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COMMISSION STAFF WORKING DOCUMENT

Study on the Union's options to update the existing legislation on the production and marketing of plant reproductive material

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Contents

| | |
|---|-----------|
| List of abbreviations | 2 |
| Executive Summary | 3 |
| 1. Background..... | 6 |
| 2. Legal and political context..... | 7 |
| 3. Description of the problems..... | 9 |
| 3.1. Complex, incoherent and fragmented legal framework | 10 |
| 3.2. Complexity and rigidity of procedures | 11 |
| 3.3. Internal market problem/non-level playing field..... | 13 |
| 3.4. Lack of harmonised rules on official controls..... | 15 |
| 3.5. Obstacles to innovation..... | 16 |
| 4. Objectives: What is to be achieved? | 16 |
| 5. What are the possible policy options? | 18 |
| 5.1. Option 0: Do-nothing..... | 18 |
| 5.2. Option 1: Improve procedures and coherence of the legislation and introduce <i>ad hoc</i> measures to increase sustainability | 18 |
| 5.3. Option 2: Flexibility to adapt to technological developments, to improve access to genetic resources and to address the sustainability objectives in a coherent way..... | 19 |
| <i>Sub-option 2A: Balancing flexibility and harmonisation – more guarantees for users</i> | <i>19</i> |
| <i>Sub-option 2B: Full harmonisation – high guarantees for users</i> | <i>20</i> |
| 6. Conclusions..... | 20 |
| 7. Annex 1 – 2013 PRM Proposal for review of the Directives | 21 |
| 8. Annex 2 – Developments of the PRM legislation | 23 |
| 9. Annex 3..... | 25 |
| 9.1. Part A: Summary of feedback to open questions in validation survey | 25 |
| 9.2. Part B: Original replies to open question in the validation survey..... | 28 |

LIST OF ABBREVIATIONS

BMT – Bio-molecular techniques

CAP – Common Agricultural Policy

CPVO – Community Plant Variety Office

DUS – Distinctness, Uniformity, and Stability

FRM – Forest reproductive material

GMO – Genetically Modified Organism

ISTA – International Seed Testing Association

ITPGRFA – International Treaty on Plant Genetic Resources for Food and Agriculture

NCA – National Competent Authority

OCR – Official Controls Regulation

OECD – Organisation for Economic Co-operation and Development

PRM – Plant reproductive material

QPs – Quarantine pests

RNQPs – Regulated Non-Quarantine Pests

TFEU – Treaty on the Functioning of the European Union

UPOV – Union internationale pour la protection des obtentions végétales

VCU – Value for Cultivation and Use

EXECUTIVE SUMMARY

The Council requested under Article 241 of the Treaty on the Functioning of the European Union (TFEU), through Council Decision (EU) 2019/1905 of 8 November 2019¹, the European Commission (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 (‘PRM study’)², as well as a proposal, if appropriate in view of the outcomes of the study.

The Commission study was supported by the work of an external contractor³. The following key elements have emerged from the PRM study:

- 1) The fragmented legislation, developed over several decades, causes lack of coherence between the marketing Directives and leaves room for interpretation. Such interpretation contributes to non-harmonised implementation resulting in a non-level playing field for the operators. Moreover, the legislation offers the possibility of many derogations. Member States have applied these derogations in different ways.
- 2) Complex and rigid procedures, including detailed technical requirements in the marketing Directives, hinder *de facto* technical amendments, create a cumbersome decision-making process, and put a high burden on competent authorities carrying out certification. The basic legislation does not facilitate the introduction of lighter registration requirements for traditional and locally adapted plant varieties and tree species which could contribute to seed diversity and security. Likewise, it does not facilitate the introduction of testing requirements for the development of organic varieties suitable to organic production. In addition, the legislation does not support the conservation and sustainable use of plant genetic resources and forest genetic resources, and biodiversity under the Biodiversity Strategy.
- 3) Lack of clarity of the PRM and FRM legislation and the outdated provisions cause non-harmonised implementation of the legislation. The incorporation of sustainability criteria in all sectors, including the forestry sector, which could ensure seed and food security supporting sustainable agri-food production and resilient forests is impeded. The rigidity of the current legal framework complicates the creation of synergies with other policies. All of this poses difficulties to address policy issues identified in the Green Deal and its related strategies such as the Farm to Fork Strategy, the EU Adaptation Strategy on mitigating the impact of, and adapting to climate change, the new EU Forest Strategy on healthy and resilient forests and the European Digital Strategy.

¹ 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. 105-106.

² In principle, the term plant reproductive material (PRM) covers all types of PRM including forest reproductive material (FRM). However, to allow distinguishing between PRM and FRM, PRM will be used to identify all PRM other than FRM.

³ The work of the contractor will be referred to as ‘contractor’s report’ (<https://doi.org/10.2875/406165>).

- 4) The lack of a harmonised and risk-based framework for official controls and IT support systems creates a non-level playing field for official controls within the Union, limiting the ability for competent authorities to enforce risk-based measures, and to ensure an efficient use of control resources.
- 5) The current PRM legal framework (which includes also FRM) does not allow taking account of all technical and scientific developments. The rigidity of the regulatory framework may create barriers for the market access of PRM and FRM and new production processes obtained through scientific and technical progress. The current rules impede the use of scientific and technical developments that could support the production and registration of PRM and FRM and the certification of PRM.

The results of this study confirm that the main findings of the 2007-2008 evaluation and impact assessment, on which a previous Commission proposal was based, remain generally valid.

However, since 2013, there have been new technical developments in the seed production and breeding sector, several research activities on breeding, conservation varieties and organic PRM, an increasing demand for sustainability in agriculture and the increasing need for conservation of agrobiodiversity and adaptation to climate change.

This study has therefore identified new challenges beyond confirming the already existing ones. The possible follow-up to this study should identify the most appropriate policy approach, and elaborate and assess the possible options identified for amending the current legal framework. The legislation should be modernised and comprehensive, reflecting the developments that have occurred in the sector. It should be uniformly applied, efficient and effective, more open to integrate new and future developments, sustainable, more supportive of biodiversity and climate proof.

This study presents the following possible options for updating the legislation on the production and marketing of PRM and FRM.

- **Option 0: Do nothing:** no change in the current situation; focus on implementing the legislation in a way, which takes into account the objectives of the Green Deal and the Farm to Fork Strategy.
- **Option 1: Improve procedures and coherence of the legislation, and introduce *ad hoc* measures to increase sustainability.**

This option would include amendments to the Directives to align their structure and decision-making procedures, as well as to introduce measures in support of sustainability.

- **Option 2: Flexibility to adapt to technological developments, to improve access to genetic resources and to address the sustainability objectives in a coherent way**

This option would introduce amendments to the Directives responding more comprehensively to the need for more sustainability and more biodiversity. It would contribute to climate change adaptation and mitigation by creating more flexibility in the registration and marketing of varieties and procedures in general. It would finally consider the particularities of exchange of seed between farmers, and allow for an easy adaptation of the legislation to scientific and technical developments. It includes two sub-options, 2A and 2B, which address different policy choices relating to the scope of application of the Directives, the extent of the flexibility afforded to operators and competent authorities, and official controls.

1. BACKGROUND

In November 2019, the Council, on the basis of Article 241 of the Treaty on the Functioning of the European Union, requested the Commission ‘to submit, by 31 December 2020, a study on the options to update the existing legislation on the production and marketing of plant reproductive material’. This study (the ‘PRM study’) responds to that request. The existing legislation assessed in this study, comprises a Directive on the Common Catalogue of varieties of agricultural plant species and 11 marketing Directives covering seed, plant propagating material, and forest reproductive material (FRM). The COVID-19 pandemic led to a four-month delay of its submission to the Council.

The Council’s request and this study are the most recent steps of a process that started more than a decade ago. Based on an evaluation in 2007-2008⁴, an Action Plan in 2009 and an impact assessment⁵ in 2011-2012, the Commission submitted in May 2013 a proposal for a Regulation on the production and marketing of PRM including FRM replacing 12 Directives⁶ (the ‘2013 PRM proposal’). The main objective was to create a common and simplified framework for all sectors of seed and other PRM including FRM, and in particular to:

- Grant more responsibility and flexibility to operators;
- Decrease administrative burden and costs by making the rules more flexible and efficient across the EU; create more opportunities for niche markets and for small producers;
- Make the rules more compatible with policy aims such as a more sustainable agriculture and the enhancement and conservation of biodiversity;
- Streamline administrative procedures to support innovation; and
- Establish a level playing field by introducing the principle of cost recovery.

Moreover, the aim was to create links with the new rules and principles of the plant health and official controls legislation, which were revised at the same time and which entered into force in 2016 and 2017, respectively. The proposal was rejected by the European Parliament in 2014 and withdrawn by the Commission in March 2015. Annex 1 provides further details on the positions of the European Parliament and the Council to the proposal.

The environment in which the Union PRM and FRM legislation operate is constantly changing. The initial objectives of the current legislation are to ensure the supply of high quality PRM and FRM to EU agricultural, horticultural and forestry production and to help create an internationally highly competitive sector. The evaluation of 2007–2008 concluded that the current legislation achieved these objectives very well, as the objectives set were achieved to a high degree. The evaluation however identified also a number of problems, which are described below. The current legislation has unnecessarily burdensome procedures

⁴ Food Chain Evaluation Consortium ‘Evaluation of the Community acquis on the marketing of seed and plant propagating material (S&PM)’,

https://ec.europa.eu/food/sites/food/files/plant/docs/ppm_legis_review_s_pm_evaluation_finalreport.pdf;

https://ec.europa.eu/food/sites/food/files/plant/docs/ppm_legis_review_s_pm_evaluation_finalreport_ann.pdf

⁵ https://ec.europa.eu/food/sites/food/files/plant/docs/ppm_legis_review_ppm_impact.pdf

⁶ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52013PC0262>

to be followed and complied with by operators and competent authorities to register new plant varieties and to authorise these varieties for marketing. Due to the complexity of the legislation and the way how the Directives were transposed into national law by Member States, the rules applicable in different Member States diverge. Furthermore, the evaluation concluded that the objectives are partly outdated, as they do not take into account new policy priorities. The experience of the years since the evaluation suggest that at least some of these problems might have worsened and new problems might have emerged. It has become increasingly clear that the existing legislation is not adequately addressing these problems and that it cannot fully serve, in the most effective way, the purpose of attaining the Green Deal objectives of creating and facilitating the use of climate proof plant varieties and tree species to adapt to, and mitigate, the impact of climate change, whilst at the same time contributing to sustainable agri-food production and food security, and protecting biodiversity.

The Farm to Fork strategy underlines the importance of seed security and diversity for sustainable food systems and calls on the Commission ‘to take measures to facilitate the registration of seed varieties, including for organic farming, and to ensure easier market access for traditional and locally-adapted varieties’. This study also takes into account the European Parliament’s and the Council’s earlier input on the 2013 PRM proposal and the results of 2007-2008 evaluation. Considering the fact that legislation did not change since the last evaluation, the PRM study assessed the relevance of new evidence that has emerged from the implementation since the conclusion of the last evaluation and of the problems identified in the evaluation carried out in 2007-2008. The PRM study builds on an updated analysis of the problems around the PRM and FRM legislation, takes stock of new technical developments and their impact on PRM issues, and fills knowledge gaps, in particular on the amateur gardener market and the FRM sector. The PRM study addressed the amateur gardener market and the FRM sector because this was not done during the 2007-2008 evaluation. Stakeholders also had the opportunity to express their views on problems encountered with the legislation and on how the legislation should be revised (see Annex 3). The objectives of the Green Deal and its strategies in particular the Farm to Fork and Biodiversity Strategies have also been taken on board to identify possible options for future development.

2. LEGAL AND POLITICAL CONTEXT

Marketing of seed and other PRM, including FRM, is currently regulated by 12 Council Directives, the oldest of them dating back to 1966 (see Annex 2). Those 12 Directives are structured into one horizontal Directive on the Common Catalogue of varieties of agricultural plant species and 11 vertical Marketing Directives.

- Five seed Directives (fodder plant seed, cereal seed, beet seed, seed of oil and fibre plants and vegetable seed, including a catalogue of varieties of vegetable seed);
- Three plant propagating material Directives (vine, seed potatoes, vegetable reproductive material other than seed);
- Two Directives that cover both seed and propagating material (fruit plant propagating material and fruit plants and ornamental plants); and

- One Directive that covers FRM.

The 11 Directives on PRM are based on two main pillars, namely the registration of varieties and the certification/inspection of individual PRM lots (excluding FRM). The most widely marketed plant species are regulated in those Directives. In the case of FRM, the legislation is based on the approval and registration of basic material and the traceability and quality control of FRM. Plant varieties should be listed in a national catalogue and then in the EU (Common) catalogues (for agricultural and vegetable seeds) to be marketed throughout the EU. In order to be listed, it has to be demonstrated that varieties are Distinct, Uniform and Stable and that variety denomination rules are observed. Moreover, varieties of agricultural crop species and industrial chicory must be tested for their Value for Cultivation and Use (VCU).

The FRM production process is very different from that of seed and other PRM. In the case of FRM, the competent authorities must approve the planted trees (basic material) from which FRM will subsequently be collected and produced. Similar to the registration of plant varieties, each Member State draws up lists of registered basic material containing a description of the basic material (tree species, type of basic material, location). However, there is no need to assess the distinctness, uniformity and stability of basic material as for plant varieties. Moreover, there are no certification requirements for FRM as for PRM (e.g. seed certification). Hence, during the evaluation of the legislation, many stakeholders indicated that the FRM legislation should be addressed separately.

Current political priorities in agriculture and food are no longer restricted to the policy aims of the 1960s prioritising food security. Agri-food policy in the EU has come to be seen in the past years as strategically important for contributing to the mitigation of environmental degradation, to enhancing biodiversity and to climate change adaptation and mitigation. PRM and FRM legislation are critically important for reaching these objectives. Moreover, technological developments, such as bio-molecular techniques (BMT) and digitalisation, need to be taken into account. These developments can help improve the efficiency and security of PRM and FRM production systems and enhance traceability along the production and marketing chains.

In 2019, the Commission announced the European Green Deal, an ambitious project for the EU to become climate neutral by 2050. The European Green Deal contains several accompanying strategies: the Farm to Fork Strategy⁷, the Biodiversity Strategy⁸, the EU Adaptation Strategy⁹, the new EU Forest Strategy¹⁰ and the European Digital Strategy¹¹.

The Farm to Fork Strategy aims to accelerate our transition to a sustainable food system, which is resilient, has a neutral or positive environmental impact, helps to mitigate climate

⁷ https://ec.europa.eu/food/sites/food/files/safety/docs/f2f_action-plan_2020_strategy-info_en.pdf

⁸ https://eur-lex.europa.eu/resource.html?uri=cellar:a3c806a6-9ab3-11ea-9d2d-01aa75ed71a1.0001.02/DOC_1&format=PDF

⁹ https://ec.europa.eu/clima/policies/adaptation/what_en#tab-0-1

¹⁰ https://ec.europa.eu/info/food-farming-fisheries/forestry/forestry-explained_en#theeforeststrategy

¹¹ <https://ec.europa.eu/digital-single-market/en/content/european-digital-strategy>

change and adapt to its impacts, reverses the loss of biodiversity, ensures food security, nutrition and public health, making sure that everyone has access to sufficient, safe, nutritious, sustainable food, preserves affordability of food while generating fairer economic returns, fostering competitiveness of the EU supply sector and promoting fair trade.

The EU Adaptation Strategy emphasises the need to make better use of genetic diversity and plant and forest genetic resources for adaptation, and to facilitate the broadening of the supply of suitable high-quality PRM and FRM to support adaptation in agriculture, forestry, and land ecosystem management.

Seeds play a key role in achieving a more sustainable, productive and diversified EU agriculture and contribute to the ‘Green Deal’ and to the 2030 EU Vision for sustainable food systems as presented in the ‘Farm to Fork’ strategy. New and improved plant varieties are essential for farmers to ensure better productivity and improved food quality, for adaptation to climate change and for fighting plant pests with a reduced use of plant protection products. Plant breeding in general, and more in particular the development of new seed production as well as innovation in plant breeding play an important role in developing new plant varieties and thus are essential in contributing to seed diversity and food security. In addition, the threat of an increasing loss of agrobiodiversity in the EU and worldwide affects the breeding of new varieties as genetic diversity is the reservoir for plant breeding.

In relation to organic varieties, new objectives have been introduced through the adoption of the Organic Regulation (EU) 2018/848¹². These objectives concern, amongst others, the development of PRM adapted to the specific needs of organic agriculture as well as the contribution to a high level of biodiversity in particular by using ‘organic varieties’ and ‘organic heterogeneous material’. The Commission is empowered to adopt rules for the production and marketing of PRM of organic heterogeneous material (legal text under preparation).

Finally, genetically diverse forest seeds and the availability of high-quality tree planting material with known ecological traits form the basis for the establishment of resilient forests able to adapt to, and mitigate the impact of, climate change.

3. DESCRIPTION OF THE PROBLEMS

The fragmented legislation that developed over several decades causes a lack of coherence between the marketing Directives, and leaves room for interpretation. This has caused a non-harmonised implementation and a non-level playing field because of different conditions for operators depending on the Member State (e.g. costs, possibility of certification under official supervision). Complex and rigid procedures including detailed technical requirements in the basic legislation put a high burden on competent authorities and operators, and create a cumbersome decision-making process. There is a lack of coherence with other EU legislative

¹² 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. 1–92.

frameworks on Plant health, Official Controls and genetically modified organisms (GMOs). Adapting the legislation to new policy priorities and to new scientific and technical developments is hindered by detailed rules in the basic Directives.

3.1. Complex, incoherent and fragmented legal framework

The legislation is composed of 12 basic Directives and dozens of other legal acts¹³. The Directives have been developed since the 1960s, reflecting different political objectives and are applied within a constantly evolving scientific-technical context (see Annex 2). The large number of Directives and their long history of amendments have led to a complex, outdated, incoherent and fragmented legal framework. The following paragraphs illustrate these issues in more detail.

The PRM Directives do not clearly define their scope of application when it comes to exemptions. Empowerments defining harmonised conditions for a certain exemption have never been used and therefore Member States apply exemptions differently¹⁴. In other cases, the vague description of the exemption resulted in the exemption not being used consistently¹⁵. The FRM Directive applies to FRM marketed for forestry purposes only. This creates uncertainties about applicable rules when species regulated by the FRM Directive are marketed for non-forestry purposes¹⁶.

The Directives do not allow exchange of material between farmers because the definition of marketing covers any supply or transfer of seed for commercial exploitation. The possibility to exchange seed between farmers is seen by some stakeholders as human right¹⁷ and is recognised by the International Treaty on Plant Genetic Resources for Food and Agriculture¹⁸.

The 2013 PRM proposal, including FRM, was part of a broader package of proposals for new legislation on plant health, animal health and official controls. In 2014, the European Parliament rejected the 2013 PRM proposal for the following main reasons. One Regulation could not address the requirements of the broad range of PRM. The European Parliament did not want the single Regulation to cover FRM. The European Parliament expressed concerns regarding the marketing of ornamental PRM and marketing to amateur gardeners. Definitions

¹³ A compilation of the legal acts can be found here:

https://ec.europa.eu/food/plant/plant_propagation_material/legislation/specific_legislation_en

¹⁴ For example, for the sealing and labelling of small packages of PRM different rules apply in different Member States and this can cause obstacles to the free movement of such packages.

¹⁵ For example, the marketing of special wheat varieties for baking purposes is exempted from EU provisions in France under the 'industrial use' exemption, but not in Hungary; See p. 37 in

https://ec.europa.eu/food/sites/food/files/plant/docs/ppm_legis_review_s_pm_evaluation_finalreport.pdf.

¹⁶ See section 5.8 of the contractor's report.

¹⁷ NGOs find support for this interpretation in the United Nations Declaration on the Rights of Peasants and Other People Working in Rural Areas from 2018, which in its Article 19(1)(d) states that peasants have '(t)he right to save, use, exchange and sell their farm-saved seed or propagating material'; the full text of the Declaration is available at <https://digitalibrary.un.org/record/1650694?ln=en#record-files-collapse-header>.

¹⁸ Article 9 of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), to which the EU and all its Member States are Contracting Parties, establishes Farmers' Rights. Article 9(3) acknowledges the right of farmers to save, use, exchange and sell farm-saved seed/propagating material, subjects this right, however, to national law (in particular intellectual property rights).

were vague and the 2013 PRM proposal placed an unnecessary burden on operators and competent authorities. The 2013 PRM proposal contained too many empowerments for delegated acts and not enough biodiversity provisions. The withdrawal of the 2013 PRM proposal caused an ensuing lack of coherence between the PRM marketing legislation, including FRM, and the plant health legislation. This problem would have been solved if the PRM and FRM legislation and the plant health legislation had been amended at the same moment. Currently, the inclusion of the reference to certain plant pests both in the plant health legislation and the marketing Directives causes confusion for competent authorities and operators^{19,20}. There are also overlaps between the Directives and the EU GMO legislation. The Directives establishing the common catalogues of agricultural and vegetable varieties²¹ contain outdated references to GMO legislation. Moreover, the rules on official controls of PRM and FRM are not in line any more with the rules applicable in the plant health area, pursuant to Regulation (EU) 2017/625 on official controls.

3.2. Complexity and rigidity of procedures

Stringent registration procedures are in place to ensure that varieties are distinct, uniform, and stable, and perform well, which creates burdens for both operators and competent authorities. This applies in particular to varieties of agricultural and vegetable species, and fruit and vine propagating material.

Breeding and development of new varieties, which precedes the registration process, is expensive and time consuming (more than 10 years). The registration process of new varieties is burdensome in terms of costs and time for both operators and competent authorities. The time-consuming registration process for certain species can delay the point at which revenue streams can be established to recoup upfront costs and establish a profitable product. This also creates a competitive disadvantage for SMEs exacerbated by the different national practices with regard to costs²². The 2013 PRM proposal was criticised for not taking into account the needs of amateur gardeners^{23,24}. The registration of varieties marketed exclusively to amateur gardeners was considered too burdensome and restrictive. According to some stakeholders this limits the diversity of varieties available on the amateur market. It also concerns varieties intended for organic production where testing requirements may not reflect the needs of organic varieties suitable for organic production²⁵.

¹⁹ Plant pests regulated for quarantine purposes (Union quarantine pests, Union QPs) as well as the ones regulated for quality purposes (Union Regulated non-quarantine pests, Union RNQPs) are listed under the new Plant Health Regulation (EU) 2016/2031. The Union RNQPs remain also listed in PRM legislation. The QP requirements as well as RNQP requirements for some PRM sectors are listed under the Plant Health Regulation, while RNQP requirements for other PRM sectors remain only listed under the PRM legislation.

²⁰ See section 4.4.1 in the contractor's report

²¹ Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species. OJ L 193, 20.7.2002, p. 1–11, and Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed. OJ L 193, 20.7.2002, p. 33–59.

²² See section 4.1.1 in the contractor's report.

²³ See

https://ec.europa.eu/food/plant/plant_propagation_material/legislation/review_eu_rules/replies_consultation_en

²⁴ See section 4.5 in the contractor's report.

²⁵ See section 4.1.1 in the contractor's report.

Certification ensures the identity, health and quality of PRM but puts a high burden on competent authorities, and limits the flexibility of operators as procedures for issuing the certificates for certain species are lengthy and costly. Certification under official supervision which is a lighter form of official certification relying more on operators input is only possible for certain categories of seed of agricultural species²⁶.

Since 2013, issues around seed diversity, biodiversity and the conservation and sustainable use of plant and forest genetic resources have gained more importance. The Commission has committed to take action on these topics within the frame of the Biodiversity strategy. The lack of flexibility of the legal framework and complex procedures hamper progress in this domain.

The FRM Directive currently does not contain any provisions on the conservation and sustainable use of forest genetic resources. The FRM legislation focusses on breeding and thus creates an imbalance between the conservation of genetic diversity and tree improvement²⁷. This hampers the introduction of any initiatives related to the conservation of genetic diversity and biodiversity.

There is some evidence suggesting that the current rules on variety registration could limit the diversity of plant varieties available on the market despite the rules on conservation of varieties. These rules may create unnecessary burdens for the registration and marketing of certain types of varieties such as varieties exclusively marketed to amateur gardeners and locally adapted conservation varieties. The use of locally adapted conservation varieties has been restricted to a limited number of marketing Directives²⁸. When the new Organic Regulation (EU) 2018/848 was adopted, the Commission acknowledged the need to establish conditions under which organic varieties suitable for the organic production should be developed. The Commission committed to develop specific testing requirements for such varieties.

Furthermore, there are no incentives for the breeding of neglected and underutilised species²⁹ that contribute to nutritional diversity and security and tend to be more climate resilient.

²⁶ In agricultural species, only official field inspections of pre-basic and basic seed crops are possible. Field inspections under official supervision are only allowed for the certified category.

²⁷ See section 4.7.1.2 of the contractor's report.

²⁸ The concept of conservation varieties is currently reflected only in two marketing Directives (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. 13–19, and 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. 44–54). Several stakeholders have asked to extend the concept of conservation varieties to fruit plants and vine (see Annex 3).

²⁹ Neglected and underutilised species are crop species with potential or actual value for food and nutrition security, but which have been paid limited attention by agricultural researchers, plant breeders, seed companies, and policymakers.

Likewise, varietal mixtures of agricultural species³⁰ and heterogeneous material³¹ face limitations because of the PRM marketing legislation. The Organic Regulation (EU) 2018/848 has defined ‘organic heterogeneous material’ as a new category of PRM. The Commission has adopted a proposal for a delegated act setting specific rules on the production and marketing of PRM of organic heterogeneous material.

The tool foreseen by the legislator to introduce in certain cases technical amendments to the PRM legislation, such as the addition of certification requirements for new species and amendments based on successfully concluded temporary experiments is the ordinary legislative procedure. This procedure is cumbersome and disproportionate compared to the objectives of the amendments³².

According to the existing legal framework, non-EU countries seeking to export PRM and FRM to the EU shall meet the same criteria for characteristics of the material, examination, identification, marking, control and packaging as material harvested and controlled in the EU. PRM produced in non-EU countries shall offer the same guarantee of identity, health and quality as in EU PRM. The EU decision-making process for granting this kind of equivalence at EU level is disproportionate compared to the objectives of the amendments, and it is inconsistent across species. In addition, the decision to grant equivalence does not take into consideration the economic impact of imports from non-EU countries on EU operators.

3.3. Internal market problem/non-level playing field

Directives need to be transposed into national legislation. The complexity of the PRM and FRM marketing Directives and the lack of coherence between the marketing Directives has led to differences between nationally transposed rules, which affected negatively competition among operators in different Member States³³ as illustrated by the following examples.

Member States charge different fees for the registration of certain types of varieties. This causes different conditions for operators in different Member States. In some Member States the registration fees for conservation and amateur varieties³⁴ are lower than for conventional varieties³⁵ whereas in other Member States the fees are identical³⁶. When the registration fees

³⁰ Art. 13(1) of Directive 66/402/EEC. Farmers can create their own mixtures from pure varieties.

³¹ The marketing of heterogeneous material is currently only allowed if produced under organic conditions pursuant to a delegated Regulation adopted in 2021 under the Organic Regulation (Regulation (EU) 2018/848).

³² Amendments following the successful conclusion of the temporary experiment as regards field inspections under official supervision would require the ordinary legislative procedure (Commission Implementing Decision 2012/340/EU 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. 90–92).

³³ See section 4.3 in the contractor’s report.

³⁴ Amateur varieties are varieties with no intrinsic value for commercial production but developed for growing under particular conditions.

³⁵ The term ‘conventional varieties’ is used here as an encompassing term of varieties that are registered through the normal process of Distinctness, Uniformity, and Stability (DUS) and Value for Cultivation and Use (VCU) testing. It refers to commercial production of varieties usually bred for high input agriculture, as opposed to, for instance, conservation and amateur varieties, preservation seed mixtures etc.

³⁶ See section 4.6.2 in the contractor’s report.

for conservation and amateur varieties are identical to those of conventional varieties, there is little incentive to register conservation and amateur varieties.

VCU testing is restricted to varieties of agricultural species. Yield remains an important criterion in VCU tests of agricultural crops aiming to ensure food security. Even though the cultivation of fruit, vine and vegetable varieties may have larger environmental impacts (e.g. more pesticide use), varieties of these crop groups are not subject to VCU testing during registration. If VCU tests for vegetable varieties were to be considered, the great number and diversity of uses of these varieties and the wide range of production chains would make it very difficult to devise standardised VCU tests in this sector.

The cost and the time needed to test the VCU of new, improved varieties of agricultural species can differ significantly between Member States³⁷. EU legislation³⁸ only stipulates very broad criteria that shall be applied in VCU testing. Member States have wide discretion to design their VCU procedures and rules according to agro-climatic conditions and other national needs. Sustainability is not an explicit focus in VCU testing although sustainability characteristics can fall under the four criteria set in the legislation (yield, resistance to plant pests, behaviour with respect to factors in the physical environment, quality characteristics)³⁹. However, the visible effects of climate change have put into question breeding targets focussed solely on crop productivity. The resilience of the main crop species to biotic and abiotic threats has recently received increased attention⁴⁰. The lack of clear rules on VCU testing and the absence of sustainability criteria in the EU legislation have caused considerable differences between Member States in relation to the sustainability characteristics of new varieties. In this respect, the conditions for registering new varieties are not harmonised across Member States.

In addition, current VCU testing requirements are not appropriate for the specific needs of organic varieties and Member States have applied different approaches to register organic varieties.

Another problem caused by non-harmonised implementation of the legislation concerns the approach taken by Member States to verify traceability along the FRM production chain. Traceability systems are often not efficient nor effective, as they fully rely on the document management system put in place and the availability of financial and human resources to execute official controls. Likewise, there is room for improving the harmonisation and efficiency of the traceability system when PRM and FRM are marketed, which may minimise

³⁷ See section 4.3 in the contractor's report.

³⁸ 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. OJ L 254, 8.10.2003, p. 7–10.

³⁹ Annex III to Commission Directive 2003/90/EC.

⁴⁰ Kahiluoto, H., Kaseva, J., Balek, J. et al. (2019) Decline in climate resilience of European wheat. *Proc. Nat. Acad. Sci.* 116: 123-128; DOI: 10.1073/pnas.1804387115; for a different perspective see Voss-Fels, K.P., Stahl, A., Wittkop, B., et al. (2019) Breeding improves wheat productivity under contrasting agrochemical input levels. *Nat. Plants* 5: 706-714.

the risk of fraud. Digital illiteracy, poor connectivity and costs remain key barriers in the adoption of digital technologies, which could address the issue of traceability⁴¹.

The FRM Directive does not contain clear rules on the information to be provided to the end users that will be planting the forest seedlings and forest plants. The Commission has provided guidelines but Member States do not apply these guidelines in the same way, which creates uncertainty for the buyer of the material. Moreover, the end user cannot obtain any information on the material when placing an order and consequently, cannot make any informed decision on the best suited forest seedlings and forest plants for his needs.

3.4. Lack of harmonised rules on official controls

After the withdrawal of the 2013 PRM proposal there was no agreement on the inclusion of the PRM and FRM Directives in the Official Controls Regulation⁴². The lack of a harmonised and risk-based framework for official controls does not enable a level playing field for operators subject to official controls and may limit the ability for competent authorities to enforce risk-based measures⁴³. The provisions on controls in the PRM and FRM Directives leave room for interpretation and result in differences in the extent and nature of control and enforcement across Member States. Costs charged for official controls differ between Member States creating different conditions for operators. Certain Member States do not have sufficient financial and human resources to execute official controls⁴⁴. Moreover, as plant health controls for the same PRM and FRM are covered by the Official Controls Regulation, plant inspection services are confronted with two different control regimes⁴⁵. In addition, the tools included in the Official Controls Regulation such as training and IT support systems can currently not be used in the PRM and FRM sectors limiting the efficiency and effectiveness of official controls. Currently, there is a lack of a secure IT system to exchange information on seed fraud in relation to the voluntary EU Seed Fraud Network, which hampers the functioning of this network. The EU Seed Fraud Network was set up in response to some fraudulent cases about official labels and imports of seed lots to facilitate cooperation when competent authorities are confronted with possible intentional violations of the Directives on the marketing of seed with a cross-border impact. However, this network could function in a

⁴¹ See section 4.2.2 in the contractor's report.

⁴² 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 095 7.4.2017, p. 1-142.

⁴³ These issues are described in sections 4.4.2 and 5.3 of the contractor's report.

⁴⁴ See section 4.6.1.6 in the contractor's report.

⁴⁵ The same would occur, when the current proposal for a delegated act on organic heterogeneous material will be in force as organic products are covered by the Official Controls Regulation.

more efficient way if it were part of the existing IT support systems under the Official Controls Regulation.

3.5. Obstacles to innovation

The European breeding sector is a highly innovative sector characterised by rapid scientific and technical developments. In certain cases the rigidity of the regulatory framework creates barriers for the market access of PRM and FRM obtained through scientific and technical progress. Sometimes the scope of the legislation does not cover innovative production processes⁴⁶.

The current rules impede the use of scientific and technical developments such as BMT⁴⁷ that could support the production and registration of PRM and FRM and the certification of PRM. The rigidity of the legal framework hampers the introduction of rules in the marketing Directives on innovative production processes such as *in vitro* propagation of fruit propagating material and somatic embryogenesis⁴⁸ to produce FRM.

There are also issues with organic varieties. The Farm to Fork Strategy includes the aim of reaching 25% of agricultural land under organic farming by 2030. However, the availability of organic seed and of varieties suitable for organic cultivation is insufficient because untreated non-organic seed is still used to varying extent in different countries⁴⁹. This practice, together with differences in organic VCU tests between Member States (see Section 3.3), discourages the breeding of varieties specifically adapted to organic cultivation.

4. OBJECTIVES: WHAT IS TO BE ACHIEVED?

Certain key objectives on which the 2013 PRM proposal were built have remained valid.

These key objectives are:

- To ensure the identity, health and quality of PRM for the users;
- To ensure a level playing field/harmonised market for producers and users of PRM and FRM;

⁴⁶ For example, new approaches to breed and propagate potatoes using true botanical seed of potatoes harvested from potato fruits (true potato seed, TPS) are not covered by the existing marketing Directive on seed potatoes. Lindhout, P., Meijer, D., Schotte, T., Hutten, R. C. B., Visser, R. G. F. & Van Eck, H. J. (2011). Towards F1 hybrid seed potato breeding. *Potato Research* 54: 301-312.

⁴⁷ There is a rapid development and growing importance of bio-molecular techniques (BMT) in plant breeding and testing of PRM due to a better understanding of the use of the genetic information, increasing IT capacity and decreasing laboratory costs. The Organisation for Economic Co-operation and Development (OECD), International Seed Testing Association (ISTA), and the Union internationale pour la protection des obtentions végétales (UPOV) have established working groups to explore the introduction and use of BMT in the testing of material of plant varieties (variety testing, seed certification, post-control tests). See also section 4.2.1 of the contractor's report.

⁴⁸ Somatic embryogenesis is an artificial process by which plants can regenerate bipolar structures from a somatic cell – i.e. ordinary plant tissue.

⁴⁹ The use of untreated, conventional seed is allowed under point 1.8.5 of Part I of Annex II to Regulation (EU) 2018/848. This derogation shall expire in 2036 but this deadline could be changed in view of the Commission report to the European Parliament and the Council after 2028.

- To support innovation and competitiveness of the EU PRM industry;
- To support sustainable production, biodiversity protection, adaptation to -and mitigation of- climate change, and to contribute to food security.

The 2013 PRM proposal also defined a number of specific objectives, of which the following have remained the same:

- To increase clarity and coherence of the legal framework through simplified, clarified and harmonised basic rules on fundamental principles presented in an improved legal form;
- Increase the efficiency/effectiveness of the PRM sector through the establishment of simplified, more flexible and proportionate procedures and to increase flexibility for operators without compromising the general policy objectives;
- Establish a level playing field while keeping a reasonable level of flexibility to account for regional differences in agricultural and environmental conditions;
- Empower competent authorities to enforce risk-based measures through a harmonised and risk-based framework for official controls;
- Support innovation by allowing the legislation to adapt to new scientific and technical developments.

Furthermore, the current analysis has identified the need to:

- Clarify the rules in relation to:
 - certain activities (exchange of seed) and marketing to certain PRM users (amateur gardeners);
 - information to be provided by operators in FRM documentation;
- Clarify the scope of the FRM marketing Directive in case EU-regulated tree species are marketed for non-forestry purposes (agroforestry and biodiversity purposes, biomass and energy generation);
- Introduce, further strengthen, and harmonise measures in relation to the European Green Deal and the Farm to Fork Strategy by:
 - including sustainability criteria in VCU testing;
 - extending the scope of conservation varieties to other PRM sectors,
 - facilitating registration and marketing of conservation varieties, lighter rules for variety mixtures;
 - addressing the needs of organic varieties, actions addressing *in situ* conservation and sustainable use of plant and forest genetic resources; to conserve and promote agrobiodiversity and possible participatory testing schemes;
- Support the development of digital technologies⁵⁰.

⁵⁰ See sections 4.2.2 and 5.5 in the contractor's report

5. WHAT ARE THE POSSIBLE POLICY OPTIONS?

5.1. Option 0: Do-nothing

No new initiative would be taken concerning any revision of the PRM and FRM marketing legislation. The use of existing empowerments for adopting specific rules and derogations for the production and marketing of certain types of PRM and FRM would take into account the objectives of the European Green Deal and the Farm to Fork Strategy.

5.2. Option 1: Improve procedures and coherence of the legislation and introduce *ad hoc* measures to increase sustainability

This option would include amendments to the Directives to align their structure and decision-making procedures, as well as to introduce measures in support of sustainability⁵¹.

In particular, the amendments would concern:

- Streamlining decision-making procedures relying on tertiary legislation to set requirements and to adapt these requirements to technical and scientific developments;
- Increasing the number of tasks that operators may carry out under supervision of the competent authorities when the risk so allows, and simplifying decision-making procedures at EU level;
- Improving coherence between the PRM, FRM and the plant health legislation by avoiding the risk of duplications, the risk of inconsistent rules applicable to the same material and the risk of different rules applicable to similar procedures; and ensuring coherence with the GMO legislation and the organic legislation;
- Clarifying and harmonising information to be provided by operators in FRM documentation;
- Supporting the Green Deal objectives through-measures addressing, in particular, the conservation and sustainable use of plant and forest genetic resources, the protection of biodiversity and climate change mitigation and adaptation;
- Contributing to the goals of the Farm to Fork Strategy by ensuring coherence with the future legislative framework on sustainable food systems. Special attention will be given to improving the availability of varieties adapted to the needs of organic agriculture;
- Creating a harmonised and risk-based system for official controls, which would allow for a more efficient and effective use of control resources, by amending existing control rules in the Directives and adding new rules, catering for the specific needs of the sector.

⁵¹ Objections raised by the European Parliament in 2014 are taken into account, as sector-specific Directives will remain in force. As also pointed out by Council at that time, this respects the specificities of the FRM sector, while it facilitates and encourages the protection of biodiversity. Contrary to what was requested by the European Parliament and the Council, this option does not distinguish between the identity, quality and health of PRM for professional and non-professional users. It would, however, increase flexibility for operators and competent authorities, in line with the position expressed by the Council in 2014.

5.3. Option 2: Flexibility to adapt to technological developments, to improve access to genetic resources and to address the sustainability objectives in a coherent way

This option would introduce amendments to the Directives responding more comprehensively to the need for more sustainability and more biodiversity. It would contribute to climate change adaptation and mitigation by creating more flexibility in the registration and marketing of varieties and procedures in general. It would finally consider the particularities of exchange of seed between farmers, and allow for an easy adaptation of the legislation to scientific and technical developments.

The sub-options 2A and 2B refer to both the PRM and FRM marketing Directives. They outline policy choices with different degrees of flexibility granted to operators and competent authorities, and with a different approach to official controls.

Horizontal measures⁵²:

In addition to the measures proposed under bullet points 1 to 7 in option 1 (which would apply here as well), the following measures would be proposed in combination with sub-option 2A or 2B:

- Improving label security, traceability and the integrity of the PRM and FRM production chain by promoting the use of digital technologies;
- Introducing new provisions to enhance the efficiency of the certification/inspection and variety registration system through modern and flexible processes and rules for the use of new technologies.

Sub-option 2A: Balancing flexibility and harmonisation – more guarantees for users⁵³

This sub-option consists of all the horizontal measures plus the following specific measures:

- Limiting the scope of application of the PRM marketing Directives to marketing to the professional sector. Extending the scope of the FRM marketing Directive to certain clearly defined non-forestry purposes;
- Streamlining the existing derogations to allow competent authorities and operators in the PRM and FRM sectors to adjust to specific national environmental circumstances;
- Creating a harmonised and risk-based system for official controls, which would allow a more efficient and effective use of control resources, by amending existing control rules in the Directives and adding new ones which cater for the specific needs of the sector.
- Establishing an *ad hoc* framework for the exchange of seed between farmers;

⁵² The underlying principles concerning the registration of varieties, DUS and VCU testing do not apply to FRM. Consequently, any references to these terms in the following paragraphs do not concern FRM.

⁵³ Following the request of the European Parliament and the Council, sub-option 2A includes the possibility to exclude marketing to non-professional end users from the scope of application of the legislation.

- Clarifying and extending exemptions to the scope of application of the PRM and FRM legislation and the regime applicable to exempted PRM and FRM.

Sub-option 2B: Full harmonisation – high guarantees for users⁵⁴

This sub-option consists of all the horizontal measures plus the following specific measures:

- Applicability of the PRM legislation to the marketing of varieties of PRM to professional and non-professional end users. Applicability of the FRM legislation exclusively to FRM marketed for forestry purposes.
- Improving conditions for the free circulation of PRM and FRM within the internal market by restricting derogations and national measures to a strict minimum;
- Creating a harmonised and risk-based system for official controls by including PRM and FRM into the scope of the Official Controls Regulation, which would allow a more efficient and effective use of control resources and also a high level of consistency with rules governing official controls along the entire agri-food chain, including plant health, GMOs, and organic production.
- Regulating exchange of seed between farmers as ‘marketing’, without developing a specific framework for this type of exchange.

6. CONCLUSIONS

As requested by the Council, the Commission has carried out a study on the options to update the existing legislation on the production and marketing of PRM.

The Commission intends as a follow-up, taking due consideration of the outcome of an impact assessment, to adopt a legislative proposal reviewing the current legal framework.

⁵⁴ Sub-option 2B addresses the issue of the exchange of seed between farmers raised during European Parliament discussions. Sub-option 2B also includes PRM and FRM in the scope of the Official Controls Regulation, thereby following the approach taken, and supported by the European Parliament and the Council, for the 2013 PRM proposal.

7. ANNEX 1 – 2013 PRM PROPOSAL FOR REVIEW OF THE DIRECTIVES

European Parliament

The proposal was rejected by a majority in the European Parliament in March 2014. The lead AGRI Committee referred in its report to the Plenary to the ENVI Committee opinion of 30 January 2014 asking to reject the proposal and to submit a new one for the following reasons:

- (a) The ‘one size fits all’ approach (one Regulation) does not meet the requirements of the broad range of PRM and the needs of operators, consumers and competent authorities;
- (b) FRM should not be covered;
- (c) Concerns in relation to PRM for ornamental purposes and sale to home gardeners;
- (d) Poor quality of impact assessment and extended remit to the Community Plant Variety Office (CPVO);
- (e) Vague definitions and unnecessary administrative burden placed on Member States and operators;
- (f) The large number of delegated acts hampers proper assessment of consequences;
- (g) Need to facilitate and encourage biodiversity.

Other reasons expressed by some Members of the European Parliament concerned the unfortunate timing (shortly after the Common Agricultural Policy (CAP) review and before the elections) and the need for more time for discussions. It was also questioned whether exchange of seed between farmers should be considered as marketing.

Council

Following the rejection by the European Parliament, the AGRIFISH Council continued discussions with Member States and the Commission. In June 2014, the AGRIFISH Council decided to continue the work subject to the Commission developing an amended proposal with substantive changes. This position was stated in the report from the Greek Presidency to the Council, and reiterated under the Italian Presidency in the AGRIFISH Council meeting of 16 December 2014.

The Commission was invited to introduce the following main improvements in relation to:

1. The scope of the proposal and simplification: remove the FRM sector, improve the structure as the ‘one size fits all’ approach does not work, cover only commercial activities (professional operators) and simplify the procedures for traditional varieties and niche markets.
2. Legal security and delegated/implementing acts: reduce the number of empowerments and write more detailed rules in the proposal about the separate sectors, in particular on PRM other than seeds.
3. Cost recovery: introduce sufficient flexibility for the Member States but delete the exemption from fees for micro-enterprises.

4. Efficiency, harmonisation, and decrease of administrative burden: simplify derogation processes, extend certification under official supervision and allow participatory testing for variety registration.

8. ANNEX 2 – DEVELOPMENTS OF THE PRM LEGISLATION

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:

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>)

Council Directive 66/401/EEC on the marketing of fodder plant seed (<http://data.europa.eu/eli/dir/1966/401/2020-02-16>)

Council Directive 66/402/EEC on the marketing of cereal seed (<http://data.europa.eu/eli/dir/1966/402/2020-02-16>)

Council Directive 2002/54/EC on the marketing of beet seed (<http://data.europa.eu/eli/dir/2002/54/2017-04-01>)

Council Directive 2002/55/EC on the marketing of vegetable seed (<http://data.europa.eu/eli/dir/2002/55/2020-07-01>)

Council Directive 2002/56/EC on the marketing of seed potatoes (<http://data.europa.eu/eli/dir/2002/56/2020-02-16>)

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>)

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>)

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>)

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>)

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>)

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 Member States since 1966, for example in the number of species covered. A more recent change was the adoption of Council Directive 2008/90/EC on the marketing of fruit plant propagating material and fruit plants intended for fruit production.

9. ANNEX 3

9.1. Part A: Summary of feedback to open questions in validation survey

The Commission received feedback to the open questions from 53 participants: 31 were from national authorities (including national competent authorities, national seed certification agencies, inspections services and ministries), 21 from stakeholders (including NGOs, nurseries, research institutes and farmer/breeders organisations) and one anonymous contribution.

The main issues raised in the feedback can be grouped into three main categories: issues in relation to registration requirements, technical and scientific developments and difficulties for producers and users of PRM.

Concerning the first category, there was the request for an overall simplification of the registration requirements and less restrictive rules for niche products, such as conservation varieties and varieties intended for the amateur market. Quantitative restrictions and legislative ambiguities limit the potential for these varieties to enter the market.

A number of stakeholders would like to extend the concept of conservation varieties to fruit plants and vine. The concept of varieties intended for local or limited circulation should be introduced, with less stringent registration requirements, like already in place for amateur and conservation varieties. Several stakeholders requested allowing pre-marketing authorisations for fruit plants and vine. A few stakeholders highlighted issues specific to the marketing Directive on fruit plants. They asked to distinguish between material intended for breeding and selection purposes through identification and labelling provisions and to review the plant pests listed in the EU certification scheme for fruit plants (Commission Implementing Directive 2014/98/EU⁵⁵). In addition, they proposed extending the scope of certification to include seeds/seedlings, not yet listed varieties, and developing certification requirements for *in vitro* propagated material. They asked for varieties of fruit propagating material marketed to amateurs to be exempted from the mandatory DUS test.

Some stakeholders highlighted that the amendments of the last decades make the outdated Directives difficult to read and to locate the information needed for the production of certain seeds. The rigid structure hinders the timely implementation of necessary scientific and technical developments, such as

- Use of molecular markers for registration and certification, and in post control tests;
- Adoption of modern testing methods for viruses;
- Common rules for labelling and sealing, small packages, and lot reference numbers;
- Common databases containing data on certified seed lots (lot number, weight, category etc.);
- More possibilities for varietal mixtures;

⁵⁵ 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. 22–61.

- Deletion (deregulation) of species with a low number of varieties/of low commercial importance;
- Optional, instead of mandatory, certification in the interest of consumers and competition in PRM markets. Customers should have the possibility for customers to buy certified or uncertified (standard) seed;
- Limiting the scope of the legislation to certain PRM and a certain group of actors;
- Exempting informal seed systems and the making available of PRM to amateur gardeners from the scope of application of the legislation;
- Exempting small producers making available PRM only on the local market (local circulation) from the scope of application of the legislation;
- Equal and non-restricted access to the market of PRM, which does not meet the requirements of distinctness, uniformity and stability;
- Provision of a legal framework, which allows for the development of quality standards responding to farming models other than the industrial farming model;
- Preventing loopholes in the system by weakening or deleting registration requirements for certain users. The latter will endanger a proper enforcement of the seed marketing legislation;
- Extending the scope of Directive 2002/56/EC to propagation material such as true potato seeds (TPS) , plantlets and tubers derived from TPS;
- Allowing small actors, such as seed savers or gardeners cultivating a large diversity of varieties to sell small amounts of PRM freely to other gardeners.
- Allowing market access of PRM not fulfilling DUS-requirements.

Synergies with other policies

The alignment with other policies on plant health, organic agriculture and official controls should be improved. Some stakeholders mentioned the overlapping rules in the organic Regulation (EU) 2018/848 regarding the production of PRM of certain species. Some answers stated that the duplication of plant health requirements concerning Regulated Non-Quarantine Pests (RNQPs) in the PRM Directives and the Plant Health Regulation complicate the amendment of certain plant health requirements and the makes it difficult for the producers to comply with the plant health rules.

VCU requirements

Stakeholders expressed mixed views with regard to VCU requirements.

The different stakeholders commented about the extension of VCU requirements to certain species, about more sustainable VCU for mainly organic varieties and made some concrete proposals, such as:

- Abolishing VCU and relying on self-regulation in the commercial market;
- Harmonising VCU for conventional and organic varieties;
- Encouraging testing and seed certification under official supervision;
- Abolishing the mandatory VCU testing for market access or at least abolishing minimum VCU standards in order to allow for more diversity of products for the grower and end consumer;

Proposals in relation to the vegetable seeds sector

- Safeguarding fair market opportunities through DUS;
- No VCU trials to allow for more diversity of products for the end consumer;
- No introduction of VCU trials because these limit market access for niche products and for small breeding companies enormously.

Some industry stakeholders referred to the non-harmonised implementation of certain Directives causing a non-level playing field damaging the common market. One stakeholder proposed to turn the marketing Directives into Regulations. Other proposals concerned:

- Harmonised data exchange between Member States, and between Member States and the Commission;
- Evaluation of Directives 2008/62/EC, 2009/145/EC and 2010/60/EU⁵⁶;

Enhancement of close cooperation between the competent authorities from agricultural seed control and nature conservation.

⁵⁶ 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. 10–14.

9.2. Part B: Original replies to open question in the validation survey

| Classification stakeholders | Are there any additional problems with the legislation on the production and marketing of plant reproductive material that you would like to highlight? | Do you have any views on how the legislation on the production and marketing of plant reproductive material should be revised? |
|-----------------------------|--|--|
| National authority | | Reduce administrative burden, especially for medium sized and small seed companies, such as farmers associations or family owned companies. Facilitate marketing of amateur and conservation varieties. Small and medium sized companies would suffocate under high costs for variety registration, controls and certification. NCS's in small countries can therefore never apply cost-recovering fees. OCR does NOT help to reduce costs or administrative burden! |
| National authority | To achieve a level playing field, national subsidies in relation to PRM activities should be stopped. | The current system and legislation has proven to be satisfactory for the past decades. Some of the statements in this survey on amateur varieties, conservation varieties and preservation seed mixtures are incorrect or subjective, as there is already sufficient flexibility for this material in the current legislation. |
| National authority | | In this moment necessary to update 2 very old Directives - 66/6401/EEC and 66/402/EC. |
| National authority | | A high quality VCUS is a guarantee to register varieties that bring genetic progress to the seed user. |
| National authority | There are some Member States that are much more permissive when registering a variety, therefore the varieties that do not pass trials in Italy are registered in some other Member State (and it's not a matter of climate or soil differences) | |
| National authority | Import of PRM is not regulated in current PRM legislation; provisions regarding equivalence are not sufficient for solving this problem. | New legislation should be in form of Regulation, there should be two Regulations - for seeds (agricultural and vegetable species) and for other PRM. |
| National authority | - plant health requirements under both PHR and the marketing Directives may impose double - and therefore unduly - fees on small seed producers, thereby rendering their activities unprofitable; these small enterprises are often focused on 'diversity seeds' - following the entry into force of the PHR, public (i.e. non-commercial) gene banks are faced with problems to comply with issuing of plant health certificates and, in particular, their associated costs | - Consider revisiting the idea of derogating SMEs (below a certain annual turnover) - The conservation variety Directives were supposed to be revised three years after their entry into force - this has not yet been done. Despite good intentions, success is feeble and due to production restrictions and rigid country of origin requirements. This PRM sector is very small, mainly restricted to enthusiasts, and does not pose any true threat to the larger commercial PRM sector. - provide incentives for public gene banks to multiply 'diversity seed' |

| | | |
|--------------------|--|---|
| Company / business | | A strong division in seeds intended for professional growers or for hobby/home garden market. Costs / profits cannot be compared and risks (phytosanitary!) are much lower at the hobby home garden side. A more delicate regime would therefore work much better and could ensure the preservation of “old” varieties / genetic differences. |
| Company / business | | Relevant stakeholders (nurseries, seed suppliers, end users) should be consulted more before legislation is put in place. |
| National authority | The Regulations are old-fashioned and difficult to read. It’s too detailed for some issues and not detailed enough for some other issues, especially with regard to vegetable seeds and agricultural seeds of different seed classes. There are problems with how to handle seed production at companies that grow different types of varieties and seeds such as potato lower classes and conservation varieties of potatoes on the same property. There are problems with labelling of conservation varieties/amateur varieties and control of quality as well as varietal identity. In order to increase the cultivation of conservation varieties of agricultural crops, there is a threshold barrier in terms of the amount of seed available at genetic institutions and the amount that a seed grower needs to cultivate in order to obtain economy on the cultivation. | |
| Academic | See letter send by CTIFL and Naktuinbouw, also as the letter send by French government in 2020 to the Commission (Fruit Reproductive Material) | See Annex of the letter send by CTIFL and Naktuinbouw in 2020 to the Commission (Fruit Reproductive Material) |
| Trade association | VCU is not really important nowadays. We work in potatoes. Nobody pays attention to it. All industries look at own requirements. VCU works if there is one use of the crop, like in e.g. sugar beet. But not if there are multiple purposes like in vegetables and potatoes. | There is no real differences between conservation varieties and normal varieties. Normal varieties can be 80 years old. Make sure the quarantine diseases will be spread through amateurs. This will be a disaster. |
| National authority | In comparison to the situation in Switzerland, the subject of the EU PRM legislation framework is broadly defined around the key aim to safeguard the quality, identity and phytosanitary harmlessness for the farmer. Therefore it is quite an extensive approach to regulate | The strength and unique element of the legislation are the therein-defined categories of plant reproductive material, which are obviously honoured by all professional agricultural and horticultural stakeholders. Furthermore, the sense of the PRM legislation strongly depends on the proof of identity (and therewith varietal performance), quality and enhanced plant health of a certain category. In my view, the focus in this revision should therefore be laid on an effective, efficient and |

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| | <p>derogations for niche markets an exhaustive and adequate manner. On the other hand, this broad definition of the subject allows effective market controls under the PRM legislation, as the intended use for agricultural production of the marketed seed does not have to be proven. I would like to highlight the definition of the subject of PRM legislation in this revision procedure as potential element for an administrative simplification of the Regulation and for increased acceptance of collateral stakeholders like home gardeners and amateur producers.</p> | <p>harmonised control of the production within these categories and less on the control of the restriction of marketing of PRM to these categories or a harmonised implementation of adequate derogations.</p> |
| Business organisation | <p>no reference to the farmer seed system, impossible in closed answers to find space to present specific needs</p> | <p>Two different seed systems exist and operate in Europe: a system based on certified varieties (UPOV) and the way the seed industry operates, and a farmer seed system based on dynamic on-farm biodiversity management and operating on the basis of the ITPGRFA requirements (in particular articles 5, 6 and 9). The two systems need to be recognised and each has its own legal framework to regulate them.</p> |
| Company / business | <p>General problem is the system of “one key several doors” - registration and variety protection requirements in one and the same testing frame. This leads to enhancing strictness in DUS requirements.</p> | <p>not affecting the current new possibilities of marketing of “organic heterogeneous material” not affecting the “seven years temporary experiment” for organic varieties (better market access)</p> |
| Academic | <p>Most issues were addressed. However, fodder species used in the 2010/60/EU Directive should not be treated as 66/401/EEC varieties since they should not follow the DUS requirements when used for conservation purposes.</p> | <p>A certification scheme is needed for the native seed market in order to successfully meet UN restoration targets. I have proposed one the uses bar coding in my PhD thesis that is consistent with Bio-banking used for conservation purposes. The 2010/60/EU Directive needs significant revisions or should be scraped and a new Directive created with flexibility based on market needs. It is not working well for most Member States, which results in an unregulated market.</p> |
| National authority | | <p>PRM to enter control Regulation</p> |
| National authority | | <p>This reply only applies to ornamental plants, vegetable plants (no seeds) and fruit plants. It is not practical that RNQP lists are in two legislations. To the extent as possible, RNQPs should only be in the plant health legislation.</p> |
| National authority | | <p>Conservation, amateur and non-conventional varieties or other small-market type of production should not be emphasized too much in the new legislation. The legislation should allow seamless processes for the main production. Would it be possible to separate the ‘main’ production from the small-scale production in the new legislation? Fees should not be regulated by legislation. E.g., there may be different requirements for cost correlation. Legislation should not cause new administrative</p> |

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| | | burden. |
| National authority | <p>1. The difficulties regarding the legislation of New Breeding techniques. We will need these modern plant breeding techniques if we want to reach to goals set in Farm2Fork</p> <p>2. On many questions the answer given is 'No opinion'. In all these cases, the questions were ambiguous, hard to understand, illogical, with double denials, or with questionable assumptions, which are impossible to answer with a radio-button.</p> | <p>In general, we are very satisfied with the current EU legislation. The existence of Directives instead of Regulations we see as a strength, fitting to the different situations in differing EU member states. Collaboration with the EC and the member states works very well to achieve maximum harmonization. 100% harmonization will prove too difficult, looking at all the different factors involved, (agro-climatic, size of seed industry, size and structure of farmers, cultural aspects, economies of scale etc. etc.). Also from the side of the industry or from the perspective of users of the system (farmers) we don't hear major complaints about the current legislation. There is a healthy competition between breeders, providing their customers with new and improved varieties year after year. Although they would not complain if the costs of the planting materials would go down, most farmers consider the cost of new planting materials reasonable. Also for amateurs, there is plenty of choice, ranging from traditional varieties (listed) to the most modern varieties. The number of landraces and hobby market varieties is very low compared to the choices out of all other varieties amateurs have in garden shops. There are a few items in the Directives that could be modernized, but in general we don't see a need for a big overhaul of the structure and scope of the legislation. We expect that with some targeted revisions the legislation can be updated.</p> |
| National authority | <p>I will send comments to the questionnaire in a separate E-Mail.</p> <p>Additional topics: - empowerment for decisions by the Standing Committee should be harmonized in the Marketing Directives - conservation varieties for vine - deletion of species with low number of varieties/ low commercial importance - evaluation of Directives 2008/62/EC, 2009/145/EC and 2010/60/EU</p> | <p>The revision should result in Directives, and not in a Regulation. Directives allow for more flexibility for the Member States, e.g. to introduce stricter tolerances and measures.</p> |
| EU agency | <p>1. The procedure of updating of the "cross reference" to the CPVO TPs creates a legal gap since the TPs become applicable for national listing with a significant delay whereas the TPs are already applicable for PBR.</p> <p>2. Variety denominations: Article 63 of Regulation 2100/94 on EU PBR is implemented by 2 different legal acts one for PBR and one for listing which is from a practical viewpoint not necessary and which creates divergences.</p> | <p>1. In species where there is no VCU requirement (vegetables) a filing for EU listing through the CPVO should become an option</p> <p>2. It should be considered if the management of the Common Catalogues for plant varieties could be taken care off by the CPVO.</p> <p>3. It should be considered if Examination offices doing variety testing in view of national listing should not be required to fulfil certain minimum quality requirements in order to carry out such testing.</p> |
| Business association | <p>This survey is 1 of 2 to provide views for horticulture plant breeding material. First of all, we think that it is very good</p> | <p>In addition to the questionnaire, we would like to refer to comments that have been shared with you earlier in an email sent to [REDACTED]</p> |

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| | <p>that you prepared a survey. Plantum is the Netherlands association of PRM-companies with over 300 members. It is not clear to us though to whom it has been sent. This is a preliminary response since we heard that our sector organization in Brussels, Euroseeds, has been in touch with you for a new deadline. We would like to make some remarks on the survey:</p> <ol style="list-style-type: none"> 1. The aggregation of issues: combining different issues in one statement or question makes answering extremely difficult: A respondent may consider different aspects differently, 2. “Leading questions”. Some questions seem biased very negatively towards the current legislation. It is difficult to provide answers that are positive towards the current legislation. 3. Generalised questions. The same example above may be answered from a field crops, vegetables or ornamentals perspective quite differently because the regulatory situation is very different with respect to both registration and certification. One answer, without the possibility to make any clarifying comments cannot provide you a complete picture. 4. A number of questions would be answerable “not applicable”, which is not the same as neither/nor or no opinion. This option is not available. We did our best to fill out the questionnaire despite the above limitations because the subject at hand is so important for the horticultural sectors that seed companies want to serve. In addition to the questionnaire, we would like to refer to comments that have been shared with you earlier in an email sent to ... on November 19th, 2020. Kind regards | <p>on November 19th, 2020.</p> |
| National authority | <p>We would like to make the following comments to some of the questions of this questionnaire: On the question of the registration and certification process for new varieties, the system should be strengthened to better allow national certification authorities to start</p> | |

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| | <p>certification examinations for varieties under a registration process in order to speed up the possibility for operators to market for innovative varieties. On the question on the control and enforcement, we do agree that the interpretation of control requirements may induce difference in the implementation of control and enforcement measures. Nevertheless, it has to be noted that controls are performed according to international rules and standards. On the question of the coherence with the plant health legislation, we would like to highlight the absence of clear mechanism on the responsibility of the national certification authority and operators where there is a lack of coherence between both legislation. On the question of a lighter regulatory regime that addresses limits on amateur gardener's exchanges, we would like to strongly emphasized the regulatory regime is already completely « free » as the current seed marketing Directives are meant to varieties for a commercial exploitation only.</p> | |
| Academic | <p>Agreeing that PRM identity (DUS and similar) and PRM health should be addressed uniformly and not by different Regulations or even different authorities, it is important to distinguish between the two. Too often in NCAs interpretation, DUS is a synonym of safety, whereas it is not. Likewise, seed mixtures do not need to comply with DUS but must comply with seed health.</p> | <p>Relegating biodiversity enhancement to e.g. conservation varieties and amateur PRM is a counterproductive approach. Quantity limitations and legislative ambiguities are limiting the potential for biodiversity improvement.</p> |
| Business association | <p>Generally, the legislation has performed extremely well. Europe is home to a highly competitive as well as uniquely diverse seed sector. This sector continuously has placed a large number of new and further improved varieties at the disposal of farmers and growers.</p> <p>These varieties are responsible for the lion's share of productivity gains (recent studies suggest 50% to 90% of all productivity gains over the past 50 years are due to genetics) and thus have contributed enormously to the (still challenging) economic situation of Europe's farmers and growers.</p> | <p>Consistency, clarity, and compatibility with international standards, norms and procedures (UPOV, OECD, ISTA, IPPC etc.) as well as commercial practice are key for a modern, user-friendly regulatory framework that takes the specific international nature of the (European) plant-breeding sector into account.</p> |

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| | <p>Identity and quality are of crucial importance for farmers' and growers as well as the entire agri-food chain and must remain key elements of the seed marketing legislation. If variety registration will be complicated by introducing requirements regarding sustainability, biodiversity, etc. the number of available varieties on the market will decrease seriously and farmers and growers will have less freedom of choice. On the other hand, weakening or deleting registration requirement for certain users, will create loopholes in the system that will endanger a proper enforcement of the seed marketing legislation.</p> <p>Consequently, this will endanger the identity (including traceability) and quality of varieties on the EU market. Still, we see possibilities for technical and managerial improvement (e.g. the scope of Directive 2002/56/EC should be broadened to propagation material such as seeds, plantlets, tubers starting from True Potato Seeds TPS) and modernisation. Next to the comments supplied here as well as to the first questionnaire, Euroseeds specifically refers to its extensive respective input to the Better Regulation exercise and specifically to the two questionnaires filled in for agricultural and vegetable species at the time.</p> | |
| National authority | Simplify rules for small packages (e.g. labelling): is there really a need to distinguish between EC A and EC B packages? We think having just "small packages" up to 10 kg would be sufficient. | To add <i>Fagopyrum esculentum</i> Moench to the cereal marketing Directive. |
| National authority | The addition of species to the list of regulated species should be possible through a more flexible process than the revision of a Directive in order to take into account new agricultural practices or new market trends. Overlapping between EU organic Regulation (2018/848) and PRM legislation is challenging: different DUS exams to pass depending on whether the variety is organic or not, and whether breeder request plant breeder's right, to achieve one unique target (organic PRM) is hardly | The European Commission's 'Farm to Fork' strategy states that "Farmers must have access to a range of quality seeds of plant varieties adapted to climate change". The ambition of this strategy reinforces the role of PRM, and therefore the challenge of their regulation, for the benefit of European agriculture sustainability and to contribute to the necessary change/transition of agri-food systems. From a general perspective, current PRM legislation based on 2 pillars (listing according to DUS and VCU criteria + certification) has given and still gives good results. Genetic progress is observed for a wide range of crops and for different characteristics (yield, resistance to diseases and pests, tolerance to cold, drought, reduced fertilization, quality of harvested product...), because of breeding efforts and VCU exam. Sustainability criteria are |

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| | <p>understandable. Data exchange between MS and between MS and Commission should be modernized. Finally, lack of pre-marketing authorization for experimental use for grape vine and fruit varieties might be problematic. Moreover, because of dynamism of grape vine breeding, there is an urgent need to include grape wine varieties in the scope of EU Regulation regarding denomination (637/2009).</p> | <p>part of VCU assessment in France. There is no good VCU if sustainable criteria are not met. Sustainable criteria are not a supplementary assessment, but are included in our decision process to check VCU of agricultural varieties. Sustainability is taken into account in both our experimental design (locations in a large diversity of environments and cultural practices including some trials carried out in organic conditions) and our decision rules (ponderation of criteria).</p> <p>Check of varieties value before they are marketed is essential; it makes it possible to reassure producers by allowing only qualified varieties and quality PRM, and to direct plant breeding and PRM marketing towards varieties that are less dependent on phytosanitary products, fertilizers, or water, adapted to new agricultural practices and climate change, and that meet the expectations of a high-quality, diversified and secure food supply. These ambitions of the evaluation could usefully be recalled by European Regulations. The current legislation allows also the commercialization of some types of PRM characterized by a lower exigence for uniformity, while a minimum characterization. At French level, applications of conservation and amateur varieties are free of charge, thanks to public or professional subsidiaries. Even if the current legislation is well adapted, some slight modifications might nonetheless be taken up to improve the general process. Indeed, both agility in the scope of PRM legislation (new species, minor uses for major crops...) and harmonization (denomination of varieties, pre-marketing authorization...) are needed. Agropedoclimatic conditions are specific to each region/area/country. It can be also the case for the use of varieties. We do not grow the same wheat varieties, and do not eat the same bread all over EU. Moreover, varieties face different pests or diseases in different countries. It is thus unappropriated to think of a unique VCU exam for the whole EU. General axis can be given at the EU level but the implementation must be defined at the national level. The better taking account of the differences in agro-pedoclimatic contexts between Europe's zones is a challenge that should be addressed in the framework of the revision of PRM legislation. For general orientations given at European level we might think of sharing good practices, and even auditing examination offices to move towards higher quality standard in experimentation and decision process. Furthermore, the possibility to market PRM that does not comply with DUS standards for intellectual protection, but meets some societal and agricultural demands, should be explored. Finally, efficiency of the whole listing process should be tackled. Reference collection, pathology tests, molecular tests, dedicated trials to check heritable traits... might be mutualized in a pool of reference examination offices. Breeder's participation under official supervision should be pre-cautious explored, by ensuring strict control by the competent authority. This option must thus be accessible not only to the major companies, but also to small breeders with small facilities.</p> |
| National | - We propose to only list the RNQP requirements in BIA and move specific | - Total revision is not needed and should be avoided |

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| authority | <p>requirements for fruit plants from MD to BIA too</p> <p>- We don't think a lighter regime as regards to amateur varieties in MD would influence plant health requirements due to 2016/2031 requirements</p> <p>A lighter regime for approving conservation varieties should be considered</p> | <p>- Encourage participatory testing and seed certification as for authorized field inspection, sampling and testing</p> <p>- Consider whether VCU should be taken out as a basic requirement also in the future and handled by the commercial market instead - If not, at least more harmonized frames for VCU testing should be considered. The common situation is basically not harmonized at all.</p> <p>- "One size fits all" approach is very difficult in PRM sector due to very different needs for different species groups - It could be good to look into the potential of the TRACES system, but be aware of the risk of placing further unnecessary burdens on the users Overall remark to the query: Difficult to answer correctly to quite a lot of the questions, as there could be several statements in one statement. There is a risk that the interviews and questionnaires do also not give a clear outcome.</p> |
| Consultancy | <p>There are some differences between member states, and this could indeed be improved, but the current divergence is not a limiting factor for the functioning of the PRM system.</p> | <p>The current system for variety listing is working well, and is being copied in other regions in the world, as it is highly effective. Any changes to the legislation should not decrease the current high quality of DUS & VCU testing. A further alignment between PRM, Plant Health and Quality Control legislations is OK, but is not a necessity to make it work.</p> |
| National authority | <p>Different interpretation of 2004/842/EC Commission Decision of 1 December 2004 Non-harmonized criteria for seed import control</p> | <p>There should be a common control and sanctioning regime, with similar rules for all ME for non-compliance in seed certification. There should be common rules for labelling and sealing, small packages and lot numbers. There should be rules for the use of biotechnology tools instead of long-in-time post control test plots. There should be common databases with certified seed lots data (lot number, weight, category...)</p> |
| National authority | <p>The long time required for the registration of fruit varieties is an enormous inconvenience to favour their arrival on the market and their certification. The requirement to verify the varietal identity of the fruit trees by means of morphological characters is technically impossible on seedlings in the nursery</p> | <p>Simplification on the registration of traditional and minority varieties for vine. Authorization for mixed material obtained by vegetative reproduction from old trees of certain species as a local value. Reduction of the time needed for the registration of fruit and vine varieties. Adoption of molecular markers for registration and certification. Adoption of modern viruses testing methods. Regulation for in vitro production Review of the list of pathogens for fruit trees. Clearer instructions regarding the level of inspection (frequency and intensity) Clearer instructions regarding control of ornamental plants</p> |
| National authority | <p>Varieties without commercial value should be more clearly defined.</p> | <p>Legislation needs to be updated and reduced because there is huge amount of acts witch need to be followed.</p> |
| NGO | <p>Conservation varieties are very restricted by current legislation, this is wrong Conservation varieties suffer from genetic erosion. We cannot afford to lose them we need them especially (but not only) for climate change adaptation as they have a large genetic base.</p> | <p>More flexibility for conservation varieties as the DUS criteria are not suitable for these varieties which have a large genetic base</p> |
| Academic | <p>I am not sure to well answer to all these complex questions but I think that an</p> | <p>Some efforts should be done on the population varieties - Indeed, some species are interested for perfume or medicinal</p> |

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| | <p>important effort should be done to preserve genetic resources and the main limit is the money. Gardeners and/or collectivises which maintain and preserve genetic resources should be help for the new varieties of tomorrow. Another point is missing in these questions and concerns the control the legislation of the UE in the member state - how this control is made? there are differences in the UE applications in the member state and these differences may have consequences on the cost or attractiveness of products on the markets</p> | <p>extracts and the homogeneity is the result of a process, which is performed on a mix of varieties or genotypes. I think that this question is not easy to resolve but it's the case for an interested market of aromatic, medicinal plants</p> |
| National authority | | <p>Many questions were too suggestive and some of the “problem” statements are incorrect. Legislation is in general for most stakeholders satisfactory. Modernization on some aspects should be considered, for instance more possibilities for mixtures.</p> |
| Other | <p>We need common rules for not yet listed varieties.</p> | <p>Most important is to review the legislation on marketing of seeds and not to mix with the seed potatoes and other species. Here are a lot places, which could be simplified- mixtures of fodder seeds, categories, marketing rules. Also is important to have same rules as in OECD seed schemes.</p> |
| NGO | <p>Climate change should be taken into account. Adaptation needs seeds with a large genetic base and these are conservation seeds. It is very unfortunate that they undergo genetic erosion and EU laws should change this situation.</p> | <p>More flexibility is needed to protect the current loss of biodiversity. Accordingly, the PRM laws concerning the conservation and amateur varieties should become much more flexible. Climate change adaptation should be taken into account.</p> |
| Business association | <p>Especially in the field of conservation mixtures for renaturation purposes, close cooperation between the competent authorities from agricultural seed control and nature conservation is necessary. Unfortunately, both areas are not well enough staffed to fulfil their sovereign control duties. In order to ensure regional production and to be able to control it sufficiently, it is essential to have personnel available for field inspections.</p> | <p>The limitation of the share of regulated fodder plant species as native forms to 5 % of the total market should definitely be lifted, as it restricts nature conservation in an unacceptable way. Furthermore, the requirements for purity and germination as well as the prescribed test procedures (INSTA) should be adapted to the characteristics of the genetically diverse wild forms and not be taken over from the specifications for cultivated forms. The cultivation of wild plant seeds should also be taken into account in the specifications for CAP subsidies.</p> |
| National authority | <p>Extend the concept of conservation varieties to fruit plants and vines as well. Introduce the concept of local or limited circulation varieties, with registration under less stringent requirements, marketing only in the Member State and specific National Register</p> | <p>Unify definition of categories and methods of control, but keep seeds separate from propagating materials of agamic propagating plants</p> |

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| Company / business | Concerning preservation seed mixtures: You pose the wrong questions / make wrong conclusions: The definition of region of origins does not reduce genetic variability in the regions. The regions of origin take care of the biodiversity in different landscapes with adapted genetic of each singular species and how the species are spread all over the country or not and so on. The achievement of a 'premium price' for 'local varieties' is not enabled by the use of regions of origin. The importance of local varieties is defined by nature protection administration and if possible best for restoration. So why should there be a reduction of the price. The limiting factor is the availability of local seeds and the organization of the seed transfer, not the potential difference of the price. | Concerning conservation seed mixtures: The 5 % limit (part of the whole seed market) for the use of wild forms should be cancelled completely. If there has to be sown in free nature there should be used wild species adapted to the region. No matter if this are 2% of the seed market or 20%! Nature needs wild forms and species rich conservation mixtures for keeping her biodiversity. There should be more information of wild seed producers and their organizations (e.g. Verband deutscher Wildsamens und Wildpflanzenproduzenten) considered in the creation of new rules (Feasibility, know-how, realistic considerations between ecological needs and necessary economical frame to achieve this) Facts/Points to take care of: - regions of origin not too big and not too small, possible use of neighbored regions as second best (This is necessary for the creation of the implementation of the marked for species rich mixtures - we have about 400 species in stock and for the availability in new defined region it is not possible to promote them at all the same time (Needs at least 10 years and at clients who buy the seeds!) - protection of donor sites in all regions of origins of the member states - different quality standards for wild seeds compared to cultivars - |
| Academic | Annex IV of Implementing Directive 2014/98 should be simplified and formulated in the same style as measures in Annex V of Regulation (EU) 2019/2072) | RNQP should be covered preferably by only one area of legislation (PHR or PRM) for all different sectors. |
| National authority | | RNQPs should be covered preferably by only one area of legislation (PRM or PHR) for all different sectors. Annex IV of Commission Implementing Directive 2014/98/EU should be simplified and formulated in the same style as the measures in Annex V of the Commission Implementing Regulation (EU) 2019/2072 |
| Company / business | | It would be highly recommended to establish specific codes of the crops to produce biodiversity conservation mixtures to obtain the CAP subsidies. In the current situation, these crops cannot access these aids |
| National authority | First, it should be emphasized that the backbone of the Regulation should be kept. The system has proven that it is possible to provide farmers with varieties with good agricultural performance. The VCU is a tool that is efficient to fulfil the objectives of performance and sustainability with regards to the Green Deal objectives. However, the Regulation could be revised in order to give flexibility or to overcome impediments. It should also take into account some minor markets that could be inhibited by the current Regulation. Rigidity of PRM Directives is problematic: due to new agricultural practices or new market trends, we | More flexibility in the scope of PRM legislation (minor uses for major crops, amateur varieties...) should allow more room for minor operators to access specific markets while allowing the current framework to continue. The VCU is a strength more than a constraint and has proven its utility to drive genetic progress according to each Member state pedoclimatic conditions. The current system works properly and has been beneficial for the French sector for more than 50 years. In order to allow an easier, consistent and more comprehensive regulatory framework, number of Directives could be merged in order to gather groups of species with common rules (ex : agricultural species with mandatory certification). A transversal Directive for protein crops would highlight the need to foster breeding development and setting up of an integrated sector with regards to the objectives of Green Deal for a self-sufficient EU agriculture. |

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| | <p>regularly need to challenge the scope of Directives: range of species and range of plant reproductive material types of propagation (for instance, potato seedlings and beetroot stecklings are not covered by any regulatory act). The lack of pre-marketing authorizations for grapevine and fruit varieties is also problematic considering the lengthy duration of the DUS and certification exams for these varieties. Because of dynamism of grapevine breeding, we definitely need to include grapevine varieties in the scope of EU Regulation regarding the suitability of denominations. More consistency and comprehensive connection are key to be considered between vine/fruit plants Directives and plant health Regulation. As RNQP measures are now common requirements for plant passport and certification/standard labels, problems of implementation and share of responsibilities between certification authorities and authorized professional operators are encountered, with a possible negative impact on the objective of harmonization. The marketing framework for preservation mixtures is very restrictive and leads to substantial administrative burden (1 given mixture with variable components = 1 authorization) with the subsidizing consequence to see diverse levels of implementation through Member states.</p> | |
| Company / business | NO | Make it simple please! We are getting lost in all this waze... |
| Company / business | Professionals should have been consulted for the last review of the legislation on the production and marketing of plant reproductive material. The efficiency of the legislation would have been increased. | <p>The legislation on some RNQP will have to be revised rapidly. Otherwise industry professional will have to stop the plant production of some species with different consequences :</p> <ul style="list-style-type: none"> - a lack of plants for some farmers to settle vineyards / orchards - Competitive advantage for professional, which operate in member state where the interpretation of the legislation will be softer. |
| National authority | | <p>In the new legislative proposal, we see that it would be best if different PRM sectors (seeds, propagating material, and forest reproductive material) would be treated as separate sectors with their own legislative needs. In this survey, there were many questions about conservation, amateur and non-conventional varieties or other small-market type of production and these themes should not be emphasized too much in the new legislation. Market for this type material is small and the needs</p> |

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| | | for legislation are maybe different. PRM legislation should not be included in the OCR since it may add administrative burdens. We feel that the fees should not be regulated by PRM legislation due e.g. different cost structures in different Member States. Legislation should not cause new administrative burden to NCA of Member States or to the actors. |
| NGO | | It is crucial that two distinct Regulations are established concerning each of the two seed systems: the industrial (formal) seed system and the peasant seed system. Moreover, we would like to stress that the answers to the questions asked cannot be the same for each of these two seed systems. This justifies our impossibility to contribute properly to this survey. |
| Business association | No serious problems with the legislation on the production and marketing of plant reproductive material, however in some parts there are shortcomings with implementation. Areas what we would highlight here are trading with un-certified seeds and massive violation of PBR when it comes to use of FSS. In the first case, legislation stipulates that trading un-certified seeds is illegal, on the other hand, there is no institution controlling this. Result – trading un-certified seeds is seriously disturbing certified seed market. In case of FSS, only less than 10% of farmers using FSS of protected varieties pay remunerations to the breeders. Driver for this problem is absence of legislation stipulating farmers control procedure. Farmers may ignore breeders’ requests for information without consequences. | |
| Academic | The addition of species to the list of regulated species should be possible through a more flexible process than the revision of a Directive in order to take into account new agricultural practices or new market trends. Overlapping between EU organic Regulation (2018/848) and PRM legislation is challenging: different DUS exams to pass depending on whether the variety is organic or not, and whether breeder request plant breeder’s right, to achieve one unique target (organic PRM) is hardly understandable. Data exchange between MS and between MS and Commission should be modernized. It is very difficult to express complex ideas in a multiple-choice questionnaire. You will find hereunder some comments on | The European Commission’s ‘Farm to Fork’ strategy states that “Farmers must have access to a range of quality seeds of plant varieties adapted to climate change”. The ambition of this strategy reinforces the role of PRM, and therefore the challenge of their regulation, for the benefit of European agriculture sustainability and to contribute to the necessary change/transition of agri-food systems. From a general perspective, current PRM legislation based on 2 pillars (listing according to DUS and VCU criteria + certification) has given and still gives good results. Genetic progress are observed for a wide range of crops and for different characteristics (yield, resistance to diseases and pests, tolerance to cold, drought, reduced fertilization, quality of harvested product...), because of breeding efforts and ambitious catalogue Regulation especially VCU exam. Sustainability criteria are part of VCU assessment in France. There is no good VCU if the sustainable criteria are not met. Sustainable criteria are not a supplementary assessment, but are included in our decision process to check VCU of agricultural varieties. Sustainability is taken into account in both our experimental design (locations in a large |

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| | <p>questions where it is difficult to understand the meaning of the question: Table 2: see our comments in the question about Any other views regarding revision? Table 3: it is true to say that, there are differences in how MS calculate their fees. But it is not necessarily the cause of possible differentiated effects according to the type of operator. The terms non-conventional players, non-conventional varieties should be defined. Table10: of course, we support the implementation of the advances in digitalization but the questions about this topic are not understandable.</p> | <p>diversity of environments and cultural practices including some trials carried out in organic conditions for more and more species) and our decision rules (ponderation of criteria). Check of varieties value before they are marketed is essential; it makes it possible to reassure producers by allowing only qualified varieties and quality PRM, and to direct plant breeding and PRM marketing towards varieties that are less dependent on phytosanitary products, fertilizers, or water, adapted to new agricultural practices and climate change, and that meet the expectations of a high-quality, diversified and secure food supply. These ambitions of the evaluation could usefully be recalled by European Regulations. The current legislation also allows the commercialization of some types of PRM characterized by a lower exigence for uniformity, while a minimum characterization. It is the case, at the French level of the applications of conservation and amateur varieties, which are free of charge, thanks to public or professional subsidiaries. Even if the current legislation is well adapted, some slight modifications might nonetheless be taken up to improve the general process. Indeed, agility in the scope of PRM legislation (new species, minor uses for major crops,... as mentioned in the previous question) and harmonization (denomination of varieties) are needed. Agropedoclimatic conditions are specific to each region/area/country. It can be also the case for the use of varieties. We do not grow the same wheat varieties, and do not eat the same bread all over EU. Moreover, varieties face different pests or diseases in different countries. It is thus inappropriate to think of a unique VCU exam for the whole EU. General axis can be given at the EU level but the implementation must be defined at the national level. The better taking account of the differences in agro-pedoclimatic contexts between Europe's zones is a challenge that should be addressed in the framework of the revision of PRM legislation. For general orientations given at European level, we might think of sharing good practices, and even auditing examination offices to move towards higher quality standard in experimentation and decision process. Furthermore, the possibility to market PRM that does not comply with DUS standards for intellectual protection, but meets some societal and agricultural demands, should be explored. Finally, efficiency of the whole listing process should be tackled. Reference collection, pathology tests, molecular tests, dedicated trials to check heritable traits... might be mutualized in a pool of reference examination offices. Breeder's participation under official supervision should be precautious explored, by ensuring strict control by the competent authority. This option must thus be easily accessible not only to the major companies, but also to small breeders with small facilities.</p> |
| National authority | <p>The possibilities of derogation are numerous in the different Directives but there are few, if any, that have conditions for the derogation decided according to the procedure set out in the Directives. Thus, the possibilities cannot be used. There are also no real</p> | <p>With care. I believe several MS value the flexibility that the Directives make possible as opposed to what would be the reality of a Regulation. However, if there are large differences in interpretation between MS that harms the common market then a Regulation might be needed. As many rules as possible should be applied regardless of the crop. For example, authorized field inspection could very well be permitted in</p> |

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| <p>possibilities for emergency derogations, i.e. the drought situation in 2018. The possibility to make a derogation, such as germination, for other properties in certain situations. For example if there are, only one or a few lots of a certain variety and it/they do not fulfil the quality criteria when it comes to the number of other species. A simple process such as the one that is used for the derogation from germination would be appreciated. The threshold levels for analytical purity as well as the RNQP need to be revised. For example there are grass weeds that have too high threshold levels today as they pose a definite threat for the farmers and forces them to use more pesticides (if there are any pesticides available). We need to be able to add species to all Directives. For example buckwheat which is increasing in acreage. The RNQPs need to be revised. <i>Tilletia laevis</i> is increasing across Europe and several MS have national legislation when it comes to <i>Tilletia</i> species. A harmonized approach would be appreciated. The check sampling of 5% of the manual sampling is not accurate and needs to be revised, as many authorized samplers do not perform much sampling during a year as most sampling is done automatically. It is important to keep focus on the most important crops (economical value and use) instead of changing details for the amateur and conservation varieties. The issue with them at the moment is the high cost for the handling of the plant passports and the lack of possibility of lowering the cost for them and/or decide that they do not need a plant passport. In Sweden an example is that, a small seed grower cultivates amateur and conservation vegetable varieties of <i>Vicia faba</i> and <i>Pisum sativum</i> and thus need to issue plant passports as the seed is sold. [As the amounts are small (less than 10 kg) there is a simple way to make sure there are no living insects in the seed - to put the seed in a regular freezer for a few days.] However, the annual cost for the permit needed to issue the plant passport and the annual control fee is too high in proportion of the value of the seed. The numbers</p> | <p>potatoes as well as in cereal. It needs to be clearer what the NDA has to do and what can be done by others. With such an old legislation as from the 1960s, several tasks are performed by habit - for good or bad! Some of them are still needed but not expressed in the legislation, and some are just done by force of habit more than by need.</p> |
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| | <p>given us is a value of the seed of 15 000 SEK and the annual costs are somewhere between 3000-5000 SEK. There was a document circulated some years back with several ideas of how the Directives could be changed, there were some good ideas in that.</p> | |
| National authority | | <p>Vitis Regarding Vitis propagating material, the loss of intravarietal diversity is one aspect that should be addressed. In order to maintain the intravarietal diversity of vine varieties, certification standards for polyclonal selection should be established, in line with the Office International de la Vigne et du Vin (OIV) resolution OIV-VITI 564B-2019. VCU - VCU testing should be reassessed, either included in a transnational testing network with testing in several countries covering various climate conditions and reducing the workload of national authorities), or carried out under official supervision - The derogation from VCU, currently only for grasses not intended for fodder propose should be extended to other species, in particular those used in mixtures, whose individual VCU do not add much value.</p> |
| Company / business | <p>Please consider difference between reproduction through seeds or vegetative reproduction, and whether the crop originates from a region in Europe or not.</p> | <p>Plant breeders rights should apply to “conventional” and organic varieties</p> |