basic material is on average registered every 5 years. Based on the current annual average of 44 registrations of basic material in EU27 and assuming a cost increase of 5%, 10% and 15% for options 1, 2 and 3 respectively, the annual average cost for registration fee of basic material would be EUR 1 565, EUR 1 640 and EUR 1 714 under options 1 to 3 respectively.

	Baseline	**Option 1**	**Option 2**	**Option 3**
Fee for registration of new basic material (EUR)	1 491	1 566	1 640	1 715
Number of registrations per year in EU27	44	44	44	44
Additional cost per registration in comparison to the baseline (EUR)	N/A	75	149	224
Total annual additional cost for registration (EUR)	**N/A**	**3 280**	**6 560**	**9 841**

Table 27. Calculation of total annual additional cost for registration of new basic material due to extended sustainability assessment.

[213] Data collected from NCAs by the targeted survey under ICF(2023).

7. INNOVATION AND DIGITALISATION

This section compares the costs of marketing controls that are conducted to confirm the identity of the variety of the marketed PRM. Those marketing controls can be done by control-plot testing (growing samples of the marketed PRM and comparing the phenotypic characteristics of those sample with the reference sample of the registered variety) (Table 28). Alternatively, BMTs and more specifically molecular markers[214] can be used to verify that the marketed PRM is identical to the registered plant variety (Table 29).

As an estimate of the data provided by some NCAs, and extrapolating across the EU, it can be concluded that around 50 000 post control tests are carried out per year on seed lots.

The following costs are estimates of the costs borne by NCAs to confirm the identity of a plant variety.

Activity	**Average Cost**
Maintenance collection plots	2 450 EUR/ha
Post-control tests per lot	250 EUR/lot

Table 28. Estimation of the costs borne by NCAs to confirm the identity of a plant variety

Equipment/staff	**Cost**
Consumables + equipment	33 EUR/test
Cost basic PCR machine	5 000 – 15 000 EUR
Amortisation equipment	10 years
Staff cost	50 EUR/test
Other fixed costs	20 EUR/test

Table 29. Estimation of the costs as regards the use of BMTs

In 10 years' time, 500 000 tests will be carried out. This will entail a total cost of 125 000 000 EUR. If 40% of those post control plot tests were done with BMTs (mainly those test that are more appropriate for the species, e.g., fruit plants, vine, vegetables...) this would lead to significant savings: 250- (33 + 50 + 20) =147 EUR saving per test; 147 x 500 000 x 40% = 29 400 000 EUR. The investment needed to carry out these tests will be worthwhile given the significant savings of using BMT instead of post control plot tests for some species.

Similarily, digitalisation of the certification system will require initial investments that can be paid-off over few years, after which there will be net benefits. OECD carried out a feasibility study on digitalisation to introduce **digital technologies** in seed certification. The study estimated the initial investment by the OECD Secretariat to be in the range of 301 000 – 481 000 USD while the tangible benefits for NCAs and operators were estimated at 398 000 USD over a period of 3 years but would continue to be realised in the longer term[215].

[214] A molecular marker (identified as genetic marker) is a fragment of DNA that is associated with a certain location within the genome. Molecular markers are used in molecular biology and biotechnology to identify a particular sequence of DNA in a pool of unknown DNA.

[215] OECD document TAD/CA/S(2021)8 OECD Seed Schemes Digitalisation Study – not published

8. DETAILED PRESENTATION OF COSTS AND BENEFITS

8.1. Costs of common measures

Overview of costs of measures common to all options		PRM/FRM users	Operators	NCAs
Measures common to all options for PRM and FRM legislation	All professional operators to be registered in a single register under the PHL	N/A	0 [Professional operators are currently registered either under the marketing Directives, or PHL, or both]	0 [NCAs currently maintain registers of professional operators either under the marketing Directives, or PHL, or both]
	All certification tasks are permitted under official supervision except the issuing of the official label (PRM) and the Master certificate (FRM).	N/A	The measure provides an additional option to operators and does not create an obligation for them, therefore it does not lead to new costs. Operators wishing to use this new option may however need to invest in staff and/or equipment. Around 50% of operators (valid also for SMEs) already use the existing options for official supervision and would make use of certification conducted by operators under official supervision for all steps of the seed certification process if this was made available. Those operators would not need any new investments. The potential needs for investments by other operators cannot be monetised. However, available data show that costs for operators are 12% less for carrying out activities under official supervision in comparison to the costs they have under official examinations	NCAs will need to reallocate resources from carrying out official inspections to training, licensing and supervising the operators' inspectors. The costs for NCAs will largely depend on the demand by the operators but are expected to be overall neutral or insignificant.
	PRM/FRM legislation will directly refer to PHL for the list of RNPQs and specific measures. Compliance with requirements for QPs and RNQPs will remain a prerequisite for the certification of PRM/FRM.	N/A	0 [Requirements remain the same]	0 [Requirements remain the same]
Measures common to	Decisions for addition of new species in (or removal	N/A	N/A	N/A

all options for PRM legislation	of species from) the scope of the PRM legislation and Decisions on the equivalence to EU rules for third countries will be taken by means of tertiary legislation			
	The transfer/notification of new varieties from national to the EU Plant Variety Portal will be managed by the MS without the need for a Commission Decision	N/A	N/A	N/A
	Allow MS to decide themselves on permitting temporarily the marketing of seed that does not satisfy the requirements in respect of minimum germination, if germination is not lower than 15 % than the required germination rate	N/A	N/A	0
	The possibility to deviate from certain requirements as regards uniformity will be provided for the DUS examination of organic varieties suitable for organic production.	N/A	0 [The registration of organic varieties will be subject to the same procedure as currently but an option is provided for such varieties to deviate from uniformity requirements of the DUS examination.]	Negligible costs not quantified. [Some training of examiners may be required in order to implement the deviation rules.]
	The rules for conservation varieties are lighter and extended to cover new locally adapted varieties	N/A	0 [Current rules are simplified and scope is extended, without addition of new requirements]	Negligible costs not quantified. [Some training of staff may be required in order to implement the new rules]
	The scope for heterogeneous material is broadened beyond organic production	N/A	0 [Current rules remain unchanged, only scope is extended]	0 [Current rules remain unchanged, only scope is extended]

	The current simple regime for ornamental plants is maintained unchanged	N/A	0 [Current rules remain unchanged]	0 [Current rules remain unchanged]
Measures common to all options for FRM legislation	The decisions on the equivalence to EU rules for third countries will be taken by means of tertiary legislation.	N/A	N/A	N/A
	The existing empowerment to define the information to be made available to users/buyers of FRM is extended to explicitly cover suitability of FRM for climatic and ecological conditions.	N/A	Negligible costs not monetised [Additional information can be easily made available within the existing procedure]	N/A

8.2. Benefits of common measures

Overview of benefits of measures common to all options				
Measures		**PRM/FRM users**	**Operators**	**NCAs**
Measures common to all options for PRM and FRM legislation	All professional operators to be registered in a single register under the PHL	N/A	EUR 1 million per year savings in registration costs [Over 20 000 duplicate registrations will be avoided and over EUR 800 000 annual savings in registration costs for operators supplying PRM of fruit plants. Over 4 000 duplicate registrations will be avoided and there will be over EUR 237 000 annual savings in registration costs for operators supplying FRM].	Marginal savings due to the fact that there will be no obligation to keep separate registers of professional operators under PRM/FRM legislation and PHL. Not monetised.
	All certification tasks are permitted under official supervision except the issuing of the official label (PRM) and the Master certificate (FRM).	N/A	• EUR 1.7 million per year in reduced certification costs (direct benefit) • Efficiency gains and flexibility (indirect benefits not monetised)	N/A
	PRM/FRM legislation will directly refer to PHL for the list of RNPQs and specific measures. Compliance with requirements for QPs and RNQPs will remain a prerequisite for the certification of PRM/FRM.	N/A	0 [Requirements remain the same. Efficiency gains and flexibility, not monetised (indirect benefits)]	0 [Requirements remain the same. Efficiency gains and flexibility, not monetised (indirect benefits)]
Measures common to all options for PRM legislation	Decisions for addition of new species in (or removal of species from) the scope of the PRM legislation and Decisions on the equivalence to EU rules for third countries will be taken by means of tertiary legislation	N/A	Shorter time to reach such decisions but the benefits are rather limited as only a small number of decisions every year (0-4) are concerned. Not monetised.	Shorter time to reach such decisions but the benefits are rather limited as only a small number of decisions every year (0-4) are concerned. Not monetised.

	The transfer/notification of new varieties from national to the EU Plant Variety Portal will be managed by the MS without the need for a Commission Decision	PRM users can avail of about 4 000 new varieties every year by 1 to 4 months earlier. Not monetised.	The period between acceptance in a national catalogue and access to the common market will be shortened by 1 to 4 months for about 4 000 new varieties every year. Not monetised.	For the Commission the need for adoption of 24 Decisions every year is removed For the NCAs the need to notify new varieties to the Commission is removed. Not monetised.
	Allow MS to decide themselves on permitting temporarily the marketing of seed that does not satisfy the requirements in respect of minimum germination, if germination is not lower than 15 % than the required germination rate	Reduced waiting time for concerned PRM users by at least 15 days for each notification avoided. Not monetised.	In average 30 notifications annually (for a total of 50 000 tonnes of seed, or about 0.01% of the quantities of seed certified annually) become redundant. Reduced waiting time for operators by at least 15 days for each notification avoided. Not monetised.	In average 30 notifications annually (for a total of 50 000 tonnes of seed, or about 0.01% of the quantities of seed certified annually) become redundant. Commission and NCAs: avoiding the handling of on average 30 notifications per year. Not monetised
	The possibility to deviate from certain DUS requirements as regards uniformity will be provided for the DUS examination of organic varieties suitable for organic production.	Increased availability of organic varieties suitable for organic production. Not monetised.	The breeding period of varieties compliant with reduced uniformity requirements can be in average 2 years shorter than for varieties fully meeting those requirements. Operators making use of this possibility will therefore access the market faster, with reduced breeding costs and with varieties that up to now were restricted from the market since it was not possible to register varieties not meeting the DUS requirements. A few dozen operators across EU are likely to use this option. The number of varieties registered under these rules could be in average 100 annually. Assuming EUR 50 000 savings in breeding costs per variety, concerned operators may see savings of EUR 5 million annually.	0
	The rules for conservation varieties are lighter and extended to cover new locally adapted varieties	Increased availability of conservation and locally adapted varieties. Not monetised.	This measure creates a new market segment. Operators would benefit from lighter procedures for access to market (no DUS/VSCU requirements for variety registration and no certification of PRM). The number of operators concerned could be in the range of several hundreds. The number of varieties marketed under these rules could be a few hundred annually. However, the quantities of PRM concerned are expected to remain limited below 2% of the market. Potential value could be up to EUR 13.3 billion /year * 2%= EUR 266 million/year.	0

	The scope for heterogeneous material is broadened beyond organic production	Increased availability of heterogeneous material. Not monetised.	This measure creates a new market segment. Operators would benefit from lighter procedures for access to market. Number of operators and quantities of PRM concerned are unknown. Though number of operators could be in the range of several hundreds. Several hundred or few thousand heterogeneous material are expected to be brought in the market over the next ten years but the quantities of PRM concerned are expected to be very limited and of insignificant market value.	0
	The current simple regime for ornamental plants is maintained unchanged	N/A	0	0
Measures common to all options for FRM legislation	The decisions on the equivalence to EU rules for third countries will be taken by means of tertiary legislation.	N/A	N/A	N/A
	The existing empowerment to define the information to be made available to users/buyers of FRM is extended to explicitly cover suitability of FRM for climatic and ecological conditions.	Users of FRM will benefit from improved information as regards the suitability of FRM for climatic and ecological conditions. As a result they will be able to select the most appropriate FRM and reduce economic damage caused by the use of unsuitable FRM. This is however not quantifiable.	N/A	N/A

8.3. Costs per option

Overview of costs										
Measures		**Option 1**			**Option 2**			**Option 3**		
		PRM/FRM users	**Operators**	**NCAs**	**PRM/FRM users**	**Operators**	**NCAs**	**PRM/FRM users**	**Operators**	**NCAs**
Common elements for PRM and FRM:	Innovative production processes, BMTs and digitalisation	Adoption of guidelines on innovative production processes, BMTs and digitalisation			Introduction of basic rules on innovative production processes, BMTs and digitalisation and creation of empowerments for detailing rules according to new developments			Introduction of detailed rules on innovative production processes, BMTs and digitalisation		
		N/A	The measure provides new options and not new obligations. Therefore, there are no costs imposed. Use of new options however may require investments in equipment and/or staff. Any investment is expected to be recovered within few years due to efficiency gains and lower costs of operations.		N/A	The measure provides new options and not new obligations. Therefore, there are no costs imposed. Use of new options however may require investments in equipment and/or staff. Any investment is expected to be recovered within few years due to efficiency gains and lower costs of operations.		N/A	The measure provides new options and not new obligations. Therefore, there are no costs imposed. Use of new options however may require investments in equipment and/or staff. Any investment is expected to be recovered within few years due to efficiency gains and lower costs of operations.	
	Official controls	Harmonisation of OCs on production, marketing and imports of PRM/FRM without links to OCR			• Harmonisation of OCs on production, marketing and imports of PRM/FRM subject to the OCR • Simplified import controls at appropriate places			• Harmonisation of OCs on production, marketing and imports of PRM/FRM subject to the OCR • Stricter import controls at border control posts (BCPs) requiring special import documentation		
		N/A	Modified rate of OCs (increase or decrease) depending on current situation per MS and individual profile of each operator. Globally neutral impact.	Reallocation of resources, depending on current organisation. Marginal costs for compiling a Multi-annual national control plan and an annual report	N/A	Modified rate of OCs (increase or decrease) depending on current situation per MS and individual profile of each operator. Globally neutral impact.	Reallocation of resources, depending on current organisation. Marginal costs for compiling a Multi-annual national control plan and an annual report on OCs. Globally neutral	N/A	In comparison to options 1 and 2, the requirement of special import documentation will result in significant costs for operators (not quantifiable).	In comparison to options 1 and 2, the requirement of carrying out import controls at BCPs will result in significant costs for NCAs. There are about 500 BCPs designated for phytosanitary controls. Assuming that these would be the BCPs also for PRM/FRM, they would need to be equipped by staff to carry out sampling of imported PRM/FRM. With 1

				on OCs. Globally neutral impact.			impact.			person in average by BCP at EUR 30 000 for salary, the total annual cost for NCAs amounts to EUR 15 million.
For PRM legislation only	Assessment of new varieties for characteristics contributing to sustainable production	The sustainability considerations in the examination of new varieties are strengthened. The current VCU examination for agricultural plant species and vine is extended to include additional characteristics that contribute to sustainable production in order to better steer breeding efforts in this direction. The new examination will be called Value for sustainable cultivation and use (VSCU). • For organic varieties suitable for organic production, it will be required that the VSCU examination is carried out under conditions adapted to the specific needs of organic production. • MS will have flexibility to implement VSCU according to their agro-ecological conditions. For other crop groups (fruit plants and vegetables), the assessment will rely on information that applicants voluntarily submit along with the application for registration of a new variety			The sustainability considerations in the examination of new varieties are strengthened. The current VCU examination for agricultural plant species and vine is extended to include additional characteristics that contribute to sustainable production in order to better steer breeding efforts in this direction. The new examination will be called Value for sustainable cultivation and use (VSCU). It will also apply to new varieties of the other crop groups (fruit plants and vegetables). • MS will have flexibility to implement VSCU according to their agro-ecological conditions. • It will be possible for operators to conduct the VSCU examination under official supervision. • MS will be able to collaborate and accept results from MS with similar agro-ecological conditions, and/or create shared testing networks. • An empowerment will be created to determine the minimum requirements for carrying out the VSCU examination and the accepted methodologies for assessing the individual VSCU characteristics. • For organic varieties suitable for organic production, it will be required that the VSCU examination is carried out under conditions adapted to the specific needs of organic production.			The sustainability considerations in the examination of new varieties are strengthened. The current VCU examination for agricultural plant species and vine is extended to include additional characteristics that contribute to sustainable production in order to better steer breeding efforts in this direction. The new examination will be called Value for sustainable cultivation and use (VSCU). It will also apply to new varieties of the other crop groups (fruit plants and vegetables). In contrast to option 2: • Implementation of the VSCU will be harmonised between the MS. • Detailed rules on accepted methodologies for assessing the individual VSCU characteristics will be introduced. As under option 2: • It will be possible for operators to conduct the VSCU examination under official supervision. • MS will be able to collaborate and accept results from MS with similar agro-ecological conditions, and/or create shared testing networks. • For organic varieties suitable for organic production, it will be required that the VSCU examination is carried out under conditions adapted to the specific needs of organic production.		
		EUR 133 million annually in increased PRM costs for farmers	Increased registration costs for the PRM sector by EUR 2.45 million annually. Marginal costs for FRM.	Insignificant costs as NCAs are not required to increase significantly their capacity.	EUR 400 million annually in increased PRM costs for farmers.	Increased registration costs for the PRM sector by EUR 6.40 million annually. (PRM) Marginal costs for FRM.	EUR 43 to 98 million annually	EUR 667 million annually in increased PRM costs for farmers.	Increased registration costs for the PRM sector by EUR 7.95 million annually. Marginal costs for FRM.	EUR 43 to 98 million annually
	Seed conservation networks,	Exemption from the scope of the legislation of activities of seed conservation networks, marketing to amateur gardeners and exchange in kind of seeds between farmers			Subject activities of seed conservation networks, marketing to amateur gardeners and exchange in kind of seeds between farmers to lighter rules			Subject activities of seed conservation networks, marketing to amateur gardeners and exchange in kind of seeds between farmers to the general requirements of the legislation		

	marketing to amateur gardeners and exchange in kind of seeds between farmers	N/A	0 [No new obligations]	Negligible costs [Some training of staff may be required in order to tell apart PRM exempted from legislation]	N/A	0 [New opportunities but of insignificant market value. No new obligations.]	Negligible costs [Some training of staff may be required in order to implement the new rules.]	N/A	0 [No change in relation to current situation]	0 [No change in relation to current situation]
For FRM legislation only	Scope of FRM the legislation	Define forestry and non-forestry purposes but maintain current scope of FRM legislation			Define forestry and non-forestry purposes and extend scope of FRM legislation to include the production of FRM for specific non-forestry purposes			Define forestry and non-forestry purposes and extend scope of FRM legislation to include the production of FRM for specific non-forestry purposes		
		N/A	0 [Depending on current definitions used by MS, some uses may be added or removed from the scope, overall neutral impact in certification costs for operators]	0 [Depending on current definitions used by MS, some uses may be added or removed from the scope, overall neutral impact in enforcement costs for NCAs]	N/A	0 [Increased costs as FRM for non-forestry purposes will become subject to testing costs (certification) but limited as it concerns 10% of FRM]	0 [Increased costs as FRM for non-forestry purposes will become subject to certification but limited as it concerns 10% of FRM]	N/A	0 [Increased costs as FRM for non-forestry purposes will become subject to testing costs (certification) but limited as it concerns 10% of FRM]	0 [Increased costs as FRM for non-forestry purposes will become subject to certification but limited as it concerns 10% of FRM]
	Assessment of FRM for characteristics contributing to sustainable production	• Extend sustainability requirements to cover lower FRM categories • Adopt guidelines on sustainability requirements for all FRM categories			• Extend sustainability requirements to cover lower FRM categories • Introduce general principles on sustainability requirements for all FRM categories with flexibility for MS to implement according to their environmental conditions			• Extend sustainability requirements to cover lower FRM categories • Introduce detailed and harmonised rules on sustainability requirements for all FRM categories		

		N/A	0 [Negligible increase of costs]	0 [Negligible increase of costs]	N/A	0 [Negligible increase of costs]	0 [Negligible increase of costs]	N/A	0 [Negligible increase of costs]	0 [Negligible increase of costs]
	Address difficulties in supply of suitable FRM	• Maintain the existing empowerment to authorise MS to use FRM not fulfilling all requirements when there are difficulties in supply • Adopt guidelines on contingency planning to ensure availability of FRM			• Maintain the existing empowerment to authorise MS to use FRM not fulfilling all requirements when there are difficulties in supply • Introduce a general requirement for contingency planning in the MS to ensure availability of FRM			• Maintain the existing empowerment to authorise MS to use FRM not fulfilling all requirements when there are difficulties in supply • Introduce common rules on contingency planning in the MS to ensure availability of FRM		
		N/A	0 [Negligible increase of costs]	0 [Negligible increase of costs]	N/A	0 [Negligible increase of costs]	0 [Negligible increase of costs]	N/A	0 [Negligible increase of costs]	0 [Negligible increase of costs]
	Conservation and sustainable use of forest genetic resources	Adoption of guidelines for the registration of basic material for the purposes of conservation of forest genetic resources			Introduction of a derogation for the registration of basic material for the purposes of conservation of forest genetic resources			Introduction of a derogation for the registration of basic material for the purposes of conservation of forest genetic resources		
		N/A	0 [Negligible increase of costs]	0 [Negligible increase of costs]	N/A	0 [Negligible increase of costs]	0 [Negligible increase of costs]	N/A	0 [Negligible increase of costs]	0 [Negligible increase of costs]

8.4. Benefits per option

Overview of benefits										
Measures		**Option 1**			**Option 2**			**Option 3**		
		PRM/FRM users	**Operators**	**NCAs**	**PRM/FRM users**	**Operators**	**NCAs**	**PRM/FRM users**	**Operators**	**NCAs**
Common elements for PRM and FRM:	Innovative production processes, BMTs and digitalisation	Adoption of guidelines on innovative production processes, BMTs and digitalisation			Introduction of basic rules on innovative production processes, BMTs and digitalisation and creation of empowerments for detailing rules according to new developments			Introduction of detailed rules on innovative production processes, BMTs and digitalisation		
		N/A	The measure provides new options and not new obligations. Therefore, there are no direct benefits. Use of new options however may require investments in equipment and/or staff. Any investment is expected to be recovered within few years due to efficiency gains and lower costs of operations.		N/A	The measure provides new options and not new obligations. Therefore, there are no direct benefits. Use of new options however may require investments in equipment and/or staff. Any investment is expected to be recovered within few years due to efficiency gains and lower costs of operations.		N/A	The measure provides new options and not new obligations. Therefore, there are no direct benefits. Use of new options however may require investments in equipment and/or staff. Any investment is expected to be recovered within few years due to efficiency gains and lower costs of operations.	
	Official controls	Harmonisation of OCs on production, marketing and imports of PRM/FRM without links to OCR			• Harmonisation of OCs on production, marketing and imports of PRM/FRM subject to the OCR • Simplified import controls at appropriate places			• Harmonisation of OCs on production, marketing and imports of PRM/FRM subject to the OCR • Stricter import controls at border controls requiring special import documentation		
		N/A	Efficiency gains (not monetised)		N/A	Efficiency gains (not monetised)		N/A	Efficiency gains (not monetised)	
For PRM legislation only	Assessment of new varieties for characteristics contributing to sustainable production	• Extension of the current VCU requirements for agricultural plant species and vine to better address sustainability • For all other species, reliance on information that applicants voluntarily submit along with the application for registration of a new variety			• Extension of the current VCU requirements for agricultural plant species and vine to better address sustainability • Introduction of these requirements for all other crop groups (vegetables and fruit plants) • Flexibility for MS to implement these requirements according to their agro-ecological conditions • Permit examination of these requirements under official supervision • Creation of empowerment to adopt rules on accepted methodologies for assessing the different characteristics			• Extension of the current VCU requirements for agricultural plant species and vine to better address sustainability • Introduction of these requirements for all other crop groups (vegetables and fruit plants) • Harmonised implementation of these requirements. • Permit examination of these requirements under official supervision • Introduction of detailed rules on accepted methodologies for assessing the different characteristics		

		EUR 310 to 1 243 million annually in terms of avoided loss in crop output. Reduced losses in forestry (not monetised).	N/A	N/A	EUR 621 to 2 486 million annually in terms of avoided loss in crop output. Reduced losses in forestry (not monetised).	N/A	N/A	EUR 466 to 1 864 million annually in terms of avoided loss in crop output. Reduced losses in forestry (not monetised).	N/A	N/A
	Seed conservation networks, marketing to amateur gardeners and exchange in kind of seeds between farmers	Exemption from the scope of the legislation of activities of seed conservation networks, marketing to amateur gardeners and exchange in kind of seeds between farmers			Subject activities of seed conservation networks, marketing to amateur gardeners and exchange in kind of seeds between farmers to lighter rules			Subject activities of seed conservation networks, marketing to amateur gardeners and exchange in kind of seeds between farmers to the general requirements of the legislation		
		0 [New opportunities for seed conservation networks and for exchange in kind of seeds between farmers but of insignificant market value].	0 [New opportunities in the market to amateur gardeners but of insignificant market value].	N/A	0 [New opportunities for seed conservation networks and for exchange in kind of seeds between farmers but of insignificant market value].	0 [New opportunities in the market to amateur gardeners but of insignificant market value].	N/A	[No change in relation to current situation]	[No change in relation to current situation]	[No change in relation to current situation]
For FRM legislation only	Scope of FRM the legislation	Define forestry and non-forestry purposes but maintain current scope of FRM legislation			Define forestry and non-forestry purposes and extend scope of FRM legislation to include the production of FRM for specific non-forestry purposes			Define forestry and non-forestry purposes and extend scope of FRM legislation to include the production of FRM for specific non-forestry purposes		

		N/A	0	0	Indirect non-monetary benefits in terms of improved quality of FRM for non-forestry purposes	0	0	Indirect non-monetary benefits in terms of improved quality of FRM for non-forestry purposes	0	0
	Assessment of FRM for characteristics contributing to sustainable production	• Extend sustainability requirements to cover lower FRM categories • Adopt guidelines on sustainability requirements for all FRM categories			• Extend sustainability requirements to cover lower FRM categories • Introduce general principles on sustainability requirements for all FRM categories with flexibility for MS to implement according to their environmental conditions			• Extend sustainability requirements to cover lower FRM categories • Introduce detailed and harmonised rules on sustainability requirements for all FRM categories		
		Indirect non-monetary benefits in terms of improved quality of FRM for non-forestry purposes	0	0	Indirect non-monetary benefits in terms of improved quality of FRM for non-forestry purposes	0		Indirect non-monetary benefits in terms of improved quality of FRM for non-forestry purposes	0	0
	Address difficulties in supply of suitable FRM	• Maintain the existing empowerment to authorise MS to use FRM not fulfilling all requirements when there are difficulties in supply • Adopt guidelines on contingency planning to ensure availability of FRM			• Maintain the existing empowerment to authorise MS to use FRM not fulfilling all requirements when there are difficulties in supply • Introduce a general requirement for contingency planning in the MS to ensure availability of FRM			• Maintain the existing empowerment to authorise MS to use FRM not fulfilling all requirements when there are difficulties in supply • Introduce common rules on contingency planning in the MS to ensure availability of FRM		
		Indirect non-monetary benefits in terms of improved availability of FRM	0	0	Indirect non-monetary benefits in terms of improved availability of FRM	0	0	Indirect non-monetary benefits in terms of improved availability of FRM	0	0
	Conservation and sustainable use of forest genetic	Adoption of guidelines for the registration of basic material for the purposes of conservation of forest genetic resources			Introduction of a derogation for the registration of basic material for the purposes of conservation of forest genetic resources			Introduction of a derogation for the registration of basic material for the purposes of conservation of forest genetic resources		

	resources	Indirect non-monetary benefits in terms of increased genetic diversity of FRM	0	0	Indirect non-monetary benefits in terms of increased genetic diversity of FRM	0 [Savings due to reduction of costs but insignificant as volumes concerned are very limited]	0 [Savings due to reduction of costs but insignificant as volumes concerned are very limited]	Indirect non-monetary benefits in terms of increased genetic diversity of FRM	0 [Savings due to reduction of costs but insignificant as volumes concerned are very limited]	0 [Savings due to reduction of costs but insignificant as volumes concerned are very limited]

8.5. Net benefit and cost benefit analysis

Global costs and benefits per option (excluding common measures)									
	Option 1			**Option 2**			**Option 3**		
	PRM/FRM users	**Operators**	**NCAs**	**PRM/FRM users**	**Operators**	**NCAs**	**PRM/FRM users**	**Operators**	**NCAs**
Costs per stakeholder category (million EUR/year)	133	2	0	400	6	from 43 to 98	667	8	from 58 to 113
Global costs (million EUR/year)	**135**			**from 449 to 504**			**from 733 to 788**		
Benefits per stakeholder category (million EUR/year)	from 310 to 1 243	0	0	from 621 to 2 486	0	0	from 466 to 1 864	0	0
Global benefits (million EUR/year)	**from 310 to 1 243**			**from 621 to 2 486**			**from 466 to 1 864**		
Cost benefit analysis of options under the best scenario (highest benefits and lowest costs)									
Net benefit (million EUR/year)	1 243 – 135 = 1 108			2 486 – 449 = 2 037			1 864 - 733= 1 131		
Benefit Cost Ratio	1 243 / 135 = 9.20			2 486 / 449 = 5.53			1 864 / 733 = 2.54		
Cost benefit analysis of options under the worst scenario (lowest benefits and highest costs)									
Net benefit (million EUR / year)	310 – 135 = 175			621 – 504 = 117			466 - 788 = - 322		
Benefit Cost Ratio	310 / 135 = 2.29			621 / 504 = 1.23			466 / 788 = 0.59		

9. REDUCTION OF ADMINISTRATIVE BURDENS DUE TO SIMPLIFICATION OF ADMINISTRATIVE PROCEDURES

- **All professional operators to be registered in a single register under the PHL**

Over 20 000 duplicate registrations will be avoided and over EUR 800 000 annual savings in registration costs for operators supplying PRM of fruit plants. Over 4 000 duplicate registrations will be avoided and there will be over EUR 237 000 annual savings in registration costs for operators supplying FRM.

There will be marginal savings for the NCAs due to the fact that there will be no obligation to keep separate registers of professional operators under PRM/FRM legislation and PHL.

- **Decisions for addition of new species in (or removal of species from) the scope of the PRM legislation will be taken by means of tertiary legislation.**
- **Decisions on the equivalence to EU rules for third countries will be taken by means of tertiary legislation.**

Currently decision making by means of tertiary legislation is already the case for some marketing Directives for both the regulated species and the equivalence for third countries. However, some Directives require that for such decisions the ordinary legislative procedure is followed, which is cumbersome and disproportionate compared to the technical nature of the matter.

These measures will result in **no costs for NCAs or operators**, while there will be benefits for the Commission, the NCAs and operators in terms of **reduced hassle costs** due to shorter time to reach decisions (not monetised as per the Better Regulation guidelines). Any benefits are expected to be negligible in the short term as since the adoption of the first Directives, there have been very few changes in the lists of regulated species and about 1 or 2 requests from third countries per year are examined for equivalence. In the mid- to long-term however it is expected that shorter time to reach decisions would be beneficial in the light of rapidly changing conditions in relation to food security.

- **The transfer/notification of new varieties from national to Common Catalogues will be managed by the MS without the need for a Commission Decision.**

On the basis of notifications received from MS, the Commission publishes in the Official Journal of the European Communities under the titles 'Common Catalogue of Varieties of Agricultural Plant Species' and 'Common Catalogue of Varieties of Vegetables Species' lists of all the varieties of which the seed and propagating material can be marketed throughout the EU. The publication of the supplements to the Common Catalogues requires a Commission Decision. Currently the Commission adopts every year 12 Decisions for the agricultural plant species (in average 2564 varieties every year) and 12 Decisions for the vegetable species (on average 1384 varieties per year). This procedure creates unnecessary waiting time until a variety is included in the Common Catalogues and gets access to the common market.

The measure will result in **no costs for NCAs or operators**, while there will be benefits for the Commission in terms of **removing the need for 24 Decisions annually** and operators in terms of **reduced hassle costs** (not monetised as per the Better Regulation guidelines). Depending on the current practices of the MS, **the period between acceptance in a national catalogue of new**

varieties of agricultural plant species and vegetable species and access to the common market will be shortened by 1 to 4 months.

- **Allow MS to decide themselves on permitting temporarily the marketing of seed that does not satisfy the requirements in respect of minimum germination, if germination is not lower than 15 % than the required germination rate.**

Currently MS wishing to use this derogation have to inform the Commission and the other MS who can make an offer to cover the missing supply. If no offers are received, the MS are authorised to allow the marketing of seed with lower germination rate by a Commission Decision. This procedure is disproportionate as most often there are no suitable offers, while the quantities concerned are limited (in average 50 000 tonnes of seed annually, or about 0.01% of the quantities of seed certified annually). Over the last five years only 5 to 12% of the requested amounts could be covered by seed offered by other MS. For the remaining requests, an authorisation was granted after the period for other MS to submit offers had expired. Around 85% of the requests concern germination 15% or less below the minimum germination as laid down in the seed marketing Directives.

The measure will result in **no costs for NCAs or operators**. There will be **benefits for the Commission and the NCAs in avoiding the handling of in average 30 notifications per year**. There will also be **benefits for operators in terms of reduced hassle costs** due to shorter time (at least by 15 days for each avoided notification, not monetised) to cover the market needs when seed satisfying the minimum germination requirements is not available. The flexibility introduced by this measure is expected to gain importance in the mid- to long-term since problems of reduced germination are expected to occur more often under extreme conditions due to climate change.

ANNEX 5: BACKGROUND INFORMATION

1. THE PRM LEGISLATION AND ITS DEVELOPMENT

The PRM Directives have been in force since the mid-1960s. The legislative framework comprises one horizontal Directive on the Common Catalogue of Varieties and 11 vertical Directives dealing with specific plant groups:

1. Council Directive 2002/53/EC on the common catalogue of varieties of agricultural plant species (http://data.europa.eu/eli/dir/2002/53/2004-04-18)
2. Council Directive 66/401/EEC on the marketing of fodder plant seed (http://data.europa.eu/eli/dir/1966/401/2020-02-16)
3. Council Directive 66/402/EEC on the marketing of cereal seed (http://data.europa.eu/eli/dir/1966/402/2020-02-16)
4. Council Directive 2002/54/EC on the marketing of beet seed (http://data.europa.eu/eli/dir/2002/54/2017-04-01)
5. Council Directive 2002/55/EC on the marketing of vegetable seed (http://data.europa.eu/eli/dir/2002/55/2020-07-01)
6. Council Directive 2002/56/EC on the marketing of seed potatoes (http://data.europa.eu/eli/dir/2002/56/2020-02-16)
7. Council Directive 2002/57/EC on the marketing of seed of oil and fibre plants (http://data.europa.eu/eli/dir/2002/57/2020-02-16)
8. Council Directive 68/193/EEC on the marketing of material for the vegetative propagation of the vine (http://data.europa.eu/eli/dir/1968/193/2020-02-16)
9. Council Directive 1998/56/EC on the marketing of propagating material of ornamental plants (http://data.europa.eu/eli/dir/1998/56/2014-06-30)
10. Council Directive 2008/72/EC on the marketing of vegetable propagating and planting material, other than seed (http://data.europa.eu/eli/dir/2008/72/2020-07-01)
11. Council Directive 2008/90/EC on the marketing of fruit plant propagating material and fruit plants intended for fruit production (http://data.europa.eu/eli/dir/2008/90/2019-01-28)
12. Council Directive 1999/105/EC on the marketing of forest reproductive material (http://data.europa.eu/eli/dir/1999/105/oj)

The majority of Council Directives for the marketing of PRM were adopted between 1966 and 1971. Some Directives are more recent, such as the Council Directive for the marketing of vegetable propagating material and planting material other than seed and the one for the marketing of ornamentals. These Directives have been updated both frequently and substantially. The original Directives on fodder plant seed and cereal seed are still in force although these have been subject to a large number of amendments. The SLIM initiative launched by the Commission in 1996 has led to the recasting of the Council Directive on the marketing of ornamental plants in 1998 as well as to

the '2002' Directives (2002/53/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC, and 2002/57/EC) that are codifications of pre-existing Directives. Directives 66/401/EEC and 66/402/EEC were not included in this SLIM initiative as some amendments were on-going at the time when the Directives were recast or codified. As a follow-up to the Organisation for Economic Co-operation and Development (OECD) revision of its trade scheme for FRM in the mid-1990s, the EU undertook to renew its old Directive so that there would be only one set of definitions and rules for marketing of FRM. The new Directive 1999/105/EC has standards that reflect the increase in MS since 1966, for example in the number of species covered. A more recent change was the adoption of Council Directive 2008/90/EC, a recast of Council Directive 92/34/EEC[216] on the marketing of fruit plant propagating material and fruit plants intended for fruit production.

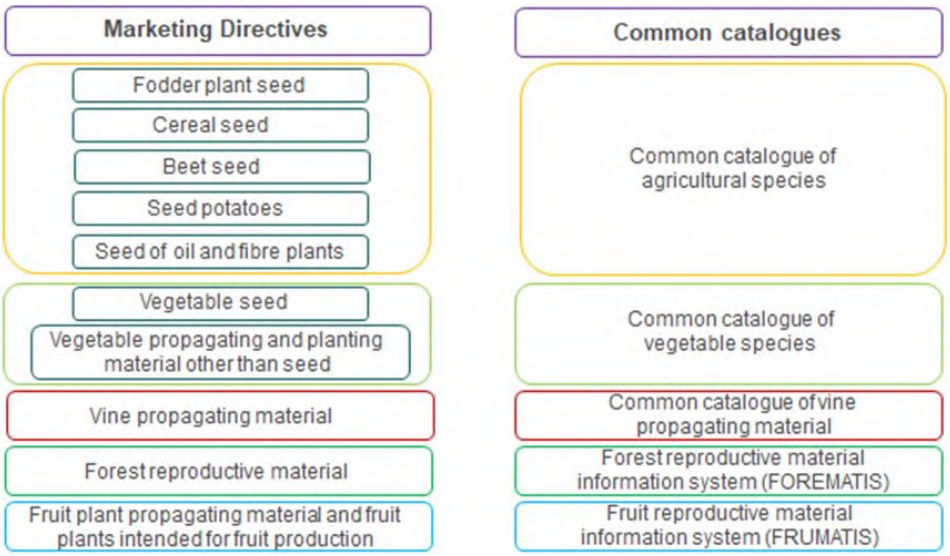

Figure 4. Overview of marketing Directives and corresponding Common Catalogues

2. PRINCIPLES OF THE PRM LEGISLATION

2.1. Variety registration

2.1.1. Distinctness, uniformity and stability (DUS)

For the purposes of variety registration ('first pillar', Figure 5), the NCAs of the MS test by field trials the candidate new plant varieties for their DUS). The characteristics (e.g. shape and morphology of the leaves) of the candidate varieties are compared with those of several existing plant varieties in the EU ('reference varieties'). New varieties need to be different from reference varieties (distinctness requirement). The characteristics of different plants within the same variety should be similar (uniformity requirement). The characteristics of the plants of a new variety should not change over time (stability requirement). DUS tests take about two years in the case of varieties of agricultural and vegetable species and 5-6 years in the case of varieties of fruit plants and vine. Upon completion of the DUS tests, varieties of vegetable species and fruit plants are registered in

[216] OJ L 157, 10.6.1992, p. 10.

the national catalogue of the MS concerned and subsequently submitted to the corresponding EU Common Catalogue. Each registered plant variety has a denomination, i.e. a name that serves to identify that variety[217]. PRM is always marketed with reference to a plant variety whereby the variety denomination is displayed on the official label/operator's label.

2.1.2. Value for cultivation and use (VCU)

In addition to the DUS test, varieties of agricultural species need to be assessed for their VCU before they can be registered. Through comparative field trials in distinct locations across the country, the NCAs compare the performance of new plant varieties as regards four characteristics with that of varieties in their national catalogues (Figure 5). The value of a variety for cultivation or use shall be regarded as satisfactory if, compared to other varieties accepted in the catalogue of the MS concerned, its qualities, taken as a whole, offer, at least as far as production in any given region is concerned, a clear improvement either for cultivation or as regards the uses which can be made of the crops or the products derived therefrom. Where other, superior characteristics are present, individual inferior characteristics may be disregarded[218]. Varieties of agricultural species are registered in the national catalogue upon completion of the DUS and VCU examinations.

New varieties of vine undergo a test similar to VCU pursuant to Commission Directive 2004/29/EC[219]. This VCU-like test forms part of the examination of the physiological characteristics of vine varieties carried out in the frame of the DUS test. Through field trials NCAs assess new vine varieties for yield, use, sensitivity/resistance to unfavourable conditions and pests. Commission Directive 2004/29/EC does not explicitly refer to VCU, but it contains requirements similar to the VCU criteria of agricultural species. MS have diverged in their implementation of the legislation. In France, the VCU examination forms part of the registration procedure of new vine varieties. There is a technical examination document ('règlement technique') for new varieties that is directly linked to Directive 2004/29. Italy modified the legislation 5 years ago. The characteristics to be assessed under the new Italian Decree no longer refer to Directive 2004/29. In total, 75 characteristics stemming from the CPVO protocol for the DUS examination of vine varieties need to be assessed [220] and the Descriptor list of grape varieties and *Vitis* species of the International Organisation of Vine and Wine (OIV)[221].

The VCU examinations of plant varieties are based on phenotypic observation of the crop in the field according to the relevant protocols. DUS protocols are common for all MS while VCU protocols are defined by each MS. The use of BMTs is gaining more importance as a supplementary tool to phenotypic observations in the field (this Annex, Section 7).

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[217] An example of a denomination of an apple variety is Boskoop Rouge Bakker.
[218] Depending on the regional conditions, the priorities could be different. For example, slightly lower yield can be accepted if the new variety is found to be tolerant to drought.
[219] OJ L 71, 10.3.2004, p. 22.
[220] CPVO-TP/050/2.
[221] https://www.oiv.int/public/medias/2274/code-2e-edition-finale.pdf

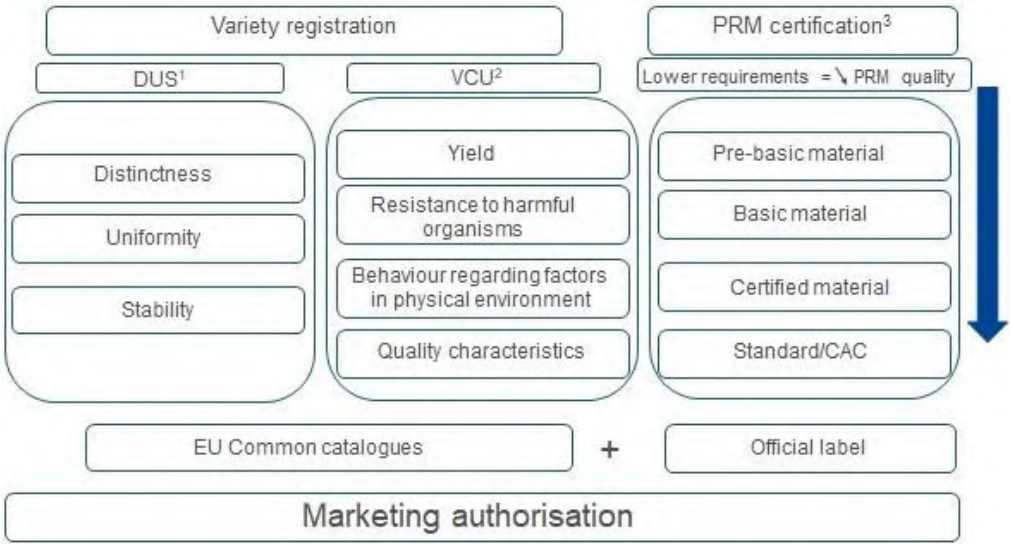

Figure 5. Pillars of the PRM legislation
[1] Applies to agricultural and vegetable species, fruit plants and vine
[2] Applies to agricultural species and vine
[3] During certification the identity, quality and health of PRM is checked
⬇ Decreasing requirements for PRM means lower PRM quality and lower market value of PRM

In the current legislation on fruit plants, vegetable seed and vegetable propagating material other than seed it is not mandatory to carry out a VCU examination as part of the variety registration process. Recital (3) to Council Directive 2008/90/EC[222] states that '*Satisfactory results in the cultivation of fruit depend to a large extent on the quality and plant health of the material used for their propagation and of the fruit plants intended for fruit production.*' Recital (9) refers to the establishment of plant health and quality standards for each genus and species of fruit plant based on international schemes. Furthermore, it states that '*it is appropriate to provide, therefore, for a for a system of harmonised rules for the different categories of propagating material and fruit plants to be marketed by reference to those international schemes, where available*'. In the absence of mandatory common rules on VCU testing, MS have diverged in their implementation of the legislation.

Poland has 5 testing stations to examine new varieties of fruit plants (apples, pears, plums, cherries, peaches, apricots, currants). Through comparative field experiments new varieties are evaluated for:

- susceptibility to diseases and pests;
- high nutritional value of fruit suitable for consumption;
- storage capacity;
- resistance to frost and susceptibility of flowers to spring frost;
- possibility of machine harvesting of fruit.

Until 1997, Czechia assessed the VCU of apples, pears, plums, cherries, apricots, small fruits under various climatic conditions in accordance with the VCU examination conducted for agricultural

[222] OJ L 267, 8.10.2008, p. 8.

crops. VCU trials were stopped because of the high costs and the time-demanding process. Since 1997, informal VCU trials are carried out by universities, research institutes and private growers. Nowadays, subsidies are given for:

- varieties intended for integrated production based on growing characteristics (disease resistance, fruit quality, frost hardiness and stability of yields);
- varieties for organic production recommended by breeders, research institutions, growers' associations and non-governmental institutions based on their experience.

Efforts are undertaken to assess sustainability characteristics of new varieties of fruit plants. The European fruit research institutes network (eufrin)[223] is an informal, voluntary organisation of university departments and research institutes. They specialise in research, development, and extension on temperate fruit crops and are based within countries of the EU, Switzerland, and Eastern Europe. They organise working groups on variety testing of new varieties of fruit plants with a proven unified descriptor list in a wide range of climatic conditions.

In the vegetable seed and vegetable propagating material sector there is a high turnover of varieties because there is a high number of vegetable varieties in the EU Plant Variety Portal (± 22 000 vegetable varieties). Each year, about 1 400 new varieties are registered. There is a large diversity of cultivation systems:

a) spring/summer/autumn crops;
b) indoor/outdoor cultivation;
c) type of medium, mechanisation and irrigation systems;
d) type of crop protection (hygiene, seed treatment, chemical, natural enemies,…).

A major part of vegetables is marketed as harvested fresh produce via retailers to consumers and a minor part as vegetable seed. There are different uses of the harvested products. Tomato can be used for direct consumption in a salad, for pasta sauces or ketchup. Consumer preferences as regards colour, size, flavour play an important role in the breeding and selection process of new vegetable varieties. It is very complicated to design harmonised VCU examinations for vegetable varieties because of the different cultivation systems, the different uses of vegetable seed and propagating material and the need to consider consumer preferences. For this reason, there is currently no official VCU examination but there is a direct interaction between the seed company and the farmer to check the performance of new vegetable varieties in relation to existing varieties.

2.2. Certification

2.2.1. Official certification

Certification of PRM ('second pillar', Figure 5) consists of checking the identity, quality, and health of PRM during the growing (= production) of that material in the field. Seeds are sampled and tested in relation to the respective technical requirements and finally the variety identity and purity is controlled by control-plot tests. The identity check serves to verify that the PRM has the same characteristics as the registered plant variety to which that PRM belongs. The quality of the

[223] https://eufrin.eu/frontpage

PRM relates to the absence of defects or the shape of the plants[224]. Depending on the quality, different marketing categories of PRM are defined. The NCAs perform regular checks during the production of PRM to verify that it does not contain any plant pests or diseases. Upon completion of all these inspections the NCAs issue an official label. That label confirms that the PRM is officially certified and that it can be marketed throughout the EU. The PRM legislation also includes rules for marketing of PRM in homogeneous lots that assure traceability and rules for packaging, sealing, labelling and documentation.

2.2.2. Certification under official supervision

The PRM legislation permits the transfer of aspects of the certification procedures to industry through a system of certification under official supervision (Figure 6). Operators and staff (company inspector, company sampler) involved in these activities can be authorised if they follow a mandatory training course given by the NCAs and are licensed. They can then perform field inspections to check the identity, quality and health of PRM in the production site. The NCAs perform official check testing on at least 5% of the field inspections performed by the company inspectors to verify that the field inspections have been carried out in a proper way. Furthermore, operators can carry out seed sampling and testing and be authorised to print official labels. The NCAs carry out official inspections on those operators (5% of which is officially check-tested) and their staff on a regular basis to ensure that they perform these tasks in a correct way. NCAs always perform pre- and post-control testing, take the decision on the certification of the PRM and authorise the issuing of the official labels. For each of the aforementioned activities the operator can apply for authorisation to carry out that activity under official supervision. For example, the NCA performs official field inspections while the operator carries out seed sampling and testing under official supervision of the NCA. This flexibility as regards the distribution of activities performed officially by the NCAs or by the operator under official supervision is called the mix and match approach. Certification under official supervision is currently allowed only for certified seed of agricultural species[225] but not for seed potatoes. The PRM legislation and the Rules and Regulations of the OECD Seed Schemes are aligned as regards the conditions for certification under official supervision[226].

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[224] In the case of fruit trees, the trees concerned should have a main stem with a number of side branches in a symmetrical form to ease mechanical harvesting.
[225] Directives 66/401/EEC, 66/402/EEC, 2002/54/EC and 2002/57/EC.
[226] OECD Seed Schemes Rules and Regulations 2022.

Official certification

1. Field inspection
   - Notification of fields by the operator to NCA
   - Field inspection by official inspector (1-2/year)
   - Data collected by official inspector sent to NCA
   - Field approval by NCA
2. Seed sampling
   - Sampling by official sampler according to ISTA
   - Data collected by official sampler sent to NCA
3. Seed testing
   - ISTA accredited laboratory
   - Official testing according to ISTA
   - Data sent to NCA
4. Pre- and post-control testing
   - NCA runs field plot testing to check varietal identity and purity
5. Official label
   - After positive results, NCA decides to issue the official label
   - NCA prints labels or authorises company to print them

Certification under official supervision

1. Field inspection
   - Notification of fields by the operator to NCA
   - Field inspection by company inspector (1-2/year)
     - Official check-testing by NCA (at least 5 %)
   - Data collected by company inspector sent to NCA
   - Field approval by NCA
2. Seed sampling
   - Sampling by company sampler according to ISTA
   - Data collected by company sampler sent to NCA
3. Seed testing
   - Authorisation of company laboratories
   - Testing in company laboratory according to ISTA
   - Data obtained by company laboratory sent to NCA
4. Pre- and post-control testing
   - NCA runs field plot testing to check varietal identity and purity
5. Official label
   - After positive results, NCA decides to issue the official label
   - NCA authorises company to print labels

Figure 6. Official certification and certification under official supervision

2.3. Activities of seed conservation networks and exchange in kind

Seed conservation networks are involved in the conservation and sustainable use of plant genetic resources. In practice this means that they conserve seeds. This can be done in a seed bank (i.e. seeds stored under cooled conditions) or in a live collection (seeds grown in a field). Seed conservation networks exchange seed with other networks to grow it under other climatic conditions or better characterise it.

Exchange in kind means the not-for-profit transfer of seeds from one farmer to another farmer. In most marketing Directives this transfer is considered to be marketing. For example, Article 2(1) point (a) of Council Directive 2002/55/EC[227] on the marketing of vegetable seed states the following: '*marketing: shall mean the sale, holding with a view to sale, offer for sale and any disposal, supply or transfer aimed at commercial exploitation of seed to third parties, whether or not for consideration*'. This means that seed exchanged in kind has to be authorised for marketing. The variety to which that seed belongs has to be officially registered in one of the national catalogues and the seed has to be certified. As mentioned in Section 2.1.2. those varieties often do not meet the variety registration requirements (DUS test) as they are not sufficiently uniform or the available seed quantity is too low to allow its proper characterisation. In the latter case of low seed quantities, all available seed would have been used upon completion of the variety registration and seed certification.

In most MS exchange in kind of seeds between farmers is not permitted. A couple of MS (Austria and France) have allowed exchange in kind of seeds between farmers under specific circumstances[228]. In France, under Article 315-5 of the Code Rural, exchange in kind of seeds and other PRM is permitted in the context of a 'mutual assistance' framework, as long as they do not belong to a variety protected by a plant variety right, they are not produced within the framework of

[227] OJ L 193, 20.7.2002, p. 33.
[228] ICF(2023), Section 5.1.2.1.

a multiplication contract, and are not intended for commercialisation[229]. In Austria[230] the "exchange of seeds for the protection of plant genetic resources between farmers and seed users" is exempted from the scope of the legislation under the following conditions (1) the farmer or seed user does not deal in seed trade, (2) the variety to which the exchanged PRM belongs is not registered in the Austrian national catalogue, the EU common catalogues or the OECD list for international seed trade (except for conservation and amateur varieties) and (3) within species-specific quantitative restrictions limiting the amounts that can be exchanged. In Italy, the national legislation was amended in 2021 to allow for in-kind exchange between farmers of a portion of their harvest[231]. The new legislation does not provide any detailed information regarding the conditions of exchange, including quantities or varieties that can be exchanged.

At international level, the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) recognises the rights of farmers "to save, use, exchange and sell farm-saved seed/propagating material, subject to national law and as appropriate"[232]. The United Nations Declaration on the Rights of Peasants and Other People Working in Rural Areas (UNDROP) also recognises that "peasants and other people working in rural areas have the right to save, use, exchange and sell their farm-saved seed or propagating material"[233].

2.4. Marketing to amateur gardeners

An amateur gardener means a person who engages in gardening as a hobby. A survey addressing amateur gardeners showed three major reasons for being involved in amateur gardening[234]. First, growing edible produce was an important reason for being involved in gardening. Second, amateur gardeners garden for enjoyment (i.e. as a hobby). Third, they garden to improve or maintain the appearance of their garden. These activities are outside the scope of the PRM legislation. For example, amateur gardeners can exchange or sell to each other PRM without any restriction.

PRM that is intended for marketing to amateur gardeners has to be authorised for marketing pursuant to the pillars of the PRM certification system (Figure 5). Consequently, the vast majority of PRM marketed to amateur gardeners belongs to registered varieties. The derogatory rules for acceptance of varieties and certification of seeds for agricultural and vegetable conservation varieties (Section 2.1.2.) cannot meet the demand of an important share of amateur gardeners for diverse and locally adapted varieties. Under the future legal framework, amateur gardeners will have the possibility to choose between more genetically diverse and less uniform PRM on the one hand and certified PRM on the other.

In 2020, France adopted a Regulation that excludes from the general PRM legislation the exclusive marketing to amateur gardeners of PRM that belongs to varieties that are not or no longer subject to intellectual property rights (i.e. plant variety rights)[235]. In practice this means that the varieties

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[229] https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000029585219/2014-10-15.
[230] Saatgutgesetz 1997 (Austrian seed law 1997) https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10011033.
[231] Decreto legislativo 2 febbraio 2021, n.20. https://www.normattiva.it/uri-res/N2Ls?urn:nir:stato:decreto.legislativo:2021;020
[232] https://www.fao.org/plant-treaty/overview/en/.
[233] https://digitallibrary.un.org/record/1650694.
[234] ICF(2021).
[235] LOI n° 2020-699 du 10 juin 2020.

concerned do not have to be registered in the French national catalogue and that the PRM does not have to be certified. The French Variety and Seed Study and Control Group (GEVES) further clarified that the varieties of PRM that are marketed to both professional users and amateur gardeners have to be registered in the French national catalogue[236].

2.5. Organic varieties suitable for organic production and organic heterogeneous material

Organic varieties suitable for organic production

According to the principles of the Organic Regulation, for the production of organic varieties suitable for organic production, the organic breeding activities shall be conducted under organic conditions and shall focus on enhancement of genetic diversity, reliance on natural reproductive ability, as well as agronomic performance, disease resistance and adaptation to diverse local soil and climate conditions. However, currently the biggest share of PRM for organic varieties marketed in the EU are varieties accepted under the DUS rules (this Annex, Section 2.1)[237]. Those varieties have a high degree of uniformity and this goes contrary to the aforementioned principle of focussing on an enhancement of genetic diversity.

Organic heterogeneous material

The Organic Regulation[238] has defined 'organic heterogeneous material' but the term 'heterogeneous material' does not exist in the PRM legislation. Organic heterogeneous material is characterised by a high level of genetic and phenotypic diversity between individual reproductive units. It is not a variety nor is it a mixture of varieties. The Organic Regulation allows the marketing of organic heterogeneous material without complying with the requirements for registration and without complying with the certification categories of pre-basic, basic and certified material or with the quality, health and identity requirements for *Conformitas Agraria Communitatis* (CAC), standard or commercial categories, set out in the PRM legislation. This derogation from the PRM legislation for organic heterogeneous material has responded to the demand for more genetically diverse PRM. The production of this type of material is restricted to certified organic producers.

2.6. Conservation varieties

For decades since the introduction of the first seed marketing directives, only DUS varieties were allowed to be marketed. As the questions of biodiversity and the conservation of plant genetic resources grew in importance, derogations to the rules for acceptance of varieties and certification of seeds were adopted for agricultural and vegetable landraces in 2008[239] and 2009[240] respectively (termed as 'conservation varieties'). Derogations were also introduced in 2010 for marketing fodder

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[236] https://www.geves.fr/actualites/suppression-de-lobligation-dinscription-au-catalogue-officiel-francais-des-varietes-du-domaine-public-pour-les-amateurs%E2%80%AF-quen-est-il-precisement%E2%80%AF/#:~:text=La%20loi%20n%C2%B0%202020,Catalogue%20officiel%2C%20fran%C3%A7ais%20ou%20europ%C3%A9en

[237] Euroseeds (2019).

[238] Regulation (EU) 2018/848 and Commission Delegated Regulation (EU) 2021/1189.

[239] Commission Directive 2008/62/EC

[240] Commission Directive 2009/145/EC

plant mixtures for use in preservation of the environment[241]. Agricultural and vegetable conservation varieties can be registered with reduced uniformity requirements (even with unofficial tests instead of DUS) and without VCU for agricultural plant species. A historical linkage to their region of origin is required. Maintenance and marketing is restricted within that region of origin. Furthermore, the Directives require that in order to benefit from these derogations, it is established that the varieties are threatened by genetic erosion. The Directives also set quantitative restrictions on the seed quantities that can be marketed annually for each conservation variety. In addition to the vegetable conservation varieties, the category of "vegetable varieties with no intrinsic value for commercial crop production that have been developed under particular conditions", otherwise known as 'amateur' varieties has been established. These are not subject to geographic or quantitative restrictions, but their seeds have to be marketed in small packages (i.e. addressed to amateur gardeners).

At the end of 2021, there were 396 conservation varieties of agricultural plant species and 177 of vegetable species registered in the common catalogues (representing around 1% of the total number of varieties)[242], i.e. the impact of these derogations has been minimal. Many landraces are cultivated in very small areas and even the derogations regime is considered too burdensome for these. The little volume of business that can be obtained from the seed commercialisation of conservation varieties (due to the quantitative and geographic restrictions) are evoked as one of the reasons for the low number of such varieties being registered in the Common Catalogues[243]. Finally, the derogations for conservation varieties are not catering for new approaches such as participatory plant breeding methodologies that aim to develop new locally adapted varieties.

3. PRINCIPLES OF THE FRM LEGISLATION

The principles of the FRM legislation are quite different from those of the PRM legislation. The FRM system relies on approved trees called 'basic material'. These trees have been selected for superior characteristics (e.g. morphological features, wood quality, health, and resistance) and from which seeds and other reproductive material will be harvested, certified, and marketed in lots (Figure 7). FRM is an important driver of the forest-based industries (timber, pulp, furniture,…).

[241] Commission Directive 2010/60/EU.
[242] Data retrieved from the Common Catalogues.
[243] Spataro G. and Negri V. (2013)

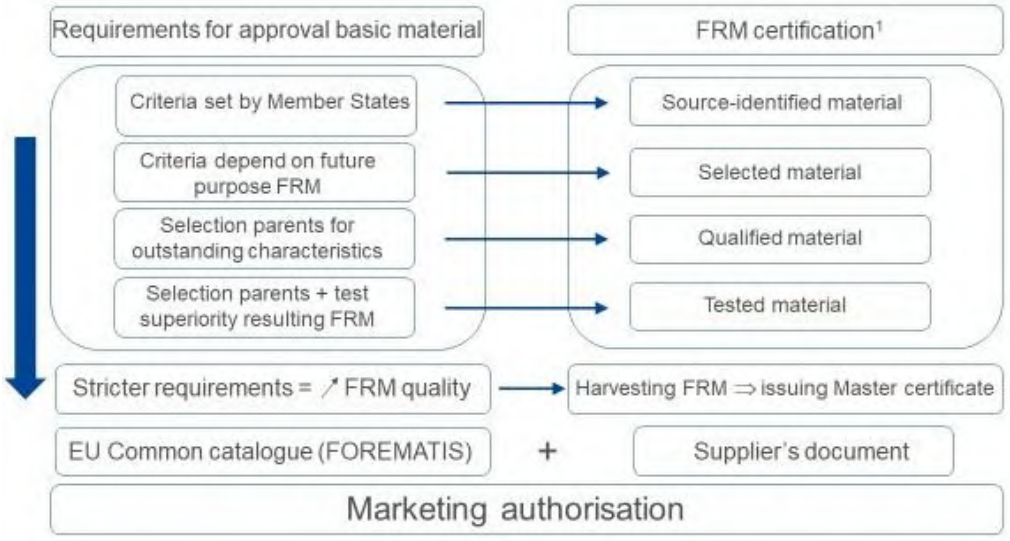

Figure 7. Pillars of the FRM certification scheme
[1] During certification the identity, quality and health of FRM is checked
⬇ Stricter requirements for approval of basic material result in higher FRM quality and higher market value of FRM

For lower quality FRM, basic material will be checked for basic characteristics (e.g. straightness of the trunk and symmetry of the side branches). In the case of source-identified material the EU legislation requires that the basic material is a seed source or stand of trees located within a single region of provenance[244]. The EU legislation does not describe any criteria to be met by that seed source and stand[245]. The selection criteria are left at the discretion of the MS. For higher quality FRM, parent trees will be selected for outstanding characteristics and crossing schemes designed. NCAs approve basic material through an official inspection following which basic material is registered in the national catalogue of the MS concerned and subsequently in the EU Common Catalogue. Upon harvesting seeds and other FRM from basic material NCAs issue a Master certificate[246]. FRM has to meet the relevant requirements (age, development, health and resistance of trees in stands to adverse climatic conditions) before the operator can issue a supplier's document or supplier's label.

The registration of basic material, the Master certificate and the supplier's document/label are prerequisites for the marketing of FRM throughout the EU (Figure 7). Seeds of agricultural crops are produced, certified, and harvested in cycles of one year, while in the case of FRM it may take 50-100 years before seeds and forest plants can be harvested from basic material[247]. Global warming has a negative and increasing impact on Europe's forests by shifting biogeographical regions northwards and uphill. FRM that used to be optimal for a given region may no longer be fit

[244] The provenance is the place in which trees are growing. It is also called the geographic source. For a tree species, the region of provenance is an area or group of areas subject to sufficiently uniform ecological conditions in which stands or seed sources showing similar phenotypic or genetic characters are found.
[245] Annex II to Council Directive 1999/105/EC. OJ L 11, 15.1.2000, p. 17.
[246] The Master certificate provides details about the harvested FRM such as: botanical name, type of FRM (seed unit, planting stock,…), FRM category (source-identified, selected, qualified or tested material), origin of basic material etc.
[247] In the Northern part of Finland and Sweden (e.g. Lapland), the main tree species (e.g. Norway spruce and Scotch pine) only flower once in a decade.

for that region because of the changing climatic conditions. This makes FRM diversity even more essential.

The current FRM legislation does not require MS to undertake provenance trials. In such trials, material of different provenances is planted in a single place or at different locations spanning a range of environmental conditions. These trials serve to reveal genetic variation among provenances, as well as differences in the ability of the trees from different provenances to react to fluctuating environmental conditions. Provenance trials rely on the observation of the phenotypic characteristics of the trees. Combining molecular markers with provenance trials provides information on the geographical scale of local adaptation. This information is crucial for selecting and using FRM in different sites and habitats. The outcome of such provenance trials would provide information about the area in which FRM is adapted and this would in turn allow FRM users to take informed decisions on where to best plant FRM. The existing derogatory regime for the **conservation of forest genetic resources**[248] has not been applied by any MS. This is because the requirements for basic material intended for the purpose of conserving forest genetic resources are totally different from those of basic material for commercial FRM production. For conservation small quantities that do not meet the requirements of basic material for commercial use are needed[249]. Actions to conserve forest genetic resources are taken at national or regional levels, with the result that knowledge about the conservation and sustainable use of forest genetic resources is scattered across the EU.

4. INTERACTION WITH OTHER EU POLICIES AND INSTRUMENTS

The revision of the PRM and FRM legislation will ensure coherence with the EGD, its implementing strategies, Common Agricultural Policy and the European Digital Strategy as described in Figure 8.

[248] Article 2(4) to Directive 1999/105/EC.

[249] For conservation purposes the entire collection of trees should be kept while only trees with superior characteristics will be selected in the case of basic material for commercial purposes. It would be necessary to lay down requirements that are specific for basic material intended for the purpose of conserving forest genetic resources. Examples of material not meeting the requirements of the FRM rules are vegetative material of poplars for conservation or restoration activities, seed orchards for conservation purposes and FRM conserved in *in situ* and *ex situ* genebanks.

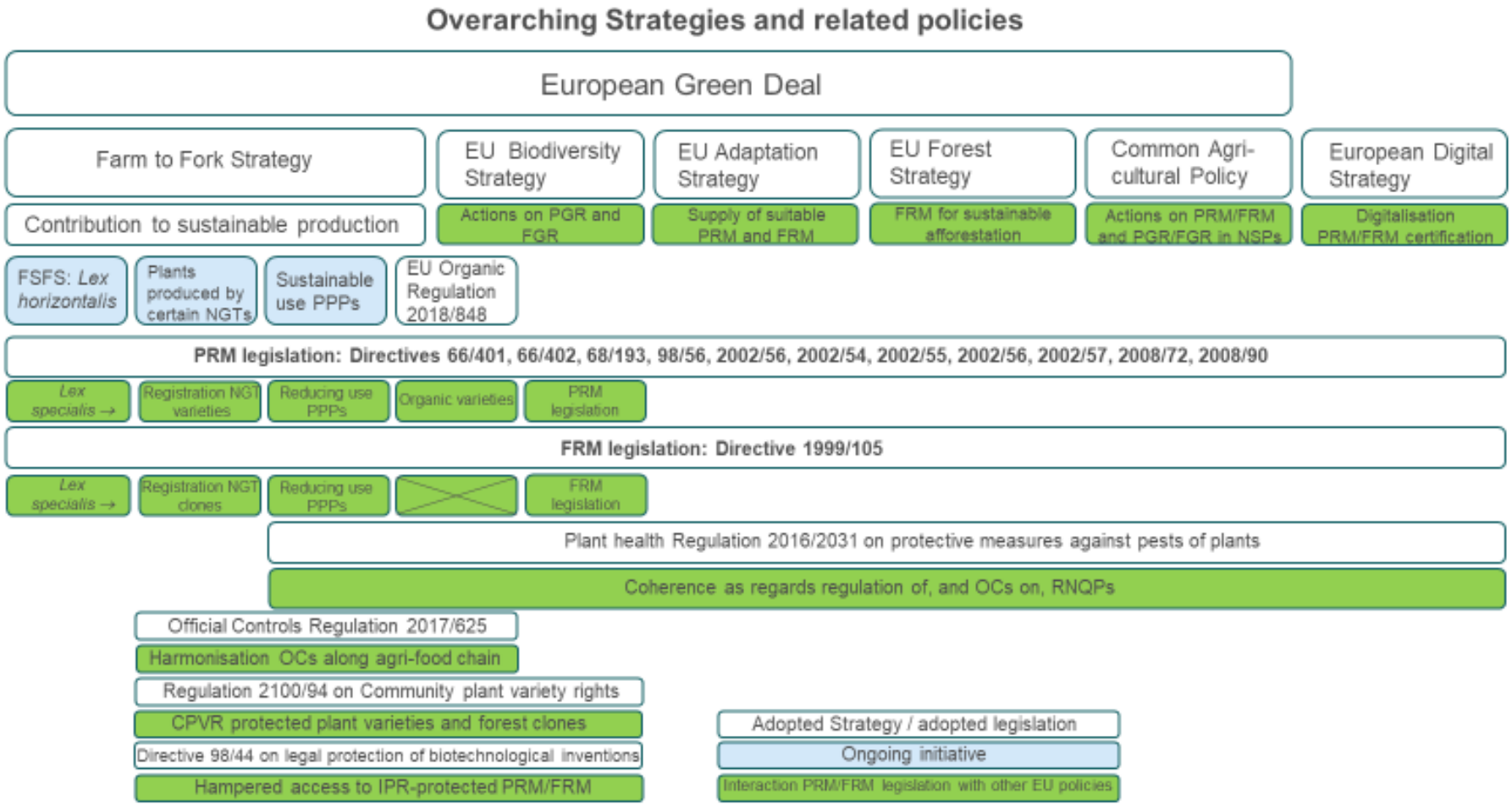

Figure 8. Interaction with other EU policies and instruments

5. INTERACTION BETWEEN FSFS, PRM/FRM AND NGTS

Figure 9 represents the interaction between the overarching legal framework of the FSFS initiative and the sectoral initiatives on PRM/FRM and NGTs.

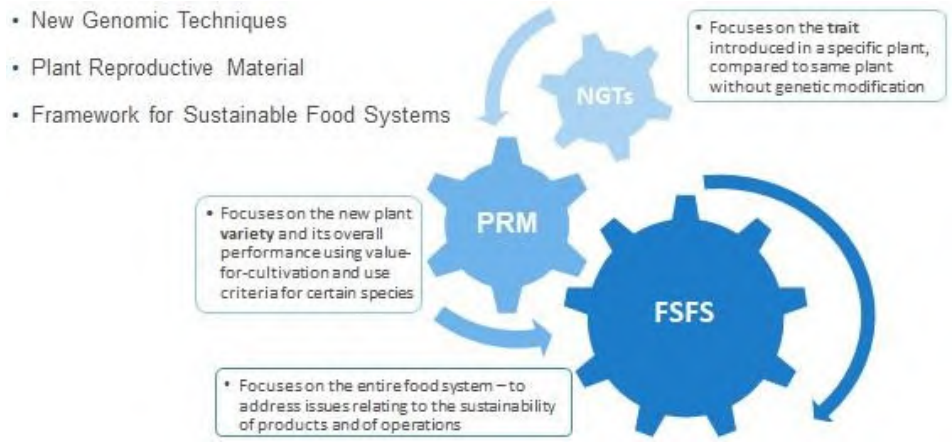

Figure 9. Interaction PRM/FRM initiative with NGT and FSFS initiatives

6. INTERPLAY BETWEEN PRM/FRM AND NGT INITIATIVES AS REGARDS SUSTAINABILITY PROVISIONS

The scope of the NGT initiative covers all plant species, while the PRM/FRM initiative covers only the economically most important species for European agriculture, horticulture and forestry.

Under all options of the PRM/FRM initiative the assessment of sustainability characteristics will be extended to all crop groups/FRM categories beyond agricultural crops on a voluntary (option 1) or mandatory basis (options 2 and 3). Both the current VCU for agricultural crops and vine and the envisaged extended sustainability assessment under the PRM initiative examine in field trials the **overall performance of new varieties** of the regulated species compared to varieties in the national catalogues in relation to a number of characteristics that would go beyond one or more introduced traits. The same principle of an overall assessment of basic material in relation to a number of defined sustainability characteristics holds true for FRM. The PRM/FRM systems will not provide for the possibility to reject a variety or basic material based on a single trait as inferior characteristics may be discarded if the variety/basic material as a whole offers clear improvements in comparison with existing varieties/basic material.

The NGT initiative will regulate the deliberate release including placing on the market of plants produced using targeted mutagenesis and cisgenesis. NGT plants of the species subject to the PRM/FRM initiative will need to follow the regulatory procedures of the NGT initiative for their release and will also be subject to the variety performance assessment of the PRM/FRM. These two procedures will remain distinct and will apply consecutively, in the same way as today GMOs are authorised under the GMO legislation prior to the variety assessment (where applicable) under PRM/PRM.

The NGT initiative is considering options that include certain sustainability-related provisions as well as options that do not. Should the preferred option include sustainability considerations, the

coherence between the approaches to sustainability will need to be ensured on the basis of the following considerations:

- The NGT initiative considers plants from the perspective of the genetic modification introduced. In that regard, any sustainability-related provisions (if introduced) would focus only on the potential of an individual trait introduced to contribute to sustainability (as opposed to the overall performance in the PRM/FRM systems).
- The sustainability considerations relating to an individual trait in the NGT initiative (if any) would not replace the conduct of or prejudge the outcome of the overall assessment of performance in the PRM/FRM systems.
- Should regulatory consequences in the context of the specific procedure to deliberately release / place NGTs on the market be introduced in the NGT initiative for specific traits as regards their potential contribution to sustainability, the relevant traits would need to be coherent with the list of VCU/sustainability characteristics.

7. INTERPLAY BETWEEN PRM/FRM LEGISLATION AND PHL

Union regulated non-quarantine pests (RNQPs) are currently regulated both under the PHL and under the marketing Directives as part of the certification requirements. In certain cases, the RNQP provisions overlap (Table 30). Furthermore, amendments to the PHL and the marketing Directives are not simultaneous, because changes to the PHL are directly applicable while changes to the marketing Directives need to be transposed into national legislation.

Regulation of RNQPs under PHL

Implementing Regulation (EU) 2019/2072 sets out specific measures for QPs and RNQPs. Article 5 and Annex IV of that Implementing Regulation establish the list of plants and the respective thresholds of RNQPs, for internal movement and import while Article 6 and Annex V establish the measures to be taken in the fields and on the lots of the plants, for internal movement and imports in order to comply with those thresholds. With the exception of the measures against RNQPs of fruit plants and vine, the RNQP measures are laid down in Annex V to Implementing Regulation (EU) 2019/2072. RNQPs for FRM are exclusively regulated under Implementing Regulation (EU) 2019/2072 and thus not under Council Directive 1999/105.

Regulation of RNQPs under marketing Directives

RNQPs are regulated under several PRM acts (Table 30). Currently there are no RNQPs for beet seed (Directive 2002/54).

In 2020, the provisions of the PRM/FRM legislation were aligned with the requirements of the PHL including the requirements of Annex V to Implementing Regulation (EU) 2019/2072 through the following clause: the material "*shall also comply with the requirements concerning Union QPs, protected zone QPs and RNQPs provided for in implementing acts adopted pursuant to Regulation (EU) 2016/2031 as well as the measures adopted pursuant to Article 30(1) of that Regulation*". This means that compliance with RNQP rules, as well as rules on QPs, is a requirement for the issuance of an official label (under the PRM legislation) or a supplier's label/document (under the FRM legislation) following the certification process (official or under official supervision), as applicable per marketing category of PRM (i.e. pre-basic, basic or certified) or FRM (source-

identified, selected, qualified or tested). Compliance with RNQP and QP rules is also a requirement for the issuance of a supplier's label following a verification process for standard/*Conformitas Agraria Communitatis* (CAC) material). However, the measures on RNQPs for fruit plants and vine are only included in the respective acts (Commission Implementing Directive 2014/98 and Annexes to Council Directive 68/193) and not in Annex V to Implementing Regulation (EU) 2019/2072.

Type of PRM/FRM	**PHL: relevant reference under Implementing Regulation 2019/2072)**	**PRM/FRM: relevant reference in PRM/FRM marketing Directive**
Fodder plant seed	Part A of Annex IV Part A of Annex V	**Council Directive 66/401:** **Article 2(3) A and B** Point 5 of Annex I and point 3 of Annex II: duplication of Part A of Annex IV (see column 2)
Cereal seed	Part B of Annex IV Part B of Annex V	**Council Directive 66/402:** **Article 2(3) A and B** Point 5 of Annex I and point 3 of Annex II: duplication of Part B of Annex IV (see column 2)
Vine	Part C of Annex IV	**Council Directive 68/193:** Annex I: duplication of Part C of Annex IV (see column 2) RNQP measures set out exclusively under PRM and not in Annex V to Implementing Regulation 2019/2072
Ornamental plants	Part D of Annex IV Part C of Annex V	**Commission Directive 93/49:** Annex: duplication of Part D of Annex IV (see column 2)
FRM	Part E of Annex IV Part D of Annex V	**Council Directive 1999/105:** No listing of RNQPs and thus no duplication of Part E of Annex IV (see column 2)
Beet seed	Currently no RNQPs	**Council Directive 2002/54:** Currently no RNQPs
Vegetable seed	Part F of Annex IV Part E of Annex V	**Council Directive 2002/55:** Annex II: duplication of Part F of Annex IV (see column 2)
Seed potatoes	Part G of Annex IV Part F of Annex V	**Council Directive 2002/56:** Article 3 (only official certification) Annexes I and II: duplication of Part G of Annex IV (see column 2)
Seed of oil and fibre plants	Part H of Annex IV Part G of Annex V	**Council Directive 2002/57:** **Article 2(3) A and B** Annex II: duplication of Part H of

		Annex IV (see column 2)
Vegetable propagating material	Part I of Annex IV Part H of Annex V	**Commission Directive 93/61:** Annex: duplication of Part I of Annex IV (see column 2)
Fruit plants	Part J of Annex IV	**Commission Implementing Directive 2014/98:** Annexes I, II and III: duplication of Part J of Annex IV (see column 2) RNQP measures set out exclusively under PRM and not in Annex V to Implementing Regulation 2019/2072
Seed of *Solanum tuberosum* L.	Part K of Annex IV Part I of Annex V	**Not regulated** under Directive 2002/56 on seed potatoes
Plants for planting of *Humulus lupulus* L. other than seeds	Part L of Annex IV Part J of Annex V	Plant species **not regulated** under the marketing Directives
Fruit propagating material and fruit plants intended for fruit production of *Actinidia* Lindl. other than seeds	Part M of Annex IV Part K of Annex V	Plant species **not regulated** under Council Directive 2008/90 on fruit plants

Table 30. Overview of RNQPs per type of PRM and FRM and their regulation in the PHL and marketing Directives. Annex IV to Implementing Regulation (EU) 2019/2072 lists the RNQPs and specific plants for planting with marketing categories and thresholds. Annex V to Implementing Regulation (EU) 2019/2072 lists the measures to prevent the presence of RNQPs on specific plants for planting

Currently, RNQPs are regulated both under the PHL and under the marketing Directives. Under the PHL, plant passports are issued if it is confirmed that the plants are free from QPs and also comply with the RNQP thresholds (Annex IV to Implementing Regulation 2019/2072). Under the PRM/FRM legislation, official labels (or supplier's labels) are issued if it is confirmed that the plants comply with the RNQP thresholds. Compliance with those thresholds is ensured through measures under the regulated certification system (officially or under official supervision): inspections in the field/production place/production site and sampling and testing of the lots of the PRM intended for marketing/internal movement. These measures are laid down in Annex V to Implementing Regulation 2019/2072. However, the rules on the certification system as such are missing (notification of fields to NCAs, data provision and authorisation process to carry out certification under official supervision). In the case of fruit plants these measures are described in Commission Implementing Directive 2014/98 and in the case of vine in Council Directive 68/193.

The PHL falls under the scope of the OCR while the marketing Directives do not. Where risk management measures against RNQPs are regulated under the marketing Directives (fruit plants and vines) while the RNQPs are listed in the PHL, there is uncertainty as to whether RNQPs fall under the scope of the OCR.

The regulation of RNQPs under the PRM/FRM and PHL frameworks, the overlaps between those frameworks and the different scope of OCs (inside/outside the OCR) leads to uncertainty for MS and operators about which legislation to adhere to. Consequently, this also results in differences in implementation and conditions for the operators that could eventually undermine the enforcement and the quality of controls.

Currently, in 12 out of 27 MS the inspections for RNQPs have been delegated to the NCA responsible for PRM certification.

8. INNOVATION AND DIGITALISATION

The application of BMTs in variety registration and PRM/FRM certification

BMTs is a group of molecular biological techniques comprising amongst others DNA sequencing, molecular markers, genotyping and polymerase chain reaction. BMTs are a promising tool for plant breeding and PRM certification because they can speed up the identification of plant varieties with interesting traits. In FRM certification, BMTs can help to certify the origin of FRM, i.e. to confirm that FRM has been harvested from a particular seed source.

Several EU Horizon 2020 research projects explore the potential of BMTs in variety testing. The CPVO has created an *ad hoc* working group on the 'Integration of molecular data into DUS testing' (IMMODUS) and published the CPVO IMMODUS strategy paper in 2017[250]. The 'Innovation in variety testing' (INVITE) project seeks to develop new phenotyping and genotyping tools to measure bioindicators associated with plant resource use efficiency, sustainability and resilience. It aims to improve both the efficiency of variety testing and the information available to stakeholders on variety performance under a range of production conditions and biotic and abiotic stresses[251]. The 'Innovations in plant variety testing' (Innovar) project aims to augment and improve the efficacy and accuracy of European crop variety testing and decision-making using an integrated approach incorporating genomics, phenomics and machine learning[252].

In PRM, BMTs can be used to speed up DUS testing during the variety registration process or to allow the rapid and precise confirmation of the identity of the variety during the PRM certification process and the marketing controls. The DUS test serves to compare the candidate variety with a number of existing plant varieties ('reference varieties'). BMTs can help identify which plant varieties show the highest level of similarity with the candidate variety thus accelerating the selection of reference varieties for variety examination. During marketing controls, samples of the marketed PRM are taken and grown in the field whereby the variety to be checked is compared to the sample of the variety that was retained at the time of variety registration ('control plot testing').

Sometimes the observation of the phenotypic characteristics of the variety during the DUS test can be difficult because the morphological characteristics are not well-expressed. Likewise, the control plot tests, carried out in the frame of marketing controls, can be inconclusive. Moreover, the large number of existing varieties, together with the great dynamism of the market as regards new varieties in many species, make it impossible for inspectors to have technical knowledge of all existing varieties, as it is impossible to be trained to know hundreds of varieties. This is aggravated by staff turnover, which makes it in some cases difficult to acquire knowledge through experience.

The OECD Seed Schemes have developed a general rule for the situation when field inspection and control plot testing are inconclusive. In that case, they allow the use of any other test to obtain

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[250] https://cpvo.europa.eu/sites/default/files/documents/cpvo_imoddus_strategy_paper-endorsed_ac_march2017.pdf
[251] https://www.h2020-invite.eu/
[252] https://www.h2020innovar.eu/variety-testing-community/

supplementary information in support of the certification decision for the seed lot concerned including internationally recognised biochemical and molecular techniques performed by an official laboratory[253]. Moreover, the OECD maintains a list of internationally recognised methods that are currently used by the National Designated Authorities.

UPOV has so far developed two models for the use of BMTs in variety testing. The first concerns the use of BMTs for identifying in the variety reference collection (i.e. varieties of common knowledge in the EU) the varieties with the highest level of similarity to the candidate variety for the purpose of the DUS test. The second concerns the use of trait-specific molecular markers whereby the reliability of the link between the marker and the trait is verified[254]. UPOV, OECD and the International seed testing association have joint initiatives in relation to BMTs. In spite of the fact that BMTs offer the means to increase the efficiency of PRM/FRM certification and render the PRM/FRM sector more competitive, the PRM/FRM legal framework currently does not contain any common rules on BMTs that explicitly allow the use of BMTs, with the exception of the verification of varietal identity in the certification of agricultural plant species[255]. This creates legal uncertainty around the use of BMTs. For example, during marketing controls the verification of the identity of the variety by means of BMTs could be contested in the case of fraud due to the absence of a legal framework. As described above, the OECD and UPOV allow the use of BMTs under certain conditions. This has led certain MS to adopt national approaches on BMTs while others have not[256]. Additionally, the PRM/FRM legal framework is increasingly diverging from the ongoing developments at international level.

Digitalisation

The EU digital strategy aims to make the transformation to digital technologies work for people and businesses, while helping to achieve its target of a climate-neutral Europe by 2050. The PRM/FRM legal framework does not contain any common rules on the use of digital technologies. COVID-19 has demonstrated that digital technologies can help improve the resilience of agricultural supply chains during emergency situations by issuing digital certificates. Moreover, the use of digital certificates and documents reduces the risk of fraud. Therefore, the use of digital labels and certificates should also be introduced in the PRM/FRM legislation. The OECD Seed Schemes and the OECD Forest Scheme already use digital labels. Those labels can be downloaded from a secure website. If the National Designated Authority of an OECD member country wants to use digital labels for the marketing of PRM/FRM, they need to complete the digital label and ask the OECD Secretariat to authorise the use of those digital labels.

The use of digital technologies can be taken a step further by digitalising the entire seed certification system. The OECD Secretariat has conducted a feasibility study on this topic that was finalised in 2021. In 2023, the OECD Secretariat will launch a project on digitalisation of the OECD Seed Schemes applied to the seed certification system for seed moving in international trade, with the intention to develop a seed certification hub where all certification information will

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[253] OECD Seed Schemes Rule and Regulations 2022, common rules 7.4.5.1.
[254] UPOV TGP15: Guidance on the Use of Biochemical and Molecular Markers in the Examination of Distinctness, Uniformity and Stability (DUS).
[255] Commission Implementing Directive (EU) 2021/971.
[256] For example, in Spain BMTs are used in plant breeding, to select reference varieties for the DUS test and to carry out marketing controls. In Germany, BMTs are used to certify the origin of FRM.

be stored. In the future this can be augmented by the use of blockchain technology. A blockchain keeps records shared between parties in a network and stores information about all transactions between those parties in a chronological order. The advantage is that there is no central record-keeping authority. The advantages that have been identified in OECD's feasibility study would also apply to PRM/FRM certification. Digitalisation represents a significant opportunity to future-proof the existing certification system and modernise the PRM and FRM sector.

The following benefits are expected from digitalisation of PRM/FRM certification:

- Efficiency gains and cost reduction: reduced administrative burden, simplified reporting requirements, reduced transition costs, and identification of new opportunities.
- Risk reduction: increased trust in the EU certification framework by reducing the risk of fraudulent products and increasing transparency and traceability.
- Business continuity: build a more resilient PRM/FRM sector, help protect supply chains against future disruptions and help identify and manage risks more quickly.
- Spark innovation: create a sustainable future for the PRM/FRM sector and the value chain that utilises certified PRM/FRM.

There are also some disadvantages of digital transformation of the agri-food sector. It involves significant transaction and infrastructure costs[257]. For the transformation to be successful all parties involved should be able to benefit from it[258]. There are concerns that not all stakeholders or MS will. It may be economically challenging for SMEs to adapt to new technologies bringing them in a disadvantageous position in comparison to larger enterprises. Most NCAs agreed that the cost of the technology should decrease for the benefits of its implementation to outweigh the risks as regards the security of new technology and costs. They recognised that there are already systems in place that could be extended and applied in the PRM sector with one NCA stating that in most MS data is already digitalised[259].

[257] Goedde, Lutz, Joshua Katz, Alexandre Menard and Julien Revellat (2020) Agriculture's connected future: How technology can yield new growth. McKinsey. Available at: https://www.mckinsey.com/industries/agriculture/our-insights/agricultures-connected-future-how-technology-can-yield-new-growth#

[258] Wang, Y., Han, J. H., and Beynon-Davies, P. (2019). Understanding blockchain technology for future supply chains: a systematic literature review and research agenda. Supply Chain Management: An International Journal.

[259] Reponses to interviews Section 4.2.2.4 to ICF(2021) Data gathering study.

9. OFFICIAL CONTROLS

9.1. Legal analysis

Table 19 compares the requirements on OCs in the PRM and FRM Directives with those in the OCR. To allow this comparison the provisions in several PRM Directives on official certification and the issuance of an official label were interpreted as provisions on 'official attestations' within the meaning of the OCR. The OCR makes provisions on official attestations issued by operators under the official supervision of the NCAs, or by the NCAs themselves. However, in the PRM/FRM legislation official certification is a product authorisation process. In the case of the PRM and FRM legislation this means that official certification and the issuance of an official label can only be decided by the NCAs themselves (Annex 5, Section 2.2.1.).

Table 19. Requirements on official controls in the PRM and FRM marketing Directives against OCR requirements

OCR requirements	PRM and FRM Directives											
	Directive 66/401/EEC – marketing of fodder plant seed	Directive 66/402/EEC – marketing of cereal seed	Directive 2002/53/EC – common catalogue of agricultural plant species	Directive 2002/54/EC – marketing of beet seed	Directive 2002/55/EC – marketing of vegetable seed	Directive 2002/56/EC – marketing of seed potatoes	Directive 2002/57/EC – marketing of seed of oil and fibre plants	Directive 68/193/EEC – marketing of material for the propagation of the vine	Directive 1998/56/EC – marketing of propagating material of ornamental plants	Directive 2008/72/EC – marketing of vegetable material, other than seed	Directive 2008/90/EC – marketing of fruit propagating material and fruit plants for fruit production	Directive 1999/105/EC – marketing of forest reproductive material

OCR requirements	PRM and FRM Directives											
	Directive 66/401/EEC – marketing of fodder plant seed	Directive 66/402/EEC – marketing of cereal seed	Directive 2002/53/EC – common catalogue of agricultural plant species	Directive 2002/54/EC – marketing of beet seed	Directive 2002/55/EC – marketing of vegetable seed	Directive 2002/56/EC – marketing of seed potatoes	Directive 2002/57/EC – marketing of seed of oil and fibre plants	Directive 68/193/EEC – marketing of material for the propagation of the vine	Directive 1998/56/EC – marketing of propagating material of ornamental plants	Directive 2008/72/EC – marketing of vegetable material, other than seed	Directive 2008/90/EC – marketing of fruit propagating material and fruit plants for fruit production	Directive 1999/105/EC – marketing of forest reproductive material
Definitions (Art. 2 and 3)	N Only a definition of 'official measures' [260]	N Only a definition of 'official measures'[261]	Y Definition of 'official measures'[262]	N Only a definition of 'official measures'[263]	N Only a definition of 'official measures'[264]	N Only a definition of 'official measure[265]	N Only a definition of 'official measures'[266]	N Only a definition of official measures[267]	Y Definition of 'supplier', 'responsible official body'[268].	Y Definition of 'supplier', 'responsible official body'[269]; 'official measures'[270]; 'official inspection'[271]; 'official statement'[272]	Y Definition of 'supplier', 'responsible official body'[273], "official inspection'[274]	Y Only a definition of 'supplier', 'official body'[275]

[260] Art. 1.E: "Official measures: measures taken (a) by State authorities, or (b) by any legal person whether governed by public or by private law, acting under the responsibility of the State, or (c) in the case of ancillary activities which are also subject to State control, by any natural person duly sworn for that purpose, provided that the persons mentioned under (b) and (c) derive no private gain from such measures." Key concepts not defined such as: 'official inspections'; 'official inspectors'; 'official examination'; 'seed certification authority'; 'official seed samplers'; 'official label'; 'official seal'.
[261] Art. 2(1)(H), *Ibidem*. Key concepts not defined such as: 'official inspections'; 'official inspectors'; 'official examination'; 'seed certification authority'; 'official seed samplers'; 'official label'; 'official seal'.
[262] Article 2.
[263] Article 1(g). Ibidem.
[264]Article 2(1)(f), *Ibidem*. Key concepts not defined such as: 'official inspections'; 'official inspectors'; 'official examination'; 'seed certification authority'; 'official seed samplers'.; 'official label' ; 'official seal'.
[265] Article 2(d), *Ibidem*. Key concepts not defined such as: such as: 'official inspections'; 'official examination'; 'certification authority'; 'official label'; 'official seal'.
[266] Article 2(1)(k), *Ibidem*. Key concepts not defined such as: 'official inspections'; 'official inspectors'; 'official examination'; 'seed certification authority'; 'official seed samplers'; 'official label'; 'official seal.
[267] Article 2(1)(H), Ibidem. Key concepts not defined, such as 'official control authority'; 'official inspection'; 'official examination';'officially certified'; ''officially checked' ; 'official label'; 'official controls'.
[268] Article 2(4) : « 'Responsible official body': (a) an authority, established or designated by the Member State under the supervision of the national government and responsible for questions concerning quality; (b) any State authority established: — either at national level, or — at regional level, under the supervision of national authorities, within the limits set by the constitution of the Member State concerned".
[269] Article 3(e): « 'responsible official body' means: (i) the sole and central authority, established or designated by the Member State under the supervision of the national government and responsible for questions concerning quality; (ii) any State authority established: — either at national level, — or at regional level, under the supervision of the national authorities within the limits set by the national legislation of the Member State concerned.".
[270] Article 3(f): "'official measures' means measures taken by the responsible official body;".
[271] Article 3(g): « 'official inspection' means an inspection carried out by the responsible official body;".
[272] Article 3(h) : « 'official statement' means a statement issued by, or under the responsibility of, the responsible official body;".
[273] Article 2(11): " 'responsible official body' means: (a) an authority, established or designated by the Member State under the supervision of the national government and responsible for questions concerning the quality of propagating material and fruit plants; (b) any State authority established: — either at national level, or — at regional level, under the supervision of the national authorities, within the limits set by the national legislation of the Member State concerned;".

OCR requirements	PRM and FRM Directives											
	Directive 66/401/EEC – marketing of fodder plant seed	Directive 66/402/EEC – marketing of cereal seed	Directive 2002/53/EC – common catalogue of agricultural plant species	Directive 2002/54/EC – marketing of beet seed	Directive 2002/55/EC – marketing of vegetable seed	Directive 2002/56/EC – marketing of seed potatoes	Directive 2002/57/EC – marketing of seed of oil and fibre plants	Directive 68/193/EEC – marketing of material for the propagation of the vine	Directive 1998/56/EC – marketing of propagating material of ornamental plants	Directive 2008/72/EC – marketing of vegetable material, other than seed	Directive 2008/90/EC – marketing of fruit propagating material and fruit plants for fruit production	Directive 1999/105/EC – marketing of forest reproductive material
Rules on competent authorities[276] (Art. 4 to 8)	N[277] .	N[278]	Y Confidentiality obligations[279], other obligations of competent authorities[280]	N[281]	Y Provisions on confidentiality obligations[282]	N	Y Limited provisions on confidentiality obligations[283]	N	Y Limited in the form of: designation of a responsible official body[284] and notification thereof to the Commission [285]; official registration of suppliers[286]	Y Limited in the form of designation of a responsible official body and notification thereof to the Commission[287]	Y Limited in the form of designation of a responsible official body; official registration of suppliers[288]	Y Limited in the form of designation of an official body and notification thereof to the Commission [289]; official registration of

[274] Article 2(12): "'official inspection' means inspection carried out by the responsible official body or under the responsibility of the responsible official body;"
[275] Article 2(k): 'Official body: (i) an authority, established or designated by the Member State under the supervision of the national government and responsible for questions concerning the control of marketing and/or the quality of FRM; (ii) any State authority established:
- either at national level, or- at regional level, under the supervision of national authorities, within the limits set by the constitution of the Member State concerned.".
[276] i.e. designation, general obligations, audits, right of appeal, confidentiality obligations.".
[277] There are rules on the responsibilities of the seed certification authority prior to certification, in particular in the context of official examination under supervision, with no further specifications.
[278] There are rules on the responsibilities of the seed certification authority prior to certification, in particular in the context of official examination under supervision) with no further specifications.
[279] Art. 7(3).
[280] Where acceptance of a variety is refused or revoked, the results of the examinations shall be made available to persons affected by such decision (Art. 10(5)).
[281] There are rules on the responsibilities of the seed certification authority prior to certification, in particular in the context of official examination under supervision) with no further specifications.
[282] Article 7(3) (in the framework of examination of the genealogical components, obligation to treat as confidential the results of the examination and the description of the genealogical components, if the breeder so requests); Article 10(3) (information exchanged by MS and the Commission in relation to the files compiled by MS on each variety accepted must be treated as confidential); Article 10(5) - in case the acceptance of a variety is refused or revoked, the results of the examinations shall be made available to persons affected by such decision.
[283] Article 8: « Member States shall provide that the description of genealogical components which may be required is, if the breeder so requests, treated as confidential.".
[284] Article 2(4)(a) and (b).
[285] Article 2(4), last subparagraph.
[286] Article 6.
[287] Article 3(e).
[288] Article 5(1).
[289] Article 2(k) last subparagraph.

OCR requirements	PRM and FRM Directives											
	Directive 66/401/EEC – marketing of fodder plant seed	Directive 66/402/EEC – marketing of cereal seed	Directive 2002/53/EC – common catalogue of agricultural plant species	Directive 2002/54/EC – marketing of beet seed	Directive 2002/55/EC – marketing of vegetable seed	Directive 2002/56/EC – marketing of seed potatoes	Directive 2002/57/EC – marketing of seed of oil and fibre plants	Directive 68/193/EEC – marketing of material for the propagation of the vine	Directive 1998/56/EC – marketing of propagating material of ornamental plants	Directive 2008/72/EC – marketing of vegetable material, other than seed	Directive 2008/90/EC – marketing of fruit propagating material and fruit plants for fruit production	Directive 1999/105/EC – marketing of forest reproductive material
												suppliers[290]
Risk based controls[291] (Art. 9(1) and (2))	N - random checks on marketing[292]; fixed percentage of checks for official supervision (5%)	N - random checks on marketing[293]; fixed percentage of checks for official supervision (5%)	N	N - random checks onmarketing[294];fixed percentage of checks for official supervision (5%)	N -random checks on marketing[295]; fixed percentage of checks for official supervision (5%)	N - random checks on marketing[296]	N -random checks[297]; fixed percentage of checks for official supervision (5%)	N	N	N	Y In the form of sampling and testing requirements on the basis of an assessment of the risk of infection of plants[298]	N

[290] Article 6(4).
[291] with appropriate frequency, including criteria for risk-based controls and including to identify fraudulent activities.
[292] Article 19(1): "Member States shall ensure that official inspections are carried out in relation to the marketing of fodder plant seed, at least by random checks, to verify compliance with the requirements and conditions of this Directive."
[293] Article 19(1): " Member States shall ensure that official inspections are carried out in relation to the marketing, at least by random checks, to verify compliance with the requirements of this Directive."
[294] Article 25(1): "Member States shall ensure that official inspections are carried out in relation to the marketing of beet seed, at least by random checks, to verify compliance with the requirements and conditions of this Directive.
[295] Article 39(1): "Member States shall ensure that official inspections are carried out in relation to the marketing of vegetable seed, at least by random checks, to verify compliance with the requirements and conditions of this Directive."
[296] Article 23(1) : «Member States shall ensure that official inspections are carried out in relation to the marketing of seed potatoes, at least by random checks, to verify compliance with the requirements and conditions of this Directive."
[297] Article 22(1) : «Member States shall ensure that official inspections are carried out in relation to the marketing of seed of oil and fibre plants, at least by random checks, to verify compliance with the requirements of this Directive.".
[298] Annex IV to Implementing Directive 2014/98/EU.

OCR requirements	PRM and FRM Directives											
	Directive 66/401/EEC – marketing of fodder plant seed	**Directive 66/402/EEC – marketing of cereal seed**	**Directive 2002/53/EC – common catalogue of agricultural plant species**	**Directive 2002/54/EC – marketing of beet seed**	**Directive 2002/55/EC – marketing of vegetable seed**	**Directive 2002/56/EC – marketing of seed potatoes**	**Directive 2002/57/EC – marketing of seed of oil and fibre plants**	**Directive 68/193/EEC – marketing of material for the propagation of the vine**	**Directive 1998/56/EC – marketing of propagating material of ornamental plants**	**Directive 2008/72/EC – marketing of vegetable material, other than seed**	**Directive 2008/90/EC – marketing of fruit propagating material and fruit plants for fruit production**	**Directive 1999/105/EC – marketing of forest reproductive material**
Regular controls (prior to placing on the market)(Art. 9(1))	Y detailed rules on examination under official supervision[299] + rules on official examination prior to certification[300]	Y detailed rules on examination under official supervision[301] + rules on official examination prior to certification[302] + minimum number of field inspections (official or under official supervision[303]	Y MS to provide that the acceptance of varieties be based on the results of official examinations, particularly growing trials, covering a sufficient number of characteristics for the variety to be described[304]+ minimum requirements for official examinations [305]	Y detailed rules on examination under official supervision[306]+ rules on official examination prior to certification[307] + minimum number of field inspections (official or carried out under official supervision)[308]	Y detailed rules on examination under official supervision+ minimum number of field inspections (official or under official supervision)+ rules on official examinations for the acceptance of varieties[309]	Y Limited rules on examination under official supervision[310]. Official examination required prior to placing on the market[311].	Y Detailed rules on examination under official supervision[312] + rules on official examination prior to certification[313] + minimum conditions and minimum number of field inspections (official or under official supervision)[314] + examinations to be carried out in accordance with current	Y Official examination required prior to certification[316] + detailed rules on official inspections of growing crops[317] + rules on official examinations for the acceptance of varieties[318].	Y Random checks + implementing powers[319]	Y Accreditation of suppliers[320] + rules on regular supervision and monitoring of suppliers, establishments and laboratories[321] + implementing powers + MS to ensure official inspection by sampling checks on material during production[322] +implementing powers for detailed procedures for such controls[323] see also Article	Y Official inspection required to determine if material meets conditions[325] + MS to ensure that material/ fruit plants are officially inspected during production[326] + detailed rules on official inspections[327]+ rules on examination of varieties prior to registration[328]	Y Approval of 'basic material', re-inspection at regular intervals[329] and national registry[330]

[299] Article 2(3).
[300] only seed found to satisfy applicable conditions by means of official examination or examination under official supervision can be certified.
[301] Article 2(3).
[302] only seed found to satisfy applicable conditions by means of official examination or examination under official supervision can be certified.
[303] Annex I, point 7.
[304] Article 7(1).
[305] Article 7(2) and Commission Directive 2003/90/EC of 6 October 2003 setting out implementing measures for the purposes of Article 7 of Council Directive 2002/53/EC as regards the characteristics to be covered as a minimum by the examination and the minimum conditions for examining certain varieties of agricultural plant species (Text with EEA relevance).
[306] Article 2(3).

[307] Only seed found to satisfy applicable conditions by means of official examination or examination under official supervision can be certified.
[308] Annex I (2): "In the case of basic seed, at least one official field inspection shall be carried out. In the case of certified seed, at least one field inspection shall be carried out, officially controlled by means of check inspection of at least 20 % of the crop of each species".
[309] MS to provide that acceptance of varieties be based on the results of official examinations, particularly growing trials (Article 7(1)); possibility to provide in EU implementing acts that acceptance is subject to official tests (Art. 7(1), last subparagraph); the characteristics to be covered as a minimum by the examinations of the various species and the minimum requirements for carrying out the examinations are established in implementing acts (See Commission Directive 2003/91/EC of 6 October 2003 setting out implementing measures for the purposes of Article 7 of Council Directive 2002/55/EC as regards the characteristics to be covered as a minimum by the examination and the minimum conditions for examining certain varieties of vegetable species (OJ L 254, 8.10.2003, p. 11).
[309] Article 12(1) and 13 (1)(a).
[310] Article 12(1) and 13 (1)(a):possibility of package sealing and of indelible printing of the prescribed particulars on the package under official supervision.
[311] Article 2 (seed must be found by official examination to satisfy the conditions laid down in the Directives).
[312] Article 2(5).
[313] Article 2 (only seed found to satisfy applicable conditions by means of official examination or examination under official supervision can be certified).
[314] Annex I.5.
[316] Article 2(1) (D) to (G) (Material must be found by official examination to satisfy the conditions established in the Directive in view of the certification). Similarly, propagating material not intended for use as rootstocks, may only be placed on the market if it is officially checked standard material (Article 3(1)(a)).
[317] Annex I (stock nurseries and cutting nurseries, including in relation to RNQP (visual inspection, sampling and testing)). This includes including annual official crop inspections, by the official control authority, in accordance with rules established in Section 8 of Annex (Annex I, Section 5).
[318] Article 5d(1) (MS to ensure that acceptance of varieties is based on the results of official examinations, particularly growing trials, covering a sufficient number of characters for the variety to be described. The methods used for determining characters must be exact and reliable).
[319] Article 12.
[320] Article 6(1) (by the responsible official body after it has verified that their production methods and establishments meet the requirements of the Directive).
[321] Article 6(4).The supervision and monitoring of suppliers, establishments and laboratories shall be carried out regularly by or under the responsibility of the responsible official body.
[322] Article 17.
[323] Article 18.
[325] Article 2(5)(d) ; 2(6)(d) ; Article 2(7)(a)(iv) ; Article 2(7)(b)(iv).
[326] Article 13(1).
[327] Article 30 and Annex IV of Implementing Directive 2014/98/EU (visual inspections, sampling and testing).
[328] Article 7(5) and Article 6 of Commission Implementing Directive 2014/97/EU.
[329] Article 4 and Annex II (It shall be at the discretion of the Member State in each individual case as to whether a formal inspection is required except that, a formal inspection must be made where the material is destined for a specific forestry purpose), Annex III, IV and V.
[330] Article 10(1).

OCR requirements	PRM and FRM Directives											
	Directive 66/401/EEC – marketing of fodder plant seed	**Directive 66/402/EEC – marketing of cereal seed**	**Directive 2002/53/EC – common catalogue of agricultural plant species**	**Directive 2002/54/EC – marketing of beet seed**	**Directive 2002/55/EC – marketing of vegetable seed**	**Directive 2002/56/EC – marketing of seed potatoes**	**Directive 2002/57/EC – marketing of seed of oil and fibre plants**	**Directive 68/193/EEC – marketing of material for the propagation of the vine**	**Directive 1998/56/EC – marketing of propagating material of ornamental plants**	**Directive 2008/72/EC – marketing of vegetable material, other than seed**	**Directive 2008/90/EC – marketing of fruit propagating material and fruit plants for fruit production**	**Directive 1999/105/EC – marketing of forest reproductive material**
							international methods[315].			10(3). + rules of Directive 2002/55 apply for acceptance and maintenance of varieties[324].		
Regular controls - on the marketing (Art. 9(1))	**Y** Minimum rules- random checks[331]	**Y** Minimum rules – random checks[332]	Y There are no specific rules, there are solely provisions on maintenance and revocation of varieties	Y Minimum rules – random checks[333]	Y Minimum rules -random checks[334] + rules on verification of maintenance of accepted varieties[335].	Y Minimum rules - random checks[336] + further official examination required on tubers which are not rejected after	Y Minimum rules - random checks[338]	Y Accepted varieties shall be officially checked at regular intervals[339] + rules on verification of maintenance for	Y Minimum rules, at least random checks and at least in respect of marketing to persons professionally engaged in production or	Y Regular supervision and monitoring of suppliers, establishments and laboratories + implementing powers[344]	Y MS to ensure material/ fruit plants are officially inspected during marketing[348] + detailed rules on official inspections in implementing act[349]	Y Official inspections of registered suppliers to be carried out regularly[351]. MS to make suitable

[315] Article 3(4).
[324] Article 9(2) and (3). The provisions laid down in Articles 4 and 5 and Article 9(3) of Directive 2002/55/EC shall apply to the conditions for acceptance. Article 3(2) and (4), Articles 6, 7, 8, 9(1), (2) and (4) and Articles 10 to 15 of that Directive shall apply mutatis mutandis to the procedures and formalities for acceptance and maintenance production. Varieties officially accepted in accordance with paragraph 2 shall be entered in the Common Catalogue of Varieties of Vegetable Species referred to in Article 17 of Directive 2002/55/EC. Articles 16(2), 17, 18 and 19 of that Directive shall apply mutatis mutandis.
[331] Article 19(1): "Member States shall ensure that official inspections are carried out in relation to the marketing of fodder plant seed, at least by random checks, to verify compliance with the requirements and conditions of this Directive."
[332] Article 19(1): "Member States shall ensure that official inspections are carried out in relation to the marketing, at least by random checks, to verify compliance with the requirements of this Directive."
[333] Article 25(1): "Member States shall ensure that official inspections are carried out in relation to the marketing of beet seed, at least by random checks, to verify compliance with the requirements and conditions of this Directive."
[334] Article 39(1): "Member States shall ensure that official inspections are carried out in relation to the marketing of vegetable seed, at least by random checks, to verify compliance with the requirements and conditions of this Directive." Random checks also to verify compliance with the obligations of the persons responsible for affixing the labels for the standard seed intended for marketing (Article 41(1) last subparagraph). In addition, it is required that MS ensure that seed of the categories 'certified seed' and 'standard seed' is subject to official post-control in the field by inspection to compare their varietal identity and varietal purity against standard controls
[335] Article 11(1) to (3). It must at all times be possible to check maintenance of accepted varieties from the records kept by the person or persons responsible for the variety. These records shall also cover the production of all generations prior to basic seed.

OCR requirements	PRM and FRM Directives											
	Directive 66/401/EEC – marketing of fodder plant seed	Directive 66/402/EEC – marketing of cereal seed	Directive 2002/53/EC – common catalogue of agricultural plant species	Directive 2002/54/EC – marketing of beet seed	Directive 2002/55/EC – marketing of vegetable seed	Directive 2002/56/EC – marketing of seed potatoes	Directive 2002/57/EC – marketing of seed of oil and fibre plants	Directive 68/193/EEC – marketing of material for the propagation of the vine	Directive 1998/56/EC – marketing of propagating material of ornamental plants	Directive 2008/72/EC – marketing of vegetable material, other than seed	Directive 2008/90/EC – marketing of fruit propagating material and fruit plants for fruit production	Directive 1999/105/EC – marketing of forest reproductive material
						sorting[337]		conservation of accepted varieties[340]. + MS to establish a system of official controls of material during marketing, at least by check sampling[341]	sale[342]; implementing powers for detailed implementing procedures for official inspections[343]	MS to ensure official inspection by sampling checks on material during marketing[345] +implementing powers for detailed procedures for	+ trials or tests shall be carried out in the MS on samples[350]	arrangements for FRM to be officially controlled during production with a view to marketing and marketing[352].

Samples may be requested from the person responsible for the variety. Such samples may if necessary be taken officially (Article 40).

[336] Article 23(1) : « 1. Member States shall ensure that official inspections are carried out in relation to the marketing of seed potatoes, at least by random checks, to verify compliance with the requirements and conditions of this Directive."

[338] Article 19(1): "1. Member States shall ensure that official inspections are carried out in relation to the marketing of fodder plant seed, at least by random checks, to verify compliance with the requirements and conditions of this Directive."

[339] Article 5e(1).

[344] Article 6(4).

[348] Article 13(1).

[349] Article 30 and Annex IV of Implementing Directive 2014/98/EU (visual inspections, sampling and testing).

[351] Article 16(1). MS to ensure, by an official control system set up or approved by them, that FRM from individual units of approval or lots remains clearly identifiable through the entire process from collection to delivery to the end user

[337] Article 3(1).

[340] Article 5g(2). Verification of maintenance for conservation of varieties accepted in the catalogue on the basis of records to be kept by those responsible for maintenance; samples may be requested from those responsible for maintenance of a variety. Where necessary, samples may be taken officially.

[341] Article 11(1).

[342] Article 12(1): "Member States shall require that suppliers take all necessary measures to guarantee compliance with the requirements of this Directive. To this end Member States shall ensure that propagating material is officially inspected: — at least by random checks, and
— at least in respect of marketing to persons professionally engaged in production or sale of ornamental plants or propagating material, to verify compliance with the requirements. Member States may also take samples in order to verify compliance. In carrying out supervision and monitoring, the responsible official bodies shall have free access to all parts of suppliers' establishments at all reasonable times."

[343] Article 12(2).

[345] Article 17.

OCR requirements	PRM and FRM Directives											
	Directive 66/401/EEC – marketing of fodder plant seed	Directive 66/402/EEC – marketing of cereal seed	Directive 2002/53/EC – common catalogue of agricultural plant species	Directive 2002/54/EC – marketing of beet seed	Directive 2002/55/EC – marketing of vegetable seed	Directive 2002/56/EC – marketing of seed potatoes	Directive 2002/57/EC – marketing of seed of oil and fibre plants	Directive 68/193/EEC – marketing of material for the propagation of the vine	Directive 1998/56/EC – marketing of propagating material of ornamental plants	Directive 2008/72/EC – marketing of vegetable material, other than seed	Directive 2008/90/EC – marketing of fruit propagating material and fruit plants for fruit production	Directive 1999/105/EC – marketing of forest reproductive material
										such controls[346] +trials or tests shall be carried out in the MS on samples[347]		
Other general rules on official controls[353] (Art. 11 to 15)	N	Y Limited[354]	Y Limited[355]	Y Limited[356]	Y Limited[357].	N	Y Limited[358].	Y [359] + implementing powers[360] +obligations for certain operators[361]	Y Limited in the form of obligations of suppliers[362]; supplier label[363].	Y In the form of operators' obligations[364]+ implementing powers[365]	Y Limited, in the form of operators' obligations[366].	Y Limited in the form of suppliers's obligations[367]

[350] Article 14(1).
[352] Article 16(5).
[346] Article 18.
[347] Article 20(1).
[353] Transparency of official controls; documented control procedures; written records of official controls; methods and techniques of official controls; obligations of operators.
[354] In the form official examination of seed to be carried out in accordance with current international methods (Article 3(3)). Also, use of examination techniques in accordance with applicable international standards for the examination of the varietal identity of the seed.
[355] Obligation for operators (record keeping in relation to maintenance of varieties (Art. 11(2)).
[356] MS to ensure that official examinations of seed are carried out in accordance with current international methods (Article 3(2)).
[357] MS to ensure that official examinations of seeds are carried out in accordance with current international methods (Article 20(4).
[358] In the form of official examinations for certification to be carried out in accordance with current international methods (Article 3(4)).
[359] In the form of methods used for official examination varieties acceptance (Article 5d(1)). The requirement is that those methods must be exact and reliable.
[360] On minimum requirements for examinations, in particular crop inspections Article 5d(2). See Commission Directive 2004/29/EC of 4 March 2004 on determining the characteristics and minimum conditions for inspecting vine varieties.
[361] Obligation of recipient of the material for the vegetative propagation of the vine to keep the official label for at least one year and to make it available to the official control authority (Article 10(5)). Obligation of those responsible for maintenance of varieties for conservation to keep records in view of inspection. Keeping of records of varieties maintained for conservation.
[362] Suppliers engaged in production of propagating material shall keep information, for examination when requested by the responsible official body (Article 7(1)). Reporting obligations (Article 7(2)). Record keeping (Article 7(3)).
[363] Article 8(2) and Commission Directive 1999/66/EC of 28 June 1999 setting out requirements as to the label or other document made out by the supplier pursuant to Council Directive 98/56/EC (Official Journal L 164 , 30/06/1999 P. 0076).

OCR requirements	PRM and FRM Directives											
	Directive 66/401/EEC – marketing of fodder plant seed	Directive 66/402/EEC – marketing of cereal seed	Directive 2002/53/EC – common catalogue of agricultural plant species	Directive 2002/54/EC – marketing of beet seed	Directive 2002/55/EC – marketing of vegetable seed	Directive 2002/56/EC – marketing of seed potatoes	Directive 2002/57/EC – marketing of seed of oil and fibre plants	Directive 68/193/EEC – marketing of material for the propagation of the vine	Directive 1998/56/EC – marketing of propagating material of ornamental plants	Directive 2008/72/EC – marketing of vegetable material, other than seed	Directive 2008/90/EC – marketing of fruit propagating material and fruit plants for fruit production	Directive 1999/105/EC – marketing of forest reproductive material
Staff training (Art. 5(4))	N[368]	N[369]	N	N[370]	N[371]	N	N[372]	N	N	N	N[373].	N

[364] Own checks (Article 5(2): Obligation of suppliers to carry out own checks, or have them carried out by an accredited supplier or by a responsible official body based on principles laid down in the Directive to guarantee compliance at all stages of production and marketing; identification of critical points; establishment and implementation of methods for monitoring and checking the critical points; taking samples for analysis in a laboratory accredited by the responsible official body for the purpose of checking compliance with the standards established by the Directive; keeping a written record or a record registered in an indelible fashion of the data referred to in the first, second and third indents, as well as records on production and marketing of propagating and planting material, to be held at the disposal of the responsible official body. These documents and records shall be kept for a period of at least one year); reporting obligations and to take corrective actions (Article 5(3)).
[365] Article 5(4).
[366] Article 30(3) of Implementing Directive 2014/98/EU (to keep records of the results and dates of all field inspections, sampling and testing carried out by them).
[367] Ariticle 16(3): "Suppliers shall provide official bodies with records, which shall contain details of all consignments detained and marketed".
[368] Requirements are established only for inspectors and seed samplers working under official supervision.
[369] Only requirements for inspectors and seed samplers working under official supervision.
[370] Only requirements for inspectors and seed samplers working under official supervision.
[371] Only requirements for inspectors and seed samplers working under official supervision.
[372] Only requirements for inspectors and seed samplers working under official supervision
[373] Competence of suppliers' staff is to be checked in official inspections (Article 30(2)(b) of Implementing Directive 2014/98/EU).

OCR requirements	PRM and FRM Directives											
	Directive 66/401/EEC – marketing of fodder plant seed	Directive 66/402/EEC – marketing of cereal seed	Directive 2002/53/EC – common catalogue of agricultural plant species	Directive 2002/54/EC – marketing of beet seed	Directive 2002/55/EC – marketing of vegetable seed	Directive 2002/56/EC – marketing of seed potatoes	Directive 2002/57/EC – marketing of seed of oil and fibre plants	Directive 68/193/EEC – marketing of material for the propagation of the vine	Directive 1998/56/EC – marketing of propagating material of ornamental plants	Directive 2008/72/EC – marketing of vegetable material, other than seed	Directive 2008/90/EC – marketing of fruit propagating material and fruit plants for fruit production	Directive 1999/105/EC – marketing of forest reproductive material
Methods of sampling, analysis, tests and diagnoses (Art. 34)	Y[374] But no cascade of applicable methods as in Art. 34 of the OCR	Y[375] But no cascade of applicable methods as in Article 34 of the OCR.	Y See minimum requirements for examinations	Y[376] But no cascade of applicable methods as in Article 34 of the OCR.	Y[377] But no cascade of applicable methods s as in Article 34 of the OCR.	Y[378] But no cascade of applicable methods as in Article 34 of the OCR.	Y[379] But no cascade of applicable methods as in Article 34 of the OCR.	Y[380]	N	N	Y A cascade of methods to be used for sampling[381]	Y See provisions in Annexes II to V

[374] MS are to require that sampling is performed in accordance with 'appropriate methods' (Art. 7); Detailed requirements on 'sampling under official supervision (Article 7(b); seed samplers must carry out seed sampling in accordance with current international methods; Detailed technical rules (requirement of sampling from homogenous lots; maximum eight of the lot and minimum weight of the sample (Article 7(2) and Annex III).

[375] MS to require that, for the checking of varieties, and for the examination of seed for certification, samples are drawn officially or under official supervision in accordance with appropriate methods (Art. 7(1); seed samplers shall carry out seed sampling in accordance with current international methods (Art. 7(1a)(b)); detailed provisions on seed sampling (Article 7(2) and Annex III: for the examination of seed for certification, samples shall be drawn from homogeneous lots; the maximum weight of a lot and the minimum weight of a sample are given in Annex III); authorised seed testing laboratories shall carry out seed testing in accordance with current international methods (Article 2(3)(b));

[376] Article 9(1) : "Member States shall require that, for the checking of varieties, and for the examination of seed for certification, samples are drawn officially or under official supervision in accordance with appropriate methods (…)."; detailed requirements on 'sampling under official supervision'; seed samplers must carry out seed sampling in accordance with current international methods (Article 9(1a)(b)); detailed provisions on seed sampling (Annex I, Section 2, point 4 : "As regards sampling and testing, Member States shall apply protocols of the European and Mediterranean Plant Protection Organisation (EPPO), or other protocols which are internationally recognised. Where such protocols do not exist, the relevant protocols established at national level shall be applied. In that case, Member States shall, on request, make available those protocols to the other Member States and to the Commission. As regards sampling and testing of vines in the stock nurseries intended for the production of initial propagating material, Member States shall apply biological indexing on indicator plants to assess the presence of viruses, viroids, virus-like diseases and phytoplasmas, or other equivalent protocols which are internationally recognised."); authorised seed testing laboratories shall carry out seed testing in accordance with current international methods (Article 2(3)(B)(b), last subparagraph); Use of examination techniques in accordance with applicable international standards (Annex I, A, 5a); MS shall require that, for the examination of seed for certification, samples are drawn officially or under official supervision in accordance with appropriate methods (Article 25); See samplers shall carry out seed sampling in accordance with current international methods (Article 25(1a)(b)).

[377] Authorised seed testing laboratories shall carry out seed testing in accordance with current international methods (Article 2(4)(B)); the methods used for determining characteristics must be accurate and reliable (Article 7(1)); for the examination of seed for certification and for post-control tests, samples shall be drawn from homogeneous lots; the maximum weight of a lot and the minimum weight of a sample are given in Annex III (Article 25(2)); examination in accordance with the applicable international standards (Annex I (3a)).

[378] MS shall require that, for the examination of seed potato tubers for certification, samples are taken officially in accordance with appropriate methods (Article 7).

[379] MS shall require that, for the checking of varieties, the examination of seed for certification and the examination of commercial seed, samples are drawn officially or under official supervision in accordance with appropriate methods (Article 9(1)); detailed requirements on 'sampling under official supervision'; seed samplers must carry out seed sampling in accordance with current international methods (Art. 9(1a)(b)); detailed provisions on seed

OCR requirements	PRM and FRM Directives											
	Directive 66/401/EEC – marketing of fodder plant seed	Directive 66/402/EEC – marketing of cereal seed	Directive 2002/53/EC – common catalogue of agricultural plant species	Directive 2002/54/EC – marketing of beet seed	Directive 2002/55/EC – marketing of vegetable seed	Directive 2002/56/EC – marketing of seed potatoes	Directive 2002/57/EC – marketing of seed of oil and fibre plants	Directive 68/193/EEC – marketing of material for the propagation of the vine	Directive 1998/56/EC – marketing of propagating material of ornamental plants	Directive 2008/72/EC – marketing of vegetable material, other than seed	Directive 2008/90/EC – marketing of fruit propagating material and fruit plants for fruit production	Directive 1999/105/EC – marketing of forest reproductive material
Second expert opinion (Art. 35)	N	N	N[382]	N	N	N	N	N[383]	N	N	N	N
Sampling of animals and goods offered by means of distance communication (Art. 36)	N	N	N	N	N	N	N	N	N	N	N	N

sampling (Article 9(2) : « 2. For the examination of seed for certification and the examination of commercial seed, samples shall be drawn from homogeneous lots; the maximum weight of a lot and the minimum weight of a sample are given in Annex III."

Annex I. 3a); use of examination techniques in accordance with applicable international standards (Annex I. 3a).

[380] In relation to methods of sampling and testing of stock nurseries and cutting nurseries.

[381] See recital 14 of Implementing Directive 2014/98/EU: "Where sampling and testing is carried out, it should take place in accordance with the protocols of the European and Mediterranean Plant Protection Organization (EPPO), or other protocols which are internationally recognised. This is necessary to ensure that the practice of sampling and testing carried out in the Union is up to date with the international scientific and technical developments. Where such protocols are not available, sampling and testing should take place in accordance with relevant protocols established at national level."

[382] To be noted that MS are to ensure that any doubts which arise after the acceptance of a variety concerning the appraisal of its distinctness or of its name at the time of acceptance are clarified (Art. 13(1)).

[383] There is only a reference to the obligation of the official control authority to carry out additional checks on stock nurseries and cutting nurseries in case of cases of disputes on matters which can be decided without prejudice to the quality of the propagating material (Annex I, Section 5, point 3).

OCR requirements	PRM and FRM Directives											
	Directive 66/401/EEC – marketing of fodder plant seed	Directive 66/402/EEC – marketing of cereal seed	Directive 2002/53/EC – common catalogue of agricultural plant species	Directive 2002/54/EC – marketing of beet seed	Directive 2002/55/EC – marketing of vegetable seed	Directive 2002/56/EC – marketing of seed potatoes	Directive 2002/57/EC – marketing of seed of oil and fibre plants	Directive 68/193/EEC – marketing of material for the propagation of the vine	Directive 1998/56/EC – marketing of propagating material of ornamental plants	Directive 2008/72/EC – marketing of vegetable material, other than seed	Directive 2008/90/EC – marketing of fruit propagating material and fruit plants for fruit production	Directive 1999/105/EC – marketing of forest reproductive material
Delegation of tasks of the competent authorities (Art. 28 to 33)	N[384]	N[385]	N[386]	N[387]	N[388].	N[389]	N[390]	N[391]	Y But in accordance with national law [392] + implementing powers for the approval of other legal persons[393]	Y But in accordance with national law[394]+ implementing powers for the approval of other legal persons[395]	Y But in accordance with national law[396]+ implementing powers for the approval of other legal persons[397]	Y But in accordance with national law[398]+ implementing powers for the approval of other legal persons[399]

[384] In the definition of 'official measures' reference is made to measures taken by any legal person whether governed by public or by private law, acting under the responsibility of the State; or in the case of ancillary activities which are also subject to State control, by any natural person duly sworn for that purpose. However, there are no further specifications. Similarly, Union comparative tests and trials may be performed by State authorities, but also by legal persons acting under the responsibility of the State. However, there are no further provisions concerning these legal persons.
[385] Ibidem.
[386] In the definition of 'official measures' reference is made to measures taken by any legal person whether governed by public or by private law, acting under the responsibility of the State; or in the case of ancillary activities which are also subject to State control, by any natural person duly sworn for that purpose.
[387] Ibidem.
[388] Ibidem.
[389] Ibidem.
[390] Ibidem.
[391] Ibidem.
[392] Article 2(4), second subparagraph: « The bodies referred to above may, in accordance with their national legislation, delegate the tasks provided for in this Directive to be accomplished under their authority and supervision to any legal person, whether governed by public or by private law, which, under its officially approved constitution, is charged exclusively with specific public functions, provided that such person, and its members, has no personal interest in the outcome of the measures it takes." In addition, Community comparative tests and trials may be performed by State authorities and also by legal persons acting under the responsibility of the State (Article 14(7)).
[393] Article 2(4), third subparagraph.
[394] Article 3(e), second and third subparagraph. See also Article 20(7) in relation to comparative tests and trials.
[395] Article 3(e), fourth subparagraph (established on behalf of the responsible official bodies and acting under the authority and supervision of such body).
[396] Article 13(2), first subparagraph: 'The responsible official bodies may, in accordance with their national legislation, delegate the tasks provided for in this Directive to be accomplished under their authority and supervision to any legal person, whether governed by public or private law, which, under its officially approved statute, is charged exclusively with specific public functions, provided that such person, and its members, has no personal interest in the outcome of the measures it takes.". See also definition of 'official inspections'. See also provisions on tests and trials only by State authorities or legal persons acting under the responsibility of the State Tests and trials only by State authorities or legal persons acting under the responsibility of the State (Article 14(7)).
[397] Article 13(2), second subparagraph.

OCR requirements	PRM and FRM Directives											
	Directive 66/401/EEC – marketing of fodder plant seed	Directive 66/402/EEC – marketing of cereal seed	Directive 2002/53/EC – common catalogue of agricultural plant species	Directive 2002/54/EC – marketing of beet seed	Directive 2002/55/EC – marketing of vegetable seed	Directive 2002/56/EC – marketing of seed potatoes	Directive 2002/57/EC – marketing of seed of oil and fibre plants	Directive 68/193/EEC – marketing of material for the propagation of the vine	Directive 1998/56/EC – marketing of propagating material of ornamental plants	Directive 2008/72/EC – marketing of vegetable material, other than seed	Directive 2008/90/EC – marketing of fruit propagating material and fruit plants for fruit production	Directive 1999/105/EC – marketing of forest reproductive material
Official laboratories (Article 37 to 42)	Y Limited[400], no requirement on designation or accreditation of similar to the OCR	Y Limited[401], no requirement of designation or accreditation similar to the OCR	N	Y Limited[402], no requirement of designation or accreditation similar to the OCR	Y Limited[403], no requirement of designation or accreditation similar to the OCR	N[404]	Y Limited[405], no requirement of designation or accreditation similar to the OCR	N	Y Partly included--- but minimal, laboratories where samples are analysed should have "suitable facilities and expertise"	Y Responsible official body to accredit laboratories after verification of compliance + implementing powers[406]	Y in view of certification, obligation of responsible official bodies to submit samples to laboratories officially accepted by them, but no requirements on 'acceptance '[407]	N
Risk based import controls (Article 43 OCR)	N	N	N	N	N	N	N	N	N	N	N	N

[398] Article 2(k), second subparagraph: «The bodies referred to above may, in accordance with their national legislation, delegate the tasks provided for in this Directive to be accomplished under their authority and supervision to any legal person, whether governed by public or by private law, which, under its officially approved constitution, is charged exclusively with specific public functions, provided that such person, and its members, has no personal interest in the outcome of the measures it takes.».
[399] Article 2(k), third subparagraph.
[400] Article 2(3)(b), limited, in the form of provisions on official seed testing in the framework of examination under official supervision with no further specifications/requirements.
[401] Provisions on official seed testing in the framework of examination under official supervision, with no further requirements.
[402] Provisions on official seed testing in the framework of examination under official supervision, with no further requirements.
[403] Provisions on official seed testing in the framework of examination under official supervision, with no further requirements.
[404] There are no rules on seed testing.
[405] Provisions on official seed testing in the framework of examination under official supervision, with no further requirements.
[406] Provisions on official seed testing in the framework of examination under official supervision, with no further requirements (Article 6(2)).
[407] Annex IV of Implementing Directive 2014/98.

OCR requirements	PRM and FRM Directives											
	Directive 66/401/EEC – marketing of fodder plant seed	Directive 66/402/EEC – marketing of cereal seed	Directive 2002/53/EC – common catalogue of agricultural plant species	Directive 2002/54/EC – marketing of beet seed	Directive 2002/55/EC – marketing of vegetable seed	Directive 2002/56/EC – marketing of seed potatoes	Directive 2002/57/EC – marketing of seed of oil and fibre plants	Directive 68/193/EEC – marketing of material for the propagation of the vine	Directive 1998/56/EC – marketing of propagating material of ornamental plants	Directive 2008/72/EC – marketing of vegetable material, other than seed	Directive 2008/90/EC – marketing of fruit propagating material and fruit plants for fruit production	Directive 1999/105/EC – marketing of forest reproductive material
Import controls (Art. 43 to 64)	N[408]	N[409]	N	N[410]	N[411]	N[412]	N[413]	N[414]	N[415]	N	N	N
Actions in the event of non-compliance of animals and goods entering the Union (Art. 65 to 76)	N	N	N	N	N	N	N	N	N	N	N	N
Approval of the pre-export controls (Art. 73 and 74)	N	N	N	N	N	N	N	N	N	N	N	N
Cooperation between authorities in	N	N	N	N	N	N	N	N	N	N	N	N

[408] The general requirement of 'random checks' on marketing applies. There is also a requirement on supply of certain information during the marketing of quantities >2kg of seed imported from TCs (Art. 19(2)).
[409] The general requirement of 'random checks' on marketing applies. There is also a requirement on supply of certain information during the marketing of quantities >2kg of seed imported from TCs (the particulars are: species; variety; category; country of production and official inspection authority; country of dispatch; importer; quantity of seed).
[410] The general requirement of 'random checks' on marketing applies. There is also a requirement on supply of certain information during the marketing of quantities >2kg of seed imported from TCs (the particulars are: species; variety; category; country of production and official inspection authority; country of dispatch; importer; quantity of seed - Article 25(2)).
[411] The general requirement of 'random checks' on marketing applies. No specific rules on import controls, with the exception of the requirement on supply of certain information during the marketing of quantities >2kg of seed imported from TCs (Article 39(2)).
[412] The general requirement of 'random checks' on marketing applies. No specific rules on import controls, with the exception of the requirement on supply of certain information during the marketing of quantities >2kg of seed imported from TCs Article 23(2)).
[413] The general requirement of 'random checks' on marketing applies. No specific rules on import controls, with the exception of the requirement on supply of certain information during the marketing of quantities >2kg of seed imported from TCs (Article 22(2)).
[414] No specific rules on import controls, with the exception of the requirement on supply of certain information to the competent authorities during the marketing of propagating material imported from a third country (Article 11(2)).
[415] See however Article 11(3) (obligation of importer to notify the responsible official bodies of material imported under Article 11(2) and to keep documentary evidence of his contract with the supplier in the third country) and implementing powers in Article 11(4) for rules on the procedure to be followed and further requirements to be met by importers.

OCR requirements	PRM and FRM Directives											
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relation to consignments from TCs (Art. 75 and 76)												
Financing of official controls by the Member States (Art. 78 to 85)	N[416]	N[417]	N	N[418]	N[419]	N[420]	N[421]	N[422]	N[423]	N[424]	N[425]	N
Official certification[426]	N[427]	N[428]	N	N[429]	N[430]	N[431]	N[432]	N[433]	N	N	N[434]	Y[435]

[416] There are provisions in relation to EU contribution to Community comparative tests and trials.
[417] Ibidem.
[418] Ibidem.
[419] Ibidem.
[420] Ibidem.
[421] Ibidem, Article 23.
[422] Ibidem, Article 16(4) and (5).
[423] Ibidem, Article 14(5) and (6).
[424] Ibidem, Article 20(5) and (6).
[425] Ibidem, Article 14(5) and (6).
[426] General requirements, signature and issuance, guarantees of reliability of certificates, implementing powers.
[427] The rules referring to official certification in the Directive qualify as rules on 'official attestations' within the meaning of the OCR; 'official label' in the Directive qualifies as an 'official attestation' within the meaning of the OCR See definition of 'official attestation' in Article 3(28) of the OCR and Article 91 of the OCR. There is no requirement of the 'official label' to be signed by a certifying office.
[428] Ibidem.
[429] Ibidem.
[430] Ibidem.
[431] Ibidem.
[432] Ibidem.
[433] Ibidem.
[434] Ibidem.
[435] Master certificate for all reproductive material derived from approved basic material (Article 12) and model thereof (Annex VIII).

OCR requirements	PRM and FRM Directives											
	Directive 66/401/EEC – marketing of fodder plant seed	Directive 66/402/EEC – marketing of cereal seed	Directive 2002/53/EC – common catalogue of agricultural plant species	Directive 2002/54/EC – marketing of beet seed	Directive 2002/55/EC – marketing of vegetable seed	Directive 2002/56/EC – marketing of seed potatoes	Directive 2002/57/EC – marketing of seed of oil and fibre plants	Directive 68/193/EEC – marketing of material for the propagation of the vine	Directive 1998/56/EC – marketing of propagating material of ornamental plants	Directive 2008/72/EC – marketing of vegetable material, other than seed	Directive 2008/90/EC – marketing of fruit propagating material and fruit plants for fruit production	Directive 1999/105/EC – marketing of forest reproductive material
(Art. 3(25) and (26), Art. 87 to 90)												
Official attestations (Art. 3(28) and 91)	Y[436] no requirements comparable to Article 91 (2)(a), (3) and (4) of the OCR.	Y[437] no requirements comparable to Article 91 (2)(a), (3) and (4) of the OCR.	N no requirements comparable to Article 91 (2)(a), (3) and (4) of the OCR.	Y[438] no requirements comparable to Article 91 (2)(a), (3) and (4) of the OCR.	Y[439] no requirements comparable to Article 91 (2)(a), (3) and (4) of the OCR.	Y[440] no requirements comparable to Article 91 (2)(a), (3) and (4) of the OCR.	Y[441] no requirements comparable to Article 91 (2)(a), (3) and (4) of the OCR.	Y[442] no requirements comparable to Article 91 (2)(a), (3) and (4) of the OCR.	N	N	Y[443] no requirements comparable to Article 91(2)(a), (3) and (4) of the OCR.	N

[436] Seed must be officially certified in order to be placed on the market and packages of basic seed and certified seed must be labelled on the outside with an official label (Article 10(1)(a))and contain an official document (Article 10(1)(b)).

[437] Seed must be officially certified in order to be placed on the market (Article 3(1) : "Member States shall provide that cereal seed may not be placed on the market unless it has been officially certified as 'basic seed', 'certified seed', 'certified seed, first generation' or 'certified seed, second generation'."). Packages of basic seed and certified seed must be labelled on the outside with an official label (Article 10(1)(a)) and contain an official document (Article 10(1)(b)) .

[438] Seed must be officially certified in order to be placed on the market (Article 3(1) : "Member States shall provide that cereal seed may not be placed on the market unless it has been officially certified as 'basic seed', 'certified seed', 'certified seed, first generation' or 'certified seed, second generation'."). Packages of basic seed and certified seed must be labelled on the outside with an official label (Article 12(a)) and contain an official document (Article 12(b)).

[439] MS shall provide that seed of industrial chicory may not be placed on the market unless it has been officially certified as 'basic seed' or 'certified seed' (Article 20(1)); MS shall provide that seed of other vegetable species may not be placed on the market unless it has been officially certified as 'basic seed' or 'certified seed', or is standard seed (Article 20(2)). Packages of basic seed and certified seed must be labelled on the outside with an official label (Article 28(1)(a)) and contain an official document (Article 28(1)(b)). Vegetable seed may no be certified, verified as standard seed and marketed unless the variety is officially accepted in one or more Member States (Article 3(1)).

[440] Seed potatoes may not be placed on the market unless they have been officially certified as 'basic seed potatoes' or 'certified seed potatoes' (Article 3(1)). Packages and containers of basic seed potatoes and certified seed potatoes must be labelled on the outside with an official label (Article 13(1)(a)) and contain an official document (Article 13(1)(a)).

[441] Seed may not be placed on the market unless they have been officially certified (Article 3(1) to (3)). Packages of basic seed, certified seed of all categories and commercial seed must be labelled on the outside with an official label (Article 12(1)(a)) and contain an official document (Article 12(1)(b)).

[442] Propagating material may not be placed on the market unless it has been officially certified as 'initial propagating material', 'basic propagating material' or 'certified propagating material' (Article 3(1)(a)). MS to require that an official label in one of the official languages of the Community, conforming to the specification in Annex IV, be affixed on the outside of packages and bundles of propagating material (Article 10(1)). All conditions applicable to the official labelling and plant passports are defined and must be recognised as equivalent (Article 10(4)).

[443] Requirement of official certification of material and fruit plants for placing on the market (Article 3(1)).

OCR requirements	PRM and FRM Directives											
	Directive 66/401/EEC – marketing of fodder plant seed	Directive 66/402/EEC – marketing of cereal seed	Directive 2002/53/EC – common catalogue of agricultural plant species	Directive 2002/54/EC – marketing of beet seed	Directive 2002/55/EC – marketing of vegetable seed	Directive 2002/56/EC – marketing of seed potatoes	Directive 2002/57/EC – marketing of seed of oil and fibre plants	Directive 68/193/EEC – marketing of material for the propagation of the vine	Directive 1998/56/EC – marketing of propagating material of ornamental plants	Directive 2008/72/EC – marketing of vegetable material, other than seed	Directive 2008/90/EC – marketing of fruit propagating material and fruit plants for fruit production	Directive 1999/105/EC – marketing of forest reproductive material
Reference laboratories and reference centres (Art. 92 to 101)	N	N	N	N	N	N	N	N	N	N	N	N
Administrative assistance and	Y Very limited[444]	Y Very limited[445]	Y Limited[446]	Y Very limited[447]	Y Limited[448].	N	Y Very limited[449]	Y Limited[450]	N	Y Limited[451]	Y Limited[452]	Y Detailed rules on

[444] MS making use of a specific derogation are required to "assist each other administratively as regards inspection".
[445] MS to assist each other administratively as regards inspection in case they make use of the derogation to authorize official certification and marketing although not all applicable conditions are met (Article 4(4)).
[446] Implementing powers for administrative assistance in relation to growing trials (Art. 7(2)(c)). Notification to the other MS and to the Commission of any application or withdrawal of an application for acceptance of a variety, any entry in a catalogue of varieties as well as any amendment (Article 10(1)). Where maintenance takes place in a Member State other than the one in which the variety was accepted, the Member States concerned shall assist each other administratively as regards verification (Art. 11(4)).
[447] MS to assist each other administratively as regards inspection in case they make use of the derogation to authorize official certification and marketing although not all applicable conditions are met (Article 5, last subparagraph).
[448] Where maintenance of accepted varieties takes place in a MS other than that in which the variety was accepted, the MS concerned shall assist each other administratively as regards checks (Article 11(4)). Notification obligations to other MS and the Commission in relation to accepted varieties (Article 10).
[449] MS to assist each other administratively as regards inspection in case they make use of the derogation to authorize official certification and marketing although not all applicable conditions are met (Article 5).
[450] MS to immediately communicate to the other MS ad the Commission all applications or withdrawals of applications for acceptance of a variety, entries in a catalogue of varieties and amendments made to it (Article 5e(2)). In case maintenance of a variety for conservation is carried out in a MS other than that in which the variety was accepted, MS in question to assist each other administratively as regards control (Article 5g(4)).
[451] In the form of obligation of the MS to notify to the Commission and to the competent national authorities in the MS if a supplier is forbidden to market vegetable propagating and planting material (Article 19(2)).
[452] In the form of obligation of the MS to notify to the Commission and to the competent national authorities in the MS if a supplier is forbidden to market propagating material and fruit plants (Article 16(3)).

OCR requirements	PRM and FRM Directives											
	Directive 66/401/EEC – marketing of fodder plant seed	Directive 66/402/EEC – marketing of cereal seed	Directive 2002/53/EC – common catalogue of agricultural plant species	Directive 2002/54/EC – marketing of beet seed	Directive 2002/55/EC – marketing of vegetable seed	Directive 2002/56/EC – marketing of seed potatoes	Directive 2002/57/EC – marketing of seed of oil and fibre plants	Directive 68/193/EEC – marketing of material for the propagation of the vine	Directive 1998/56/EC – marketing of propagating material of ornamental plants	Directive 2008/72/EC – marketing of vegetable material, other than seed	Directive 2008/90/EC – marketing of fruit propagating material and fruit plants for fruit production	Directive 1999/105/EC – marketing of forest reproductive material
cooperation (Art. 102-108)												administrative assistance[453]+ communication to Commission and other MS[454]
Planning (Art. 109- 111)	N	N	N	N	N	N	N	N	N	N	N	N
Reporting to the Commission (Art. 113)	N	Y[455]	N	N	N	N	N	N	N	N	N	N
Coordinated control programmes and information and data collection (Art.112 OCR)	Y Data collection in the form of Community comparative tests and trials[456]	Y Data collection in the form of Community comparative tests and trials shall be carried[457].	N	Y Data collection in the form of Community comparative tests and trials[458].	Y Data collection in the form of Community comparative tests and trials[459].	Y Data collection in the form of Community comparative tests and trials[460]	Y Data collection in the form of Community comparative tests and trials[461].	Y Data collection in the form of Community comparative tests and trials[462].	Y Data collection in the form of Community comparative tests and trials [463]	Y Data collection in the form of Community comparative tests and trials[464]	Y Data collection in the form of Community comparative tests and trials[465]	N

[453] Article 16(2) and Commission Regulation (EC) No 1598/2002 of 6 September 2002 laying down detailed rules for the application of Council Directive 1999/105/EC as regards the provision of mutual administrative assistance by official bodies. MS to ensure that the respective official bodies assist each other administratively in order to obtain appropriate information necessary to ensure the proper functioning of this Directive, particularly where FRM moves from one Member State to another (Art.16(2)).

[454] MS to communicate to the Commission and to the other MS maps showing the demarcations of the regions of provenance of basic material intended for the production of reproductive material of the "source-identified" and "selected" categories (Art. 9(2)). A national list of the basic material of the various species approved on its territory shall be drawn up by each Member State and shall be available on request to the Commission and the other Member States (Art. 10(2)).

[455] Reporting obligation until 28 February 2030 for the responsible certification authority to the Commission and the other MS (Annex I, 5b, last subparagraph).

[456] Article 20. See also 2004/11/EC: Commission Decision of 18 December 2003 setting out the arrangements for Community comparative trials and tests on seeds and propagating material of certain plants of agricultural and vegetable species and vine under Council Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 92/33/EEC, 2002/54/EC, 2002/55/EC, 2002/56/EC and 2002/57/EC for the years 2004 and 2005 (Text with EEA relevance) (notified under document number C(2003) 4836) (OJ L 3, 7.1.2004, p. 38); Commission Decision of 27 December 2004 setting out the arrangements for Community comparative trials and tests on seeds and propagating material of certain plants of agricultural and vegetable species and vine under Council Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 92/33/EEC, 2002/54/EC, 2002/55/EC, 2002/56/EC and 2002/57/EC for the years 2005 to 2009 (notified under document number C(2004) 5264) (Text with EEA relevance) (2005/5/EC)((OJ L 002, 5.1.2005, p.12).

[457] Article 20.

OCR requirements	PRM and FRM Directives											
	Directive 66/401/EEC – marketing of fodder plant seed	Directive 66/402/EEC – marketing of cereal seed	Directive 2002/53/EC – common catalogue of agricultural plant species	Directive 2002/54/EC – marketing of beet seed	Directive 2002/55/EC – marketing of vegetable seed	Directive 2002/56/EC – marketing of seed potatoes	Directive 2002/57/EC – marketing of seed of oil and fibre plants	Directive 68/193/EEC – marketing of material for the propagation of the vine	Directive 1998/56/EC – marketing of propagating material of ornamental plants	Directive 2008/72/EC – marketing of vegetable material, other than seed	Directive 2008/90/EC – marketing of fruit propagating material and fruit plants for fruit production	Directive 1999/105/EC – marketing of forest reproductive material
Commission controls in MS (Art. 116 to 119)	N	N	N	N	N	N	N	N	Y[466]	Y[467] as a possibility ('may')	Y As a possibility ('may')[468]	Y As a possibility ('may')[469]
Commission controls in the TCs (Art. 120 to 124)	N	N	N	N	N	N	N	N	N	N	N	N

[458] Article 26(2).
[459] Article 43.
[460] Article 20.
[461] Article 23(2).
[462] Article 16(2).
[463] Article 14.
[464] Article 20(2). The Commission to inform the PAFF committee of the results.
[465] Article 14.
[466] Article 14(1): "1. Where appropriate, trials or tests shall be carried out in the Member States on samples to check that propagating material complies with the requirements and conditions of this Directive. The Commission may organise inspections of trials by representatives of the Member States and of the Commission."
[467] On the spot checks, in particular to verify compliance by the suppliers, but as a possibility, not as an obligation + implementing powers (Article 7). Inspections of the trials, but as a possibility (Article 20(1): The Commission may organise inspections of the trials by representatives of the Member States and of the Commission).
[468] The Commission may organise inspections of the trials by representatives of the MS and of the Commission (Article 14(1)). On the spot checks, in particular to verify compliance by the suppliers, but as a possibility, not as an obligation and implementing powers (Article 15).
[469] Article 16(5): "Experts from the Commission may, in cooperation with the official bodies of the Member States, make on-the-spot checks so far as this is necessary to ensure uniform application of this Directive. They may in particular verify whether FRM is complying with the requirements of this Directive. A Member State in whose territory a check is being carried out shall give all necessary assistance to the experts in carrying out their duties. The Commission shall inform the Member States of the results of the investigation".

OCR requirements	PRM and FRM Directives											
	Directive 66/401/EEC – marketing of fodder plant seed	Directive 66/402/EEC – marketing of cereal seed	Directive 2002/53/EC – common catalogue of agricultural plant species	Directive 2002/54/EC – marketing of beet seed	Directive 2002/55/EC – marketing of vegetable seed	Directive 2002/56/EC – marketing of seed potatoes	Directive 2002/57/EC – marketing of seed of oil and fibre plants	Directive 68/193/EEC – marketing of material for the propagation of the vine	Directive 1998/56/EC – marketing of propagating material of ornamental plants	Directive 2008/72/EC – marketing of vegetable material, other than seed	Directive 2008/90/EC – marketing of fruit propagating material and fruit plants for fruit production	Directive 1999/105/EC – marketing of forest reproductive material
Import conditions, (Art. 125 to 128)	Y Only officially certified seed may be placed on the EU market[470]	Y Only officially certified seed may be placed on the EU market[471]	N	Y Only officially certified seed may be placed on the EU market[472]	Y Only officially certified seed may be placed on the EU market[473]	Y Only officially certified seed may be placed on the EU market[474]	Y Only officially certified seed may be placed on the EU market[475]	Y Only officially certified seed may be placed on the EU market Pending equivalence decisions, MS are authorised to take such decisions[476].	Y Pending equivalence decision, import is prohibited except where the importer provides assurances [477]	Y By MS, pending an equivalence decision by the Commission[478].	Y By MS, pending an equivalence decision by the Commission[479]	Y By Council acting on a proposal from the Commission[480] By MS, pending an equivalence decision by Council[481]

[470] Article 3.
[471] Article 3(1) OCR. There are specific rules on official certification in MS of cereal seed harvested in a TC in Article 15(3).
[472] Article 3(1). Specific rules on official certification in MS of cereal seed harvested in a TC (Article 22(3)).
[473] There are also specific rules on official certification in MS of cereal seed harvested in a TC.
[474] Article 3(1).
[475] Article 3. There are also rules concerning official certification of seed harvested in a TC (Article 19(3)) and of seeds produced from seeds officially certified in a TC which has been granted equivalence (Article 19(1)).
[476] Article 15(2)(c).
[477] Article 11(2) and (3).
[478] MS importing such material from TCs may, until 31 December 2022, apply to such products import conditions at least equivalent to those applicable to similar Union products (Article 16(2) and Commission Implementing Decision (EU) 2022/1400 of 11 August 2022 amending Council Directive 2008/72/EC to extend the period during which Member States may decide on the import conditions for vegetable propagating and planting material, other than seed, from third countries (notified under document C(2022) 5723) (OJ L 213, 16.8.2022, p. 57)).
[479] MS importing such material from TCs may, until 31 December 2022, apply to such products import conditions at least equivalent to those established pursuant to Article 4 (Article 12(2) and Commission Implementing Directive 2014/97/EU).
[480] In addition to the equivalence decision, Council is to determine the species, type of basic material and categories of FRM, together with its region of provenance, which may be permitted to be marketed within the Union (Article 19(2)).
[481] Article 19(3) and Commission Implementing Decision (EU) 2021/773 of 10 May 2021 authorising Member States, in accordance with Council Directive 1999/105/EC, to temporarily decide on the equivalence of FRM of certain categories produced in certain third countries (notified under document C(2021) 3194)
C/2021/3194 (OJ L 169, 12.5.2021, p. 1). Master certificate or official certificate to be issued by the TC of origin.

OCR requirements	PRM and FRM Directives											
	Directive 66/401/EEC – marketing of fodder plant seed	Directive 66/402/EEC – marketing of cereal seed	Directive 2002/53/EC – common catalogue of agricultural plant species	Directive 2002/54/EC – marketing of beet seed	Directive 2002/55/EC – marketing of vegetable seed	Directive 2002/56/EC – marketing of seed potatoes	Directive 2002/57/EC – marketing of seed of oil and fibre plants	Directive 68/193/EEC – marketing of material for the propagation of the vine	Directive 1998/56/EC – marketing of propagating material of ornamental plants	Directive 2008/72/EC – marketing of vegetable material, other than seed	Directive 2008/90/EC – marketing of fruit propagating material and fruit plants for fruit production	Directive 1999/105/EC – marketing of forest reproductive material
Equivalence TC requirements (Art. 129)	Y [482] [483]	Y[484]	Y[485]	Y[486]	Y[487]	Y[488]	Y[489]	Y[490]	Y[491]	Y[492]	Y[493]	Y[494]
EU training of staff (BTSF) (Art. 130)	N	N	N	N	N	N	N	N	N	N	N	N

[482] Recognition by Council acting by a qualified majority on a proposal from the Commission of equivalence of field inspection and of seed (Article 16).
[483] competence of the COM to adopt such measures; conditions for the granting of equivalence; implementing powers to set out the practical arrangements for the entry into the Union of such goods.
[484] Recognition by Council, acting by a qualified majority on a proposal from the Commission of equivalence of field inspection and of seed.
[485] Recognition by Council, acting by qualified majority, on a proposal from the Commission, that official examinations of varieties carried out in the TC afford the same assurances as those provided for in Article 7 and carried out in the Member States; the checks on practices for the maintenance of varieties carried out in the third country afford the same assurances as those carried out by the Member States (Article 22).
[486] Recognition by Council, acting by a qualified majority on a proposal from the Commission. See Council Decision 2003/17/EC of 16 December 2002 on the equivalence of field inspections carried out in third countries on seed-producing crops and on the equivalence of seed produced in third countries (Text with EEA relevance) (OJ L 008 14.1.2003, p. 10).
[487] Recognition by Council, acting by a qualified majority on a proposal from the Commission official examinations of varieties, checks on practices for the maintenance of the varieties, of field inspections, of vegetable seed harvested in a third country (Article 37(1)).
[488] Recognition by Council, acting by a qualified majority on a proposal from the Commission that seed potatoes harvested in a third country are equivalent to basic seed potatoes or certified seed potatoes harvested within the Community and complying with the provisions of this Directive (Article 21(1)).
[489] Recognition by Council, acting by a qualified majority on a proposal from the Commission of equivalence of field inspections and of seed of oil and fibre plants.
[490] Determination by Council, acting by a qualified majority on a proposal from the Commission whether material for the vegetative propagation of the vine produced in a TCs offers, as regards the conditions for its acceptance and the measures taken to ensure its production with a view to its marketing, the same guarantees as material produced in the Community and meets the requirements of the Directive (Article 15(2)(a)). Determination of the types of material and the categories of material for the vegetative propagation of the vine that may be admitted to marketing within the territory of the Community under equivalence (Article 15(2)(b)).
[491] By the Commission Implementing Acts on equivalent guarantees of propagating material produced in a TCs in all respects to material produced in the Community in accordance with this Directive (Article 11(1)).
[492] In Commission implementing acts, decision whether vegetable propagating and planting material produced in a third country is equivalent to vegetable propagating and planting material produced in the Community and complying with the requirements and conditions of this Directive (Article 16(1)).
[493] In Commission implementing acts, decision whether propagating material and fruit plants produced in a third country is equivalent to material/plants produced in the Community and complying with the requirements and conditions of the Directive (Article 12(1)).
[494] Recognition by Council acting by a qualified majority on a proposal from the Commission that FRM provides the same assurances as regards the approval of its basic material and the measures taken for its production with a view to marketing as does FRM produced within the Union and complying with the provisions of this Directive (Art. 19(1)).

OCR requirements	PRM and FRM Directives											
	Directive 66/401/EEC – marketing of fodder plant seed	Directive 66/402/EEC – marketing of cereal seed	Directive 2002/53/EC – common catalogue of agricultural plant species	Directive 2002/54/EC – marketing of beet seed	Directive 2002/55/EC – marketing of vegetable seed	Directive 2002/56/EC – marketing of seed potatoes	Directive 2002/57/EC – marketing of seed of oil and fibre plants	Directive 68/193/EEC – marketing of material for the propagation of the vine	Directive 1998/56/EC – marketing of propagating material of ornamental plants	Directive 2008/72/EC – marketing of vegetable material, other than seed	Directive 2008/90/EC – marketing of fruit propagating material and fruit plants for fruit production	Directive 1999/105/EC – marketing of forest reproductive material
Information management system (Art. 131 to 136)	N	N	N	N	N	N	N	N	N	N	N	N
Enforcement action (Art. 137 and 138)	Y Limited	N	Y[495]	Y	Y[496]	Y Limited[497]	Y Limited[498]	Y Limited[499].	Y appropriate measures in relation to material [500] and to the particular supplier[501] + withdrawal of measures[502]	Y[503]	Y in relation to non-compliant material[504] and to non-compliant suppliers[505]	Y Limited[506]

[495] Revocation of acceptance of variety (Art. 14) and its deletion (Art. 15).
[496] Member States shall ensure that any doubts which arise after the acceptance of a variety concerning the appraisal of its distinctness or of its name at the time of acceptance are removed and related implementing powers (Article 13). Replacement or revocation of acceptance of a variety (Article 13(2) and 14) and deletion (Article 15). Adaptation of the name of an accepted variety (Article 13 (3)). MS to prohibit marketing of seeds in case of repeated non-compliance found during post-control tests carried out in the field (Article 42(1)). MS shall ensure that any certification of the seed sampled is annulled in the event of contravention unless it can be shown that such seed still meets all relevant requirements (Article 25(1a)(f)).
[497] Sorting of seed potatoes which do not, during marketing, satisfy the minimum conditions laid down in Annex II (Article 3(1).
[498] Only in relation to examination under official supervision, MS to ensure that any certification of the seed sampled is annulled in the event of contravention unless it can be shown that such seed still meets all relevant requirements (Article 2(5)(A)(e) ; Article 2(5)(B)(f)).
[499] Revocation of acceptance of varieties and deletion from the catalogue if any of the conditions for acceptance for certification or checking is no longer satisfied (Article 5e(1)).
[500] Article 13(1) : «If, during official inspections referred to in Article 12, or the trials referred to in Article 14, it is found that propagating material does not meet the requirements of this Directive, the responsible official body shall ensure that the supplier takes appropriate corrective action or, if that is not possible, shall prohibit the marketing of that propagating material in the Community."
[501] Article 13(2) : « If it is found that propagating material marketed by a particular supplier does not comply with the requirements of this Directive, the Member State concerned shall ensure that appropriate measures are taken in relation to that supplier."
[502] Article 13(3) : « 3. Any measures taken under paragraph 2 shall be withdrawn as soon as it has been established with sufficient certainty that the propagating material intended for marketing by the supplier will, in future, comply with the requirements and conditions of this Directive."
[503] The responsible official body must take appropriate action in case official controls reveal non-compliance (Article 6(4) last subparagraph), including in relation to accreditation of suppliers and laboratories (Article 6(3)). MS shall take appropriate action to ensure that: non-compliant material does comply or, if that is not possible, to ban its marketing in the Community (Article 19(1)) and take appropriate measures against the supplier (Article 19(2)). MS to take appropriate official measures to eliminate any plant health risk (Article 23(2)).
[504] Article 16(2).
[505] Article 16(3).

OCR requirements	PRM and FRM Directives											
	Directive 66/401/EEC – marketing of fodder plant seed	Directive 66/402/EEC – marketing of cereal seed	Directive 2002/53/EC – common catalogue of agricultural plant species	Directive 2002/54/EC – marketing of beet seed	Directive 2002/55/EC – marketing of vegetable seed	Directive 2002/56/EC – marketing of seed potatoes	Directive 2002/57/EC – marketing of seed of oil and fibre plants	Directive 68/193/EEC – marketing of material for the propagation of the vine	Directive 1998/56/EC – marketing of propagating material of ornamental plants	Directive 2008/72/EC – marketing of vegetable material, other than seed	Directive 2008/90/EC – marketing of fruit propagating material and fruit plants for fruit production	Directive 1999/105/EC – marketing of forest reproductive material
Penalties (Art. 139(1))	Y Limited[507]	Y Limited[508]	N	Y Limited[509]	Y Limited[510]	N	Y[511]	N	N	N	N	N
Penalties for violations through fraud (Art. 139(2))	N	N	N	N	N	N	N	N	N	N	N	N
Whistle blowing (Art. 140)	N	N	N	N	N	N	N	N	N	N	N	N
EU enforcement measures (Art. 141)	N	N	N	N	N	Y[512]	N	N	N	N	N	N

[506] Withdrawal of approval of basic material (Art. 4(3)(a)).
[507] Only in relation to penalties applicable to infringements of the national provisions governing examination under official supervision and the focus is on infringements by field inspectors, seed testing laboratories, and not on infringements by the operators. Also, there are no rules on notification to the Commission of these rules, similar to those in the OCR.
[508] Ibidem.
[509] Ibidem.
[510] Ibidem.
[511] Ibidem (Article 2(5)(A)(e) ; Article 2(5)(B)(f).
[512] Prohibition of the marketing of seed potatoes harvested in a particular area of the Union in case of non-compliance for 3 consecutive years in Community tests and trials (Article 20(7) and (8)).

9.2. Information on official controls from consultation activities

9.2.1. Controls on operators carrying out certification under official supervision

Just under half of responding NCAs (N=25) reported that they carry out controls on certification under official supervision.

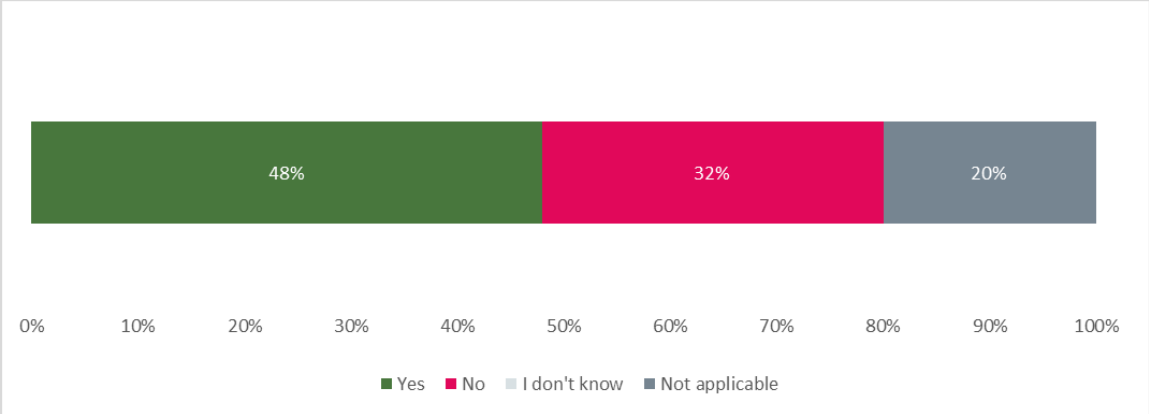

Figure 10. Overview of responses to the question 'Do you currently carry out controls of certification activities under official supervision? (N=25)

9.2.2. PRM import controls

Percentage of consignments checked	PRM	FRM
Less than 10%	3	3
10-25%	2	0
26-50%	2	0
51-75%	1	0
over 75%	6	3
I don't know	3	2

Table 31. Overview of controls on imported PRM/FRM consignments to check the identity of PRM/FRM on an annual basis

9.2.3. *Types of import controls:*

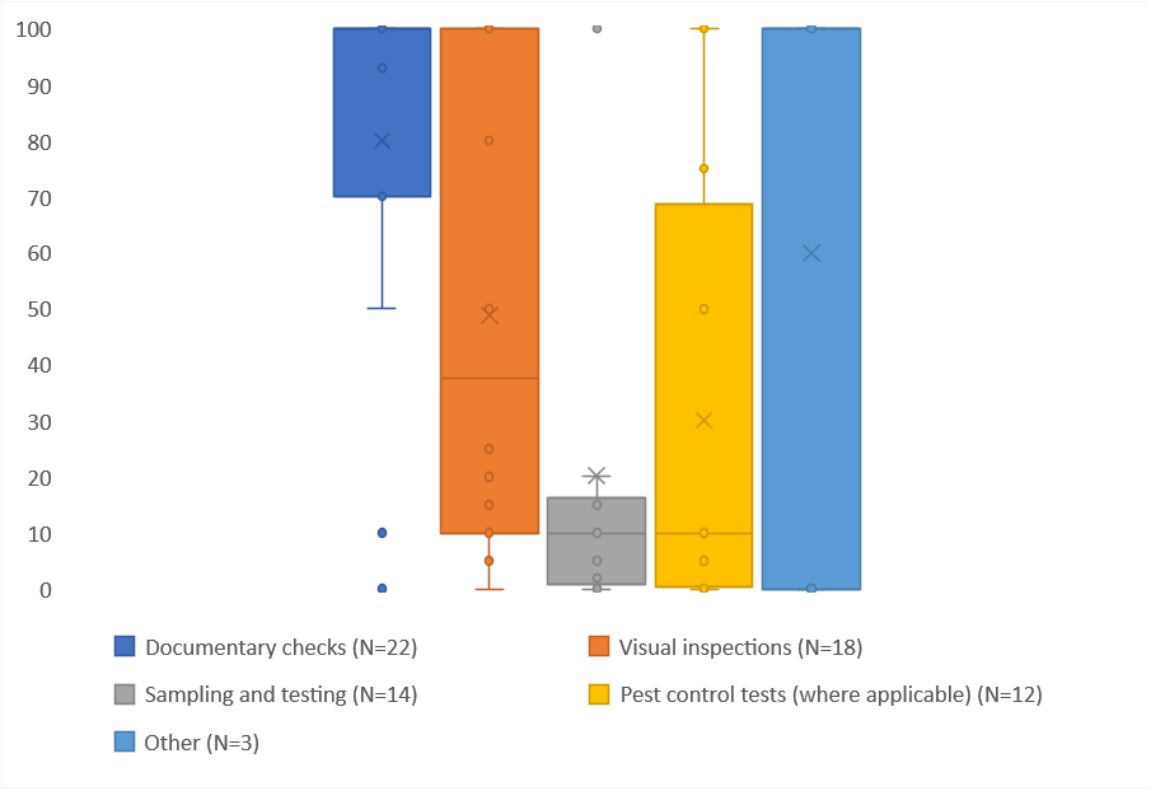

Figure 11. Overview of the type of import controls (N=3-22) and the relative proportion (%) in relation to the total number of imports. Responses to other (N=3): not responsible, post-controls depend on another NCA, all pre-basic and basic PRM of agricultural crops is checked in grow out plots.

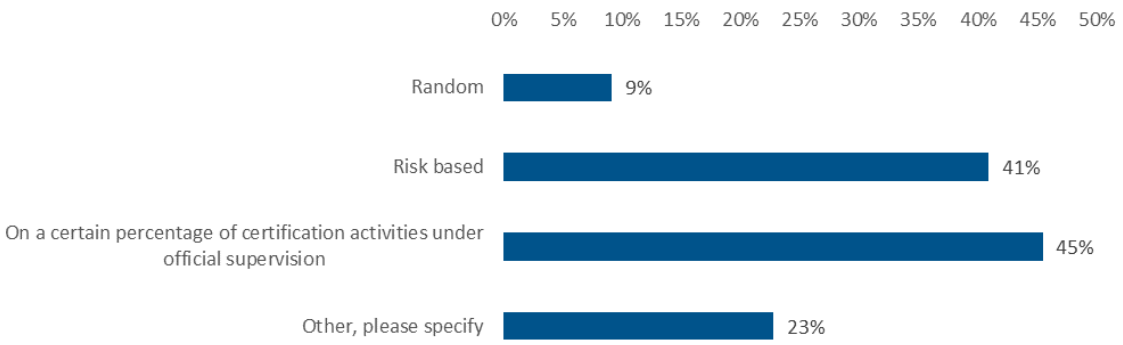

Figure 12. Overview of criteria used for carrying out documentary checks (N=22).

9.2.4. *Controls on operators at production stage of PRM/FRM*

The estimated total number of controls that NCAs carry out on operators at production stage on an annual basis, varied significantly from a few times a year to 1 000. However, the type of control varied which may explain the variation in responses. Similar to the import control checks operators

at the production stage are also most frequently undergoing documentary checks and visual inspections while pest control tests are the least frequent.

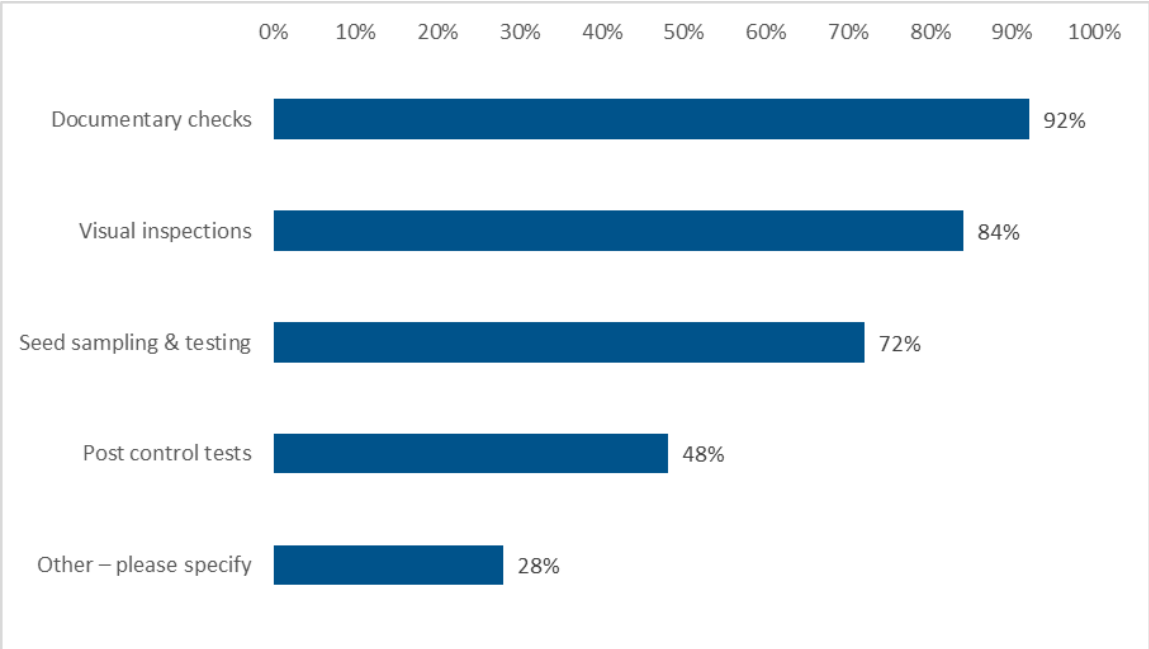

Figure 13. Overview of types of controls on operators at production stage of PRM/FRM? (N=25)

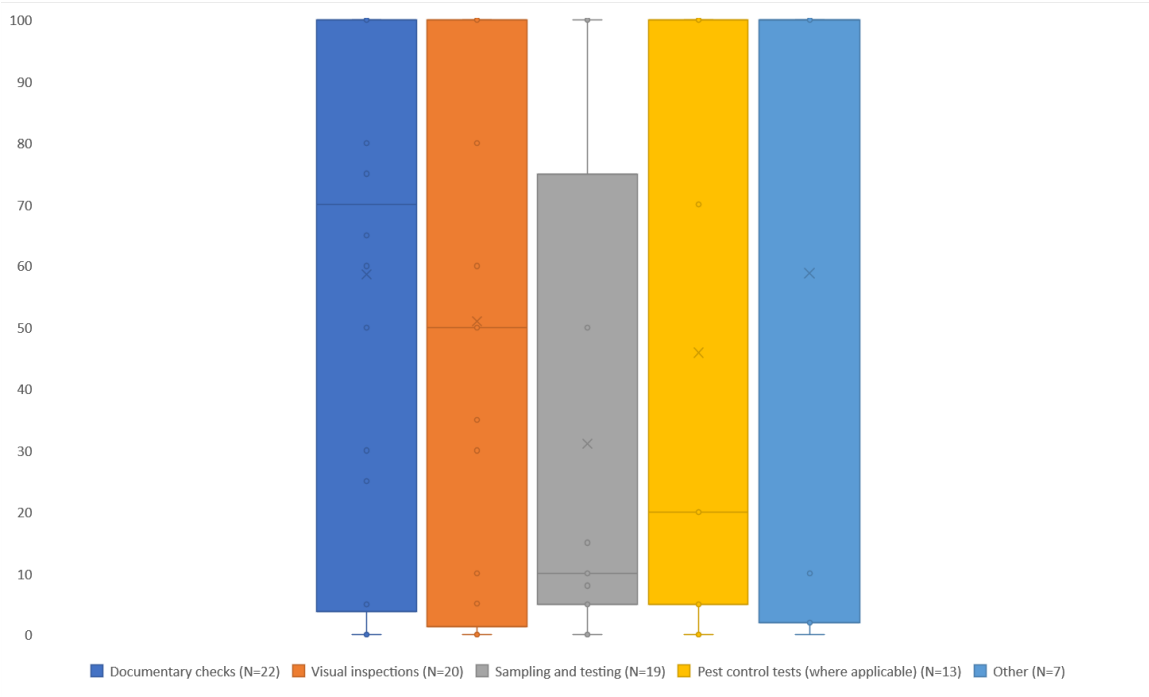

Figure 14. Overview of the type of controls on operators at production stage of PRM/FRM (N=7-22) and the percentage of operators checked at production stage. Responses to other (N=7): interview, soil and plant material sampling & testing, sampling and testing of plants other than seed, GMO tests where applicable, the answer is all regarding the certification of seed, N/A, it is not clear which type of control is involved.

Figure 15. Overview of criteria used for carrying out documentary checks (N=23).

9.2.5. PRM marketing controls

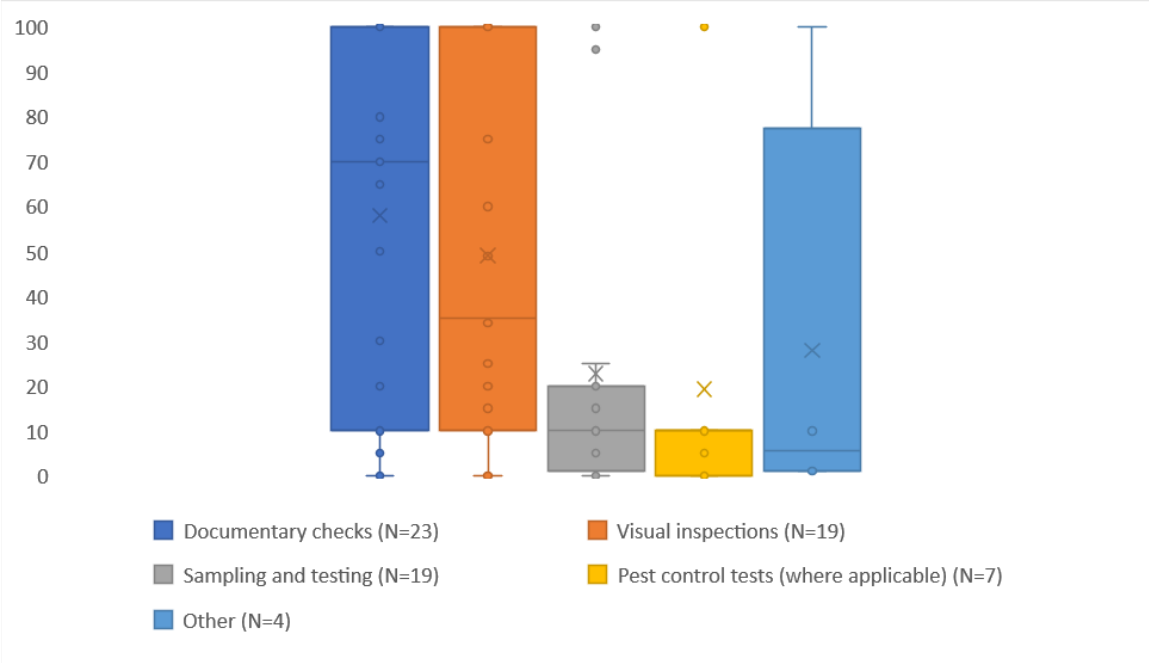

Figure 16. Overview of the type of PRM/FRM marketing controls (N=4-23) and the percentage of PRM/FRM checked during marketing.

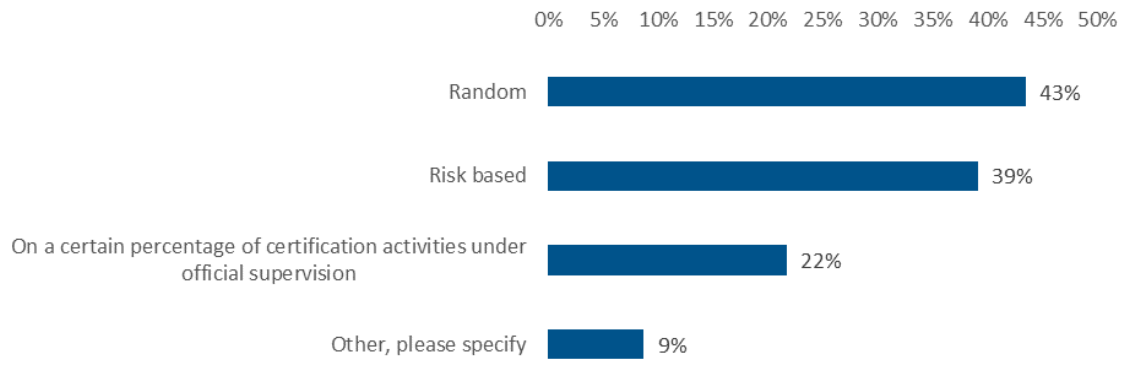

Figure 17. Overview of criteria used for carrying out documentary checks (N=23).

10. FURTHER DETAILS ON OPTION 2 (PREFERRED OPTION)

10.1. Current and potential future approach for variety registration and PRM certification

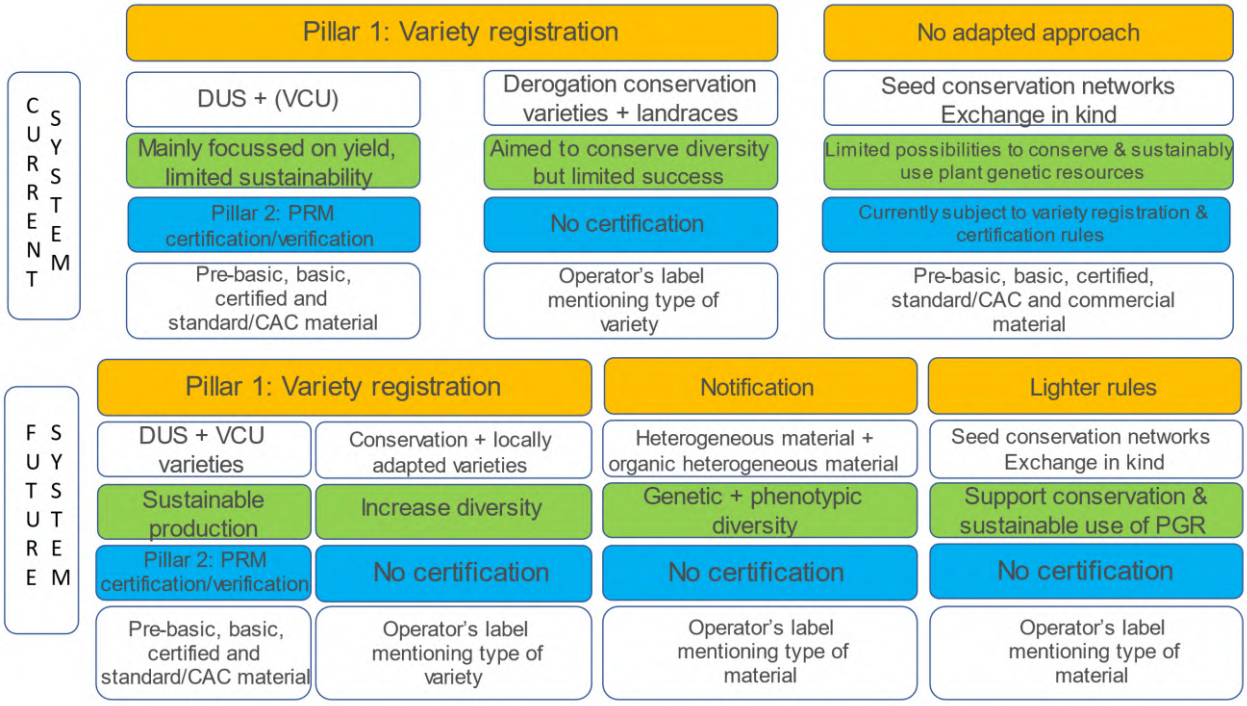

Figure 18. Schematic representation of the current and potential future approach for variety registration and PRM certification under policy option 2

The upper part of Figure 18 shows the current legal framework. The lower part shows the potential future approach for variety registration and certification based on the preferred policy option of this impact assessment, namely option 2. Under the current legal framework, DUS testing and VCU examination in the case of agricultural species, seed potatoes and vine is a condition for variety registration. As regards the VCU examination, MS can decide which characteristics of the VCU examination they deem to be important. In practice, the VCU examination is mainly focussed on yield while limited attention is given to the assessment of characteristics contributing to sustainable production. PRM of registered varieties is certified as pre-basic, basic or certified material or meets the requirements of standard or *Conformitas Agraria Communitatis* (CAC) material. PRM is marketed under one of those 4 categories.

Derogations from the DUS testing requirement for variety registration have been introduced through the legislation on conservation varieties (including landraces). The intention of these derogations was to increase the diversity of PRM available on the market, but a limited number of conservation varieties has been authorised for marketing. The PRM concerned is not certified. It is marketed with a label issued by the operator that mentions the type of variety.

The current legislation has limited possibilities as regards the conservation and sustainable use of plant genetic resources because transfer of PRM is considered as marketing. This implies that the activities of seed conservation networks and the exchange in kind of PRM between farmers fall within the scope of the marketing legislation. The varieties concerned have to be officially registered and the PRM certified and marketed as pre-basic, basic or certified or the PRM meets the requirements to be marketed as standard/*Conformitas Agraria Communitatis* (CAC) material.

Under the future legal framework, the variety registration and certification pillars will remain but in addition there will be a notification procedure for heterogeneous and organic heterogeneous material and lighter rules for the activities of seed conservation networks and exchange in kind of seeds between farmers. Under the first pillar of variety registration the existing derogatory regime for conservation varieties and landraces will be expanded to include new locally adapted varieties. Lighter rules for the activities of seed conservation networks and exchange in kind of seeds between farmers will ensure a minimum level of quality and traceability of the PRM concerned.

As regards the second pillar, only PRM of registered varieties will be certified as pre-basic, basic or certified material or meet the requirements of standard or *Conformitas Agraria Communitatis* (CAC) material. PRM will be marketed under one of those 4 categories. PRM of conservation varieties and new locally adapted varieties, heterogeneous/organic heterogeneous material, PRM exchanged by seed conservation networks or farmers will not be subject to certification.

10.2. Potential future approach for variety registration, activities of seed conservation networks and exchange in kind of seeds

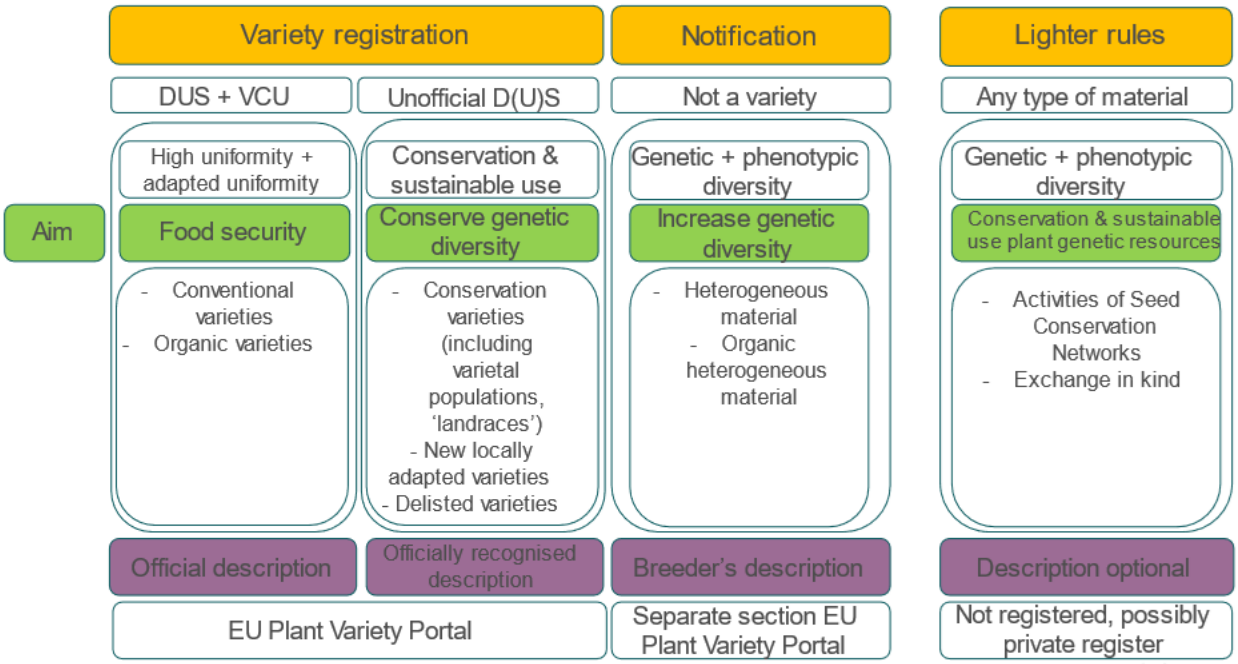

Figure 19. Schematic representation of the potential future approach for variety registration, activities of seed conservation networks and exchange in kind of PRM between farmers under policy option 2

Figure 19 describes the potential future approach for variety registration, notification of heterogeneous/organic heterogeneous material, PRM exchanged by seed conservation networks or

farmers based on the preferred policy option of this impact assessment, namely option 2. Upon registration of a new conventional or organic variety based on an official description, there will be an assessment of characteristics contributing to sustainable production (VSCU). Furthermore, the DUS and VSCU examinations will be adapted to cater for the needs of organic varieties suitable for organic production that cannot meet the stringent uniformity requirements applied to conventional varieties. For varieties of fruit plants and vegetables there will be, instead of the VCU examination, trials assessing the performance of varieties containing sustainability characteristics in relation to a number of reference varieties without those sustainability characteristics.

In the case of conservation varieties and new locally adapted varieties, the registration will not require an official examination but will be based on an officially recognised description. The notification procedure for heterogeneous and organic heterogeneous material will be based on the existing notification procedure for organic heterogeneous material[513]. PRM of heterogeneous and organic heterogeneous material will be allowed for marketing following a notification made by the breeder to the NCA based on a dossier containing (1) the contact details of the applicant, (2) the species and the denomination of the heterogeneous/organic heterogeneous material as applicable, (3) the description of the main agronomic and phenotypic characteristics that are common to that plant grouping and a declaration by the applicant concerning the truth of the elements in points (1), (2) and (3). Upon acceptance by the NCA that heterogeneous/organic heterogeneous material will be listed in a separate section of the EU Plant Variety Portal.

The future legal framework will establish lighter rules for the activities of seed conservation networks and exchange in kind of PRM between farmers. Any natural or legal person involved in one of the aforementioned activities cannot have a contractual relationship with a seed company (e.g. service contract to multiply seed for a seed company). The PRM concerned does not belong to a variety that is registered in the EU Plant Variety Portal, nor does it belong to a variety protected by a national or Community plant variety right. MS will lay down species-specific quantitative restrictions.

10.3. Value for sustainable cultivation and use (VSCU)

In the future PRM legislation Member States will need to assess the value for sustainable cultivation and use (VSCU) of candidate varieties of all crop groups. The aim of this examination is to assess if the characteristics of those candidate varieties, taken as a whole, offer a clear improvement either for sustainable cultivation or as regards the uses, which can be made of the crops, other plants or the products derived therefrom. Where other, superior characteristics are present, individual inferior characteristics may be disregarded. The characteristics, as regards that examination, would be as appropriate for the species, regions and uses concerned:

a) Yield and yield stability;
b) Tolerance/resistance to biotic stresses including plant diseases caused by nematodes, fungi, bacteria, viruses, pests;
c) Tolerance/resistance to abiotic stresses, including climate adaptation;
d) Improved utilisation of resources;
e) Enhanced storage performance;

[513] Article 13(2) to Regulation (EU) 2018/848. OJ L 150, 14.6.2018, p. 1

f) Production of substances or characteristics of industrial interest;
g) Quality or nutritional characteristics and characteristics important for processing.

In the future FRM legislation a list of sustainability characteristics will be established in order to ensure that basic material will have improved performance in relation to one of those listed characteristics. Even though this list will be established under tertiary legislation, indicatively the following characteristics would be considered:

a) Suitability of tree species for particular climatic conditions (including conditions under future climate change projections);
b) Suitability of provenances of basic material for particular climatic conditions (including conditions under future climate change projections);
c) Adaptability of FRM (e.g. to water stress, drought, heat, cold, wind hoses, wind throws);
d) Resistance of FRM to plant pests.

10.4. Certification under official supervision

All certification tasks will be permitted under official supervision for all PRM categories (pre-basic, basic and certified material) and all crop groups. In the case of agricultural species certification under official supervision will be extended to the pre-basic and basic categories (Figure 20). Certification under official supervision will also become possible for seed potatoes and vegetables species[514].

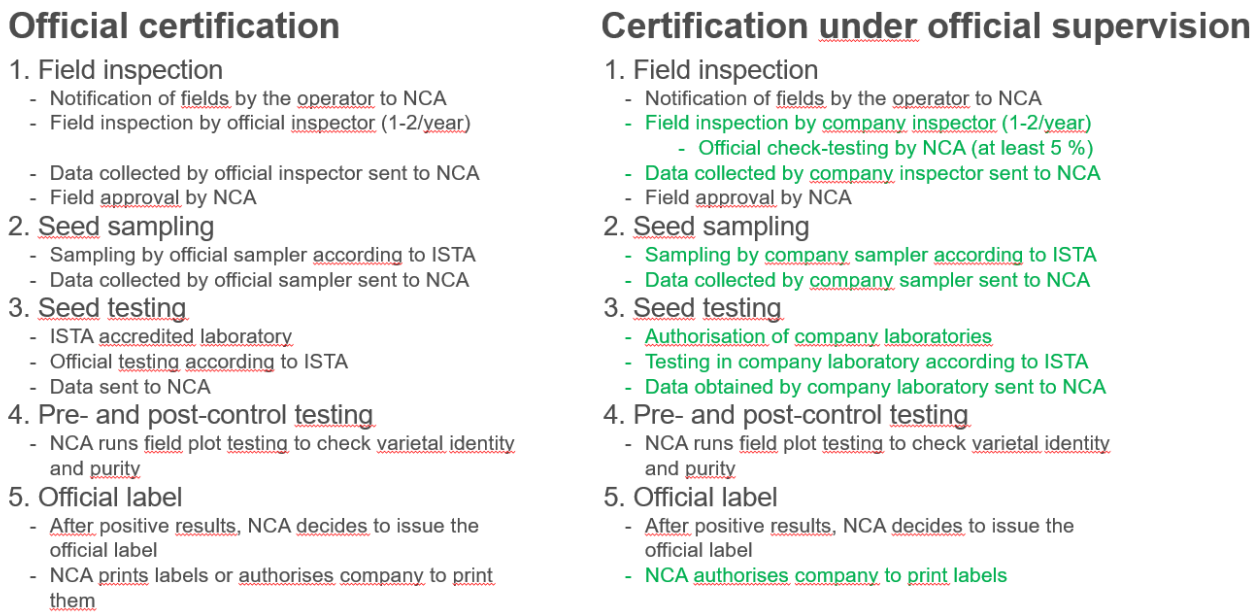

Figure 20. Official certification and certification under official supervision – agricultural species

[514] Certification under official supervision will also apply to Directives 2002/55/EC, 2002/56/EC and 2008/72.

Official certification

1. Inspection of production site/place
   - Notification of production site/place by the operator to the NCA
   - Inspection by official inspector of the requirements of the production site/place
   - Data collected by official inspector sent to NCA
2. Inspection of PRM
   - Verification of the trueness of the PRM to the variety description by official inspector
   - Verification of defects affecting PRM quality
   - Data collected by official sampler sent to NCA
3. Approval of PRM production site/place and PRM
   - Approval by NCA
4. Official label
   - After positive results of inspection production site/place and PRM, the NCA decides to issue the official label
   - NCA prints labels or authorises company to print them

Certification under official supervision

1. Inspection of production site/place
   - Notification of production site/place by the operator to the NCA
   - Inspection by company inspector of the requirements of the production site/place
     - Risk-based controls by NCA
   - Data collected by company inspector sent to NCA
2. Inspection of PRM
   - Verification of the trueness of the PRM to the variety description by company inspector
   - Verification of defects affecting PRM quality
   - Data collected by company sampler sent to NCA
3. Approval of PRM production site/place and PRM
   - Approval by NCA
4. Official label
   - After positive results of inspection production site/place and PRM, the NCA decides to issue the official label
   - NCA authorises company to print labels

Figure 21. Official certification and certification under official supervision – Fruit plants and vine

Figure 21 shows a preliminary scheme to conduct certification under official supervision in the case of fruit plants and vine. The terminology used is slightly different. Reference is made to the production site or place because the highest category or reproductive material (pre-basic material in the case of fruit plants and initial propagating material for vine) is produced in insect proof facilities, but there may be exceptions to this rule. The lower PRM categories are produced under non-insect proof conditions in the field (fruit plants) and nurseries (vine). Plant health requirements are an important aspect for the certification of PRM of fruit plants and vine. Compliance with plant health requirements will be dealt with under the PHL (Annex 6, Section 6.5.). The main part of the certification scheme will concern the inspection of the production site/place and of the PRM. The principles of certification under official supervision will be similar to those of seed certification under official supervision. The operators and their staff may be authorised to conduct certain activities under official supervision if they are trained and licensed by the NCA. NCAs will regularly verify that the activities carried out under official supervision are done in a correct way. NCAs will always approve the production site/place, decide about the certification of PRM and authorise the issuing of the official labels.

Official certification

1. Activities prior to FRM collection
   - Identification of areas for FRM collection by official inspector
   - Assessment of conditions for FRM collection by official inspector
2. FRM collection and processing
   - FRM collection under supervision of official inspector
   - Extraction, cleaning and grading of seeds under supervision of official inspector
3. Master certificate
   - NCA decides to issue Master certificate for FRM collected from approved basic material
4. Seed sampling
   - Sampling by official sampler according to ISTA rules
5. Seed testing
   - NCA testing laboratory
   - Official testing according to ISTA rules
6. Supplier's label/document
   - After positive results, the NCA decides to issue the supplier's label/document
   - NCA prints supplier's label/document or authorises company to print them

Certification under official supervision

1. Activities prior to FRM collection
   - Identification of areas for FRM collection by company inspector
   - Assessment of conditions for FRM collection by company inspector
   - Risk-based controls by NCA
2. FRM collection and processing
   - NCA authorises operator to collect FRM
   - NCA authorises operator to extract, clean and grade seeds
   - Risk-based controls by NCA
3. Master certificate
   - NCA decides to issue Master certificate FRM collected from approved basic material
4. Seed sampling
   - Sampling by company sampler according to ISTA rules
5. Seed testing
   - NCA authorises company laboratory
   - Testing in company laboratory according to ISTA rules
6. Supplier's label/document
   - After positive results, the NCA decides to issue the supplier's label/document
   - NCA authorises company to print labels

Figure 22. Official certification and certification under official supervision – FRM

The marketing Directive on FRM implicitly refers to certification under official supervision but does not specify which activities may be carried out under official supervision[515]. Operators can be authorised to perform the FRM certification process under the official supervision of the NCAs, as depicted in Figure 22. This authorisation to conduct certification activities under official supervision will be subject to the same principles as described above for the seed certification scheme: training and licensing of operators and OCs on the activities carried out under official supervision. The following activities will always be carried out officially: the decision to issue the Master certificate regarding all FRM collected from approved basic material and the authorisation for the operator to print the supplier's label/document.

10.5. Future regulation of RNQPs

1. The current repetition of RNQP requirements in the two legal frameworks (PHL and PRM) will be abolished.
2. The identification of RNQPs, their thresholds and specific measures will be laid down under the PHL only.
3. The PRM/FRM legislation will only refer to compliance with PHL requirements as regards QPs and RNQPs.
4. Compliance with QPs and RNQPs would lead to the issuance of plant passport under plant health rules.
5. The certification rules under the PRM/FRM legislation will concern the identity and quality and also require compliance with the plant health rules (QPs and RNQPs).

[515] Article 2, point k to Directive 1999/105/EC

6. The PRM/FRM legislation will make, for the purpose of clarity, a general reference to PHL, as is already now the case in several marketing Directives.
7. The material shall also comply with the requirements concerning Union quarantine pests, protected zone quarantine pests and RNQPs provided for in Annex IV to Implementing Regulation (EU) 2019/2072 as well as the measures in Annex V to that Implementing Regulation.

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SWD(2013) 162 final - COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL On the production and making available on the market of plant reproductive material (plant reproductive material law) https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52013SC0162&from=EN and https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52013SC0163&from=EN

SWD(2013) 0163 final - COMMISSION STAFF WORKING DOCUMENT EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL On the production and making available on the market of plant reproductive material (plant reproductive material law) https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A52013SC0163

SWD(2021)90 final - COMMISSION STAFF WORKING DOCUMENT Study on the Union's options to update the existing legislation on the production and marketing of plant reproductive material https://data.consilium.europa.eu/doc/document/ST-8287-2021-INIT/en/pdf

SWD(2023) 4 final COMMISSION STAFF WORKING DOCUMENT Drivers of food security. https://commission.europa.eu/system/files/2023-01/SWD_2023_4_1_EN_document_travail_service_part1_v2.pdf

3. EU LEGISLATION (OTHER THAN THAT LISTED IN SECTION 1 OF ANNEX 5)

Commission Delegated Regulation (EU) 2021/1189 of 7 May 2021 supplementing Regulation (EU) 2018/848 of the European Parliament and of the Council as regards the production and marketing of plant reproductive material of organic heterogeneous material of particular genera or species. OJ L 258, 20.7.2021, p. 18 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021R1189

Commission Directive 2004/29/EC of 4 March 2004 on determining the characteristics and minimum conditions for inspecting vine varieties. OJ L 71, 10.3.2004, p. 22 https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32004L0029

Commission Directive 2008/62/EC of 20 June 2008 providing for certain derogations for acceptance of agricultural landraces and varieties which are naturally adapted to the local and regional conditions and threatened by genetic erosion and for marketing of seed and seed potatoes of those landraces and varieties. OJ L 162, 21.6.2008, p. 13 https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32008L0062

Commission Directive 2009/145/EC of 26 November 2009 providing for certain derogations, for acceptance of vegetable landraces and varieties which have been traditionally grown in particular localities and regions and are threatened by genetic erosion and of vegetable varieties with no intrinsic value for commercial crop production but developed for growing under particular conditions and for marketing of seed of those landraces and varieties. OJ L 312, 27.11.2009, p. 44 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32009L0145

Commission Directive 2010/60/EU of 30 August 2010 providing for certain derogations for marketing of fodder plant seed mixtures intended for use in the preservation of the natural environment. OJ L 228, 31.8.2010, p. 10 https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32010L0060

Commission Implementing Decision 2012/340/EU of 25 June 2012 on the organisation of a temporary experiment under Council Directives 66/401/EEC, 66/402/EEC, 2002/54/EC, 2002/55/EC and 2002/57/EC as regards field inspection under official supervision for basic seed and bred seed of generations prior to basic seed. OJ L 166, 27.6.2012, p. 90. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02012D0340-20170705

Commission Implementing Decision 2014/150/EU of 18 March 2014 on the organisation of a temporary experiment providing for certain derogations for the marketing of populations of the plant species wheat, barley, oats and maize pursuant to Council Directive 66/402/EEC. OJ L 82, 20.3.2014, p. 29. https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32014D0150

Commission Implementing Decision (EU) 2020/1106 of 24 July 2020 on the organisation of a temporary experiment under Council Directives 66/401/EEC, 66/402/EEC,2002/54/EC and 2002/57/EC as regards the official checking rate for field inspection under official supervision for

basic seed, bred seed of generations prior to basic seed and certified seed. OJ L 242, 28.7.2020, p. 7. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32020D1106

Commission Implementing Directive 2014/98/EU of 15 October 2014 implementing Council Directive 2008/90/EC as regards specific requirements for the genus and species of fruit plants referred to in Annex I thereto, specific requirements to be met by suppliers and detailed rules concerning official inspections. OJ L 298, 16.10.2014, p. 22 https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:32014L0098

Commission Implementing Directive (EU) 2021/971 of 16 June 2021 amending Annex I to Council Directive 66/401/EEC on the marketing of fodder plant seed, Annex I to Council Directive 66/402/EEC on the marketing of cereal seed, Annex I to Council Directive 2002/54/EC on the marketing of beet seed, Annex I to Council Directive 2002/55/EC on the marketing of vegetable seed and Annex I to Council Directive 2002/57/EC on the marketing of seed of oil and fibre plants, as regards the use of biochemical and molecular techniques. OJ L 214, 17.6.2021, p. 62 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021L0971

Commission Implementing Directive (EU) 2022/1647 of 23 September 2022 amending Directive 2003/90/EC as regards a derogation for organic varieties of agricultural plant species suitable for organic production. OJ L 248, 26.9.2022, p. 46 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2022.248.01.0046.01.ENG&toc=OJ%3AL%3A2022%3A248%3ATOC

Commission Implementing Directive (EU) 2022/1648 of 23 September 2022 amending Directive 2003/91/EC as regards a derogation for organic varieties of vegetable species suitable for organic production. OJ L 248, 26.9.2022, p. 52 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2022.248.01.0052.01.ENG&toc=OJ%3AL%3A2022%3A248%3ATOC

Commission Implementing Regulation (EU) 2019/2072 of 28 November 2019 establishing uniform conditions for the implementation of Regulation (EU) 2016/2031 of the European Parliament and the Council, as regards protective measures against pests of plants, and repealing Commission Regulation (EC) No 690/2008 and amending Commission Implementing Regulation (EU) 2018/2019. OJ L 319, 10.12.2019, p. 1 https://eur-lex.europa.eu/eli/reg_impl/2019/2072/oj

Commission Implementing Regulation (EU) 2022/1372 of 5 August 2022 as regards temporary measures to prevent the entry into, the movement and spread within, the multiplication and release in the Union of *Meloidogyne graminicola* (Golden & Birchfield). OJ L 206, 8.8.2022, p. 16 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022R1372

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 https://eur-lex.europa.eu/eli/dec/2019/1905/oj

Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights. OJ L 227, 1.9.1994, p. 1 https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A31994R2100

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, 17.04.2001, p. 1 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32001L0018

Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. OJ L 268, 18.10.2003, p. 1 https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32003R1829

Regulation (EC) No 138/2004 of the European Parliament and of the Council of 5 December 2003 on the economic accounts for agriculture in the Community OJ L 33, 5.2.2004, p. 1 https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A32004R0138

Regulation (EU) 2016/2031 of the European Parliament of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC. OJ L 317, 23.11.2016, p. 4 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32016R2031

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 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32017R0625

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 https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32018R0848

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 MS 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. 1–186 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02021R2115-20220422