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IMPACT ASSESSMENT

Accompanying the document

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

On the production and making available on the market of plant reproductive material (plant reproductive material law)

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1. PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES

1.1. Overview

The revision of the Directives on the marketing of plant reproductive material (PRM) is part of the 2012 Commission Legislative and Work Programme and is included in the Commission strategy for simplifying the EU legislation.

Plant reproductive material (PRM) is a cornerstone input for agricultural, horticultural and forestal production and it is the first link in the food and feed chain. Union legislation has been in place since 1966 for cereal seed, beet seed, fodder plant seed, seed potatoes and forest reproductive material. Later on, legislation was adopted for other groups of plant species, for example material for the vegetative propagation of the vine in 1968 to vegetable seed in 1970. A number of Directives were to a large degree overhauled between 1998 and 2002. By 2011, PRM legislation has grown to include around 90 legal acts. A full list of basic legal acts and a short history of the legislation can be found in Annex II.

1.2. Preparatory work

The impact assessment builds on the results of the evaluation of the European Union legislation on the marketing of seed and plant propagating material (hereafter plant reproductive material, PRM) that was carried out in 2007/2008 by the Food Chain Evaluation Consortium (FCEC), on the results of a study on variety registration conducted by the same consortium in the first half of 2010 and on a PRM certification study conducted by the Commission's services. It also incorporates discussions with stakeholders, in particular the competent authorities in the Member States, private sector representatives at EU and at national level, relevant international standard setting bodies, non-governmental organisations and the Community Plant Variety Office (CPVO), an EU regulatory agency mandated to grant plant breeders' rights valid throughout the EU.

Key messages of the evaluation of the PRM legislation

Primary strengths:

- Role of official authorities is considered crucial by stakeholders in guaranteeing the equal access to all EU players onto the PRM market
- Evaluation of distinctness, uniformity and stability (DUS) and the value for cultivation and use (VCU) are considered essential and robust tools for conventional agriculture
- Reasonable and proportionate costs linked to the implementation of the legislation
- The Common Catalogues on agricultural and vegetable species are perceived as a powerful tool by private operators to facilitate marketing of PRM

- Provisions for certification have helped European seed industry to become a world market leader
- Alignment with international standards and guidelines (i.e. OECD, ISTA, UPOV)

Areas for improvement

- Room for cost reduction and increased efficiency
- Complex legislation with lack of flexibility
- Non-harmonised implementation in Member States
- Niche and emerging markets are disadvantaged

The respective documents related to the preparatory stages of the legislative review can be found at **http://ec.europa.eu/food/plant/propagation/evaluation/index_en.htm**.

1.3. Consultations

Stakeholders at various levels were first consulted in the context of the evaluation conducted in 2007/2008. Following the evaluation, internal consultations, discussions with Member states and further dialogues with stakeholders were carried out. Annex III gives list of all the meetings.

1.3.1. Internal consultation

Within the Commission, internal consultation has been pursued through an Inter-Service Steering Group (ISSG) set up in 2009. The ISSG was led by the Directorate-General Health and Consumers, with the participation of DGs Agriculture, Trade, Environment and the Secretariat General.

1.3.2. Member States consultation

A number of Commission Horizontal Working Party meetings covering all the plant species were held in 2009-2011. In May 2011, four task forces created by the Hungarian presidency worked on specific topics. In addition, the Commission consulted the working group 'Seeds and Propagating Material' of the Advisory Group on the Food Chain, Animal and Plant Health on several occasions from 2009 – 2011.

1.3.3. Stakeholder consultation

On 18 March 2009 an open conference on Ensuring Seed Availability in the 21st Century was organised to present and discuss the evaluation results with different stakeholders. Overall, stakeholders supported the Commission's intention to revise the legislation.

Finally, a web-based stakeholder survey using an “Interactive Policy Making” (IPM) questionnaire to collect comments on an "options and analysis paper was organised from 19 April to 30 May 2011. It yielded more than 257 responses from a very wide

range of stakeholder groups. All replies to the questionnaire can be found in **http://ec.europa.eu/food/plant/propagation/evaluation/options_review_legislation_replies_en.htm**. The results are summarised in section 6.2 and in more detail in Annex VI.

Main outcome of the stakeholder consultation

- A majority of stakeholders support the continued existence of the main pillars of variety registration and certification of lots of listed species.
- **Competent authorities** support the idea that the revised legislation should reflect a combination of scenarios, combining obligatory variety registration and certification of lots of listed species with more responsibilities for operators, the introduction of cost recovery and a lighter system for conservation varieties.
- **Breeders, suppliers and users of PRM** support the maintenance of current technical provisions and accept the idea that certain tasks should be shifted to operators under official supervision. The concept of cost recovery is also accepted.
- A majority of **stakeholder groups mainly interested in biodiversity issues** support a liberalised and flexible system with no obligatory variety registration and certification of lots.
- **Forest stakeholders** support the scenario with no changes in the Directive on forest reproductive material.

1.4. Action Plan

Based on the evaluation results and the stakeholder consultations, the Commission services presented a PRM Action Plan (SEC(2009) 1272 final) on 2 October 2009, which was subsequently discussed with the Member States.

Main issues raised in the Action Plan

- Single horizontal legal framework
- Harmonised implementation of legislation in Member States
- Reduction of administrative burden and costs
- Consistency with other EU policies:
- Possible extension of the role of the CPVO
- Enhancing the role of the Common Catalogue
- Strengthening the EU role on international standards
- Setting structures for stakeholder involvement

1.5. Impact Assessment Board

The impact assessment report was submitted to the IA board on 14 December 2011 and was formally presented on 18 January 2012. Following this meeting the board issued on 20 January 2012 an opinion on the draft Impact Assessment emphasising four main points to be addressed in the final version of the report.

(1) Strengthen the evidence base of the problem definition

- The problem definition in section 2.3. now more clearly describes which elements of the current system are problematic and why amending the current legislation is not sufficient;
- The problem definition now in more clarity explains how the current legislation creates obstacles to a level playing field for all operators;
- It is stated in section 2.3. that the problem definition is based on the evaluation and consultations with Member States' experts and stakeholders;
- Section 2.5 emphasizes that a better implementation of the current legislation is not a solution to the identified problems;
- The current market structure is described in the baseline scenario (section 5 – Option 0) and in Annex VIII. The baseline scenario also contains detailed descriptions of the different sub-sectors. Annex X provides details on inspection in the FRM sector;
- The relevant elements of the EU Plant health Regime, links with the Official Controls Regulation and the fact that GMOs are dealt with in a parallel legal framework are mentioned at the end of section 2.1.

(2) Improve the intervention logic and the presentation of the objectives

- Problem definition 2.3.4. shows which specific elements of the current legislation are insufficient to promote sustainability and 2.3.5. demonstrates in detail the obstacles that delay the flow of innovation to the market;
- The report now clearly demonstrates that the introduction of cost recovery regime does constitute a proportionate measure (section 5: impact assessment of Option 1 and tables 3 and 4) and that it is an instrument to promote a level playing field for all operators;
- Section 4 lays out that the major trade-off is between transferring costs and tasks to operators and the resulting flexibility;
- The description of each option is now accompanied by a text box outlining how the options achieve the objectives (section 4).

(3) Better present the options and their possible combinations

- The presentation of the policy options clarifies that simplification refers exclusively to the legal structure (from 12 Directives to one Regulation) and demonstrates that legal simplification and cost recovery are horizontal provisions common to all options. The substantial differentiation of the options is mainly based on the other instruments (see next point);
- The first paragraph of section 4 explains that options 1-4 were designed to reflect internal consistency of the instruments mainly with respect to the flexibility afforded to operators, while option 5 envisages a centralised, fully harmonised system. It is emphasized that combinations are feasible if consistency is respected;
- The preferred option is now presented in the same way as all the other options (Section 6.2.), also stating which elements originate from which of the options 2, 4 and 5. A summary of the impacts of the preferred option is included as well (Section 6.2.1). The preferred option is also included in the qualitative comparison of all options in table.

(4) Present the expected impacts in a more transparent way

- In the context of assessing the impacts of cost recovery a more detailed quantitative analysis of costs and benefits was carried that also explicitly addresses the different sectors (section 5: assessment of Option 1);
- The impact of cost recovery on SMEs and micro-enterprises is analysed in detail in the assessment of option 1. Available, but incomplete, information from sectors other than the sector of agricultural crops is taken into account. The analyses of impacts of all other options explicitly take SMEs and micro-enterprises into account where appropriate;
- The impacts on international competitiveness and trade flows are in detail dealt with in the analysis of all options, but have particularly been strengthened in Options 3 and 4;
- The employment impact is analysed separately for the private and public sector. Other social impacts are analysed in a dedicated section for each option;
- The fact that GMOs are dealt with in a parallel legal framework is mentioned at the end of section 2.1., where it is also stated that invasive alien species are outside the scope of the PRM legislation. Environmental impacts are analysed for each option, specifically agro-biodiversity: this analysis for option 3 shows specifically how VCU can have an impact of land use;
- Available quantitative information on costs, benefits and industry structure has been taken into account in the analysis of all options, in particular in the analysis of option 1. Available quantitative information on costs is summarised in Annex XIV.

(D) Procedure and Presentation

- The analysis of the stakeholder survey is presented in Annexes V and VI. Responses are analysed for different stakeholder groups. The report refers to stakeholder opinions in several places (for example section 2.3.4). The report states that stakeholder input has been relevant for identifying the options (section 4) and emphasizes that the preferred option also strikes a balance between different stakeholder groups (section 6.2.);
- The IA executive summary has been changed accordingly to reflect the changes of the main report.

Following the resubmission the board issued on 29 March 2012 a further opinion on the draft Impact Assessment emphasising four issues to be addressed in the final version of the report.

(1) Strengthen the evidence base of the problem definition

- Sections 2.3.1. – 2.3.5. now include several new footnotes that make specific references to findings of the evaluation of the existing S&PM legislation

(2) Reformulating the objectives to better address the issues raised in the problem definition and by clarifying trade-offs

- The overall and specific objectives (Sections 3.1. and 3.2.) now correspond almost exactly to the problems identified in Sections 2.3.1. – 2.3.5.
- Trade-offs are explicitly identified following the presentation of the policy objectives in Sections 3.1. – 3.3.

- In the assessment of Option 1 it is now explicitly stated that cost recovery regime is a proportionate measure in the light of the main objective.

(3) Improve the presentation of impacts and the comparison of options

- In Section 4 it is now spelled out in more detail which elements of the options are compatible with each other and which elements are not.
- In the assessment of Option 2, point 3, data are presented that demonstrate the potential cost savings for some sectors if official supervision of certification is introduced.
- The comparison of the options now includes a summary graph that in a semi-quantitative manner summarises the impacts of the initial and also the preferred option.

(D) Procedure and presentation

- Stakeholder input has been frequently and constantly sought during the entire revision process and has helped identifying problems, devising objectives and options and assessing specific impacts. The objectives (see Section 3) thus also reflect well the diversity of stakeholder attitudes. Stakeholder groupings are presented in Annex V and opinions are summarised in detail in the newly added Section 6.2.

2. PROBLEM DEFINITION

2.1. Background

Plant reproductive material is an input of fundamental importance for the productivity, the diversity, and the quality of plant production and food. This fact has been reflected in national legislation since the late 19th century and in European legislation since the 1960s. Productivity is determined by two basic elements. First, varieties of agricultural and horticultural crop species and forest reproductive material shall be of good quality and identifiable. This means that the plants show a strong and healthy growth, are resistant or tolerant to attacks of some harmful organisms, and to adverse environmental conditions and finally have the right characteristics for their intended use. Wheat varieties, for instance, could be suitable for bread but not for pasta, or exactly the opposite. Second, the PRM lots brought to the market should be in a state so that growers have the best guarantee on the identity of the material and that the plants are able to realise their good characteristics when properly maintained after sowing or planting.

At the time when the PRM EU legislation was first developed, its objective was to contribute to improving the productivity of agriculture in order to ensure food security in the EU, to improve the competitiveness of the related sectors and to play part in the harmonisation of the legislation at EU level, leading to more open markets. This policy has proved to be successful: the PRM sector in the EU is diverse and competitive (see Annex VIII) and has developed into the world's largest PRM exporter. But agricultural policy is no longer restricted to the policy aims formulated

in the 1960s. In the past years agricultural policy in the EU has come to be seen as strategically important for food security and safety, the nutritional value of food, the environment, biodiversity and climate change. "Sustainable intensification" of food crop production in which yields are increased without adverse environmental impact and without the cultivation of more land has become a central concern. PRM legislation is critically important for reaching this aim as well.

The EU legislation on the marketing of PRM is based on two main pillars, namely the registration of varieties/material[1] and the certification[2] of individual PRM lots of plant species used for agriculture marketed in the EU and identified in the Annex of the Directives ('EU listed species') or the approval and registration of basic material and the traceability and quality control of forest reproductive material. It consists of 12 basic Council Directives and is structured into one horizontal Directive on the Common Catalogue of varieties of agricultural plant species and 11 vertical Marketing Directives, among which five seed Directives (fodder plant seed, cereal seed, beet seed, seed of oil and fibre plants and vegetable seed[3]), three plant propagating material Directives (vine propagating material[4], seed potatoes, vegetable reproductive material other than seed) and three Directives that cover both seed and propagating material (fruit plant propagating material, ornamental plants and forest reproductive material[5]). Annex VII summarises the processes of registration and certification and provides a tabular overview over the current requirements for the different plant groups covered by the legislation.

Community Plant Variety Office (CPVO)[6]

To better appreciate the assessment of one of the options developed here, it is also necessary to succinctly describe the present role of the CPVO and to keep in mind the difference between **plant variety rights** and **plant variety marketing**. CPVO manages the Union's **intellectual property rights system** for new plant varieties. After an application has been submitted, the CPVO first studies the administrative file, including payment of fees, and whether the variety is in fact novel with regard to previous marketing. If no formal impediment is found for granting protection, the CPVO arranges for a technical examination of the variety submitted. The purpose of this examination is to ensure that the criteria of distinctness, uniformity, and stability

[1] Depending on the plant species, the term variety or material is used in the basic Directives. For the ease of reading, in this document the term variety is used for both cases.
[2] Certification refers to intervention of official services which includes (1) visual inspections on growing field and (2) sampling and analysis of PRM lots before marketing, while inspection could be work done by official services or by the supplier in a number of cases. For the ease of reading, in this document the term certification is used to cover both cases.
[3] The Marketing Directive for vegetable seeds includes the reference to the Common catalogue of varieties of vegetables species.
[4] The marketing Directive on vine propagating material includes reference to national vine varieties officially accepted.
[5] The Marketing Directive for forest reproductive material includes the reference to national registers of basic material of the various species on national territory and national list.
[6] CPVO is self-sustained from a financial point of view because of fees levied for its activities on commercial operators, with an annual budget of EURO 12.8 Mio and a total number of staff of 46 in 2011.

(DUS) are complied with. The technical examination is entrusted to Member States competent bodies (examination offices) or carried out in cooperation with third countries. They are conducted in accordance with protocols established by the CPVO, based on UPOV guidelines, and are monitored by its technical experts. In addition to the technical requirements, a variety must be identified by a variety denomination, which is proposed by the applicant in the form of a code or a "fancy" name. To be approved, a variety denomination must fulfil several criteria that ensure clear and unambiguous identification.

CPVO is currently only responsible for the granting of intellectual property rights for plant varieties – **granting of this intellectual property right for a new variety is entirely independent from the right to market the variety**.

The current EU PRM legislation sets out general principles that operators[7] need to comply with before reproductive material of plant varieties can be **marketed:**

1. Plant varieties should be listed in a national and then in the EU (Common) catalogues (for agricultural and vegetable crops) to be marketed.[8] The purpose is to ensure that the varieties are clearly identified. In order to be listed, it has to be demonstrated that varieties are Distinct, Uniform and Stable (DUS) and that variety denomination rules are observed. Moreover, varieties of agricultural crop species must be tested for their Value for Cultivation and Use (VCU).[9] The tests should be conducted as official examinations. The above general principles are not applicable to ornamentals. The principles for forest reproductive material are based on national registers of approved basic material.

2. Individual lots of seed and plant propagating material are subject to a pre-market certification system on the basis of official certification or certification under official supervision of the competent authorities. However, for seed potatoes and for the categories of pre-basic and basic seed only official inspections shall be carried out.

The above general principles are not applicable to ornamentals or vegetable standard seeds, while for fruit plants EU mandatory rules will only apply as from 2012.

For forest reproductive material the Member States shall, by an official control system set up or approved by them, ensure that reproductive material from individual units of approval or lots remains clearly identifiable through the entire process from collection

[7] As economic operators on the PRM sector we include breeders, seed multipliers, seed cleaners (seed companies or mobile processors), seed packaging and traders.

[8] The EU common catalogues for agricultural plant species and vegetable species are available online at http://ec.europa.eu/food/plant/propagation/catalogues/database/public/index.cfm. The European catalogues offer added value compared to the national catalogues. For example, the website of GNIS (Groupement National Interprofessionnel des Semences et Plants) provided information on both national registration and European registered varieties. In 2010 the European listed varieties received more hits (approx. 200 000 hits in total) than the varieties registered on the national French catalogue (information received from GNIS).

[9] VCU evaluation encompasses the assessment of yield, quality, disease resistance and behaviour with respect to physical factors in the environment. The characters evaluated in each of these four categories are species-specific and defined in national protocols.

to delivery to the end user. Therefore a master certificate is required, showing the unique register reference for all reproductive material derived from approved basic material.

3. The more recent Directives require the registration of suppliers, in particular because most of the PRM concerned is brought to the market carrying a suppliers' label.

In the recent years, to meet objectives such as preserving biodiversity, supporting in situ conservation and the protection of natural environment, specific legislations creating derogation for less stringent marketing requirement for so called conservation and amateur varieties and preservation seed mixtures were developed.[10]

The legislation on PRM applies without prejudice to the provisions of Directive 2001/18/EC, Regulation (EC) No 1829/2003 and Regulation (EC) No 1830/2003 concerning the deliberate release into the environment, including cultivation, placing on the market, traceability and labelling of GMOs.

As regards harmful organisms, the so-called non-quarantine pests are listed together with other certification requirements in the various PRM Directives. In addition the Directive on seed potatoes list some quarantine pests which should today only be listed under the umbrella of the Plant Health legislation.

The scope of the new legislation should exclude from marketing authorisation material belonging to plants which are injurious to plants exclusively through competition for nutrients and/or ecological niche or allelopathy (invasive alien species, IAS). With regard to IAS, the new legislation on PRM will apply without prejudice to the EU 2020 Biodiversity Strategy adopted in May 2011.

Finally, the enforcement of PRM legislation is currently not framed by a general legal framework providing the competent authorities in the Member States with a solid and comprehensive set of rules which affords them the necessary powers and tools to deliver their enforcement duties in an efficient and reliable fashion. In fact, official controls performed by competent authorities to verify compliance with PRM legislation are not covered at present by Regulation (EC) No 882/2004 governing official controls along the food chain, nor do equivalent provisions exist for official controls for the purpose of enforcing PRM legislation. The required official control system for forest reproductive material is already set up by member states and may be checked by the Commission. Nevertheless, a harmonised European approach is not yet in place. This issue will be addressed in the context of the on-going Impact Assessment for the review of the Regulation (EC) No 882/2004.

[10] A conservation variety is defined as a landrace or plant variety that is naturally adapted to local and regional conditions and is threatened by genetic erosion. The term amateur varieties refers to varieties that are not used for commercial agricultural production ('with no intrinsic value for commercial crop production but developed for growing under particular conditions'), i.e. varieties that are only grown for private use by for example hobby gardeners. Preservation seed mixtures of fodder plants are collected in designated areas contributing to the conservation of plant genetic resources. The seeds of those species are then mixed to create a mixture which is composed of those genera, species and subspecies which are typical for the habitat type of the collection site.

2.2. International dimension

The EU is the world's largest exporter of PRM with an estimated export value of EUR 4.4 billion representing roughly 60% of the total worldwide PRM export value of EUR 7.7 billion[11]. The high quality of European PRM is an asset in the global market – and an asset for food security.

The legal framework established in the EU has facilitated – if not enabled – this development, but it needs to be underlined that rules and standards have been established in a wider international context than the EU (see also Annex IV). The EU is an active member in these international fora and EU rules have had considerable influence on the elaboration of international rules and standards. Internationally accepted standards for seed sampling and testing are developed by the International Seed Testing Association (ISTA) and applied in the EU by seed analysis laboratories. EU protocols for the technical examination of varieties are based on test guidelines elaborated by UPOV experts (Union Internationale pour le Protection des Obtentions Végétales); EU is member of UPOV since July 2005. Varietal identity and purity standards for the certification of PRM lots in view of their marketing are based on OECD (EU has a status of participant) seed rules and forest reproductive material control, which are also open to non OECD countries, or on UNECE standards for seed potatoes. The plant health legislation is framed in the wider context of the International Plant Protection Convention (IPPC). In general, the EU standards are in line with OECD standards, but not fully coherent with UNECE standards on seed potatoes. The UNECE standard is an evolving framework, while the EU Directive has not changed since its adoption. Regarding plant genetic resources, the EU is a contracting party to the International Treaty for Plant Genetic Resources for Food and Agriculture (ITPGRFA) since 2004.[12]

PRM which are developed in Europe can later be exported, commercialized and grown in third countries, in particular through the OECD seed scheme or OECD forest reproductive material scheme, directly in similar agro-climatic conditions areas or by being introduced to breeding programs. The rules which are developed in the Union are following the principles of the international standards in order to assure coherence with all countries following such standards and to facilitate international trade. 67 countries are members of the OECD seed schemes, including India, Argentina, Brazil; Senegal is candidate to one of the OECD seed schemes.

The revision of the PRM legislation will continue to take into consideration the productivity in the agricultural, horticultural, and forestal production and will strengthen sustainability criteria in the variety registration process in order to adjust production to major challenges such as climate change, food security and to reinforce the link between breeders and user/farmer in the plant **innovation system.** The control and certification system along the PRM production chain will maintain the high quality of the material and continue to contribute to food/feed safety and security. The rules on forest reproductive material conform to the standard developed at OECD level which will be further used by third countries for the production of tropical wood PRM.

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[11] http://www.worldseed.org/isf/seed_statistics.html.
[12] ITPGRFA: http://www.planttreaty.org/.

The revision of the PRM legislation also contributes to achieving the millennium goals, including measures in favor of preservation of biodiversity through the facilitation of market access for conservation varieties.

2.3. What are the issues or problems that may require action?

In line with the Europe 2020 Strategy and Commission SMART Regulation policy[13] aiming at simplifying and improving regulation and at developing an economy based on knowledge and innovation, it is necessary to review PRM legislation, streamline and remove overlaps to ensure that it is consistent and does not create unnecessary burdens for operators and citizens.

This is especially relevant due to the fact that the EU PRM sector is not only the world's biggest exporter of seeds (net market value EUR 4.4 billion) but also has an average R&D/net sales ratio of around 15% of its annual turnover (EUR 6.8 billion) in seed market.[14] Maintaining the comparative advantage of the EU industry on the global market, while ensuring at the same time innovation and diversity as crucial element, is therefore one main objective of this review.

The external evaluation carried out in 2007-2008 concluded that most of the stakeholders consider that the EU's PRM legislation has been effective in achieving its initial objectives and that free movement of marketed PRM is observed in the internal market. However, the evaluation also highlighted a number of problems regarding the application of the legislation in practice. The five key problems, identified in the evaluation and through consultation with member States' experts and stakeholders, form the basis of this review.

2.3.1. Complexity, rigidity and fragmentation of legislation and gaps

Driver: The legislation is composed of 12 basic Directives and approximately 90 other legal acts. The Directives have been developed over several decades and within different political and scientific-technical contexts. Furthermore, the alignment with other legislative acts that concern the sector also needs improvement. The problems cannot be corrected by only amending the legislation.

Problem:

- Understanding the requirements laid down in the Directives and other legal acts in their entirety is not simple.[15] In some PRM sectors, the operators must implement 2-3 Directives at the same time in order to fulfil their obligations. There is also a lack of consistency, such as cross-referencing to outdated

[13] COM(2010) 543 Final of 8 October 2010.
[14] ESA document ESA_07.0243.5A2 (2007).
[15] For example, there currently are different requirements and tests depending on the crop (DUS, VCU), several levels of variety catalogues (EU, national, for export or list of recommended varieties in some Member States).

legislation or concerning definitions and some obligations.[16] The current legislation is in a form of Directive requiring national transposition. The Directives are implemented at different points of times and give room for substantial differences in national interpretation;[17]

- Certain work-intensive parts of the certification process (field inspections for pre-basic and basic seed, seed potatoes, FRM) and the examinations for variety registration (DUS, VCU) can only be carried out as official examinations. This may limit the flexibility of operators to adapt to the more quickly changing demands of an increasingly global market for PRM[18];
- As regards variety registration, it is well known in the sector that some Member States use much larger variety reference collections than others[19] and that there are considerable differences how extensively VCU tests are carried out (criteria, testing, calculation of results, etc.)[20];
- The current legislation gives the possibility for additional national rules. For example, in the case of certification of seed potatoes, different marketing categories exist in different Member States leading to national systems taking precedence over the EU legislation and thus undermining the internal market;
- The current legislation does not contain a solid and comprehensive set of rules for competent authorities in the Member States performing official controls and in the majority does not include the empowerment for the Commission to audit/visit the Member States' control system;
- There are currently no EU rules on fees for variety registration or official controls including PRM certification;
- The majority of the current Directives do not require the registration of operators.

It therefore seems sensible to envisage a review of the PRM legislation with a view to its simplification and increased consistency with itself and with other legal acts that govern PRM marketing.

2.3.2. High level of administrative burden in particular for public authorities

Driver: Public competent authorities are to a high degree involved in variety registration and in the certification of PRM lots brought to the market, as the required tests and examinations (DUS, VCU) are currently nearly exclusivley carried out by the authorities.

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[16] See p. 57, p. 62 and pp. 155-156 in: FCEC (2008), *Evaluation of the Community acquis on the marketing of seed and plant propagating material (S&PM). Final Report*.

[17] The Krakow Declaration (2011) stressed the importance of reducing transposition and compliance deficits. This proposal is thus fully in line with this target.

[18] See pp. 151-152 in: FCEC (2008), *Evaluation of the Community acquis on the marketing of seed and plant propagating material (S&PM). Final Report*.

[19] See the example of winter oilseed rape in: FCEC (2008), *Evaluation of the Community acquis on the marketing of seed and plant propagating material (S&PM). Final Report*. Pp. 82-83.

[20] See the example of winter oilseed rape in: FCEC (2008), *Evaluation of the Community acquis on the marketing of seed and plant propagating material (S&PM). Final Report*. P. 66.

Problem: As Member State national budgets are under strong pressure and the need to prioritise resources is becoming more and more severe, it seems pertinent to consider the possibility to reduce the level of public resources required by PRM legislation.[21]

The system therefore needs to become more efficient and less burdensome. It should be examined whether, and if so to what extent, certain tasks could or should be assigned to the private sector or can be shared between Member States while ensuring that the quality of the marketed PRMs remains at least as high as under the current regime and that the operational capacity of SMEs is not compromised.

2.3.3. Non-harmonised implementation of the current legislation

Driver: The evaluation of the current regime found that implementation of the legislation in the Member States varies significantly. There are currently no rules for fees at EU level for public services rendered to private operators, and therefore there is no harmonised framework for costs and responsibility sharing. Some Member States recover the whole cost of technical examination of varieties and of certification from the producer, some only recover a part.

Furthermore, the variety examination procedures and associated costs can vary considerably from Member State to Member State.[22] For certification, additional or stricter national requirements for national production are applied in several Member States.

Problem: This lack of harmonisation causes obstacles to the establishment of a level playing field for all operators in the internal market. While costs for registration and certification amount to no more than 3% of the annual market value of agricultural seed crops[23], the burden for public services is quite significant in some Member States: in Germany and France annual costs for registration and certification are approximately EUR 26 Mio and EUR 24 Mio, respectively. However, in Germany only around 50% of these costs are recovered, while in France 67% of registration costs and 97% of certification costs are recovered (see Annex XIV). The 'user pays' principle is not evenly applied across all Member States.

2.3.4. Weaknesses concerning horizontal coordination with recent EU strategies concerning biodiversity, sustainability and climate change

Driver: For historical reasons, the current system is mainly focused on the improvement of productivity of agricultural crops and for all listed species to a certain

[21] See p. 88, and p. 105 in: FCEC (2008), *Evaluation of the Community acquis on the marketing of seed and plant propagating material (S&PM). Final Report*.

[22] FCEC (2008), *Evaluation of the Community acquis on the marketing of seed and plant propagating material (S&PM). Cost analysis*. For example, the study mentions that VCU-testing of winter oilseed rape costs around EUR 2000 in Italy and around EUR 9000 in the UK. Both countries claim to have cost recovery, thus the differences are, as the study shows, to a large extent due to the number of conditions tested during VCU.

[23] FCEC (2008), *Evaluation of the Community acquis on the marketing of seed and plant propagating material (S&PM). Cost analysis*.

extent on the resistance to biotic and abiotic stress and diversification of uses, in addition to the harmonisation of the market.

Problem: The evaluation stressed that although productivity is still an important factor for the development of new varieties, other aspects have gained in importance.[24] In the past decade the need for "greening" of the Common Agricultural Policy (CAP) has emerged and policy objectives related to sustainability, biodiversity protection and climate change have gained importance in addition to food security (including feed) and food safety. Specific products such as old varieties or minor crops are increasing their market share. Breeders and competent authorities in some Member States have taken these developments proactively into account, but efforts should be spread over the entire EU. For low-input agriculture the rules are seen to be far too strict and costly. Certain stakeholders are stating that the less stringent requirements developed in the recent years in the EU for conservation and amateur varieties are still too restrictive, burdensome and costly.[25] Basic Council Directives 66/402/EEC and 2002/55/EC stipulate limitation to region of origin for conservation varieties and appropriate quantitative restrictions. Some stakeholder groups are strongly against both these stipulations, while others are adamant that no changes should be considered.

2.3.5. Removing obstacles to quick market access of innovations

Driver: The registration process of varieties is a heavy procedure requiring time, technical knowledge and staff both at the level of competent authorities and operators' in order to fulfil the registration criteria. Rules governing the variety registration process can place a series of small obstacles in the way to market access, which in their combination can delay the flow of innovations to the market.

Problem:

- As part of the registration process, Member States' notifications are to be transferred to the EU Common Catalogue. Some Member States only report national registrations twice per year for transfer to the EU Common Catalogue. At the EU level, depending on the time of the year, the administrative procedure concerning the transfer of varieties to the Common Catalogues (Official Journal) takes roughly 8 weeks;
- Member States may have limited resources for growing trials for variety testing. Therefore in some Member States the number of applications in certain species per year are limited;
- Strict deadlines for submission of application and material;
- Number of years required for the technical examination varies between Member States;

[24] See p. 94 and pp. 168-172 in: FCEC (2008), *Evaluation of the Community acquis on the marketing of seed and plant propagating material (S&PM). Final Report*.
[25] See pp. 105-106 in: FCEC (2008), *Evaluation of the Community acquis on the marketing of seed and plant propagating material (S&PM). Final Report*.

- Breeders have to accept the practical conditions for testing (e.g. locations of fields) in the examination office, which might be suboptimal for variety in question;
- For a new type of variety the development of the necessary testing protocols can take several years.

In addition, variety registration procedures put a high burden on competent authorities. This is amplified by the difficult current economic environment which leads to a reduced availability of public funds: the consultation process demonstrated that a number of Member States are under pressure to reduce staff and to close some testing stations. The current administrative procedures might delay the flow of innovation onto the market.

2.4. Who is affected, in what way and to what extent?

- Member State authorities: financial and staff resources are under severe pressure and it becomes increasingly difficult for competent authorities to fulfil the obligations laid down in the legislation;

- Breeders of varieties, as changes in the legislation may affect their right to commercialise the products of their breeding activity, taking into account that breeding activities represent at least 10 years of work, and the cost of doing so;

- PRM suppliers, if quality requirements for lots brought to the market would be altered or if costs of certification would be transferred more systematically to the private sector operators;

- PRM users, as a revision of the legal framework with regard to minimum conditions for PRM marketing could affect the availability, quality and the cost of PRM brought to the market;

- Consumers of produced commodities, because PRM is a primary input of any agricultural, horticultural or forestal production and as such the changes felt by PRM users will be reflected in the availability, quality and costs of the commodities (food) offered to the final consumers;

- PRM suppliers, agricultural stakeholders and consumers outside the EU, because, as the EU is the world leader in PRM production and export, changes to the EU PRM marketing legislation will have consequences worldwide. EU has an important role to play in global food security and thus in avoiding food crises.

2.5. How would the problems evolve, all things being equal?

The current provisions on variety registration only allow examinations by official authorities and do not allow examinations to be carried out by private operators. As regards certification, the current legislation caters for a possibility in certain cases to transfer part of the work related to certification of lots of PRM to the industry through

a system of certification under official supervision. However, limitations of the legislation do not allow certain plant species (e.g. potatoes) and categories of seed (pre-basic and basic) to fully benefit from officially supervised examination. This will in particular have an impact on big companies and competitive, innovative SMEs in big Member States, which are limited in their room to operate. If no action was taken, the shortcomings of the system will grow and become an increasingly larger burden for both official authorities and business with consequences for competitiveness, adaptation to market demands as well as export capacities vis-à-vis to non EU competitors.

The provisions contained in the EU PRM marketing legislation on registration of varieties and on certification of individual PRM lots are strict. This could become more problematic given the current financial situation as in today's global market operators need to react quickly to market demands and opportunities. The current variety registration system can be improved with a view to support innovation. These improvements are needed to ensure quick access to the market for new improved varieties, especially those giving a higher and more regular yield on the same land surface with less need for irrigation, fertilisers or pesticides. Developments in plant breeding have contributed significantly to yield increases, but with regard to the European strategy to further reduce the use of plant protection products and fertilisers, plant breeding efforts will have to be strengthened in order to be able to take such requirements into consideration.

Furthermore, discrepancies with regard to technical examinations and evaluations in the context of registration and certification would continue to exist across the Member States. This would prove disadvantageous to some operators and may continue to be an obstacle to the establishment of a level playing field in the internal market.

Finally, the complexity and fragmentation of the existing legislation is likely to perpetuate existing uncertainties and discrepancies in its implementation. This would further maintain or aggravate current difficulties of national authorities and operators. In addition, without amending legislation, the possibility to move more technical requirements to the implementing measures and thus the increase in flexibility of the legislation would be lost.

As regards the current legislation on conservation varieties, the strict requirements for variety testing, restriction to production in region of origin and quantitative restrictions might compromise achievement of the aim of conservation of agro-biodiversity in situ. Therefore there are few opportunities for the growth and expansion of this sector.

No synergies with the Plant Health Law concerning the plant health checks that are part of the PRM certification process or integration of general principles concerning official controls embedded in Regulation (EC) n°882/2004 would be obtained.

2.6. Does the EU have the right to act (subsidiarity)?

2.6.1. Right of the EU to act (Treaty basis)

The PRM legislative framework is based on the Treaty on the Functioning of the European Union (TFEU) **Article 43** (ex-Article 37) implementing the Common Agricultural Policy (CAP). The objectives of that policy are to increase agricultural productivity, to ensure a fair standard of living for the agricultural community, to stabilise markets, to assure the availability of supplies and to ensure that supplies reach consumers at reasonable prices. The Lisbon Treaty qualifies agriculture as shared competence between the EU and its Member States. It is obvious, however, that to a very large extent all fields of agricultural activity as well as ancillary activities upstream and downstream, have been regulated at the EU level. This means that legislation is predominantly a role for the institutions of the European Union.

Article 114 provides the legal basis for the establishment and functioning of the internal market and the approximation of provisions laid down by the law, regulation or administrative actions in this respect.

Article 191 states as the objectives of EU environment policy the preservation of the environment, the prudent and rational use of natural resources as well as promoting measures at international level to deal with environmental problems.

2.6.2. Necessity for the EU to act

The introduction of the EU framework legislation on the marketing of PRM in the sixties has been a major contributor to the creation of an internal market. As confirmed in stakeholder consultation, performed as part of the current systems evaluation, a large majority of the respondents believe that the EU rules on marketing of PRM have had a positive impact on **free movement, availability and quality** of PRM on the EU market and have thus facilitated trade within the EU. If there was no action at EU level, 27 systems instead of one would be in place. This would put obstacles to the movement of PRM on the internal market and increase the financial burden associated with the necessary controls on health and quality of PRM.

International standards or recommendations have been established not only for PRM quality (OECD, UNECE, ISTA) but also for plant health (IPPC, WTO/SPS agreement) which require an adequate transposition in all EU27 Member states. In order to avoid a more non harmonised implementation of EU rules on the **internal market**, a common EU framework is the most appropriate approach.

2.6.3. Added value

A common legislative framework adds weight to EU positions and approaches for addressing issues of PRM on the global level, notably in **international agreements**.

At the same time, transparent and reliable rules ensuring the **highest product quality** are of particular relevance to the EU PRM industry in its role as the largest exporter in the world. The competitive advantage of EU exporters relies heavily on the high quality of its products.

Certification and marketing of PRM relies on a system of pre-market authorisation, such as DUS- and VCU-evaluation for variety registration and field inspection and sampling of PRM production as well as approved basic material and traceability of forest reproductive material. These are performed by national authorities, but in line

with a **'one key, several doors'** principle, are valid in all EU27 Member states. This ensures the quality of EU products while safeguarding open and fair competition on the Single market, and facilitating the marketing of innovative products. A certain margin for higher efficiency herein is possible with the introduction of the possibility for direct EU-wide authorisations by CVPO.

2.6.4 Proportionality

With a view to ensuring proportionality of measures, notably reducing administrative burden for Member States and private actors, the system of pre-market control must take into consideration the freedom and economic viability of stakeholders as well as SME and micro-entities regarding the more specific parts of the PRM market. Varieties of common knowledge, conservation or amateur varieties help to ensure access of growers, including amateur gardeners, to PRM of varieties that would not pass modern variety evaluation. Conservation varieties could play an important role in maintaining resilient systems in agriculture production and genetic diversity at the field level. Smart growth is fostered by specifically focusing on niche markets (e.g. old varieties), such as in allowing simplified market access for specific varieties and PRM.

2.6.5 Citizens' and Human Rights

Provide Member States' competent authorities with efficient tools for the performance of official controls and, consequently, allow for a more efficient use of national control resources in line with the principles of equity and fairness and in full compliance with the Charter of Fundamental Rights of the EU, in particular the right to protection of personal data and the right to an effective remedy.

3. OBJECTIVES

3.1. Overall objectives

- To assure the health and high quality of PRM;
- To provide a single and harmonised regulatory framework which is supportive for innovation and the competitiveness of the European PRM industry;
- To support sustainable production, biodiversity protection, adaptation to climate change and to contribute to food security and poverty alleviation.

3.2. Specific objectives

- To ensure a level playing field across the EU through simplified, clarified and harmonised basic rules on fundamental principles presented in an improved legal form;
- To reduce unnecessary costs and administrative burden and to increase flexibility for operators without compromising the general policy objectives;
- To align PRM legislation with other recent Union strategies (plant health law, official controls regulation, agriculture, biodiversity, food security, climate change, bio-based economy);

- To foster innovation in plant breeding, especially in SMEs, in order to improve PRM users' choice and access to a wide diversity of plant varieties adapted to conditions in Europe.

3.3. Operational objectives

- To provide a simplified legal framework for marketing of PRM – "PRM Law" - with the establishment of simplified, more flexible and proportionate procedures;
- To promote a more harmonised implementation of legislation throughout the EU by audits and training;
- To foster innovation by increasing the timeliness and level of information provided in the Common Catalogue;
- To enhance market transparency and improve traceability through the registration of operators.

The objectives also reflect the diversity of opinions and aims among stakeholder groups in the PRM sector (see Annexes V and VI). Attempting to realise all these objectives simultaneously is constrained by a number of potential **trade-offs** between or even within objectives: (1) Transferring tasks to the private sector and broadening the scope of official supervision may have an impact on the health and quality of PRM; (2) the reduction of costs for competent authorities and the transfer of tasks to the private sector may burden in particular SMEs that may not be able to bear the additional costs or to carry out the tasks themselves; (3) Breeding for sustainability traits of crops (drought resistance etc.) may compromise yield increases.

4. POLICY OPTIONS

Based on the evaluation, on internal discussions and on discussions with Member States' experts and various stakeholder groups, a number of policy options were developed.

The problem definition identified the following main axes along which the system has to change in order to be fit for the new economic, environmental, social, and scientific circumstances:

> (i) Simplification of the basic legal acts (from 12 Directives to one Regulation),
>
> (ii) Cost recovery and improvement of the effectiveness and efficiency of the system,
>
> (iii) Horizontal coordination with recent, already adopted EU policies.

Various measures – increased flexibility, deregulation or centralisation – are explored for improving the efficiency of the system, while maintaining the assurances for high quality PRM, competitiveness and addressing new challenges such as hold of loss of biodiversity. These measures have been translated into the content of the options as

regards the main instruments of the legislation: registration of varieties/material, certification, registration of operators and conservation varieties.

The preparatory work for the Impact Assessment identified 5 options that address all or most of the identified problems and are characterised by internal consistency, especially with respect to the level of responsibility sharing between private and public actors and the obligatory or voluntary nature of instruments such as registration or certification. The options were chosen so that, for example, responsibility sharing between operators and competent authorities or deregulation extends to all main instruments of the legislation and are not arbitrarily restricted to certain instruments. Option 5 (centralisation) is compatible with increased flexibility of operators concerning certification, but is more limiting concerning variety registration. Option 5 is by and large incompatible with deregulation. It should be noted that simplification of the legal architecture (replacing 12 Directives by one Regulation) and cost recovery are constant for all options and compatible with deregulation, increased flexibility and centralisation.

In the various options, issues concerning SMEs and micro-enterprises have been addressed throughout, especially in order to ensure access for these enterprises to public services for the execution of certain tasks they cannot perform themselves and to support and further develop their flexibility to gain improved access to the PRM market.

Specific attention is given to the **trade-off** between transferring operational work and maintenance of PRM quality

A graphical presentation of the five options can be found in Annex XI. A detailed quantitative analysis of stakeholder attitudes towards the options can be found in Annex VI.

Option 1 - Cost recovery: No change to technical provisions and allocation of tasks but complete recovery of registration and certification costs by competent authorities

Cost recovery and the simplification of the basic legal acts (replacing 12 Directives by one Regulation) are horizontal provisions common to all options.

Option 1 does not foresee any changes to the technical provisions of the current legislation or to the allocation of responsibilities for the implementation and the control of the implementation of the legislation. The registration and certification systems will continue to exist as they are for the same plant species. The involvement of public authorities in the management of the system is not changed. The only change with potential significant impacts consists in a recovery from the stakeholders of costs incurred by the competent authorities in all the Member States. This will be achieved via the introduction of a mandatory fee system or any other way of authorities' compensation. Currently there is a wide divergence in the extent to which this is done in the Member States.

Linking main objectives to instruments

- Simplification and harmonisation - from 12 Directives => one Regulation;
- Reducing administrative costs - recovery of substantive costs for variety registration and PRM certification;
- Transparency and traceability – no specific provisions;
- Access of innovation to the market - no specific provisions;
- Environmental aims – no specific provisions.

Option 2 - Co-system: No change to technical provisions but certain tasks performed by industry under official supervision; improved coherence between the PHR and PMR regimes

Cost recovery and the simplification of the basic legal acts (replacing 12 Directives by one Regulation) are horizontal provisions common to all options.

This option foresees the shifting of certain tasks and responsibilities from the competent authorities to the private sector. As a result, the system focuses more on process- than on product-control.

1. Registration of varieties and material

Variety registration continues to be obligatory for crops covered by EU legislation. However, more responsibilities will be given to industry to carry out DUS and VCU evaluations subject to validation and audit by the competent authorities. For VCU evaluation harmonised and more detailed EU criteria will be developed on the basis of the requirements set up in the Member States. Official examination shall remain possible on request. Provisions related to variety denomination and the management of the Common Catalogues will remain unchanged. In this option all administrative tasks at EU level will be attributed to the Community Plant Variety Office (CPVO).

2. Certification/inspection of PRM

The certification requirements for lots of PRM remain unchanged. However, as a standard procedure, the PRM certification is carried out by the operator under supervision of the competent authority. On request of the operator certification under official examination is still possible. Marketing of lots of PRM covered by a suppliers' label equally remains unchanged. Pests currently regulated under the PRM will be listed under PHL; definitions and provisions between PHL and PRM Law will be aligned. This should allow removing any obstacles for combine health inspections under the two regimes.

3. Registration of operators

In a context where a more significant role is given to the industry, all operators (breeders, growers, suppliers) are registered, allowing a monitoring of their activities and facilitating traceability in case of identified problems. This registration will be

valid both for the EU plant health regime and for the PRM marketing legislation and implemented through a shared register to reduce burden.

4. Approach to conservation varieties/amateur varieties/niche markets

This approach is not changed. Specific provisions continue to apply for conservation varieties and landraces of agricultural crops, for vegetable varieties, mixtures of fodder plant seed and for forest reproductive material intended for gene conservation purposes.

Linking main objectives to instruments

- Simplification and harmonisation - from 12 Directives => one Regulation;
- Reducing administrative costs for competent authorities; increasing flexibility for operators – recovery of substantive costs for variety registration and PRM certification, transfer of tasks to the operators under official supervision;
- Transparency and traceability – register of operators and operators' labelling;
- Access of innovation to the market – more flexibility and responsibility for operators;
- Environmental aims – no specific provisions.

Option 3 - Deregulation: VCU-evaluation and official certification are optional. Harmonised tests are developed. Reallocation of tasks as under option 2

Cost recovery and the simplification of the basic legal acts (replacing 12 Directives by one Regulation) are horizontal provisions common to all options.

In this option, tasks and responsibilities are not only shifted from the competent authorities to the private sector, but also reduced: VCU-evaluation and official certification are no longer legal requirements. Furthermore, ornamentals will no longer fall within the scope of the PRM marketing legislation and therefore will be totally deregulated.

1. Registration of varieties and material

DUS-test for variety registration continues to be compulsory for the crops regulated by the EU legislation, and the verification of compliance with the requirements will be passed to industry as in option 2.

VCU-evaluation for agricultural crops will no longer be a legal requirement. It is the responsibility of plant breeders to provide information on the value of varieties. For the sake of transparency, harmonised evaluation methods will be developed at EU level. In this option, all administrative tasks at the EU level related to variety registration, including the checking of variety denomination, will be attributed to the CPVO.

2. Certification/inspection of PRM

All lots of PRM are marketed solely on the basis of a suppliers' label (i.e. no pre-market inspection but only marketing controls carried out by consumer protection services), and there is no obligation to certify. Certification of lots will only be done for PRM lots intended for export. However, lots under suppliers' label will need to meet certain minimum criteria, which are set at the EU level. As it is envisaged to include PRM under the scope of the new Regulation on official controls along the food chain (see the related IA), marketing controls will be carried out in accordance with the latter framework, in particular following the principle of risk based controls.

3. Registration of operators

In a context where a more significant role is given to the industry, all operators (breeders, growers, suppliers) are registered, allowing a monitoring of their activities and facilitating traceability in case of identified problems. This registration will be valid both for the EU plant health regime and for the PRM marketing legislation and implemented through a shared register to reduce burden.

4. Approach to conservation varieties/amateur varieties/niche markets

This approach is not changed. Specific provisions on less stringent requirements continue to apply for conservation varieties and landraces of agricultural crops, for vegetable varieties, mixtures of fodder plant seed and for forest reproductive material intended for gene conservation purposes.

Linking main objectives to instruments

- Simplification and harmonisation – from 12 Directives => one Regulation;
- Reducing administrative costs for competent authorities; increasing flexibility for operators – recovery of substantive costs for variety registration and PRM certification, transfer of tasks to operators, VCU evaluation and certification are optional;
- Transparency and traceability – register of operators and operators' labelling;
- Access of innovation to the market – more flexibility and responsibility for operators;
- Environmental aims – no specific provisions.

Option 4 - Enhanced flexibility system: Mandatory basic provisions for registration with a voluntary level of higher assurance for registration and certification

Cost recovery and the simplification of the basic legal acts (replacing 12 Directives by one Regulation) are horizontal provisions common to all options

This option envisages a substantial flexibility regarding the allocation of tasks and responsibilities among the actors. The system can thus be process- or product-centred, depending on the priorities of the operators. Furthermore, basic general EU criteria with regard to plant health and fitness for purpose, as well as for traceability/labelling, will apply to all PRM brought to the market.

A dual system is put in place allowing a broader choice for operators: (i) official description of the variety and a right for certification and (ii) official recognised description provided by the operator and no right for certification.

1. Registration of varieties and material

All varieties and material of specified crops (in principle those covered by the current EU marketing Directives with a closed list of species) will be registered in national and subsequently in EU catalogues, which will be composed of two sections. For both sections, the variety description should be based on criteria complying with CPVO and UPOV rules. All administrative tasks at the EU level related to variety registration will be attributed to the CPVO.

Section 1 will comprise "officially tested" varieties that have been tested and described officially or under official supervision. Technical examination will include DUS, mandatory VCU criteria (sustainability of resistance/tolerance to pests, adaptation to the physical environment and sustainability criteria such as sensitivity to input level or plant competitiveness) and denomination. Only varieties that are listed in this part of the catalogues will have the right to certification.

Section 2 will comprise "not officially tested" varieties that are registered on the basis of an accepted harmonised description of the variety prepared by the applicant, including the denomination – this amounts to an "officially recognized description". Competent authorities will only be responsible for checking the denomination and registration and for controls of material present on the market, focussing on labelling in particular. Varieties in this category will not have the right for certification because the authorities, in the absence of officially verified and accepted results of identity testing (official examinations), cannot certify the identity of individual PRM lots.

2. Certification of PRM

Certification of certain species is no longer an obligation, but is converted into a right that only the officially tested varieties can have. Obligatory certification of PRM could be maintained for crops that cause specific risks in terms of plant health or other aspects with societal relevance such as possible content of toxic substances, sustainability of production, food security. In case of no certification, competent authorities will only carry out marketing controls, possibly under the new Regulation on official controls along the food chain (see Scenario 3, point 2).

3. Registration of operators

In a context where a more significant role is given to the industry, all operators (breeders, growers, suppliers) are registered, allowing a monitoring of their activities and facilitating traceability in case of identified problems. This registration will be

valid both for the EU plant health regime and for the PRM marketing legislation and implemented through a shared register to reduce burden.

4. Approach on conservation varieties/amateur varieties/niche markets

The marketing of conservation or certain "niche market" varieties is liberalised. As there is no obligatory technical examination of varieties and no obligatory certification of PRM, the marketing of conservation varieties or "niche market" varieties can take place under the provisions of the regime for non-tested varieties. Suppliers whose PRM lots hold no particular plant health risk (in line with priorities to be set by a revised EU plant health legislation).

Linking main objectives to instruments

- Simplification - from 12 Directives => one Regulation;
- Reducing administrative costs for competent authorities; increasing flexibility for operators – recovery of substantive costs for variety registration and PRM certification, transfer of tasks to operators, voluntary higher level of control with regard to registration or certification;
- Transparency and traceability – register of operators and operators' labelling;
- Access of innovation to market - system includes non-tested varieties for which access to the market is free;
- Environmental aims – less stringent conditions for conservation varieties, sustainable VCU criteria.

Option 5 - Centralisation: Centralised EU registration procedure with CPVO managing and making final decisions, and fully harmonised certification requirements; improved coherence between the PHR and PMR regimes

Cost recovery and the simplification of the basic legal acts (replacing 12 Directives by one Regulation) are horizontal provisions common to all options.

In this option, registration is centralised at the CPVO, while some other tasks and responsibilities can be allocated to the private sector. Variety registration and PRM certification, where applicable, will remain mandatory for crops covered by the existing EU legislation and detailed technical requirements will be defined in the legislation.

1. Registration of varieties and material

The CPVO will be mandated to coordinate and decide on variety registration, covering both technical examination (DUS and VCU) as well as variety denomination. Applications for registration of new varieties will be sent directly to CPVO. In addition, this would allow breeders to obtain in the same office the intellectual property title and the authorisation for marketing ("one key, 27 locks").

The EU catalogue(s) will be published online, and will be continuously updated. To make them more informative, they will contain hyperlinks leading to standardised descriptions of the registered varieties, including possible relevant data related to food safety aspects.

National catalogues may still coexist alongside the EU (Common) catalogue(s). They could contain additional VCU information that has been validated at national level or play a role for species that are not covered by the EU marketing legislation.

2. Certification of PRM

The certification requirements for lots of PRM remain unchanged. However, as a standard procedure, the control of compliance with the criteria for PRM marketing is carried out by the operator under supervision of the competent authority. On request of the operator certification under official examination is still possible. Possible stricter requirements of the Member States that apply to their domestic production will be subject to approval at EU level. Pests currently regulated under the PRM will be listed under PHL; definitions and provisions between PHL and PRM Law will be aligned. This should allow removing obstacles for combine health inspections under the two regimes. The Union system of comparative tests and trials – which have not been carried out since 2008 – will be replaced by "Reference Certification Centres". These centres will have the task to develop and share best practices, carry out comparative tests and trials, carry out studies in support of policy development and to disseminate knowledge of PRM certification. This all should contribute to the health and quality of PRM and to the development and harmonisation of PRM certification in the Union.

3. Registration of operators

In a context where a more significant role is given to the industry, all operators (breeders, growers, suppliers) are registered, allowing a monitoring of their activities and facilitating traceability in case of identified problems. This registration will be valid both for the EU plant health regime and for the PRM marketing legislation and implemented through a shared register to reduce burden.

4. Approach on conservation varieties/amateur varieties/ niche markets

Conservation varieties have a strong link with their region of origin and should be evaluated in that same region for their contribution to agro-biodiversity. This evaluation should be carried out on the basis of harmonised criteria. Deviations from the normal regime ought to be kept to an absolute minimum.

Linking main objectives to instruments

- Simplification - from 12 Directives => one Regulation;
- Reducing administrative costs for competent authorities; increasing flexibility for operators – recovery of substantive costs for variety registration and PRM certification; "one key, 27 locks": possibility for breeders to obtain in the same office the intellectual property title and the authorisation for marketing;
- Transparency and traceability – register of operators;
- Access of innovation to the market – one EU office with several related tasks will strengthen the innovation and protection of the innovation;
- Environmental aims – no specific provisions.

Discarded options

The following option was also considered but given its incompatibility with the objectives of the revision it has been excluded at an early stage and not been analysed in detail.

Abolishing the EU legislation on PRM marketing

Variety registration and seed certification schemes have a long history in Europe: in the Netherlands, government seed testing services were already offered in 1877, in Germany a seed certification programme was established in the late 19th century[26] and Sweden created an official system in 1888.[27] Variety registration developed in the early 20th century; Germany passed the first seed law that included variety registration in 1929.

The development of some type of regulatory system concerning PRM is predicated on the fact that any inadequacies concerning identity of or quality in purchased seed are difficult or impossible for the farmer to recognise. Due to long production circles, this issue is also crucial for forestry. Regulation is best seen as a response to insufficient information in a market, which may limit transactions. In these cases a third party helps ensure that adequate information is available to guide market transactions or to enforce standards of public safety. Abolishing the current EU-wide legislation on PRM marketing would most likely not lead to a complete disappearance some form of variety registration or of certification of seed as the transparency of the market has to be maintained. A complete replacement of the current well-functioning official system by a similar, but private system thus does not appear to be an efficient course of action. If these private schemes were mainly run on a national level, new problems may well arise as can be illustrated using the example of certification.

In the absence of any EU regulations concerning PRM marketing, the principle of free movement of goods has still to be respected. At intra-EU level, the private sector certification schemes would most likely not be identical. This would lead to a lack of

[26] Rutz, H.W. (1990) Seed certification in the Federal Republic of Germany. *Plant Varieties and Seeds* **3**, 157-163.
[27] Kahre, L. (1990) The history of seed certification in Sweden. *Plant Varieties and Seeds* **3**, 181-193.

transparency, making choice for farmers more difficult. As the PRM industry would have to take account of diverging rules and required specifications depending on the customer to whom and the Member State in which they sell their products, this would have a strong negative impact on the administrative burden for the industry and consequently, on its competitiveness. In the absence of mandatory minimum standards, part of the operators may seek to gain a part of the market through low prices based on the reduction of production costs. This could ultimately affect agricultural production and productivity as well as forestry. This option could also increase the risk of spreading plant pests. On the whole, it is considered that this option will not contribute to the achievement of the overall objectives.

In the absence of any EU regulations concerning PRM marketing, trade with third countries will only be regulated in line with the OECD rules and internationally recognised rules on seed testing. This entails that Member States will have to maintain a system of certification. This implies furthermore, that the EU equivalence system would have to be abolished as it would represent a technical trade barrier within the WTO system.

As one underlying objective of the review is the reduction of cost and administrative burden, possible options that would lay down stricter rules, such as centralising certification or a full VCU evaluation for all groups of plant species, were discarded.

5. ANALYSIS OF IMPACTS

Option 0 - Baseline

Structure and dynamics of the sector

In 2009 – 2010, the EU commercial seed market has reached a value of approximately EUR 6.8 billion and it thus represents more than 20% of the total worldwide market for commercial seed. There is still an important potential on the international market for improved seed; an annual growth rate of about 5% for field crops at global level can be expected. The value of the PRM market other than agricultural seed is approximately an additional EUR 6-7 billion.

The PRM industry is very dynamic. Traditionally, the seed markets were national markets with quite a low volume of international exchanges. This has changed dramatically in the past 20 years. The industry has undergone considerable consolidation and continues to evolve. This sector now comprises a complex and dynamic network of ownerships (partial and complete), joint ventures, partnerships or strategic alliances.[28]

[28] For an analysis see Howard, P.H. (2009) Visualizing Consolidation in the Global Seed Industry: 1996–2008. Sustainability 1, 1266-1287.

The situation in old Member States can be characterized as follows: a large proportion of SMEs with a high R&D rate, strong interlinkages and production for the global market. The situation in the new Member States is still quite different: breeding of new varieties is still largely done by public bodies, but SMEs are in charge of seed multiplication and sales. Therefore, companies in the new Member States such as Poland, Hungary and Romania are not research intensive and a large proportion are likely seed multipliers or seed traders. Annex IX shows on the basis of variety registration data from the Common Catalogue the still significant differences between some selected old and new Member States in terms of new varieties registered and the provenance of variety maintainers.

Situation in specific subsectors

Vegetable seeds are mainly multiplied outside the EU in a wide range of countries in which labour costs are lower than in the EU. The produced seeds are shipped to the EU, mainly to the Netherlands, for treating, sampling and packaging and re-exported to their final destination in the EU or outside the EU. The production has a value of about EUR 1 billion. Main producers are FR, IT, NL, HU DK, PL. The five biggest companies have 95% of the seed market.

In the EU, forest nursery activities are linked to reforestation and afforestation, which could concern forested area, agricultural land (agricultural abandonment of marginal area), creation/renovation of hedges or agro-forestry. European forests serve different aims: economical (raw materials like sawn wood for construction purposes or furniture, pulpwood for cellulose, insulation, packaging, paper and source of renewable energy), environmental (e.g. protection against soil erosion, avalanche control, regulation of streams and rivers, CO_2 capture) and societal (e.g. recreation, employment in rural areas).

Regarding the control of nursery activities, registration of new selected seed stands and qualified seed orchards, deliverance of Master certificates, responsibility is at the level of the competent authority in the Member States. Generally, there are two different competent authorities for plant health control and PRM control, except in few Member States (FR, IE). Regarding the practical modalities of control and the costs involved, the situation is very diverse among the Member States as is shown in Annex X.

The existing legal framework for forest reproductive material is accepted and supported by all stakeholder groups.

The propagating material of fruit plants is produced in all EU countries, but the largest quantity of the propagating material marketed in the Union is produced in specialised areas concentrated in few countries (ES, IT, NL, FR, PT, UK and HU). The production of propagating material is held by a large number of suppliers accredited by the responsible official bodies of the Member States. Only a low number of suppliers have a large business specialised in fruit plant propagating material breeding or reproduction. Some suppliers are specialised in the production of particular material e.g. stone fruits, citrus fruit or apple trees only. In some cases the same company is involved in production of fruit plants and ornamental plants propagating material, it is accredited as supplier for fruit plants and registered as supplier for ornamental plants. In other cases the production of propagating material

is a part of other farming business. Basic research is still generally carried out by universities or other public Research Institutes.

DG SANCO consolidated some key figures in 2007-08 and concluded that more than 12,000 enterprises are involved in production of fruit plants in the EU; and about 90% of them are small to medium enterprises frequently based in rural areas where alternative business is not possible. The estimated value of this business was estimated at about EUR 2.5 billion.

The EU is world leader in the market for vine nursery products, with an annual output of 360 million cuttings. The steady decline in prices for cuttings on the world market and stronger competition from other producer countries has resulted over recent years in an exponential increase in the number of nursery closures in Europe and has plunged the entire sector into crisis. In Italy, for instance, it is estimated that in 2009 the market for cuttings has shrunk by 30 %, and up to 60 % in areas experiencing severe difficulties. In France, over the past three years alone, 130 of the country's 830 vine nurseries have closed down owing to the collapse in market prices for cuttings, which have fallen well below production costs.

Implementation costs of the legislation

The current cost of implementing the variety registration provisions amounts to approximately EUR 55-60 Mio per year in the EU according to information provided by Member States.[29] DUS and VCU account for 45% and 55% of the cost, respectively (see also Annex XIV).

The cost of certification is more difficult to estimate since in a number of Member States staff involved in certification is also involved in plant health inspections, and it is not straightforward to assign costs.

From information provided by Member States (evaluation of 2007/2008 and certification questionnaire) it is estimated that the expenditure by Member States' authorities on certification of PRM are in the range of EUR 73-79 Mio.[30] Seed lot sampling and analysis represents more than 50% of the total certification costs, while field inspection costs represent in between 20-30% on average (Annex XIV). For agricultural and vegetable crops the 2007/2008 evaluation calculated an approximate combined cost for variety registration and certification incurred by competent authorities of just under EUR 120 Mio and that across the EU approximately 60% of these costs are recovered. These figures serve as a basis for the analysis of the costs in the other options. Table 1 and 2 provide information on the current distribution of variety registration and seed certification costs between public and private bodies in the Member States. Annex XIV provides further information on the cost structure of registration and certification for Member States for which detailed information could be gathered during the evaluation.

[29] Extrapolation of data obtained in the 2010 PRM testing and registration study. It concerns all species for which variety registration is mandatory under EU legislation.
[30] This figure includes the additional cost flowing from stricter national provisions. Also, it should be stressed that part of the expenditure is compensated by incoming fees.

Controls for the possible presence of harmful organisms (HO) at growing stage and in lots of PRM brought to the market are an important cost factor and an integration of plant health and certification inspection schemes could lead to some cost savings. This possibility is analysed in options 2 and 5.

Table 1 – Current distribution of seed registration costs between public and private bodies in the MS

MS	Transfer of Registration costs	Additional information
AT		
BE	Yes	Partial transfer of costs (around 50% of DUS and VCU costs)
BG*		No transfer of DUS costs, partial transfer of VCU costs
CY	Yes	Partial transfer of costs (around 50% of DUS and VCU costs)
CZ	Yes	Partial transfer of costs (between 70% and 80% of DUS and VCU costs)
DE	Yes	Partial transfer of costs (around 50% of DUS and VCU costs)
DK	Yes	Full transfer of DUS and VCU costs (100%)
EE	Yes	Full transfer of DUS and VCU costs (100%)
ES	Yes	Partial transfer of costs
FI	Yes	Full transfer of DUS and VCU costs (100%)
FR	Yes	Around 2/3 of DUS and VCU costs are transferred to the industry)
GR	Yes	
HU	No	
IE	No	
IT	Yes	Full transfer of DUS and VCU costs (100%)
LT	No	
LU	Yes	Partial transfer of costs
LV	No	
MT	No	
NL	Yes	Full transfer of DUS and VCU costs (100%)
PL	Yes	Partial transfer of costs (around 25 to 30% of DUS and VCU costs)
PT	Yes	Partial transfer of costs

RO*	No	
SE	Yes	Full transfer of DUS and VCU costs (100%)
SI		Almost no DUS testing performed in Slovenia, around 70% of VCU costs are transferred
SK	Yes	Partial transfer of costs (around 70% of VCU costs)
UK	Yes	Full transfer of DUS and VCU costs (100%)

*Source: compiled on the basis of the data provided in the qualitative and the cost questionnaire. * Information received from these Member States leads to the conclusion that by now full (BG) or at least partial (RO) cost recovery is in place.*

Table 2 – Current distribution of seed certification costs between public and private bodies in the Member States

MS	Certification costs are transferred to industry	Additional information
AT	Yes	Partial transfer of costs
BE	Yes	30% of costs are transferred to the industry
BG	Yes	Partial transfer of costs
CY	Yes	Partial transfer of costs
CZ	Yes	Partial transfer of costs
DE	Yes	Between 30% and 70% depending on the Federal Land concerned
DK	Yes	Full transfer of costs (100%)
EE	Yes	Partial transfer of costs
ES	Yes	Partial transfer of costs
FI	Yes	Full transfer of costs (100%)
FR	Yes	97% for seed, 65% for vine
GR	Yes	The fee = (reference price) x (certified quantity) x 3%. The rate of the reference price is fluctuating between the farmer's price and the final selling price of the seed.
HU	Yes	Full transfer of costs (100%)
IE	Yes	Partial transfer of costs
IT	Yes	Full transfer of costs (100%)
LT	Yes	8% is financed by private sector
LU	Certification is mostly financed by national authorities	
LV	Yes	Partial transfer of costs
MT	No	
NL	Yes	Full transfer of costs (100%)

PL	Yes	Full transfer of costs (100%)
PT	Yes	Full transfer of costs (100%)
RO	Yes	
SE	Yes	Full transfer of costs (100%)
SI	Yes	
SK	Yes	
UK	Yes	70-80 of costs transferred to the industry and target of 100%

Source: compiled on the base of the answers provided to the cost questionnaire and by official authorities to the preliminary questionnaire.

Rating of impacts

To facilitate comparisons between options, impacts have been rated:

0	**No or neutral impact**	**0**	**No or neutral impact**
+	**Small positive impact**	-	**Small negative impact**
++	**Significant positive impact**	--	**Significant negative impact**

Option 1 - Cost recovery: No change to technical provisions but complete recovery of registration and certification costs by competent authorities

Under this option, the impacts of the horizontal measures (cost recovery, the simplification of the basic legal acts and the registration of operators) are assessed. The current situation concerning the distribution of costs between the public and the private sector are shown in tables 1 and 2.

1. Impact on health and quality of PRM

No significant impacts compared to the baseline are expected on health and quality of PRM.

2. Impact on employment and jobs

Employment in the public sector might escape some of the cuts that would be necessary under the budgetary austerity measures if there is no change in the system. No noticeable effects on the private sector are expected.

3. Impact on administrative burden for authorities and private sector operators

The main instruments having impacts in these respects will be legal simplification and cost recovery. No additional costs are expected from the simplification and harmonisation of the legislation. Benefits are expected as legislation will become far less complex and fragmented and as all technical measures laid down by the existing basic legislation will be transferred to specific implementing acts. Member States save costs as they do not have to transpose EU legislation into national law. Increased flexibility for the management of technical implementing acts is expected both by official bodies and suppliers. Costs will decrease for competent authorities in those Member States that so far have not implemented cost recovery and the extra resources will help to maintain the pool of expertise in the public services which will secure

their functioning in the future. Costs will increase to a small extent for operators in those Member States. The impacts on the private sector can be considered in more detail for the different sectors:

Agricultural seed crops:

With an estimated cost for variety registration and certification of up to 3%[31] of the market value of the agricultural seed crops, the introduction of cost recovery is unlikely to have a direct impact on the competition of between PRM companies from different Member States – especially as at least 60% of these costs are already recovered across the EU. Two factors have to be considered in order to judge the impact of cost recovery on the PRM industry: the ability to absorb extra cost and the specific impact on SMEs and micro-enterprises. The PRM industry as a whole is one of the most research intensive industries having an average R&D/net sale ratio of 15% and thus can be expected to have the financial capability to absorb the costs for registration and certification.

Annex VIII shows that the largest numbers of SMEs are found in three Member States: Hungary, Poland and Romania. Approximately 4900 companies are located in these three Member States and more than 90% of these companies are SMEs. However, these three Member States already have cost recovery for seed certification. Variety registration costs are not recovered in Hungary and partially recovered in Romania[32] and Poland. Thus, a large majority of SMEs and micro-enterprises in the EU are already operating under cost recovery regimes for seed certification (which accounts for approximately 57% of the implementation costs of the PRM legislation). If cost recovery were to be extended to all Member States for both variety registration and seed certification, only a small increase of costs amounting to less than 1% of the market value of the agricultural seed crops (taking into account the already recovered share of the total costs) would have to be borne by operators that develop and register new varieties. It has also to be taken into account that a large share of the SMEs and micro-enterprises in the new Member States are seed multipliers and seed traders[33] and are not involved in breeding new varieties. Therefore, they are not registering new varieties to a significant extent.

Vegetables:

Vegetable varieties only undergo DUS, but no VCU and certification is not compulsory. The main producers of vegetable seed and propagating material are the Netherlands and France, two countries in which cost recovery for DUS is already in force. The impact of cost recovery on this sector will therefore be minimal.

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[31] FCEC (2008), *Evaluation of the Community acquis on the marketing of seed and plant propagating material (S&PM). Cost analysis*.

[32] When the evaluation was carried out, Romania reported no cost recovery for registration. Information received recently from Romanian authorities lead to the conclusion that presently partial, if not full, recovery for registration has been established.

[33] This can be inferred from data in Annex VIII which show that comparatively few R&D employees work in the new Member States and that most research is done in Member States with companies that have a relatively large number of employees.

Fruit propagating material:

Many of the enterprises active in this sector are small or micro-enterprises located in disadvantaged areas. In addition, it has to be taken into account that variety registration may very well be more expensive than for agricultural seed crops on which the estimate of 1.3% is based on. DUS for fruit propagating material takes at least 4 years and thus could be approximately 30% more expensive. Detailed information concerning cost recovery in this sector is not available, but on the basis of available general information from the Member States and information from experts, it can be assumed that at least partial cost recovery already exists in the major countries producing fruit plant propagating material. The effects of introducing cost recovery are most likely moderate to low.

Forest reproductive material:

Forests are atypical compared to the other sectors in their multifunctionality (including public goods such as recreation, cultural identity or environmental protection) and the long-term perspectives concerning these functions. This explains and also justifies the current strong involvement of public authorities in breeding, growing and certification. Annex X shows the practical modalities and costs involved in control of FRM, but detailed data on potentially specific cost recovery regimes for this sector are not available.

Vine reproductive material:

The problems facing vine nurseries have their root cause not in the marketing Directives. The 1999 reform of the common market organisation (CMO) for wine strengthened the goal of achieving a better balance between supply and demand on the Community market, giving producers the chance to bring production into line with a market demanding higher quality and to allow the sector to become competitive in the long term by financing the restructuring of a large part of present vineyards. This reform proved insufficient to reduce wine surpluses and considerable sums still had to be spent on disposing of them. The reform adopted by the EU in 2008 has the goals of making EU wine producers even more competitive, making the market-management rules simpler, clearer and more effective – to achieve a better balance between supply and demand and to preserve the best traditions of European wine. After 2015, current EU restrictions on planting vines will be lifted, enabling competitive producers to increase production.

Detailed data for cost recovery in this sector are not available, but assuming that practices are similar to other sectors, cost recovery will not have a significant impact, but rather help to maintain the system to control the strict quality requirements demanded of planting material.

- **Table 3 Potential impact of requiring MS to achieve cost recovery on registration**[34]

	HU	IE	LT	LV	MT	BE	CY	DE	PL	ES*	GR*	LU*	PT*	CZ	FR	RO**	SI	SK	BG**	DK	EE	FI	IT	NL	SE	UK	AT
High impact																											
Medium impact																											
Low impact																											
No impact																											

High impact: currently no cost recovery; medium impact: currently 50% cost recovery; low impact: 50% < current cost recovery < 100% and no impact: currently cost recovery.

* These Member States only stated that they achieve partial cost recovery without providing a number.

** The situation in BG and RO appears to have changed since the evaluation was carried out in 2007. Information received from those Member States lead to the conclusion that cost recovery is in place in BG and at least partial recovery in RO.

- **Table 4 Potential impact of requiring MS to achieve cost recovery on certification**

	MT	LT	LU	AT	BG	CY	CZ	EE	ES	GR	IE	LV	BE	DE	UK	FR	DK	FI	HU	IT	NL	PL	PT	RO	SE	SI	SK
High impact																											
Medium impact																											
Low impact																											
No impact																											

Data received from ESA (personal communication) on the situation of micro-enterprises, SMEs and large companies in the some European countries where the seed sector is relatively important, show that the proportion of micro enterprises ranges from around 48% in France, 68% in Italy, 82% in Hungary to up to 95% in Poland. The micro-enterprises are mainly involved in seed production and marketing.

Today in France, Italy and Poland the principle of cost recovery for variety registration and seed certification is already in place and applied to all types of companies and is not of major concern for the majority of stakeholders. In Hungary, cost recovery only applies to seed certification.

In the sector of fruit, forest and vine nurseries, the percentage of small enterprises is even higher.[35] The exemption of these sectors from the scope of the Regulation is not

[34] The data used to construct these tables are uncertain. They are intended to provide an indicative assessment of the distributional impact of requiring cost recovery based on current rates of recovery. Actual impacts will be influenced by a range of factors in addition to current cost recovery rates.

in coherence with the global request of nursery growers to increase the quality of the material in order to provide high quality material and remain competitive at global level.

Regarding a general exemption of micro-enterprises from the scope of the new Regulation, it will result in an exemption of 95% of the businesses in Poland and of 50% in France.

The cost recovery principle will not affect SMEs and micro-enterprises to a significant extent because this principle is already realised in a majority of Member States and offers benefits to these enterprises as it ensures the continuation of access to official services needed for marketing. Furthermore, operators active along the food chain share with competent authorities the responsibility of preventing that unsafe or unfit products enter the market. They are the first beneficiaries of the added value produced by an efficient control system and are thus called upon to finance the official control system through the payment of a fee which allows the competent authorities to recover its control costs. Introducing a cost recovery regime is a proportionate measure as it does not unduly burden SMEs and because it contributes significantly to achieving the objective of assuring the health and quality of PRM.

The general principle of proportionality will apply in the new PRM legislation also in a different sense: for species such as those from the ornamental sector or non-listed species (not important with regard to EU agricultural production and food quality), obligations will be limited to registration of professional operators and minimum labelling requirement affixed by the operators.

The review of PRM legislation is also linked to the review of plant health Regulation (Directive 2000/29) and control in the food chain (Regulation No. 882/2004) where the issue of SMEs and exempting small or micro enterprises from the scope of the legislation will also be addressed.

4. Impact on competitiveness and trade

The major positive impact of cost recovery consists in establishing a level playing field for all operators in the internal market. This should improve competitiveness and trade in the EU.

5. Impact on innovation and research

No significant impacts on innovation and research are expected, as the R&D budgets are far larger than the additional costs incurred through cost recovery.

6. Environmental impact

No environmental impacts are expected compared to the baseline

7. Social impact

No social impacts are expected compared to the baseline

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[35] See for example FranceAgriMer (Sep. 2011) Observatoire des exploitations horticoles et pépinières. p. 9.

Summary of the key impacts under option 1

Areas	Impacts
Impact on health and quality of PRM	**0**
Impact on employment and jobs in the public and private sector	**0**
Impact on administrative burden and costs for authorities	+ (in few MS ++)
Impact on administrative burden and costs for private sector operators	**-** (in few MS --)
Impact on competitiveness and trade	**+**
Impact on innovation and research	**0**
Environmental impact	**0**
Social impacts	**0**

Option 2 - Co-system: No change to technical provisions but certain tasks performed by industry under official supervision; improved coherence between the PHR and PMR regimes

1. Impact on health and quality of PRM

Transferring the legal requirements for registration to industry should not have a major negative impact on the health of PRM. With regard to the certification of PRM, Member States that are already using certification under official supervision (11 Member States in 2007) did not consider that widening the possibility to certify PRM "under official supervision" to all categories of PRM and to all agricultural species would lead to a general reduction of the health and quality of PRM lots of agricultural crops on the market. Propagating material will run the highest health risk, rather than true seeds, because this technique of reproduction could transfer more possible pests and diseases to the daughter generations.

Improving the coherence between the PHR and PMR regimes will make it easier to change the status of regulated harmful organisms from territorial (quarantine) to marketing (quality). This will improve the flexibility and adaptability of both legal regimes to changes in threats to PRMs. Further alignments of definitions and provisions of the EU plant health and PRM regimes can remove obstacles for Member States to combine health inspections under the two regimes and reduce burden. Where consignments require a plant passport and a certification label, the competent authorities shall issue a single document. This would allow for a reduction of operator costs up to EUR 0.7 Mio per year.[36]

[36] FCEC (2011) *Quantification of costs and benefits of amendments to the EU plant health regime*. Final report.

2. Impact on employment and jobs

Between 1300 and 1500 employees work on variety registration in official bodies in the EU. The results of the variety registration study indicate that 60% of the registration costs are in fact labour costs. If the practical work for variety registration were fully transferred to the private sector stakeholders, it could result in redundancies in Member States' competent authorities. Technical examination of the identity of varieties would then be limited to the work done for that share of varieties checked in the system of official supervision of variety evaluation activities and in the context of post-controls on lots of PRM present on the market. In terms of jobs, a certain share of those related to variety evaluation in the public sector might disappear, but part of the staff could potentially be recruited by private companies, to take advantage of their specialised expertise. This might lead to a limited increase in employment in the private sector. However, the principle of cost recovery will contribute to the maintenance of the appropriate level of expertise in competent authorities.

As for the certification of individual lots of PRM, in the current system of examination under official supervision the authorities have to inspect only 5% of the fields and lots, meaning that there could be a significant reduction in staff numbers. Some major PRM producing Member States already implement examination under official supervision for agricultural crops other than seed potatoes, and there the number of jobs lost in the competent authorities would probably be fairly limited.[37] As roughly half of PRM produced in the EU is intended for export to third countries, official certification or certification under official supervision will still have to be carried out for these lots of PRM. A rough estimate is that no more than 600-700 public sector jobs might be lost.

Part of the redundant staff may be recruited by the private sector, as it will have to control their products more thoroughly, being ultimately responsible for the PRM lots brought to the market.

3. Impact on administrative burden for authorities and private sector operators

The administrative burden related to the registration of varieties is estimated to be 55 to 60 Mio Euro per year, while the cost of the certification regime is estimated to be EUR 73-79 Mio.[38] As explained earlier, moving the inspection task to the private sector should reduce this burden significantly. The industry, however, will be required to maintain records of their variety and certification procedures. Already now, mostly large companies in the sector perform a considerable number of inspections as part of their quality assurance schemes. According to the variety registration study,[39] private

[37] In France, for basic and pre-basic crops there are approximately 6000 contracts between farmers and seed producers each year. Currently, these crops have all to be examined officially. With official supervision, at least 5% would have to be examined. This is a small number compared to the number of inspections under official supervision for certified field crops that are already undertaken, approximately 2000 – 3000 per year. (GNIS, pers. comm.).

[38] This figure includes the additional cost flowing from stricter national provisions. It should also be stressed that part of the expenditure is compensated by incoming fees.

[39] FCEC (2008) *Evaluation of the Community* acquis *on the marketing of seed and plant propagating material (S&PM)*. Final report.

companies could do the work at lower cost. It is therefore expected that the majority of these costs can be absorbed by businesses under normal business practices (business as usual) and that the additional cost will not be significant. Therefore, passing the task of inspections from the Member State authorities to the sector will lead to only a limited increase of workload for the private sector. Moreover, the sector has pointed at the importance of enhanced flexibility, timeliness and cost savings offered by examination under official supervision.

Estimating cost savings for certification under official supervision

During official certification, work that is carried in the context of companies' quality assurance schemes is to some extent or even completely duplicated. The following examples of seed potato and cereal certification provide an estimate of the costs that could be saved if official supervision of certification for these crops would be introduced.

Estimation of costs and possible savings in the seed potato sector[40]:

The total EU market of seed potatoes is approximately 2.5 Mio tons of which 400 000 tons is exported to third countries. Seed lot testing is done both by official inspection authorities and seed companies which means a potential 100% duplication of work.

Exports (400 000 tons) are tested in lots of 25 tons: this means that a total of 16 000 inspections take place every year. Assuming inspection costs of EUR 50[41] this amounts to a total cost of EUR 800 000.

Seed potatoes for the internal market (2.1 Million tons) are tested in lots of 100 tons: this means that 21 000 inspections take place per year. Again assuming that costs per inspection are EUR 50, the total inspection effort amounts to a cost of EUR 1.0 Mio. The total cost of duplicated activities during certification is thus EUR 1.8 Mio. Under official supervision, 5% of lots are checked by the competent authorities. This means that approximately **EUR 1.7 Mio** (≈ 2% of total certification costs) could be saved in the seed potato sector alone by avoiding duplicated work under a system of official supervision of certification.

Estimation of costs and possible savings for a company in the cereal sector[42]:

A large seed company produces approximately 10 000 lots of basic and pre-basic and 20 000 lots of certified cereal seeds each year. Official supervision for certified cereal seed is already in place. Field inspections cost approximately EUR 11 per visit – both if done by company staff or the competent authorities – and lot inspections EUR 35 if carried out by the company and EUR 65 if carried out by the competent authorities. If official supervision of the certification of pre-basic and basic seed was introduced and assuming complete duplication of quality assurance work and official inspection and

[40] Information from industry
[41] This number is based on the situation in the Netherlands. The main other European producers of seed potatoes are Germany, France and the UK and we assume that the inspection costs are roughly similar in these countries.
[42] Based on information from industry sources.

that on average 2 field visits are carried out, the company could save in the order of 0.95*10 000 * EUR 87 = **EUR 826 500** per year.

It is very difficult to generalise these calculations to the entire European cereal sector as internal costs for companies and costs of inspections will differ substantially between Member States.

The impacts of registration of operators will not be significant as PRM operators are to a large majority covered by the register envisaged under the new plant health legislation.

4. Impact on competitiveness and trade

Registration tests require staff with a high level of specialised technical skills. It is possible that only a small part of the breeding industry would be interested in performing registration tests themselves, namely bigger companies (10% of companies) that breed several crops and that can afford specialised staff, and some smaller companies which have become acknowledged specialists in a very limited number of crops. As already today major companies are carrying out variety evaluation work themselves, in particular for big volume crops, such a shift would allow them to act faster and more efficient, without increasing their costs. This would enhance their competitiveness.

A significant number of companies in the sector are SMEs that do not necessarily have the facilities to do the necessary technical examinations. These companies would need to outsource this work to the private sector or to facilities run by competent authorities. The aim is to provide flexibility for all operators to carry out some tasks directly if they wish to do so, but the continued existence of public services is also guaranteed, so that SMEs and micro-enterprises can have technical examinations and inspections carried out by competent authorities.

There is also the risk that staff cuts in public facilities and a lower amount of technical examination/inspection work results in an erosion of skills and knowledge in the public sector. But the cost recovery principle for the services provided should counterbalance this tendency and help to maintaining the necessary level of staffing and expertise.

The currently available opportunities for performing certification under official supervision are not widely taken up in the Member States, in part because in many Member States the cost of certification is not recovered from the private sector. In Member States where already now the costs are fully recovered, the reduction of costs for producers of PRM will be limited, but it will result in a definite improvement of flexibility in their operations, and therefore most of them would benefit from a widened certification under official supervision, regardless of the size of their enterprise.

The increased flexibility envisaged in this option will also help to maintain the competitiveness of European companies on the global market.

The forestry sector faces some specific challenges that need to be considered separately. This sector is characterised by a strong involvement of the public sector.

This involvement is justified by the long-term perspective of forestry and by the multifunctional role of forests – they not only serve economic purposes, but also contribute to several public goods such as environmental protection, cultural identity or recreation. Due to the particular conditions of forests and forestry, a specific approach has to be taken for forest reproductive material. Official examination of FRM is therefore a justifiable approach to ensure the long-term achievement of all these goals.

5. Impact on innovation and research

A transfer of tasks related to technical examination for variety registration could improve the knowledge and efficiency at the level of breeders to recognize and develop the varieties with the best commercial potential. This should have a positive impact on innovation and research.

However, a full transfer of the work and the associated costs of variety registration could have negative impacts on breeding activities in minor crops, which are normally only produced by small companies for national or regional markets. Requirements differ according to species and so does size of the markets. For example, the evaluation of fodder varieties is 3 to 4 times more expensive than evaluating cereal varieties; less money is made with fodder plant seed but there is also less competition in the EU market. There is a possibility that this option would benefit more the breeding of major crops which generate higher income. Based on the observation that cost recovery is done in approximately half of the Member States (see table 3), this could in the end have a small impact on breeding activities for less profitable species such as fodder plants and other minor crops. Breeding of small crops will not be abandoned because of variety registration cost but due to R&D investment. Once again the cost recovery principle could, to some extent, contribute to maintaining expertise or reorienting the activity at the level of competent authorities towards these crops.

6. Environmental impact

Under this regime, other possible impacts such as a shift to or away from varieties that can be grown in a more sustainable manner with less inputs (mainly pesticides, fertilisers and irrigation) are minor because the regime does not contain decisive elements to steer such evolutions. As outlined above, for the small crops there is a risk of less breeding of new varieties and a gradual abandoning of such crops by the PRM users, thus reducing biodiversity.

7. Social Impact

No negative social impact is expected. The allocation of more responsibilities to private operators will maintain staff and raise the skill level in PRM companies that are mainly located in rural areas.

Summary of the key impacts under option 2

Areas	Impacts
Impact on health and quality of PRM	**0**
Impact on employment and jobs in the public and private sector	**-** (in the public sector)

	+ (in the private sector)
Impact on administrative burden and costs for authorities	++
Impact on administrative burden and costs for private sector operators	- (more reporting obligation but less financial cost)
Impact on competitiveness and trade	+
Impact on innovation and research	+
Environmental impact	-
Social impact	+

Option 3 - Deregulation: VCU-evaluation and official certification are optional. Harmonised tests are developed. Reallocation of tasks as under option 2

1. Impact on health and quality of PRM

In this option, VCU-evaluation and certification would no longer be obligatory for any PRM. In the short term no significant effect is expected, but medium- to long-term effects on both quality and health are likely.

The modern food system is made up of a series of highly integrated chains that extend from farm to fork. Varieties are bred for very specific uses and the buyers that purchase from farmers have to be completely certain that they receive the variety with the expected characteristics. Farmers in turn have to be sure that they receive the PRM variety in guaranteed purity and quality to satisfy the demands of their customers. Official or officially supervised VCU evaluation provides PRM users with important information on the characteristics and quality of a variety and helps to ensure maximum transparency of information. VCU thus contributes to the functioning of a specialised and differentiated market. For vegetables used by agri-food industries, there are traditionally close links between breeders, growers and buyers who maintain a quality system and no VCU is carried out and it is not sought after. For most agricultural crops such strong links do not exist and thus VCU is likely to remain important.

In the medium and long term abandoning the possibility of health evaluation for variety registration of agricultural crops could potentially lead to varieties with lower pest resistance or quality and lowered food safety due to the fact that proper verification of the health status will entirely depend on the quality of the inspection work done by the operator. To the extent that the official authorities maintain a credible system of general monitoring this should not lead to increased risks for health of PRM in the Union. However, if official authorities seldom carry out e.g. field inspections for certification, there is a large risk that essential skills are lost. There could be a risk for the quality of certain groups of PRM.

Under this option, ornamentals are no longer covered under EU legislation. This will negatively affect the identity and health of the material on the market. Due to a different approach for FRM, there will be no effect on FRM under this option.

2. Impact on employment and jobs

Between 1300 and 1500 employees work in official bodies on variety registration in the EU Member States. Approximately half of this personnel works on VCU (performance) evaluation, posts that are at risk of becoming redundant. Moreover, identity evaluation would pass to the private sector and the role of the official/competent authorities would be to test a fraction (about 5%) of the varieties submitted for registration, together with identity tests and samples drawn from the market in the context of general monitoring. As a consequence up to 1300 competent authority posts for the technical examination of varieties could be lost. Companies might carry out additional work on the performance of their varieties and recruit staff from the public sector but it is unlikely that it would absorb more than a few hundred posts. This would lead to only a small direct increase in employment in the private sector. However, after a variety has been registered, recommendation trials are carried out in public, semi-public or private structures that assist PRM users and distributors in their choice. Some of the staff that was previously involved in VCU-evaluation is likely to be involved in recommendation trials as well. Furthermore, these trials will gain in importance if mandatory VCU is abolished. The principle of cost recovery will guarantee that expertise will be maintained in competent authorities to carry out the necessary tasks. Abolishing VCU could have serious consequences for SMEs that develop varieties of agricultural crops. VCU presently serves as a quality assurance that ensures that small and large companies can compete on a comparatively equal footing – VCU provides the buyer with unbiased information on the performance of a variety. The success of a variety on the market is therefore not mainly dependent on the marketing power of an operator. If this source of information were no longer available, SMEs would most likely not be able to be competitive.

Abolishing certification increases the risk that some activities, especially seed multiplication for agricultural seeds will be relocated to non-EU countries as already is the case for vegetable seed (as the EU equivalence system cannot be maintained). This could lead to considerable job losses in this part of the PRM industry (see section 4 below).

Certification costs in EU are estimated at EUR 73-79 Mio which corresponds to roughly 2000 jobs[43] which potentially could become mobile as there will be a continued need for certification of PRM lots intended for export to third countries. Given the fact that up to half of the production of PRM is intended for export,[44] this exported share will continue to have to be certified. If this is done under official supervision only 5% (currently applied percentage) need official examination. In any case, a generalised shift to certification under official supervision could make redundant up to 1500 or even 1600 posts. Certification duplicates to a good extent work done by the PRM suppliers, and hence the transfer of practical inspection work to the suppliers will not create a lot of new jobs in the private sector.

[43] Calculation on the basis of roughly equivalent percentage of labour cost for variety registration and for certification, and on the estimated cost for implementing these two elements of the seed marketing legislation.
[44] Data (as from 2009) from http://www.worldseed.org/isf/seed_statistics.html.

At EU level, in total up to 2900 jobs might be lost in authorities that are competent for variety registration and PRM certification.

3. Impact on administrative burden for authorities and private sector operators

According to the variety registration study,[45] completely removing official performance examination(VCU) for agricultural crops in the EU would save about EUR 23 Mio for private operators and for public authorities combined.

However, the study also indicated that most Member States would prefer to continue having VCU on a voluntary basis on their territory, and therefore abandoning VCU as a mandatory element of the EU legislation would only save between EUR 2.3 to 11.5 Mio as a direct impact (10 – 50% of actual VCU cost) depending on the cost recovery in Member States.

In practice, companies will continue with a limited type of VCU-evaluation in their testing programs as this provides basic information needed during their breeding and selection cycle. In addition, voluntary, but well-established and stable post registration networks, consisting of public, semi-public and private facilities, exist in a number of Member States. The costs for these services cannot be established as they form part of the business cost of private operators and are not based on obligations stemming from EU legislation.

4. Impact on competitiveness and trade

The costs saved by abandoning VCU-evaluation and official certification could lower the production costs of PRM, and hence have a positive impact on competitiveness, markets, trade and investment flows. VCU is not a statutory requirement in several important Third country competitors on the global seed market (e.g. USA, New Zealand, Australia), but it has to be noted that similar examinations are still carried out widely in these countries (see Annex XII). In addition, more varieties would more quickly enter the market, as fewer varieties would be eliminated by VCU-evaluation. This elimination rate is currently up to 50 – 60% in Denmark or 80 – 90% in Germany. As a consequence, the resources invested in those varieties could be recovered via marketing. This option may therefore increase competition on the EU market which could be to the benefit of PRM users (increased choice, less expensive varieties). On the other hand this implies that varieties with low performance might be placed on the market and micro and small enterprises with less marketing staff will be disadvantaged.

Abolishing certification would, however, have significant effects on trade with Third countries. In this case, EU equivalence cannot be maintained and trade with third countries would have to be based on compliance with OECD seed schemes and internationally recognised rules on seed testing. Such a situation is likely to significantly increase trade flows into the EU and competitive pressure on the EU PRM industry and also decrease the quality of PRM.

[45] FCEC (2008) *Evaluation of the Community* acquis *on the marketing of seed and plant propagating material (S&PM)*. Final report.

SMEs will be disadvantaged as VCU is abolished, which serves as unbiased information for users independent of market power of the seller. No supplementary measures are planned for micro enterprises and SMEs.

5. Impact on innovation and research

Money saved on expenses for VCU and official certification could potentially be directed to breeding programmes but may also be invested in internal certification procedures, VCU evaluation or marketing. Also, more varieties will be brought to the market as none will be eliminated by poor VCU. The positive effects from this option are likely to be seen over the long term rather than immediately.

6. Environmental impact

This option may contribute to increasing agricultural biodiversity if more varieties are placed on the market but there is the risk that this promise is not fulfilled if varieties are not further developed after few years of production. Abandoning VCU-evaluation and tests for disease resistance, which are part of it, could lead to less resistant varieties being marketed that need more interventions using plant protection products, which is inconsistent with EU strategy to reduce pesticide use. In addition, yield evaluation which is part of VCU will not continue to be performed and consequently agricultural productivity for crops like wheat, maize, potato will no longer be guaranteed to the farmer and could have an impact of land tenure. Certification also assures the purity (seeds of other plant species) of PRM lots entering the market. Higher impurity levels and especially the deregulation of ornamentals may increase the risk of invasive alien species (IAS) gaining a foothold in the EU.

VCU can embody both private and public aims. The "Cultivation"-part of VCU could, for example, employ criteria that support the sustainability of agriculture, that reflect the practices of low-input agriculture and that demonstrate how resilient varieties are to the consequences of climate change. The "Use"-part of VCU presently comprises of course many elements that are mainly of interest for industrial or final consumers. The “Use”-part can, nonetheless, also reflect public goods. For example, low-glucosinate cultivars of rapeseed are bred to decrease the toxicity of animal feedstuffs (feed safety). Maize varieties are developed that have high conversion efficiencies as animal feed and thus contribute to energy and land-use efficiency of agriculture. Linoleic or high oleic varieties of sunflowers are another example of the use of specific varieties that also contribute to public goods, in this case public health. A complete abandoning of VCU would thus make it difficult to steer agriculture towards more sustainability.

7. Social impact

Abolishing VCU and certification will most likely threaten SMEs and lead to the erosion of skilled jobs in disadvantaged rural areas.

Summary of the key impacts under option 3

Areas	Impacts
Impact on health and quality of PRM	--
Impact on employment and jobs in the public and private sector	--
Impact on administrative burden and costs for authorities	++
Impact on administrative burden and costs for private sector operators	++
Impact on competitiveness and trade	-
Impact on innovation and research	+
Environmental impact	-
Social impact	--

Option 4 - Enhanced flexibility system: Mandatory basic provisions for registration with a voluntary level of higher assurance for registration and certification

1. Impact on health and quality of PRM

Officially tested varieties (registration) are by and large tested as they are currently done (sustainability criteria are, though, included now in VCU-evaluation). For not officially tested varieties, not undergoing official technical examination, part of which is for pest resistance/tolerance, there would be a risk in the long term that varietal identity on the market and characteristics such as disease resistance etc. are not maintained.

As there is no obligatory certification for any of the two groups of varieties, proper verification of properties such as varietal purity, seed of other species, germination rate and health status of lots that are marketed with an operators' label will entirely depend on the quality of the inspection work done by the operator. To the extent that the official authorities maintain a credible system of general monitoring, this should not lead to increased risks for plant health and quality in the Union, especially for reproductive material. For certified lots there would not be any impact as compared to the current situation.

2. Impact on employment and jobs

As there is no obligatory official technical examination for the registration of varieties, theoretically a substantial part of the 1500 competent authority jobs involved with variety registration could be lost if all varieties would in the future be marketed as not officially tested varieties (some variety identification work would remain in the context of testing of PRM samples taken on the market and for exports as variety registration is also a precondition for certification for exports). However, based on consultation with stakeholders, this assessment is considered to be an overestimate. On average, the number of varieties with EU variety rights protection is roughly 30-35 % of the number of newly registered varieties in the common catalogues. Holders of variety-rights that seek for legal protection will most likely also accept the additional cost of the official performance evaluation in order to have access to the category of officially tested varieties and to be eligible for certification

which is a normal precondition for export of PRM to third countries. Taking into account the two elements above, this would mean that a significant part of the jobs in the public authorities are likely to be maintained. However, if the technical examination of varieties would be done under official supervision, this would end up in far fewer jobs being maintained, with accordingly more jobs created in the private sector.

Abolishing certification increases the risk that some activities, especially seed multiplication for agricultural seeds will be relocated to non-EU countries as already is the case for vegetable seed (as the EU equivalence system cannot be maintained). This could lead to considerable job losses in this part of the PRM industry (see section 4 below).

Certification costs in EU are estimated at EUR 73-79 Mio which corresponds to roughly 2000 jobs[46]. These could potentially be lost if there is no obligatory certification. Given the expected dominant position of officially tested varieties and taking into account the certification requirements for certain export markets, it could be assumed that some PRM lots of these officially tested varieties will normally be submitted to certification, especially for species which are internationally trade such as maize (less the case with wheat). As a consequence, certification would probably be done on far more than 30% of the lots on the market and this means that a good part of the jobs associated with certification would be kept. Here too, a full shift to certification under official supervision could sharply reduce the number of public sector jobs that are saved while at the same time only a small number of private sector jobs are created.

The flexibility with regard to 'not officially tested varieties' will decrease the level of technical requirements for variety description provided by micro-enterprise to competent authority.

3. Impact on administrative burden for authorities and private sector operators

As there is no obligatory official technical examination for registration, in theory 90% of 55-EUR 60 Mio could be saved, since authorities would merely have a light administrative burden in registering or listing varieties. However, again based on the assumption that 30-35% of the varieties would be officially tested varieties, the costs will be in the order of EUR 40 Mio per year. These costs will be fully recovered from or directly borne by the private operators.

Assuming a comparable situation for certification of PRM lots, if in future about one third of the lots will be certified, savings on PRM certification would be roughly EUR 50 Mio. A higher percentage of lots offered for certification would reduce the amounts saved. Again, these costs will be fully recovered and borne by the private operators.

Not officially tested varieties would constitute a 'low-burden" group that could be interesting in particular for conservation varieties and other varieties with limited

[46] Calculation on the basis of roughly equivalent percentage of labour cost for variety registration and for certification, and on the estimated cost for implementing these two elements of the seed marketing legislation.

marketing potential. It should allow access to the market of varieties of interest for conservation and other varieties that are expected to have only a local importance. For such varieties, full technical examination and certification would be a disproportionate cost when set out against the potential marketing opportunities. However, this reduction of administrative burden could lead to an expansion of this market. If breeders and PRM suppliers would use this at too large a scale as an outlet for new varieties with less potential, they would risk compromising the profitability of the markets for their top varieties. Due to a different approach for FRM, there will be no effect on FRM under this option.

4. Impact on competitiveness and trade

As there is no obligatory official technical examination for registration and no obligatory official certification, this enhanced flexibility ought to allow a more rapid market access for new, not officially tested varieties. In particular, the operators producing specific PRM for regional and local markets would benefit from this opportunity, even though this forms a very small part of the volume of PRM produced in the EU. For officially tested varieties there would not be any significant change compared to the present situation. Given the fact that the two markets of registered and unregistered varieties can be expected not to be to a significant degree in direct competition with each other, the impact on the sector is likely to be low. Also, unregistered varieties are mostly brought to the market by micro and small enterprises, while seeds for export and wide-spread commercial cultivation are drawn from the highly concentrated six global seed companies.

Abolishing certification would, however, have significant effects on trade with Third countries. In this case, EU equivalence cannot be maintained and trade with third countries would have to be based on compliance with OECD seed schemes and internationally recognised rules on seed testing. Such a situation is likely to significantly increase trade flows into the EU and competitive pressure on the EU PRM industry and also decrease the quality of PRM.

A diversity of operators, especially SME and micro-entities active in niche markets, are bound to benefit from the increased freedom to act. On the other hand, this option offers good opportunities to support sustainable agriculture and agro-biodiversity as the registration of conservation/amateur varieties is administratively simplified and should bolster market access in this area.

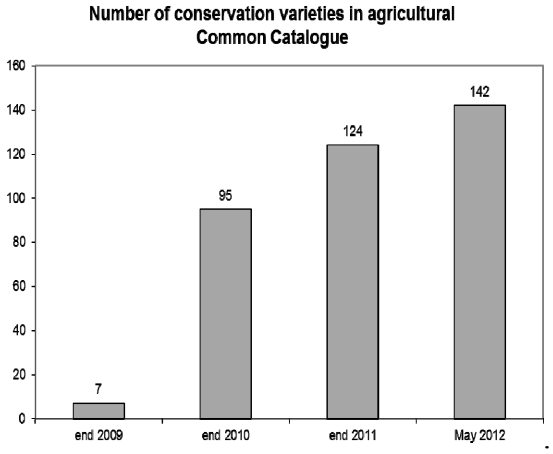
5. Impact on innovation and research

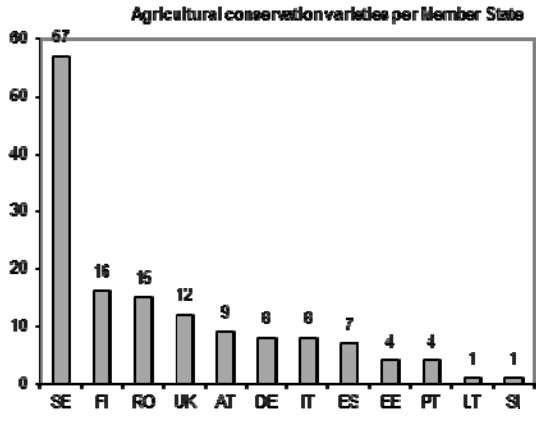
A double effect is anticipated. The enhanced flexibility should allow a more rapid and less costly access to the market for new, but not always improved varieties. The industry will be stimulated to focus its research on the sustainability of the new varieties as under this option sustainability criteria will be a mandatory element of VCU of officially tested varieties.

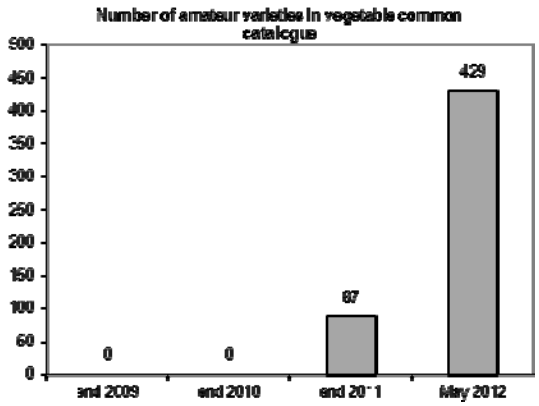
6. Environmental impact

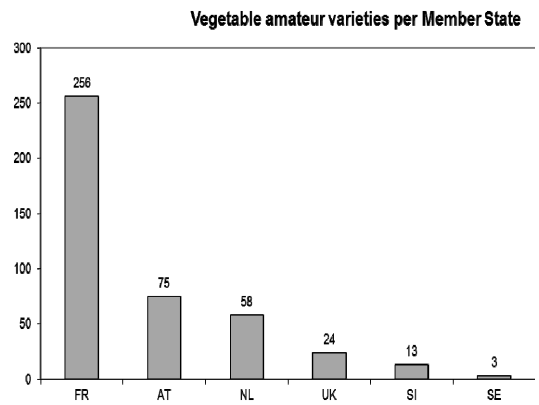
Not officially tested varieties, but with an officially recognised description provided by the operator, are intended in the first place to serve the interest of the conservation of biodiversity. It should allow access to the market of varieties of interest for conservation and other varieties that are well adapted to local conditions and that are

expected to have only local importance. It seems likely that overall more varieties will be cultivated under this option and that therefore a positive effect on agro-biodiversity can be expected. The charts below show that the introduction of conservation varieties of agricultural crops and amateur varieties for vegetables has been successful.









Officially tested varieties should constitute the bulk of the varieties. Here too, a positive effect is expected as varieties in this group will have undergone a screening for their sustainability profile. This new approach on VCU is in line with the Commission's approach to pesticides[47]. Annex III (1) to that Directive recommends to use, where appropriate, resistant/tolerant cultivars and standard/certified seed and planting material. To implement this provision, users of PRM should dispose of the proper information. Official or officially supervised sustainability evaluation would appear to be the best and probably the least costly guarantee that PRM users indeed receive this information.

[47] Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides.

7. Social impact

A positive social impact is expected concerning new operators which are involved in landraces/conservation varieties at local level and try to develop local markets in order to respond to consumer request for traditional local food.

Summary of the key impacts under option 4

Areas	Impacts
Impact on health and quality of PRM	-
Impact on employment and jobs in the public and private sector	-
Impact on administrative burden and costs for authorities	++
Impact on administrative burden and costs for private sector operators	++
Impact on competitiveness and trade	+
Impact on innovation and research	+
Environmental impact	+
Social impact	+

Option 5 - Centralisation: Centralised EU registration procedure with CPVO managing and making final decisions, and fully harmonised certification requirements; improved coherence between PHR and PMR regimes

1. Impact on health and quality of PRM

As for registration, the assessment of the description (DUS) of varieties will be centralised by CPVO and carried out in national testing stations, following audits carried out by CPVO.[48] This should result in an improved reliability of variety descriptions, including qualifications of the performance criteria of varieties placed on the EU market.

Concerning certification, the reduction of possibilities for more stringent requirements for national production should result in a better harmonisation and improved transparency. Introducing "Reference Certification Centres" will contribute to the harmonisation and dissemination of best practices and thus increase the overall quality of PRM certification in the Union.

Improving the coherence between the PHR and PMR regimes will lead to the same impacts as analysed in option 2 above.

[48] Networks for VCU evaluation are in general far larger than those for DUS. For example, in France 60 stations carry out VCU for wheat. It is not realistic to assume that CPVO will be able to audit and control all such testing stations for all species in all Member States. One possibility is that CPVO audits one or a small number of entrusted authorities, which in turn audit the rest of the national network.

2. Impact on employment and jobs

The effect of centralised variety registration is difficult to calculate as it depends on how many of the currently operating testing stations (just over 500 testing locations) with their 1500 employees would continue their activities after CPVO audits. For jobs on certification no significant impact is expected.

3. Impact on administrative burden on public authorities and on businesses

The administrative burden for industry would be lowered, as repetition of work on variety registration and on protection of plant variety rights will be avoided (some operators might, though, continue to apply in several Member States to be on the national list for marketing reasons). There will only be one single EU variety registration system instead of 27 national variety registration organisations, even though the evaluation work as before will be done in entrusted testing stations across the EU. An example from Annex XIV shows what kind of savings might be possible. In Germany and France annual DUS costs are EUR 6.7 Mio and EUR 5.2 Mio, respectively. If testing stations in the same agro-ecological regions cooperated, the number of stations could be reduced. The maximum cost reduction would be in the order of EUR 3-4 Mio if the number of test locations could be cut by half. In addition, a centralised management by CPVO of the collections for variety comparison held in the testing stations (reference collections) may reduce the cost of variety evaluation as this element accounts for 6 to 30% of the evaluation costs (based on information provided by four Member States). This saving, however, has to be balanced against the costs of running, coordinating and maintaining the databases of reference collections which would entail considerable IT and staff investment at the CPVO and this will be reflected in increased fees for operators. This option also reduces the administrative burden for the Member States and thus saves costs. With an estimated overhead for administrative costs of 10% of the registration costs in the Member States the total savings at Member State level could be around EUR 5.5 to 6 Mio. The work at CPVO level will be increased (direct application, audit, and harmonisation of DUS) and will result with more reporting obligations on public authorities (CPVO audit of national examination offices) but in the meantime it will increase the level of harmonisation of technical requirements in the internal market.

The establishment of Union Certification Reference Centres, training in the context of the Better Training for Safer Food-initiative, the development of communication and information tools and studies in support of policy development will cost EUR 2.3 Mio per year. At least 85% of these costs will be borne by the Commission. The benefits are expected to be significant as comparative tests and trials are carried out, harmonised best practices established and disseminated and staff continuously trained.

In addition, the possibility is offered to all operators to make a single application at the CPVO in order to receive plant variety registration and/or plant variety protection; this will simplify especially the work of SMEs. Due to a different approach for FRM, there will be no effect on FRM under this option.

4. Impact on competitiveness and trade

A centralised uniform EU variety registration system for the internal market improves transparency and it ensures a truly level playing field for all operators. Concentration

of all variety registration tasks in CPVO facilitates work for breeders. Trade will benefit from increased transparency and harmonisation. However, language barriers might discourage some breeders and micro-enterprises and SMEs from seeking registration at the CPVO and a distant, centralised authority might have difficulties judging the value of small and regional crops.

5. Impact on innovation and research

Uniform and harmonised EU rules and systems of variety registration support the access of new varieties to the market, and thus innovation and research.

6. Environmental impact

As outlined under health, new provisions might lead to better reassurance on the intrinsic health profile of varieties. Access to the market for varieties that draw their main interest from their contribution to biodiversity or that have enhanced qualities in respect of sustainability will not change as compared to the current situation.

7. Social impact

No social impact is expected concerning this option.

Summary of the key impacts under option 5

Areas	Impacts
Impact on health and quality of PRM	**0**
Impact on employment and jobs in the public and private sector	**-**
Impact on administrative burden and costs for authorities	+
Impact on administrative burden and costs for private sector operators	++
Impact on competitiveness and trade	++
Impact on innovation and research	+
Environmental impact	**0**
Social impact	**0**

6. COMPARING THE OPTIONS

The revision of the existing legislation aims at achieving the objectives identified in the 'Action Plan' of 2009 which are reflected in the objectives of this IA. Thus, all five options are being assessed against their potential to achieve these objectives.

6.1. Comparing the options

Drawing from the impact assessment of each of the five options, the two summary tables below and the graph provide an overall comparison (1) in terms of achieving the objectives, (2) terms of effectiveness, efficiency and coherence with overarching EU objectives, strategies and priorities and (3) semi-quantitatively in terms of aggregated and weighted impacts.

The summary table below provides an overall comparison of options in terms of achieving the objectives of the review.

		Option 1	Option 2	Option 3	Option 4	Option 5	Preferred Option
Overall objectives	To assure the health and high quality of PRM	0	0	− −	−	0	0
	To provide a single and harmonised regulatory framework which is supportive for innovation and the competitiveness of the European PRM industry	+	+	+	++	++	++
	To support sustainable production, biodiversity protection, adaptation to climate change and to contribute to food security and poverty alleviation	0	0	−	++	0	++
Specific objectives	To ensure a level playing field across the EU through simplified, clarified and harmonised basic rules on fundamental principles presented in an improved legal form	+	+	+	+	++	++
	To reduce unnecessary costs and administrative burden and for public authorities and increase flexibility for operators without compromising the general policy objectives	+	++	+	++	++	++
	To foster innovation in plant breeding, especially in SMEs, in order to improve PRM users' choice and access to a wide diversity of plant varieties adapted to conditions in Europe	0	+	0	++	++	++
	To align PRM legislation with other recent Union strategies (agriculture, biodiversity, food security, climate change, bio-based economy)	0	0	−	+	0	+
Operational objectives	To provide a simplified legal framework for marketing of PRM – "PRM Law" - with the establishment of simplified, more flexible and proportionate procedures	0	++	++	++	++	++
	To promote a more harmonised implementation of legislation	0	0	0	0	++	++

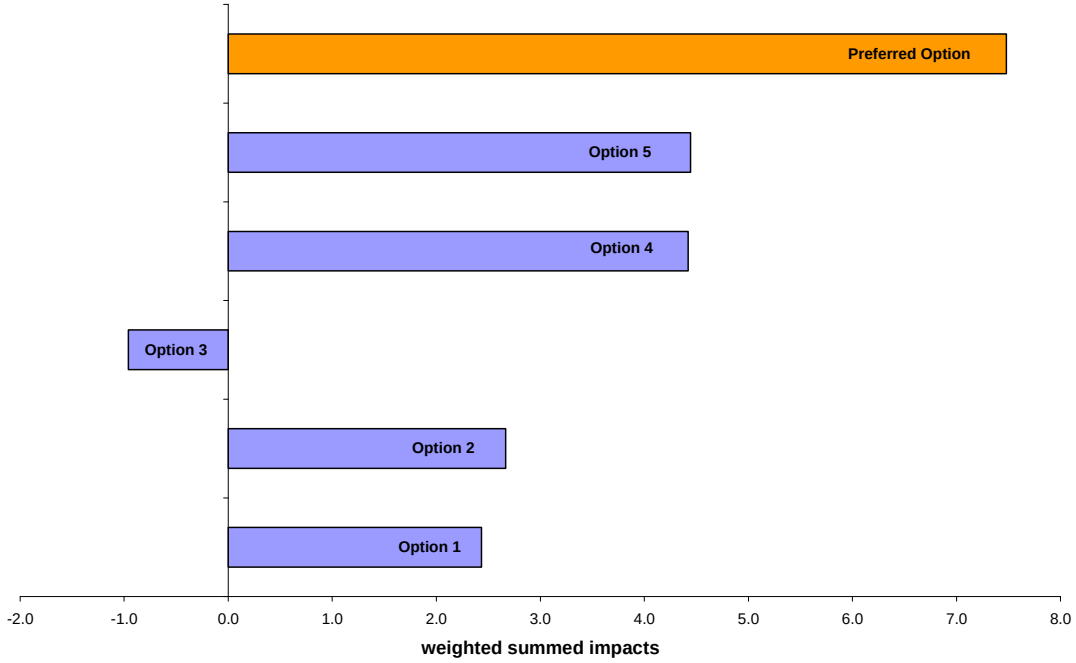
	throughout the EU by audits and training						
	To foster innovation by increasing the timeliness and level of information provided in the Common Catalogue	0	0	0	0	++	++
	To enhance market transparency and improve traceability through the registration of operators	0	++	++	+	++	++

Legend:

0 no change with the baseline option + minor positive effect ++ significant positive effect − minor negative effect − − significant negative effect

Criteria	Option 1	Option 2	Option 3	Option 4	Option 5	Preferred option
Effectiveness	The health and quality of PRM will remain high, while a more level playing field is established. There are no strong incentives to steer innovation towards environmental and sustainability aims. **0**	The health and quality of PRM will remain high, while a more level playing field is established. There are no clear incentives to steer breeding activities and innovation towards more sustainability. +	Health and quality of PRM might become compromised in the long term. Innovation is supported and agricultural biodiversity might increase, but both effects might not be persistent. –	The health and quality of some PRM might become compromised in the long term. The option offers incentives for breeding new varieties and the pursuit of environmental and sustainability aims. **0**	The health and quality of PRM will remain high, while a more level playing field is established. Strong support for innovations in conventional breeding but lack of incentives for breeding for sustainable agriculture **0**	The health and quality of PRM will remain high, while a more level playing field is established. The option offers incentives for breeding new varieties and the pursuit of environmental and sustainability aims and strong support for innovations in conventional breeding. +
Efficiency	Public financial burden is reduced, but no possibility for private operators to achieve efficiency gains through taking over responsibilities from the public sector –	As many tasks as possible are transferred to industry and cost recovery is implemented. This will lead to more efficient implementation of the legislation and the reduction of financial and administrative burden. ++	This option will lead to large cost saving for CAs and for operators as most obligations are abolished. However, many new non-EU competitors will be able to enter the market and economic activities can be relocated to non EU-countries. – –	This option will lead to large costs savings, while leaving to operators the possibility to seek added official quality assurance. However, many new non-EU competitors will be able to enter the market and economic activities can be relocated to non EU-countries. –	This option leads to a highly efficient system as most technical aspects are harmonised and centralised. The speed of market access of new, improved varieties will be increased. ++	As many tasks as possible are transferred to industry and cost recovery is implemented leading to more efficient implementation of the legislation and the reduction of financial and administrative burden. Technical harmonisation through CPVO involvement also increases efficiency. ++
Coherence with EU objectives	Achieves the goal of a single legislative framework but the lack of flexibility means it is less likely to achieve the operational objectives and is less able to be adapted to changing circumstances in the future. –	Offers a coherent framework that can achieve many of the operational objectives. The option lacks clear means to adapt to the development of PMR to the needs of sustainability and other environmental goals. **0**	The option offers a maximally flexible system that could have unintended consequences for plant health and the environment that are not in line with the objectives. – –	This option offers a flexible system that can achieve the operational objectives of CAs and most stakeholder groups. ++	Offers a maximally coherent framework that can achieve many of the operational objectives. The option lacks clear means to adapt to the development of PMR to the needs of sustainability and other environmental goals. **0**	Offers a balance between a coherent system and flexibility. The system will guarantee high quality of PRM and competitive advantage on the internal and the world markets, while possible derogations in addition will support diversity of SMEs, sustainability and biodiversity. ++

The data summarised in this graph are based on the qualitatively ranked impacts of section 5. Each "-" is given a score of -1, each "+" a score of 1, a "0" is given a score of 0. The scores for each option are added up and furthermore the standard deviation s of the scores for each option is calculated. The sum of the scores for each option is then weighted by the inverse of the squared standard deviation ($1/s^2$) of the scores. This weighting operation favours risk-aversion: options that have a high standard deviation of scores (i.e. both high and low impacts) are discounted more strongly than options with more even impacts.



6.2. Stakeholder assessment of the options

For this purpose we divided the participants of the web-based survey into five groups and quantitatively assessed the position of each group to each option. The analysis is summarised below and is in more detailed presented in Annex VI.

(1) Competent authorities and ministries

64% of competent authorities consider that **scenario 1** is slightly beneficial or neutral, 24% that it is rather negative or very negative and 12% that they don't know. 62% of competent authorities consider that **scenario 2** is slightly beneficial or fairly beneficial, 10% that it is neutral, 24% that it is rather negative or very negative and 4% that they don't know. All other scenarios are rated by the majority as rather to very negative. It was noticeable that competent authorities involved specifically in the FRM sector consider that the **scenario ''no change''**

is the most appropriate one. Accordingly it was decided to group them with the other FRM suppliers and users in order to create a more homogenous group.

(2) PRM Breeders and suppliers (PRM B&S)

77% of PRM B&S consider that the **scenario 2** is slightly beneficial or fairly beneficial. 18% consider that it is rather negative or very negative, 2% that it is neutral and 3% that they don't know. 44% of PRM B&S consider that the **scenario 5** is slightly beneficial or neutral, 30% that it is rather negative or very negative and 26 % that they don't know. All other scenarios are rated as rather to very negative by the majority in this group. The representation of PRM B&S involved in fruit or vine reproductive material was very low (3 of 60).

(3) Stakeholder groups mainly interested in biodiversity issues

54% of participants from this group consider that the **scenario 4** is slightly beneficial or very beneficial, 33% that it is rather negative or very negative and 13% that they don't know. All other scenarios are rated as rather to very negative by the majority in this group.

(4) Users, farmer growers, technical institutes

69% of this stakeholder group consider that **scenario 1** is slightly beneficial or neutral, 27% that it is rather negative or very negative and 4% that they don't know. 80% consider **scenario 2** as fairly beneficial or slightly beneficial, 8% as neutral, 8% as rather negative or very negative and 4% that they don't know. 46% consider **scenario 5** as slightly negative, 23% as neutral, 11% as slightly beneficial and 12% that they don't know.

This group is characterized by a strong opposition to options 3 and 4.

(5) FRM

This stakeholder group opposed all scenarios and stated that the option "no change" was not sufficiently assessed. Members from this often mention, that agriculture and forestry are different and that within the information provided, FRM was not specifically mentioned. Due to the missing information, some stakeholders couldn't decide among the options and have proposed to keep the existing legislation.

The analysis of the questionnaires also shows that a majority of stakeholders prefer a new option which combines elements from the options analysed in the Impact Assessment. **Competent authorities** mainly support the idea that the revised legislation should reflect a combination of scenarios (64%), with a large majority supporting the inclusion of elements from option 2 (64%) and 30% for the inclusion of elements from scenarios 4 and 5. 22% support the inclusion of the element of cost recovery. 18% espouse inclusion of elements from scenario 3. **PRM Breeders and suppliers** strongly back a combination of scenarios (74%), with 56% for taking up elements from option 2 and 39% for elements from scenario 5. A minority supports the introduction of elements from scenario 4 (14%), scenario 1 (8%) and scenario 3 (6%). A majority of **stakeholder groups mainly interested in biodiversity issues** supports the idea that the revised legislation should reflect combination of scenarios (54%). These groups mainly state that the scenario 4 should be the basis for the revision. A minority support the introduction of elements from scenario 3 (8%). **Users of PRM** strongly support the idea that the revision should reflect a combination of scenarios (96%). They mainly state that scenario 2 should be the basis for the revised legislation (89%). 27% consider that the

revised legislation could also include the element of cost recovery and some centralization for DUS (23%). A minority supports the introduction of elements from scenario 4 (8%). **Forest stakeholders** support the scenario with no changes in the Directive on FRM.

No stakeholder provided details of entirely new elements that should be considered in the options.

6.3. Preferred option

As none of the five options delivered an optimal balance between efficiency of the system, the quality assurance of the PRM, the maintenance of competitiveness and the issue of biodiversity, and in line with a majority of stakeholders a preferred option, combining positive elements of the initial options while maintaining as much choice and flexibility as possible for operators, was designed and selected in the end. An exhaustive presentation of the preferred option is in Annex XIII.

Option 6 – Preferred Option

The preferred option takes up elements from options 2, 4 and 5. This combination aims at striking a balance between flexibility for operators (option 2 and 4) and biodiversity (option 4) and the necessary rigor in health and quality requirement (elements of option 2 and 5) for the fair functioning of the market and for maintaining the quality and health of the products. A balance is also achieved between the interests of different stakeholder groups (see Annex VI). It includes the horizontal principles of simplification of the PRM legal architecture, transparency and cost recovery. Furthermore, basic general EU criteria with regard to plant health and fitness for purpose, as well as for traceability/labelling, will apply to all PRM brought to the market.

1. Registration of varieties and material

- Technical examinations can be carried out under official supervision. On request of the operator official technical examination is still possible.
- All varieties and material of specified crops (in principle those covered by the current EU marketing Directives with a closed list of species) will be registered in national or directly at the CPVO and subsequently entered into the EU plant variety registers, which will be composed of two sections. Administrative tasks at the EU level related to variety registration for e.g. vegetables (because no VCU is required) could be carried out by the CPVO. The CPVO will also play a more central role by centralising all information on the reference collections that are held in the various testing stations in the Member States; the CPVO audits the national examination offices which in turn allow private-sector testing stations to carry out technical examination; the CPVO shall take an increased role in the practical arrangements for the publication of the EU common catalogues. The CPVO will verify variety denominations for all applications (from option 5) at national or EU level.
- Section 1 of the variety register will comprise "officially tested" varieties that have been tested officially or under official supervision. Technical examination will include DUS, mandatory VCU criteria (for agricultural crops) and variety denomination will be checked by CPVO. VCU criteria shall principally reflect public goods and become

a “VCU for sustainability and health”. VCU shall be harmonised as much as possible across agro-ecological regions and continuously improved as much as possible to take care of any evolution of public and private needs. Varieties that are listed in this part of the catalogues could undergo certification (from option 2). Provenances and clones of forest reproductive material are identified on the basis of the criteria as currently applicable for such material and have a specific chapter in the catalogues of officially tested varieties.

- Section 2 of the variety register will comprise "not officially tested" varieties that are registered on the basis of description of the variety prepared by the applicant, including the denomination, accepted by the competent authority – this amounts to an "officially recognized description". VCU-evaluation is not required for this category of PRM. Competent authorities will only be responsible for checking the denomination and registration and for controls of material present on the market, focussing on labelling in particular. Varieties in this category cannot undergo certification because the authorities, in the absence of officially verified and accepted results of an official variety description, cannot certify the identity of individual PRM lots (from option 4).
- At the EU level, a high level group including all relevant stakeholders shall be established for further policy guidance on registration issue.
- All non-listed species, which should include ornamentals, must fulfil certain minimum conditions in order to be marketed (labelling obligations and a provision of 'fitness for use').

2. Certification of PRM

The certification requirements for lots of PRM remain unchanged for varieties and material from section 1 of the catalogue. However, as a standard procedure, the control of compliance with the criteria for PRM marketing is carried out by the operator under supervision of the competent authority. On request of the operator certification under official examination is still possible. Marketing of lots of PRM covered by a suppliers' label equally remains unchanged. Pests currently regulated under the PRM will be listed under PHL, however the certification procedure will continued to be used for the inspection; in this regard, definitions and provisions between PHL and PRM Law will be aligned. This should allow removing obstacles for combine health inspections under the two regimes. “Reference Certification Centres” shall be established to develop, harmonise and disseminate best practices in PRM certification.

3. Registration of operators

In a context where a more significant role is given to the industry, all operators (breeders, growers, suppliers) are registered, allowing a monitoring of their activities and facilitating traceability in case of identified problems. This registration will be valid both for the EU plant health regime and for the PRM marketing legislation and implemented through a shared register to reduce burden (common to all options).

4. Approach on conservation varieties/amateur varieties/niche markets

The requirements for the marketing of conservation or certain "niche market" varieties will be adapted. As there is no obligatory technical examination of varieties and no obligatory certification of PRM, the marketing of conservation varieties or "niche market" varieties can take place under the provisions of the regime for non-officially tested varieties with the

instrument of an officially recognised description based on current and/or historical information available on the variety.

5. Forest reproductive material

Following the Impact Assessment and the stakeholder consultation the basic approach on FRM identification and certification will not be changed and official controls will be maintained. A separate chapter in the proposed Regulation is dedicated to FRM.

6.2.1. Analysis of impacts of the preferred option

The impact on health and quality of PRM will be absent or negligible**.** Officially tested varieties are tested as they currently are, with further emphasis on resistance/tolerance to biotic and abiotic stress, while not officially tested varieties will not be tested for pest/resistance or tolerance. These varieties will, however, only have a small share in the total market for PRM. Certification will remain obligatory for the same species as currently is the case and thus no negative impact is expected. Introducing minimum requirements for non-listed species will improve the quality of this group of species. Including ornamentals in this group will ensure a minimum quality for this group of plant species. **The impact on employment and jobs** can be significant in the public sector as tasks are transferred to the private sector. For registration this loss could be significant, but it can be expected that a proportion of that highly specialised staff could be recruited by private operators. As for the certification of individual lots of PRM, the analysis from option 2 is relevant here. A rough estimate is that no more than 600-700 public sector jobs concerned with certification might be lost, but that part of the redundant staff may be recruited by the private sector. Nevertheless, appropriate levels of staff and expertise will have to be maintained because public services shall remain available. **The impact on administrative burden and costs** will be most noticeable for competent authorities, which will recover fully the costs for services offered and transfer responsibilities to the private sector. Larger operators already to a great extent have the resources to carry out these tasks and will most likely be able to carry them out in a more efficient manner. The possibility of directly registering varieties of some species at the CPVO will also lower administrative burden for operators. The new approach of enabling the marketing of new varieties directly at the stage of national register will save time and allow quicker market access. This and the transfer of tasks to operators will increase their operating flexibility and thus have a positive impact on **competitiveness** on the global market place. The analysis of option 2 showed, using the example of the potato and the cereal sector, that official supervision of certification tasks can lead to considerable costs savings for companies. The maintenance of VCU for officially tested varieties for certain groups of species will also contribute to maintain an open competition in the Internal Market as large companies and SMEs will compete mainly based on the quality of their products. **Trade** with Third countries will not be particularly affected by this option, but the rules that remain in place (DUS, VCU, certification) will guarantee that European PRM companies will compete with high-quality and traceable products. With regard to **micro and small companies**, the option will have rules for providing public services for variety registration and PRM certification; it will also provide flexibility with regard to 'officially recognised description'. The increased flexibility of operators should help to accelerate the market access of new, improved varieties. Adapted VCU-criteria ("sustainable VCU") will simulate the industry to focus development of varieties into new directions and thus foster **innovation and research**. This option will also have a positive **environmental impact**. The instrument of not officially tested varieties will

serve the interest of the conservation of agrobiodiversity. "Sustainable VCU" will support the trend to develop agricultural practices more robust to climate change and less reliant on pesticides and fertilisers. The social impact is also assessed as positive as a high-skill PRM industry will be maintained in disadvantaged rural areas.

Summary of the key impacts under the preferred option

Areas	**Impacts**
	Preferred option
Impact on health and quality of PRM	**0**
Impact on employment (private and public sector)	**0(-)**
Impact on administrative burden and costs for authorities	++
Impact on administrative burden and costs for private sector operators	+
Impact on competitiveness and trade	+
Impact on innovation and research	+
Environmental impact	++
Social impacts	+

The preferred option thus leads to legal architecture based on a simplified and harmonized unitary legal base with two pillars describing the provisions for listed (tested and non-tested) and non-listed species.

REGULATION ON THE MARKETING OF PLANT REPRODUCTIVE MATERIAL

Horizontal provisions:

- Cost recovery of activities carried out by competent authorities
- Possibility of official supervision for all activities carried out by operators
- Official register of operators

►Level playing field for operators in all Member States

Provisions for EU listed species

- **Registration of varieties**
  - Official description
    - DUS
    - VCU (e.g. specific crops such as agricultural crops)
  - Officially recognized description for conservation varieties e.g. *
  - Suitable denomination
- **PRM Certification**
  - Category (pre-basic, basic, certified)
  - Post-certification controls
  - Official label
- **Extended mandate of CPVO**
  - Possible direct registration for certain species
  - Harmonization of DUS testing among MS
  - Mandatory requirement for denomination checking
  - Audit of national and private examination offices
- **Listed species defined in Annex 1**
- **Standard marketing category for varieties of listed species**
  - with operator's label
  - free from harmful organisms

This pillar guarantees legal security for operators and consumers, high quality of PRM and competitive advantage on the internal and the world markets.

*Derogations on the basis of public goods and biodiversity conservation (officially recognized description)

Minimum provisions for non-listed species

- Free from harmful organisms and defects, satisfactory vigor and germination (where appropriate)
- Traceability of material and records of production keeping by the operators
- If marketed as a variety: sufficient identity and purity and denomination
- Operator's label

All species not listed in Annex 1 or for ornamental use

This pillar allows minor crops or crops with particular uses access to specific or small market segments. At the same time a level playing field is established with minimum obligations ensuring traceability, health and information to the consumer. This pillar also supports diversity of SMEs, sustainability and biodiversity.

7. MONITORING AND EVALUATION

The general monitoring of the legislation on marketing PRM will be carried out according to the principles of the Regulation 882/2004 on official controls on feed and food where the Commission (Food and Veterinary Office, FVO) controls the enforcement of the legislation in the Member States by audits.

The monitoring of the impact and effectiveness of the PRM legislation at EU level will be required not only to assess the correct implementation but also to propose further action or redirection of the measures, if necessary.

Two sets of indicators will be needed, the first one for the overall monitoring of the PRM sector and the second one for assessing the effect of the measures introduced with the revision of the legislation with regard to the objectives.

	Indicators
1. Overall monitoring of the PRM sector	
Variety registration	Number, list of species concerned and evolution
	Number of variety applications / species, MS and evolution
	Number of varieties registered / species, MS and evolution
	Number of varieties withdrawn from the EU register and evolution
	Number of maintainers / group of species, MS and evolution
PRM quality control (health and quality)	Number and list of species concerned by this legislation and evolution
	Amount of PRM yearly inspected / groups of species and evolution
	Amount of PRM yearly finally certified / groups of species and evolution
	Number, type, quantity of PRM not satisfying EU rules (post control evaluation) / MS and evolution
	Number and type of derogations requested per MS for material not satisfying EU requirements and evolution
Market	Internal PRM market per species/group of species, type of material (certified or under the responsibility of supplier's) (ha, EUR), per MS and evolution
	Import, export (quantity/value) per group of species and MS and evolution
	EU equivalence for PRM import
2. Assessment of the specific objectives of the revised legislation	
2.1 Effectiveness of the system	
	Number of complaints and requests for clarifications received from stakeholders, MS
	Number of notification received from Member States on national measures and national implementation
	Functional register of operators and evolution.
	Results of CPVO audits of national examination centres for variety registration and harmonised DUS protocol
	Results of FVO audits on implementation of the legislation in the MS and PRM official control by competent authorities
	Number of cases of developing information tools in the Member States

	concerning the implementation of the new Regulation
	Number of studies conducted for the preparation and development of Union legislation in the field of plant reproductive material
2.2 Reduction of administrative burden and costs and introduction of flexibility	
Variety registration	Application: Number, Time needed, cost recovery for variety registration per group of species and MS and evolution
	PRM companies with a focus on SMEs applying for new varieties or for withdrawing the existing ones : Number, type, evolution
	Number of varieties registered with an 'officially recognised description'
	Number of direct applications to CPVO and evolution
PRM quality control (health and quality)	% of certification under official supervision compared to official certification in the Member States (ha, type of companies especially SMEs) and evolution
	Cost recovery for PRM quality control
	Number of Union certification reference centres established
	Number of comparative tests and trials carried out
	Number of cases of amendments to legislation or establishment of protocols to improve the methodology of certification
2.3 Alignment of PRM legislation with other recent Union strategies (biodiversity, CAP, climate change, bio-based economy) and proportionate rules	
	Number, quantity of conservation varieties/landraces/amateur varieties and of minor species listed per MS and evolution
	Number, quantity of conservation varieties/landraces/amateur varieties and of minor species marketed per MS and evolution
	Number of species concerned and evolution
	Harmonised criteria for variety registration (e.g. sustainable VCU)

ANNEX I: GLOSSARY

AOA: area of adaptation

AOSCA: Association of Official Seed Certifying Agencies

CA: certifying agency

CMO: Common Market Organisation

CPVO: Community Plant Variety Office

DG: Directorate General

DUS: distinctness, uniformity, stability

ESA: European Seed Association

EU: European Union

FVO: Food and Veterinary Office

GATT: General Agreement on Tariffs and Trade

GMO: genetically modified organism

HO: harmful organisms

IAS: Invasive alien species

IPPC: International Plant Protection Convention

ISF: International Seed Federation

ISSG: inter-service steering group

OECD: Organisation for Economic Co-operation and Development

PRM: Plant Reproductive Material

R&D: Research and Development

SME: small and medium-sized enterprises

SPS: sanitary and phytosanitary measures

PRM: Plant reproductive material

UNECE: United Nations Economic Commission for Europe

UPOV: International Union for the protection of new varieties of plants

USD: US dollar

USDA: United States Department of Agriculture

VCU: value for cultivation and use

WTO: World Trade Organisation

ANNEX II: HISTORY OF THE DEVELOPMENT OF PRM LEGISLATION

PRM Marketing Directives have existed since the mid 1960s. They comprise of 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

Council Directive 66/401/EEC on the marketing of fodder plant seed

Council Directive 66/402/EEC on the marketing of cereal seed

Council Directive 2002/54/EC on the marketing of beet seed

Council Directive 2002/55/EC on the marketing of vegetable seed

Council Directive 2002/56/EC on the marketing of seed potatoes

Council Directive 2002/57/EC on the marketing of seed of oil and fibre plants

Council Directive 68/193/EEC on the marketing of material for the vegetative propagation of the vine

Council Directive 1998/56/EC on the marketing of propagating material of ornamental plants

Council Directive 2008/72/EC on the marketing of vegetable propagating and planting material, other than seed

Council Directive 2008/90/EC on the marketing of fruit plant propagating material and fruit plants intended for fruit production

Council Directive 1999/105/EC on the marketing of forest reproductive material

The majority of Council Directives for the marketing of PRM have first been issued 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 original Directives have been updated both frequently and substantially, creating the need for clarity and transparency. In some cases, such as the Directive on the Common Catalogue, this has been pursued in the current versions. In other cases, for example the Directives on fodder plant seed and cereal seed, the original Directives 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, 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 OECD revision of its trade scheme for forest reproductive material 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. The Commission has recently also developed specific legislation on conservation varieties so that varieties of agricultural and vegetable crops, which may be threatened by genetic erosion and which are adapted to regional and local conditions, may be marketed under certain derogatory rules. Directive 2008/62/EC provides that agricultural landraces and varieties which are naturally adapted to the local and regional conditions (conservation varieties) can be placed on the catalogues without official examination, once they meet some minimum standards. Directive 2009/145/EC foresees less stringent requirements as regards the acceptance of the varieties and the marketing of the seed for the vegetable landraces and varieties which have been traditionally grown in particular localities and regions (conservation varieties) and vegetable varieties with no intrinsic value for commercial crop production but developed for growing under particular conditions. Equally, conservation and preservation of natural environment of species-rich grassland has gained importance. Directive 2010/60/EU provides for less stringent rules which are necessary to allow the marketing of fodder plant seed mixtures as 'preservation seed mixtures'.

ANNEX III: SUMMARY OF THE CHRONOLOGY OF MEETINGS

No.	Action	Date
(1)	Conference on Seed Availability in the 21st Century	18 March 2009
(2)	Council WP on Agricultural Questions (Plant Breeder Rights/Seeds and Propagating Material)	1.1. 2 October 2009
(3)	Sanco Advisory Group, WG 'Seeds and Propagating Material'	30 November 2009
(4)	Commission Inter-Service Steering Group	26 January 2010
(5)	Commission Horizontal WG of MS experts	9 February 2010
(6)	Council WP on Agricultural Questions (Plant Breeder Rights/Seeds and Propagating Material)	12 March 2011
(7)	Sanco Advisory Group, WG 'Seeds and Propagating Material'	15 April 2010
(8)	Commission Horizontal WG of MS experts	3 May 2010
(9)	Commission Inter-Service Steering Group	11 May 2010
(10)	Commission Inter-Service Steering Group	3 June 2010
(11)	Commission Inter-Service Steering Group	15 September 2010
(12)	Commission Horizontal WG of MS experts	30 September – 1 October 2010
(13)	Commission Horizontal WG of MS experts	8 October 2010
(14)	Commission Inter-Service Steering Group	26 October 2010
(15)	Sanco Advisory Group, WG 'Seeds and Propagating Material'	23 November 2010
(16)	Commission Horizontal WG of MS experts	13 December 2010
(17)	Commission Horizontal WG of MS experts	11 April 2011
(18)	Web-based stakeholder survey	19 April – 30 May

		2011
(19)	Council WP on Agricultural Questions (Seed and Propagating Material)	27th April 2011
(20)	TF 1 (General requirements), TF 2 (Registration of varieties), TF 3 (Marketing requirements and controls) under Hungarian Presidency	24 May 2011
(21)	Commission Horizontal WG of MS experts	30 – 31 May 2011
(22)	TF 4 (material with spec. significance for biodiversity, spec. marketing requirements) under Hungarian Presidency	1 June 2011
(23)	Council WP Agricultural Questions (Seeds and Propagating Material/Plant Breeders Rights)	17 June 2011
(24)	TF 3 (controls) under Polish Presidency	19 July 2011
(25)	Commission Inter-Service Steering Group	11 November 2011
(26)	Council WP Agricultural Questions (Seeds and Propagating Material/Plant Breeders Rights)	12 October 2011

ANNEX IV: THE INTERNATIONAL FRAMEWORK OF THE PRM INDUSTRY

OECD Seed Schemes

Since 1958, the OECD Seed schemes are open to OECD countries as well as other U.N. Members. 58 countries participate, including EU Member States and the US, Canada, Australia, New Zealand, Japan, Russia, Ukraine, Argentina, Brazil, Egypt, India and Iran.
The OECD seed certification is applied to varieties which have obtained satisfactory results by official tests (including comparative field tests) in at least one participating country. The tests must also establish that the varieties have an acceptable value in at least one country. **The varieties are notified by National Designated Authorities (NDA) and published in official lists**: the annual OECD list of varieties eligible for certification includes about 43.000 varieties from 200 species and 400.000tons/year.
The schemes deal with the following groups of species: **Grasses and Legumes, Crucifers and other Oil or Fibre species, Cereals, Maize and Sorghum, Beet, Subterranean clover, Vegetables**.
All schemes aim at seed certification; the Vegetable Scheme provides also for "Standard Seed" which are not certified but only controlled. The schemes ensure the varietal identity and purity of the seed through appropriate harmonised requirements and controls throughout the cropping, seed processing and international recognised OECD labels (varietal identity and purity): generation control (pre-basic, basic and certified seed), isolation distances, purity standards, field inspections, lot sampling, post-control plots, compulsory official laboratory analysis for each certified seed lot.
OECD certification provides for official recognition of seed with guaranteed varietal identity and purity, thus facilitating international trade and contributing to the removal of technical trade barriers.

In order to become member, the basic requirement are the following :

- **National seed law providing a framework for variety registration and seed certification,**
- **National list of plant varieties**
- **Effective national system for seed control and certification**
- **Seed analyses laboratories working with ISTA or equivalent standards for seed testing**
- **Post-control field test to check the varietal purity of basic and certified seeds**

OECD scheme for the control of forest reproductive material moving in international trade

The scheme defines four categories of forest reproductive material recognised for certification: (i) source-identified material (minimum standard); (ii) material from selected stands located in well-delimited regions of provenance; (iii) material from untested seed orchards which can produce seed of improved quality; (iv) tested material that is genetically improved.

The scheme is open to OECD Members as well as to other States. Today 25 participating countries implement the Scheme, including tropical countries which are developing their seed exchange for reforestation purposes. Seeds and plants are produced and officially controlled

according to common harmonised procedures.

All categories included, the participating countries approved to date 253 tree species eligible for OECD certification of reproductive material, with a total area of 13.6 million hectares**.**

ISTA International Seed Testing Association

Founded in 1924, with the aim to develop and publish standard procedures in the field of seed testing, ISTA is an independent association and acts free from economic interest. Currently its membership consists of 201 member laboratories, 52 personal members and 42 associate members, from 79 countries around the world (seed scientists and analysts from universities, research centres and governmental, private and company seed testing laboratories). 120 of the ISTA Member Laboratories are accredited by ISTA and entitled to issue ISTA international seed analyses certificates for international trade of quality seed. Research, training and publishing are conducted including cooperation with related organisations such as OECD, ISO, and many others.

ISTA produces internationally agreed rules for seed sampling and testing, accredits laboratories, promotes research, provides international seed analysis certificates and training, and disseminates knowledge in seed science and technology. This facilitates seed trading nationally and internationally, and also contributes to food security.

The ISTA International Rules for Seed Testing guarantee worldwide annually updated, harmonised, uniform, seed testing methods. The ISTA Accreditation Programme (1995) includes Accreditation Standard, Proficiency Testing Programme and Auditing Programme.

17 Technical Committees are responsible for the development of new methodologies for seed testing, including bulking and sampling, flower seed testing, forest tree and shrub seed, germination, GMO, moisture, nomenclature, seed health, proficiency testing, purity, rules, statistics, seed storage, Tetrazolium, and vigour.

IPPC International Plant Protection Convention

The International Plant Protection Convention (IPPC) is an international plant health agreement, established in 1952, that aims to protect cultivated and wild plants by preventing the introduction and spread of pests and to promote appropriate measures for their control. In applying phytosanitary measures, contracting parties have obligations to comply with the Convention principles of necessity, technical justification and transparency.

IPPC began with 12 countries and measures for grapevine *Phylloxera*. Today 177 contracting party are signatories to the Convention. Each contracting party has a National Plant Protection Organization (NPPO) and an Official IPPC contact point. Nine Regional Plant Protection Organizations (RPPOs) were established to coordinate NPPOs on a regional level. The Secretariat is provided by the FAO.

Within the context of the WTO (Sanitary and Phytosanitary Measures **SPS Agreement**), the IPPC role is to encourage international harmonization and elaborate international standards to ensure that phytosanitary measures are not used as unjustified barriers to trade. In 2005, the entry into force of the new revised IPPC-Agreement emphasizes cooperation and information exchanges toward the objective of global harmonization. In addition to describing national plant protection responsibilities, it also addresses important elements of international cooperation for the protection of plant health and the establishment and use of International Standards for Phytosanitary Measures (ISPMs). Some ISPMs concern the production and trade of PRM, such as:

ISPM 07: 2011 Phytosanitary certification system

ISPM 11: 2004 Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms

ISPM 15: 2009 Regulation of wood packaging material in international trade

ISPM 21: 2004 Pest risk analysis for regulated non-quarantine pests

ISPM 33: 2010 Pest free potato micropropagative material, minitubers for international trade.

ISPM 36: 2012 Integrated measures for plants for planting (excluding seed)

United Nations Economic Commission for Europe (UNECE) Standard for Seed Potato

Work on the UNECE Standard for Seed Potatoes began in 1958. The first version of the standard was adopted by the Working Party in 1963 at its 16th session. It sets common terminology and minimum commercial quality requirements for the certification of high-quality seed intended for marketing internationally.

It is a unique international frame of reference, covering all aspects related to seed-potato certification: (a) varietal identity and purity; (b) genealogy and traceability; (c) diseases and pests; (d) external quality; (e) sizing; and (f) labelling.

The requirements are set for three categories of seed potatoes: pre-basic, basic and certified, in descending order of quality.

Within these categories and classes, countries producing seed potatoes are free to create national classes that are subject to specific national requirements. The Designated Authority is responsible for the maintenance of classification data to provide traceability.

Varieties are accepted for trade according to the Standard only if an official description and a reference sample are available from the Designated Authority. The variety should be distinct, uniform and stable (DUS) and have a denomination so that it can be identified.
The Standard prescribes rules on packaging, sealing and labelling to ensure the identity of the seed. It also provides guidelines for comparative trials of plants grown from seed potatoes sampled from marketed lots.

A List of Diseases and Pests, containing a basic description of each disease with illustrative

photographs and their status in certification, supplements the Standard.

World trade organisation and TBT

The WTO agreements cover goods, services and intellectual property. They spell out the principles of liberalisation, and the permitted exceptions. As tariff barriers are eliminated, non-tariff barriers, such as technical barriers, become possible significant obstacles to international trade.

Technical regulations, standards, conformity assessment procedures are important, but they vary from country to country due to climatic conditions or cultural, socio-economic or geographical factors; they make life difficult for producers and exporters. They are necessary for environmental protection, safety, product quality, national security and to consumer information.

If the standards are set arbitrarily, they could be used as an excuse for protectionism or market distortions. Standards can become obstacles to trade.

The **Technical Barriers to Trade Agreement (TBT) is part of WTO agreements and** tries to ensure that regulations, standards, testing and certification procedures do not create unnecessary obstacles. However, the agreement also recognizes countries' rights to adopt the standards they consider appropriate — for example, for human, animal or plant life or health, for the protection of the environment or to meet other consumer interests.

The TBT agreement states that the procedures used to decide whether a product conforms with relevant standards have to be fair and equitable. It discourages any methods that would give domestically produced goods an unfair advantage. The agreement also encourages countries to recognize each other's procedures for assessing whether a product conforms. Without recognition, products might have to be tested twice, first by the exporting country and then by the importing country.

ANNEX V: LIST OF STAKEHOLDERS

The following European stakeholders' organisations and individuals have participated in the Internet consultation. In order to be able to carry out the data analysis reported in Annex VI, the stakeholders were divided in 5 groups, as follow:

Ministries and competent authorities			
EU	AGES / BAES	AT	Austrian Agency for Health and Food Safety (AGES / BAES)
	AGES / FOFS	AT	Austrian Agency for Health and Food Safety / Federal Office for Food Safety
	Lebensministerium	AT	Federal Ministry Agriculture, Forestry, Environment and Water Management
	DGARNE	BE	DG for Agriculture, Natural Resources and Environment
	DGARNE - SPW	BE	Direction of Quality – Dep. Development - General operational Directorate of Agriculture, natural Resources and Environment - Public Service of Wallonia
	CRAW	BE	Centre Wallon de Recherches agronomiques + CRAW Département Productions et Filières - Unité Stratégies Phytotechniques
	LV-vlaanderen	BE	Flemish authority: Agency for Agriculture and Fishery
	MOA - DA	CY	Ministry of agriculture, natural resources and environment, department of agriculture, plant health and quality control section, plant propagating material
	MOA-DA-Seed control	CY	Ministry of Agriculture, Natural Resources, Environment – Dep. Agriculture
	UKZUZ	CZ	Central Institute for Supervising and Testing in Agriculture
	BSA	DE	Federal Min. Agriculture Food, Consumer Protection - Plant Variety Office
	JKI	DE	Institute for Breeding Research on Agricultural Crops, Horticultural & Fruit Crops, Plant Health of

			the Julius Kühn-Institute
	LFL-Bayern	DE	Bayerische Landesanstalt für Landwirtschaft
	LLH-Hessen	DE	Landesbetrieb Landwirtschaft Hessen
	LWK-Niedersachen	DE	Landwirtschaftskammer Niedersachsen
	LWK-NRW	DE	Landwirtschaftskammer Nordrhein-Westfalen
	SMUL-SACHSEN	DE	Sächsisches Landesamt für Landwirtschaft, Umwelt und Geologie
		DK	Danish Plant Directorate
		EE	Ministry of Agriculture
	OEVV	ES	Plant variety office – Ministerio de Medio Ambiente, Medio Rural y Marino
	EVIRA	FI	Finnish Food Safety Authority Evira
	MMM	FI	Ministry of Agriculture – Seed + Fruit and ornamental propagating material
	MAAPRAT	FR	Ministère de l'Agriculture
	GEVES	FR	Groupe d'Etude et de contrôle des Variétés Et des Semences
	CTPS	FR	Comté Technique Permanent pour la Sélection (fodder crops, protein crop, vine, President)
	SOC France	FR	Service Officiel de Contrôle et de certification des semences et plants
	IFV	FR	Institut français de la vigne et du vin
	MIN AGRIC	GR	Ministry Agriculture, Rural Development, Food - Directorate of Inputs for Crop Production
	MGSZH	HU	Central Agricultural Office + CAO - Directorate of Plant Production and Horticulture
	Min. agriculture	IE	Department of Agriculture, Fisheries and Food

	COSVIR IX	IT	Ministero delle politiche agricole alimentari e forestali
	COSVIR XI	IT	Ministero delle politiche agricole alimentari e forestali - Servizio fitosanitario
	INRAN-ENSE	IT	INRAN-ENSE
	VATZUM	LT	State Plant Service – ministry of Agriculture
	ASTA	LU	Administration des Services Techniques de l'Agriculture
	MRRA – SPMU	MT	Plant Health Directorate within the Ministry for Resources and Rural Affairs
	MINLNV	NL	Ministry of Economics, Agriculture and Innovation - Netherlands
	NAK	NL	Dutch General Inspection Service for agricultural seeds and seed potatoes
	MINROL	PL	Ministry of Agriculture and Rural Development
	COBORU	PL	Research Centre for Cultivar Testing
	INCS	RO	Ministry of Agriculture and Rural Development
		RO	Territorial Inspection for quality SPM
	JORDBRUKSVERKET	SE	Swedish board of agriculture
	SLU	SE	Sveriges Lantbruksuniversitet
	UKSUP	SK	Central Controlling and Testing Institute in Agriculture (2 answers)
	DEFRA-FERA	UK	Food and environment research agency
Non EU		NO	Norwegian Food Safety Authority

Breeding / supplier companies / associations / suppliers PRM				
EU organisation				
EU	ESA	BE	European Seed Association	Breeders / suppliers PRM
	AOHE	FR	Association des Obtenteurs Horticoles Européens	Breeders PRM
Others				
	Monsanto	BE	Monsanto Europe	Breeder / supplier PRM
	Pioneer	BE	Pioneer Hi-Bred International	Breeder / supplier PRM
	GWPPPDT-UPR	BE	Groupement Wallon Producteurs de Plants de Pommes de Terre	Breeders / suppliers PRM
	CMMSSA	CZ	Czech Seed trade association	Breeders / suppliers PRM
		DE	Bundesverband Deutscher Saatguterzeuger E.V.	Breeders PRM
	APVD	DK	Association of Plant Variety Owners in Denmark	Breeders PRM
	Seed Council	DK	Danish seed Council	Breeders / suppliers / users PRM
	DLF Trifolium	DK		Breeders PRM
	Dansk gartneri	DK	Danish Horticulture	Breeder / supplier PRM
	ANOVE	ES	Spanish Association of plant breeders	Breeders PRM
	JOVEGA	ES	Jõgeva plant Breeding Institute	Breeders PRM
	FSTA	FI	Finnish Seed Traders Association	Suppliers PRM
	Boreal	FI	Boreal Plant Breeding Ltd	Breeder PRM

	Siemen Forelia	FI		Supplier PRM
	GNIS	FR	Groupement National Interprofessionnel des Semences et Plants	Breeders / suppliers PRM
	FEDEPOM	FR	Association (Potatoes)	Breeders / suppliers PRM
	FNPPPT	FR	Fédération Nationale Producteurs de Plants de Pommes de Terre	Breeders / suppliers PRM
	FNPSMS	FR	Fédération nationale production de semences de maïs et de sorgho	Breeders / suppliers PRM
	UFS	FR	Union Française des Semencier	Breeders / suppliers PRM
	INRA	FR	Institut National de la Recherche Agronomique	Reseach / plant breeding PRM
	Agri Obtentions	FR		Breeder / supplier PRM
	CLAUSE SA	FR		Breeder / supplier PRM
	Belloy Semences	FR		Breeder / supplier PRM
	DE SANGOSSE	FR		Supplier PRM
	EMC2	FR		Supplier PRM
	EURALIS	FR	EURALIS SEMENCES + Groupe EURALIS	Breeder / supplier PRM
	INVIVO	FR		Breeder / supplier PRM
	JOUFFRAY-DRILLAUD SA	FR		Breeder / supplier PRM
	Laboulet Semences	FR		Breeder / supplier PRM
	Limagrain group	FR		Breeder / supplier PRM
	Mercier Frères Sarl	FR	(vine nurseries)	Breeder / supplier PRM

	NORIAP cooperative	FR		Supplier PRM
	Pépinières du Valois	FR	(Fruit reproductive material)	Breeder / supplier PRM
	RAGT Semences	FR		Breeder / supplier PRM
	UNEAL SCA	FR		Supplier PRM
	Semences Vertes	FR		Supplier PRM
	Semlin	FR	Syndicat établissements multiplicateurs de semences de lin textile	Suppliers PRM
	Terre de Lin	FR		Breeder / supplier / User PRM
	TOP Semences	FR	Seed company	supplier PRM
	UNISIGMA	FR		Breeder PRM
	AHPB	HU	Association of Hungarian Plant Breeders	Breeders PRM
	VSZT	HU	Hungarian Seed Association	Breeders / suppliers PRM
	ASSOSEMENTI	IT	Associazione Italiana Sementi	Breeders / suppliers PRM
	COVI	IT	COVI CONSORZIO ORTOVIVAISTI ITALIANI	Supplier PRM
		LV	Latvian Seed Association	Breeders / suppliers PRM
	KAVB	NL	KAVB - Royal General Bulbgrowers' Association	Breeders / suppliers PRM
	NAO	NL	Nederlandse Aardappel Organisatie (potato merchants)	Suppliers PRM
	PLANTUM	NL	Dutch Seed association (ornamentals, vegetable seeds, agricultural crops, vegetable plants and strawberry.)	Breeders / suppliers PRM
	Nickerson Zwaan	NL		Breeder / supplier PRM

	Rijk Zwaan	NL		Breeder / supplier PRM
	Syngenta Seeds	NL		Breeder / supplier PRM
	AGRICO U.A.	NL		
	SPS-AGRO	PL	Association of Polish Nurseries (fruit reproductive material)	Suppliers PRM
	AMSEM	RO	Association of Breeders, Producers and Traders PRM	Breeders / suppliers PRM
	SVUF	SE	Swedish seed trade association	Breeders / suppliers PRM
	Lindbloms Frö	SE		Breeder / supplier PRM
	SWSEED	SE	Lantmännen SW Seed AB	Breeder / supplier PRM
	SASTAB	SK	Slovak Association of Seed Traders and Breeders	Breeders / suppliers PRM
	HORDEUM s.r.o.	SK		Breeder / supplier PRM
	ZELSEED	SK		Breeder / supplier PRM
	BSPB	UK	British Society of Plant Breeders Ltd.	Breeders PRM
	AIC	UK	Agricultural Industries Confederation Ltd.	
	J. Hutton Institute	UK	Fruit breeder	Breeder PRM
Non EU		USA	New World Seeds & Tubers	Breeder / supplier PRM

User of PRM / Seed growers / technical institutes
EU organisation

EU	Copa-Cogeca	BE	European farmers – European agri-cooperatives	Seed growers / Users PRM
		BE	EUROPEAN FLOUR MILLERS	Users PRM
	ESGG	FR	European Seed Growers' Group	Seed growers
	C.I.B.E.	BE	International Confederation of European Beet Growers	Users PRM
Others				
EU	LK-OE	AT	Landwirtschaftskammer Österreich	Users PRM
	IRBAB	BE	Institut Royal Belge pour l'amélioration de la betterave - IRBAB-KBIVB asbl	
	AKCR	CZ	Agrarian Chamber	Users PRM
	WVZ	DE	Wirtschaftliche Vereinigung Zucker- WVZ	Users PRM
	Dansk planteskole	DK	Danish Nursery sector	User PRM
		DK	The Knowledge centre for Agriculture, Plant production	
	MTK-agriculture	FI	Central Union of Agricultural Producers and Forest Owners (MTK), Agriculture Group	Users PRM
	ARVALIS	FR	Institut du vegetal	Users PRM
	AGPB	FR	Association générale des producteurs de blé et autres céréales	Users PRM
	AGPL	FR	Association générale des producteurs de lin	Users PRM
	AGPM	FR	Association générale des producteurs de maïs	Users PRM
	BNIC	FR	Bureau National Interprofessionnel du Cognac	Users, Suppliers, Breeders

	Capseine	FR		Seed growers
	CETIOM	FR	Centre technique des oléagineux métropolitains	Users PRM
	Champagne Céréales	FR	Champagne Céréales	Users PRM
	CFSI	FR	Comité français de la semoulerie industrielle	Users PRM
	CGB	FR	Confédération générale des betteraves	Users PRM
	FNAMS	FR	Fédération Nationale Agriculteurs Multiplicateurs de Semences	Seed growers
	FNPC	FR	Federation Nationale des Producteurs de Chanvre	Users PRM
	SFG	FR	Société Française des Gazons - SFG	
	TOULEMONDE FRERES Sarl	FR		Users PRM (Fruit)
	USRTL	FR	Union syndicale des rouisseurs teilleurs de lin	Users PRM
		NL	Agriculture and horticulture Organisation – section trees and perenials	
	NFU	UK	National Farmers Union	Users PRM
		UK	Pre Basic Growers Association (seed potatoes)	Users, Suppliers PRM
Non EU	Felleskjøpet Agri	NO		User PRM

Others (biodiversity, conservation varieties, organic farming…)				
EU organisation				
EU	ECVC	BE	European Coordination Via Campesina	Users, Suppliers, breeders PRM

	IFOAM EU	BE	International Federation of Organic Agriculture Movements	Conservation varieties
	ECOPB	DE	European Consortium for Organic Plant Breeding	Breeder PRM (biodiversity)
Others				
EU	Arche Noah	AT	Verein, Austrian Seed Savers Association	NGO (Breeder, supplier, user)
	ARGE Streuobst	AT	Österreichische Arbeitsgemeinschaft zur Förderung des Streuobstbaues und zur Erhaltung obstgenetischer Ressourcen	User PRM (biodiversity)
	ASBL Terre potagère	BE	Association	Supplier PRM (biodiversity)
	thevegetablegarden	BE		Conservation varieties
	VELT	BE		Supplier & consumer (biodiversity)
	SAVE	DE	SAVE-Foundation	Conservation varieties
	VERN e.V	DE	Verein zur Erhaltung und Rekultivierung von Nutzpflanzen in Brandenburg	NGO (old varieties)
	ABDP	DE	Association of biodynamic plant breeders eV	Breeder / supplier PRM
		DE	Bingenheimer Saatgut AG	Breeders / suppliers PRM (organic farming)
	Frøsamlerne	DK	Danish Seed Savers Association "Frøsamlerne" - NGO dealing with variety conservation and biodiversity	NGO (biodiversity)
	Confederation paysanne	FR	Agricultural Union	Breeder, supplier, User PRM
	KOKOPELLI	FR	Association	Breeder / supplier PRM
	ITAB	FR	Technical Institute for Organic Farming	Technical institute

	OKOFORRAS	HU	Ökoforrás (Eco-resources) Foundation	Conservation varieties
		IE	Eco Committee of Cork Monthly Meeting of the Religious Society of Friends in Ireland	Conservation varieties
		IE	Irish Seed Savers Association	Supplier & consumer (Conservation varieties)
	Mullingar Educate together NS	IE		Consumers (biodiversity)
	AIAB	IT	Associazione Italiana per l'Agricoltura Biologica)	Biodiversity
	Bifurcated Carrots	NL		NGO (seed network)
	Fritidsodlingens Riksorganisation	SE		Consumers (gardeners)
	Röttle natur och kultur	SE		Biodiversity
Non EU	Portage Perennials	CA		Consumer (biodiversity)
	FNI	NO	Fridtjof Nansen Institute	Research institute (biodiversity)

		Forestry / Nurseries	
Competent authorities			
BFW	AT	Federal Forest Office – FRM	CA
SPW-DGO3-DNF	BE	Service public de Wallonie - Département Nature & Forest - Comptoir Forestier	CA
MMM	FI	Ministry of Agriculture and Forestry, Department of Forestry	CA

Min. Agriculture	IE	Forest Service, Department of Agriculture, Fisheries and Food	CA
SKOGSSTYRELEN	SE	Swedish forest agency	CA
NLC	SK	National forest centre	CA
EU organisation			
EFNA	UK	European Forest Nursery Association	
Nordic Forestry	BE	Bureau of Nordic Family Forestry	User
Others			
Bosgroep	BE	Bosgroep Zuidwest Brabant vzw (advice to forest owner)	Advice
IBGE	BE	Brussels Institute for Management of the Environment - Division Nature, Water and Forest - Forestry Department	Supplier
SPW	BE	Department of nature and forest in Wallonia	User
SRFB	BE	Société royale forestière de Belgique	User, breeder, supplier
DGARNE DNF	BE	Nature and Forest Administration of Walloon Region	User
UCL	BE	Université Catholique de Louvain - Earth and Life Institute - Environmental sciences Laboratory of forest sciences	User
Vallée du Chavan	BE	Groupement forestier	User
Scaldéen sprl	BE	Groupement Forestier	User
Forest Life SCA	BE		User
	BE	Nanson A.(former responsible for the regulations of Control of FRM)	Users

		Aigret G., Serstevens A., Bastin H., Baudry O., Blondel N., Bonte F., Charmetant C., Coquelet L., Corriat J., d'Aspremont Lynden F.-R., De Lannoy, De La Vallée F., De La Vallée P., De Le Court E., De Le Court J.-C., De Le Court J-F, De Lichtervelde F. de Radzitzky J., de Radzitzky P., du Parc P., Delogne J.-F., Dessain H., Egefim, Evrad D., Gobbe V., Indivision Arnould - Vandeputte, Iweins de Wavrans F., Jugnot V., Mestdagh G., Rondia G., Simon N., Sonnet J., Sosson C, Tennstedt L.-M.,.Vincent A., Wootwood	
FD-MOA	CY	Department of Forests	Supplier
NST	DK	Danish nature Agency (tree)	User, breeder, supplier
MTK-forestry	FI	Central Union of Agricultural Producers and Forest Owners (MTK), Forestry Group	Users
	FI	Union of Forest Owners West Finland	User
	FI	Finnish Forest Research Institute (2 answers)	Research
ERTI	HU	Forest Research Institute	Research
LTO	NL	Agriculture and Horticulture Organisation Netherlands section Trees and perennials	Supplier, breeder, user
LRF	SE	Federation of Swedish Family Forest Owners	
SODRA	SE	Southern Swedish Forest Owners Association	Supplier, breeder, user
	SE	Foreningen Sveriges Skogsplantproducenter (Swedish Forest Nursery Association)	Supplier
	SK	Federal Forest Office - Forest Reproductive Material	Breeder / Supplier
CONFOR	UK	Confederation of Forest Industries, Nursery Producers Group	

Individual

Consumer	FR	Coquin P., Dano C., François Rose Marie., Le Hingrat Y., André V.
Seed grower	FR	Vitu M.
Consumer	SE	A. Truedsson
Consumer	SK	Schnorrer M., Majdekova, Kása S.
Consumer	?	Anonymous

ANNEX VI: ANALYSIS OF THE PUBLIC CONSULTATION

I. Overall analysis

A web-based stakeholder survey using an "Interactive Policy Making" (IPM) questionnaire to collect comments on an "options and analysis paper" was organised from 19 April to 30 May 2011.

It yielded more than 257 responses from a very wide range of stakeholder groups. All replies to the questionnaire can be found with the following link:

http://ec.europa.eu/food/plant/propagation/evaluation/options_review_legislation_replies_en.htm.

1- Response profile

Stakeholders from 27 countries have answered to the web based consultation, including from 24 Member States (Bulgaria, Portugal and Slovenia did not answer). Canada, the US and Norway also have provided answers. 2/3 of answers were coming from 6 countries: Belgium, France (20-25%), Germany, Sweden, Finland and the Netherlands (between 4-6%).

Table V.1: Response profile

Competent authorities	
Certification	19.4%
Variety registration	16.7%
S&PM:	
Breeders	25.5 %
Suppliers	28.9 %
Users of S&PM	32.7%
User for raw material	4.9 %
Final Consumer	8.4%
Type of organisation	
SME	6.1%
National companies	10.7%
International companies	8.4%
International organisations	6.1%
Others	28.5%

The questionnaire authorised multiple answer with regard to the activities (e.g. breeders and suppliers), and thus the percentages do not add up exactly to 100%.

2- Problem definition

64% of the stakeholders consider that the problems were not defined correctly and that issues such as genetic improvement, productivity, competitiveness, global food security, adaptation to climate change, biotechnology, agro-environmental adaptation, biodiversity (minor crop and old varieties), niche markets, national stricter rules or no common solutions for all PRM were not sufficiently addressed.

71.9% of the stakeholders considered that the scenarios were not defined correctly and that certain scenarios were overlooked. Therefore, a majority of stakeholders (between 54 and 96% depending on activity and sector, with the exception of FRM where stakeholders are in favour of keeping the status quo) proposed that a combination of scenario should be developed. 79.5% feel that certain scenarios are unrealistic.

There was a majority of 57.4% to discard the baseline scenario ‘’no change’’ and the extreme scenario ‘’abolishment of S&PM Regulation’’.

Table V.2: Prioritisation of objectives

Priority objectives	1	2	3	4	5	N/A
Ensure availability of healthy high quality seed and propagating material						
	37%	23%	9%	8%	3%	21%
Secure the functioning of the internal market for seed and propagating material						
	21%	19%	14%	11%	15%	20%
Empower users by informing them about seed and propagating material						
	2%	13%	14%	32%	17%	22%
Contribute to improve biodiversity, sustainability and favour innovation						
	21%	12%	25%	11%	11%	19%
Promote plant health and support agriculture, horticulture and forestry						
	7%	15%	17%	14%	28%	18%

The analysis of the answer of stakeholders on the priority objectives shows that:

- 37% of stakeholders consider that ‘’ensuring availability of healthy high quality seed and propagating material’’ is the first priority and remains valid in 2011 and 60% that it is a priority 1 or 2.
- 40% consider that ‘’securing the functioning of the internal market for S&PM’’ is a first or second priority.
- 25% of stakeholders consider that ‘’contributing to improve biodiversity, sustainability and innovation’’ is a medium priority objective while 21% consider this to be of a high priority. This is reflected in the discussion where some stakeholders consider that the issue is already addressed while some others state that there is a definite need to do more in this field.
- Around 50% consider that ‘’empowering users by informing them about S&PM’’ has a lower priority.
- Only 7% of stakeholders consider that the objective ‘’promoting plant health and support agriculture, horticulture and forestry’’ is a first priority and 28% state that it has a low priority. This might be explained by the fact that plant health for S&PM is already addressed in the first priority through the terminology ‘’healthy high quality seed’’ and that the securing of the Internal market covers the principle of support for agriculture, horticulture and forestry.

3- Assessment of options

76.9% of stakeholders considered that the impacts of each option were not correctly analysed and that certain impacts have been overlooked or underestimated. This stakeholder view is, however, based on a preliminary assessment of the impacts in the “Options & Analysis”-paper.

Some stakeholders judge that the impacts on the various sectors of PRM (agricultural crops, vegetable, fruit, and vine or forest material) were not sufficiently addressed in the options which were described as very general and even simplistic.

Specific questions related to Forest Reproductive Material are not adequately taken into consideration and the related plant health issue neither (seed potato, fruit and vine materials).

Certain stakeholders believe that the impact of the transfer of cost to the private sector has been underestimated. Others consider that the issue of biodiversity is underestimated.

Several stakeholders consider that the issue of warranty of quality of PRM to users has been underestimated.

Table V.3: Stakeholders' support to specific options or combination of options

1	2	3	4	5	Combination of scenarios	Scenario with new features	N/A
3.1%	7.3%	2.7%	6.5%	8.0%	**28.5%**	**44.2%**	6.9%

44.2% are in favour of a new scenario with new features. 28.5% of the stakeholders support the idea that the preferred option for the review of the PRM legislation should be a combination of options.

Regarding the options which would best meet the objectives of the review, only 16 stakeholders provided an answer. ''Green'' stakeholders (37.5% of respondents answering this question, but only 2.3% of all respondents) considered that option 4 will meet them, while other groups shared the opinion that a combination of option or a scenario with new features (12.5%+37.5% of respondents answering this question, but only 3.1% of all respondents) will meet the objectives.

II. Analysis of the consultation according to sectoral stakeholder groupings

This section presents an overview of the positions taken by sectoral stakeholder groupings and the competent authorities of the Member States in reply to the consultations. The Commission has attempted to summarise these positions as accurately as possible.

1. Opinions concerning the proposed scenarios

The public consultation was based on the five scenarios presented in detail in this Impact Assessment and the discarded options of "No change" and "abolishment".

Discarded options	
SCENARIO 1 "Cost Recovery":	Complete recovery of variety registration and PRM certification costs by competent authorities
SCENARIO 2 "Co-system":	Limited flexibility for operators: technical examination for variety registration and PRM certification can be carried out by the operator under official supervision.
SCENARIO 3 "Deregulation"	Complete flexibility by deregulation: only DUS tests are mandatory and made under official supervision. VCU tests are optional. PRM certification applies only to exports.
SCENARIO 4 ''Enhanced flexibility''	Dual system: one for officially tested varieties (DUS, VCU) and one for non-officially tested varieties. Certification is limited to officially tested varieties.
SCENARIO 5: ''Centralisation''	CPVO will be given the mandate for variety registration. No change for certification (scenario 2).

Stakeholders, including competent authorities, from 24 EU Member States (no responses from Bulgaria, Portugal and Slovenia) took part. Six countries accounted for two thirds of the responses:

- France (more than 25% of all responses)
- Belgium (25% of the responses, including 40 responses from the Belgium forest sector)
- Germany, Finland, Netherlands and Sweden.

Five responses came from third countries: Norway (3 – competent authority, user of PRM and research institute), Canada (1 – user of PRM), USA (1 – breeder and PRM supplier).

North American (US and Canada) stakeholders reject all scenarios; Norwegian stakeholders consider the scenarios 1 and 5 as very negative and have a range of views on the other scenarios.

For the following analysis, stakeholders were divided into categories:

- Competent authorities and ministries: 25% of responses;
- Breeders and PRM suppliers: 30%;
- Users of PRM;
    - non FRM: 13%;
    - Users of PRM emphasizing biodiversity issues: 12%;
- FRM : 15%

Competent authorities (excluding FRM)

Scenarios	Discarded options	1	2	3	4	5
CA	disregarded	Slightly beneficial or neutral	Slightly beneficial	Rather negative	Rather negative	Rather negative

Discarded options

66% of competent authorities (excluding FRM) consider that the assessment of the discarded options was sufficient and consequently disregarded these two options.

Scenario 1

64% of competent authorities judged **scenario 1** to be slightly beneficial or neutral, 24% consider it to be rather negative or very negative and 12% state that they don't know.

Scenario 2

62% of competent authorities judged **scenario 2** to be slightly beneficial or fairly beneficial, 10% consider it to be neutral, 24% as rather negative or very negative and 4% state that they don't know.

Scenario 3

76% of competent authorities judged **scenario 3** as rather negative or very negative. 12% consider it to be slightly beneficial or fairly beneficial, 6% as neutral and 6% state that they don't know.

Scenario 4

72% of competent authorities judge **scenario 4** as rather negative or very negative. 12% consider it is slightly beneficial or fairly beneficial, 10% as neutral and 6% state that they don't know.

Scenario 5

68% of competent authorities judge **scenario 5** as rather negative or very negative. 14% consider it to be slightly beneficial or fairly beneficial, 14% that it is neutral and 4% state that they don't know.

It is noticeable that competent authorities involved specifically in the FRM-sector judge the **discarded scenario ''no change''** to be the most appropriate.

PRM Breeders and suppliers (PRM B&S)

Scenarios	Discarded options	1	2	3	4	5
Breeders and PRM suppliers (PRM B&S)	disregarded	Rather negative	Slightly beneficial	Very negative	Rather negative	Slightly beneficial or neutral

Discarded options

81% of PRM B&S consider that the assessment of the discarded scenario ''no change'' or ''abolishment'' was sufficient and consequently disregarded these two options.

Scenario 1

65% of PRM B&S consider **scenario 1** to be rather negative or very negative, 20% state that it is slightly beneficial or fairly beneficial, 6% that it is neutral and 9% that they don't know.

Scenario 2

77% of PRM B&S judge **scenario 2** to be slightly beneficial or fairly beneficial. 18% state that it is rather negative or very negative, 2% that it is neutral and 3% that they don't know.

Scenario 3

84% of PRM B&S consider **scenario 3** to be rather negative or very negative and 8% state that it is slightly beneficial or fairly beneficial, 5% that it is neutral and 3% that they don't know.

Scenario 4

80% of PRM B&S consider that **scenario 4** is rather negative or very negative and 15% state that it is slightly beneficial or fairly beneficial, 2% that it is neutral and 3% that they don't know.

Scenario 5

44% of PRM B&S consider that **scenario 5** is slightly beneficial or neutral, 30% state that it is rather negative or very negative and 26 % that they don't know.

It was conspicuous that the representation of PRM B&S involved in fruit or vine reproductive material is very low (3 between 60). It is thus not possible to arrive at strong conclusions concerning these sectors.

Stakeholder groups mainly interested by biodiversity issues

Scenarios	Discarded options	1	2	3	4	5
Stakeholders	disregarded	Very negative	Rather negative	Rather negative	Slightly beneficial	Very negative

Discarded options

65% of this group answered that the assessment of the discarded scenarios was sufficient. 30% responded that the disregarded options ''no change'' or ''abolishment'' were not sufficiently assessed.

Scenario 1

75% of respondents from this stakeholder group consider **scenario 1** to be very negative, 8% state that is neutral, 4% that it is slightly beneficial and 13% that they don't know.

Scenario 2

75% consider **scenario 2** to be rather negative or very negative, 8% state that it is neutral and 17% that they don't know.

Scenario 3

62% consider **scenario 3** to be rather negative or very negative, 8% state that is neutral, 17% that it is slightly beneficial or fairly beneficial and 13% that they don't know.

Scenario 4

54% of PRM B&S consider **scenario 4** to be slightly beneficial or very beneficial, 33% state that it is rather negative or very negative and 13% that they don't know.

Scenario 5

75% of PRM B&S consider **scenario 5** to be very negative, 8% state that it is neutral and 17% that they don't know.

This stakeholder group is generally critical to very critical concerning the various scenarios. Only scenario 4 (58%) is judged to provide some benefits concerning the question of biodiversity.

Users (non-FRM, also including technical institutes)

Scenarios	0	1	2	3	4	5
Stakeholders	Disregarded	Slightly beneficial or neutral	Slightly beneficial	Very negative	Very negative	Neutral or rather negative

Discarded options

61% of this group respond that the assessment of the discarded options ''no change'' or ''abolishment'' was sufficient and consequently disregarded these two options.

Scenario 1

69% consider **scenario 1** to be slightly beneficial or neutral, 27% state that it is rather negative or very negative and 4% that they don't know.

Scenario 2

80% consider **scenario 2** to be fairly beneficial or slightly beneficial, 8% state that it is neutral, 8 % that it is rather negative or very negative and 4% that they don't know.

Scenario 3

100% consider **scenario 3** to be very negative.

Scenario 4

100% consider **scenario 4** to be very negative.

Scenario 5

46% consider **scenario 5** to be slightly negative, 23% state that it is neutral, 11% that it is slightly beneficial and 12% that they don't know.

This stakeholder group is characterized by a common view on scenarios 3 and 4 stating that those two scenarios are very negative for the future of the PRM sector.

Forest reproductive material

Within the FRM sector, forest owners can be supplier and users at the same time. Due to the fact that public owned forests are common in Europe, sometimes the competent authorities can also be user and supplier. Therefore all participants in the public consultation involved with forestry were treated as one stakeholder group.

Scenarios	0	1	2	3	4	5
Stakeholders	Not sufficiently assessed	No opinion	Very negative	Very negative	Very negative	Very negative

Discarded options

2/3 of this group answered that the disregarded scenarios were not sufficiently assessed.

Scenario 1

46% of the group state that they don't know how to assess the possible impact of **scenario 1**. 23% consider that it would be negative, 19 % answer that the scenario would have a positive impact, 12% consider it as neutral.

Scenario 2

69% of the group consider **scenario 2** to be rather negative or very negative, 23% don't know how to assess it and 8% answer that it is neutral.

Scenario 3

69% of the group consider **scenario 3** to be rather negative or very negative, 23% don't know how to assess it and 8% answer that it is neutral.

Scenario 4

58% of the group consider **scenario 4** to be rather negative or very negative, 27% don't know how to assess it, 11% answer that it is positive and 4% consider it as neutral.

Scenario 5

61% of the group consider **scenario 5** to be rather negative or very negative and 27% don't know how to assess it, 7.7% answer that it is neutral and 4% that it is positive.

This group is opposed to all options. It is often mentioned, that agriculture and forestry are different and that FRM was not specifically mentioned in the Option & Analysis Paper provided. Due to this, some stakeholders from this sector couldn't decide yet and have proposed to keep the existing legislation.

2. Opinions concerning the proposed objectives

Obj. 1. Ensure availability of healthy high quality seed and propagating material;

Obj. 2. Secure the functioning of the internal market for seed and propagating material;

Obj. 3. Empower users by informing them about seed and propagating material;

Obj. 4. Contribute to improving biodiversity, sustainability and favour innovation;

Obj. 5. Promote plant health and support agriculture, horticulture and forestry

Objectives	Obj.1	Obj. 2	Obj. 3	Obj. 4	Obj. 5
Priorities for competent authorities	1	2	4	3	3
Priorities for breeders and PRM suppliers	1	2	3	2	3
Biodiversity stakeholders	2	4	2	1	3
PRM users, PRM growers	1	3	3	2	3
Forestry group	1	2	4	2	3

This table shows that for four stakeholder groups, except the biodiversity group, the objective of ‘’ensuring availability of healthy high quality seed and propagating material’’ is the first priority. The biodiversity group puts objective 4 first, but responds that the objective of ‘’ensuring availability of healthy high quality seed and propagating material’’ is the second priority.

For competent authorities, breeders and suppliers and forestry stakeholders, the second most important objective is to ‘’secure the functioning of the internal market for PRM’’.

It is noticeable that the objective of improving ‘’biodiversity and innovation’’ is also an important concern of nearly all stakeholder groups.

ANNEX VII: SHORT DESCRIPTION OF THE MAIN FEATURES OF THE PRM MARKETING LEGISLATION

Distinctness, Uniformity, Stability (DUS)

A variety shall be regarded as distinct if it is clearly distinguishable on one or more important characteristics from any other variety known in the Union. The characteristics of a variety must be capable of precise recognition and precise definition.

A variety shall be regarded as sufficiently uniform if, apart from a very few aberrations, the plants of which it is composed are, account being taken of the distinctive features of the reproductive systems of the plants, similar or genetically identical as regards the characteristics, taken as a whole, which are considered for this purpose.

A variety shall be regarded as stable if, after successive propagation or multiplications or at the end of each cycle, it remains true to the description of its essential characteristics.

For the official examination of a variety the CPVO- or UPOV- or national protocols are used.

Value for cultivation and use (VCU)

The value of a variety for cultivation and use shall be regarded as satisfactory if, compared to other varieties accepted in the catalogue of the Member State in question, its qualities, taken as a whole, offer, at least as far as production in any given region is concerned, a clear improvement either for cultivation or as regards the uses which can be made of the crops or the products derived there from. Where other, superior characteristics are present, individual inferior characteristics may be disregarded. The characteristics to be considered are the value for cultivation (being yield, resistance to harmful organisms and behaviour with respect to factors in the physical environment) and the value for use (quality characteristics).

Protocols and testing procedures for the four characteristics are developed on a national level.

Certification/controls on lots of PRM

Quality and health of lots of PRM on the market are guaranteed by issuing of a label, which stands for a statement that the lot concerned complies with the EU requirements applicable to the species and the category under which the lot is placed on the market.

For nearly all agricultural crops marketing is only possible in the categories of certified material or higher. It also implies that the label is an official label issued following an official examination of the field production and the lot or an examination under official supervision. This examination involves controls during the growing period of the PRM crop, examination at the stage of the preparation of the lot itself and sampling followed by laboratory testing.

Besides official certification labels, the guarantee can be based on the basis of a suppliers' label which is issued by the supplier himself, on the basis of his own verification of the compliance of the lots with the applicable standards. The only official controls on such lots are the post-controls on samples drawn from PRM that is present on the market. One of the

consequences is that the official services can only verify compliance with the standards applicable to the lot itself.

The various steps in the variety registration and certification processes are shown in the following flowchart

Figure 1. Registration of varieties and certification/inspection of PRM lots for marketing

EU system for PRM marketing[49]

Step 1: Registration of varieties

1.1 Applicant submits an application and a sample to the national competent authority

1.2 Competent authority performs technical examination:

- distinctness, uniformity, stability (DUS) for all varieties, (at least over 2 growing seasons)

- value for cultivation and use (VCU) as additional tests for agricultural crops

- suitability of the proposed variety name

⇩ if all criteria are met

1.3 Competent authority registers the variety in its national catalogue or list

For agricultural and vegetable crops, the variety is eligible for marketing in the Member State, for other crops marketing in the entire EU is permitted

1.4 The competent authority notifies the Commission of the registration of varieties of agricultural and vegetable crops

1.5 The EU includes the agricultural and vegetable varieties in a common catalogue

The variety of agricultural and vegetable crops is eligible for marketing throughout the EU

Step 2: Inspections/certification of lots of PRM

[49] Terminology not directly applicable to Forest Reproductive Material

Marketing of lots covered by an official certification label

2.1.1 Supplier submits an application to the competent authority

2.1.2 Authority performs inspections on growing seed crop and on lots prepared for marketing, including sampling and laboratory testing. Under certain conditions inspections may be done by the supplier under official supervision

if all criteria[50] are met

2.1.3 Certification label issued

lot eligible for marketing

2.1.4 Competent authority performs random post-control on lots of PRM on the market

Marketing covered by a suppliers' label[51]

2.2.1 Supplier performs inspections on his seed crop and on lots prepared for marketing

if all criteria are met

2.2.2 Suppliers' document issued

lot eligible for marketing throughout EU

[50] Criteria are crop- specific and depend on marketing category

[51] For small EU packages of fodder plants and beet seed and for lower marketing categories of non-agricultural crops

Current system on market access of varieties/material: registration and certification of all varieties/materials of plant reproductive material (PRM) of plant species regulated in the EU

Groups of pla species	Agricultural crops: seed of fodder, cereal, beet, oil and fibre plants, potatoes	Vegetable seed and propagating material	Fruit and vine propagating material and plants	Forestry reproductive material	Ornamental seed and propagating material
Registration of varieties or materials • Application is done by breeders ▪ Purpose: marketing of better varieties, with clearly identified characteristics. ▪ The varieties are registered in catalogues (for agricultural and vegetables crops) or lists for fruits and vines. ▪ The acceptance for registration is subject to examination of varieties for identity and performance as well as of denomination checking.					

	Registration of varieties in the MS (DUS examination for identity and VCU examination for performance, denomination checking) EU marketing through publication in the EU Common Catalogues	Registration of varieties in the MS (DUS examination for identity, only industrial chicory VCU testing) EU marketing through publication in the EU Common Catalogues	Registration of varieties in the MS (DUS examination) EU marketing through publication in the national list, notification of information to the EU list	Official approval of basic material on the basis of its provenance EU marketing through publication of basic material in the national list and notification of information to the EU list	No variety registration procedure: Can be marketed if plant variety rights protection or officially registered or commonly known or on suppliers list in the MS

Derogations above	Grasses for non-fodder use: no VCU testing For registration of conservation varieties in the MS and EU Common Catalogues: less stringent DUS testing and no VCU testing Preservation seed mixtures approved on basis of origin in the MS Derogative pre-authorisation marketing regime for tests and trials on farms with quantitative restrictions in the MS: 'not- yet listed varieties'	For registration of conservation varieties and amateur varieties the MS and EU Common Catalogues: less stringent DUS testing and no VCU testing	Possibility for less stringent derogative rules for varieties in the interest to preserve genetic diversity exists.		

Category/ **S&PM**	Agricultural crops: seed of fodder, cereal, beet, oil and fibre plants, potatoes	Vegetable seed and propagating material	Fruit and vine propagating material and plants	Forestry reproductive material	Ornamental seed and plant propagating material
Certification/inspection of S&PM lots • Purpose: ensure the presence of good quality and healthy lots on the market • Is subject to inspections done by national competent authorities or by the supplier under official supervision on growing seed crops and on lots prepared for marketing, including sampling and laboratory testing. Following these tests that explore various criteria such as: identity, purity, quality, plant health) certification label is issued.					
(1) Certification PRM before marketing by official authority only	Marketing categories of pre-basic and basic seed (field inspection), seed potatoes		Fruit: Marketing categories of pre-basic, basic, certified Vine: Marketing categories of initial, basic seed, certified seed	Different marketing categories under which different types of basic material may be marketed. Certification for derivation of approved basic material ('master certificate'). Official control system in the MS.	

(2) In addition to (1): possibility for certification under official supervision	Marketing categories of certified seed and commercial seed (fodder, oil &fibre plants)	Seed: marketing categories of pre-basic, basic seed and certified seed			
(3) Marketing controls only (post-controls)	Small packages of beet seed and fodder plant seed	Seed: marketing category standard seed (verification) PM: self controls, MS supervision & controls of producers, small packages	Fruit: marketing category CAC Vine: marketing category standard	Re-inspected at regular intervals	No marketing categories, general quality requirements, random checks

ANNEX VIII: MAIN FEATURES OF THE PRM MARKETING INDUSTRY

EU production and trade in true seed

The European Seed Association (ESA) estimates that in 2009-2010 the EU commercial seed market has reached a value of approximately EUR 6.8 billion and that it represents more than 20% of the total worldwide market for commercial seed. The EU seed markets for cereals and pulses are estimated at EUR 2.5 billion, maize at EUR 1.6 billion seed potatoes at EUR 900 Mio, vegetables at about EUR 1 billion, while oil and fiber plants, sugar beet and grasses are respectively from EUR 200 to 300 Mio each.

The EU is the largest exporter with an estimated export value of EUR 4.4 billion representing roughly 60% of the total worldwide export value of EUR 7.7 billion. The EU became a net exporter of planting seeds in 2002/2003, and its trade surplus has gradually increased since then.

Statistics produced by ISF (update August 2010 – ISF will not accept any responsibility for the use of their statistics by others)

	Value of domestic seed market (in US mio $ at 1€ = 1.4 US $	*Export (includes EU destinations - in US mio $ at 1€ = 1.4 US $)*		*Import (includes EU origin - in US mio $ at 1€ = 1.4 US $)*	
Country	*Agricultural + Vegetable crops*	*Agricultural seed*	*Vegetable seed*	*Agricultural seed*	*Vegetable seed*
Belgium	*185*	*160*	*4*	*160*	*31*
Bulgaria	*120*	*18*	*5*	*60*	*7*
Czech Republic	*300*	*41*	*4*	*56*	*6*
Denmark	*165*	*168*	*55*	*54*	*15*
Germany	*1950*	*458*	*48*	*457*	*72*
France	*2370*	*884*	*278*	*590*	*107*
Estonia	*n.a.*	*n.a.*	*n.a.*	*n.a.*	*n.a.*
Greece	*240*	*11*	*2*	*63*	*24*
Spain	*450*	*62*	*47*	*198*	*198*
Ireland	*80*	*4*	*0*	*16*	*5*
Italy	*715*	*123*	*94*	*186*	*162*
Latvia		*0*	*2*	*8*	
Lithuania		*6*	*1*	*17*	*3*
Luxemburg		*4*	*0*		
Hungary	*300*	*221*	*14*	*84*	*17*
Cyprus	*n.a.*	*n.a.*	*n.a.*	*n.a.*	*n.a.*
Malta	*n.a.*	*n.a.*	*n.a.*	*n.a.*	*n.a.*
Netherlands	*317*	*241*	*1058*	*282*	*310*
Austria	*150*	*115*	*3*	*91*	*14*
Poland	*260*	*39*	*4*	*78*	*44*
Portugal	*80*	*4*	*6*	*56*	*20*
Romania	*220*	*86*	*0*	*124*	*14*
Slovak	*110*	*38*	*0*	*50*	*3*

Republic					
Slovenia	*40*	*5*	*3*	*15*	*5*
Finland	*160*			*12*	*7*
Sweden	*240*	*31*	*4*	*44*	*9*
UK	*400*	*40*	*21*	*126*	*73*

n.a.: information not available
NB: The commercial world seed market for 2009-10 is assessed at approx. 42 billion US $

Seed production in EU 27 Member State for the most important agricultural crops

Wheat seed is produced on 420 000 ha. France is the biggest producer (82 000 ha) followed by Germany, the Czech Republic, Hungary and the UK. Italy has the first place with durum wheat seed production. Romania and Spain are also big cereal seed producers. Barley accounts for 300 000 ha, where Germany (38 000 ha), France (36 000 ha), Denmark (33 000 ha) and the Czech Republic (30 000 ha) are the biggest producers.

France and Germany are the two main producers of oilseed rape in the EU. In the last years production of rapeseed for sowing was increased due to the demand for rapeseed as a supply stock for biodiesel. Due to the very high multiplication factor, the number of hectares of seed production remains fairly limited.

Maize seeds are grown on 140 000 ha. The largest maize seed producers are France, Hungary and Romania.

Sugar beet seed is grown on 126 815 ha. France and Italy are the largest producers in the Union.

Grass seed production in the EU occupies 207 000 ha. Denmark is the largest producer of grass seeds with about 72 000 ha, followed by Germany (29 350 ha), France (20 500 ha), and the Czech Republic (16 700 ha) and the Netherlands (15 900 ha). All other Member States together produce grass seeds on 52 550 ha.

Vegetable seeds are mainly multiplied outside the EU in a wide range of countries in which labour costs are lower than in the EU. The produced seeds are shipped to the EU, mainly to the Netherlands, for treating, sampling and packaging and re-exported to their final destination in the EU or outside the EU. Vegetable production in the EU has a value of EUR 27 bn, where five Member States (IT, ES, RO, FR and PL) together represent more than 50% of the production. The vegetable seed production has a value of about EUR 1 billion. Main producers are FR, IT, NL, HU DK and PL. The five biggest companies have 95% of the seed market.

Seed potato production occupies around 90.000 ha in Europe; four main countries are the largest producers: The Netherlands (34.000ha), Germany and the United Kingdom (around 16.000 ha each), France (14.000ha).

The major players in the seed market

For several decades after plant breeding emerged as a recognized field of science in the late 19th century, almost all plant breeding activities took place in public institutes. Breeding activities gradually shifted to the private sector during the 20th century. This may explain why

plant breeders (public first and then public & private) have been involved to a large extent in the development of national regulatory frameworks.

The seed industry matured due to the introduction of hybrids, especially hybrid maize in North America, hybrid sugar beet in Europe, and hybrid vegetables in South East Asia and intellectual protection (plant breeder's right). In North America and Europe, the hybrid seed industry grew from regionally based family businesses. The profitability of hybrids far outstripped that of non-hybrid open pollinated seeds. This has led to eventual consolidation in the industry and the dominance of several key companies in particular crops. In the 1970s, high margins attracted the attention of several agrochemical companies, waiting to exploit possible synergies of the seed business with their own line of business (e.g. the acquisition of Northrup King (USA) by Sandoz (Switzerland).

The emergence of biotechnology in agriculture in the 1980s has led to a complete reorganization of the sector. Today, leading seed groups are largely owned or allied with the world leading chemical/plant protection companies. Consolidation through mergers and acquisitions took place in major field crops, and is currently on-going in the vegetable sector. Chemicals companies' interests in investing in biotech are linked to the fact that many pesticides used in agriculture may be replaced by transgenic crops that have a biologically inbuilt resistance.

In the top ten of the biggest seed companies at global level, five are Europe-based companies, four of which are from EU Member States.

The structure of the EU seed companies

The number of seed companies in the EU is estimated at 6,797[52] and includes breeding companies, seed producers and seed traders. About 6,580 out of 6,797 companies are based in ten Member States.

In Poland and Romania, there are a large number of companies (around 2,000) and in Hungary around 800. The next position occupies the United Kingdom with 600, followed by a group of 5 countries (Italy, France, Slovakia, Germany, Netherlands) with a number between 120 and 350 companies. In the other member States, the number is lower than 60 companies.

This highlights that the three Member States with the highest number of seed companies are Eastern countries; respectively Poland, Romania and Hungary. However, the size of seed companies in these countries is small with most of them (> 90%) being SMEs.

The total employment is estimated at about 50,000 employees with about 80% of the number of employees in the top ten Member States demonstrating that PRM sector is concentrated in a limited number of Member States. The main countries with regards to employment in the private seed sector are first France followed by Romania, Netherlands, Poland, Germany and Italy.

The combination of number of companies and seed employees shows that consolidation in France and the Netherlands is important. The number of companies is quite small but the number of employees is rather high.

[52] industry information - 2010

The percentage of micro and small enterprises per Member States is not known and is difficult to calculate as many collaborations and agreements exist between companies across Member States. Data regarding ESA membership (European Seed Association) show that around 15 individual members are medium or large companies and the others are small companies. A majority of small or micro enterprises are participating in the work of ESA through their membership in national associations (e.g. the French seed association has 130 members, the Dutch seed association 300). It can be concluded that, overall, the number of SMEs is quite high, especially in the EU12 new Member States. As consolidation is still on-going in these Member States, it can be estimated that the percentage of SMEs in the PRM sector in these Member States and then at the EU level will decrease in the future. Additionally, these figures do not distinguish between plant breeding activities and seed multiplication activities.

Another point of consideration is the correlation between the public breeding efforts and the number of SME. Indeed when national plant breeding efforts on a given crop are dominated by public activities (e.g. fruit plants and vine in the EU, all crops in Poland, marginal crops in several EU12 new Member States, etc.) varieties bred by these public institutes are marketed by SMEs in charge of seed production and sales. Some interviewees indicated that when plant breeding is privatised the number of seed companies is decreasing.

The structure of the R&D efforts (plant breeding) is presenting a quite different pattern as most of the plant breeding activities are located in the EU15 old Member States, mainly in France, Germany and Netherlands (more than 100 breeding stations, more than 2000 employees in R&D in each country), followed by Italy and Spain (more than 50 stations and around 700-800 employees each). In the new member States, the number of private breeding stations is quite important in Hungary, Romania (around 50) and in Poland (more than 25) but with different figures with regards to R&D employees: around 200 in Hungary, 600 in Poland and more than 1000 in Romania where the labour cost is cheaper. In the other Member states the number of breeding stations is lower than 20 with less than 300 employees in R&D.

The importance of individual Member State's effort in plant breeding by private actors can be estimated by calculating the ratio between the number of R&D employees/number of total seed employees. This shows that German companies are conducting half of their activities for research and half for seed production while French companies, even if they are very active in breeding (comparable date to Germany), are more involved in seed production.

In the last 40 years, the commercial seed industry has transformed dramatically. It has shifted from a competitive sector of agribusiness, composed primarily of small, family-owned firms, to an industry by transnational corporations, powerful family-owned firms, cooperatively owned companies. This transformation is now nearly complete for key commodity crop seeds but is still on-going in EU12 new Member States and in the EU-wide vegetable sector. These corporations entered the industry by acquiring numerous smaller seed companies and by merging with large competitors. The hybrid seed corn industry, which emerged in the 1930s in the US with the advent of high-yielding hybrid varieties, was the first to consolidate in the EU in early 1990s. This process accelerated in the US due to enforcement of Intellectual Protection systems, which attracted chemical and oil companies to add to their portfolio of agricultural inputs. The decade of the 1990s saw numerous mergers between pharmaceutical and chemical companies, in order to take advantage of potential synergies. These new conglomerations were described as life science companies due to their focus on biotechnologies. By 2009, six companies with chemical and/or pharmaceutical company roots remained dominant in the seed industry. In parallel to this evolution, changes of ownership in

original farmer-owned supply cooperatives have led to the appearance of cooperatively owned global seed companies (e.g. Limagrain, Svalöf Weibull, etc.). Both the fruit and the wine sectors are energized by public R&D efforts.

The hundreds of transactions and business collaborations that have reshaped the industry in recent years challenge the simplistic notion of a division of the sector between SMEs and multinationals. It is almost impossible to map the structure of the industry as the number of collaboration agreements between companies is extremely important and quite often small seed companies may have access to varieties coming from medium size companies for seed production and marketing on a given market.

Most of the interviewees and respondents to the qualitative survey consider that consolidation will continue at a rapid pace.

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Plant propagating material sectors (vine, ornamentals, fruit plants, and forest)

Data and statistics regarding the vine, fruit plants and the forestry sectors are hardly available as no consolidated sources of relevant data have been identified for the EU market. In most Member States, activities related to certification of plant propagating material of these three sectors is organised at regional level or by different organisations so that the statistics are not

consolidated at national level. One example illustrating the difficulty to collect information in these sectors is that it took the Commission more than one year to get reliable data on the fruit plants sector during the preparatory work on the revision of Directive 92/34/EC.

However, some basic data have been collected during this study:

- Regarding the tree seed market, the French forestry experts interviewed during the study indicated that for example, the seed forestry market value is, on average, not higher than EURO 2 Mio per year in France. The International Seed Federation provided some data on import/export of tree and shrub planting seed that show that seed trade is very low in this sector.

- For the fruit plants market, DG SANCO consolidated some key figures in 2007-08 and concluded that more than 12000 enterprises are involved in production of fruit plants in the EU; and about 90% of them are small to medium enterprises frequently based in rural areas where alternative business is not possible. The estimated value of this business was estimated at about EURO 2.5 billion.

The difficulty in collecting market figures for these plant propagating material sectors is also certainly linked to the fact that certification is not mandatory for all species and that breeding of the majority of these species is done by public institutes.

Summary

As demonstrated by the information above, the European PRM sector is characterized by a large segmentation (from national SMEs involved in cereals or ornamentals only to international companies with a multi-crops approach).

PRM is not one sector but several sectors in constant evolution, which are becoming more and more specific in terms of type of products, type and number of actors, competitiveness, product life cycle, R&D efforts, added value and return on investment.

The leading Europe-based seed companies are Syngenta and Limagrain and they are, like the major American companies mentioned above, operating worldwide.

We can observe two major groups of breeders:

- SMEs that breed for their local/national markets and develop partnerships with foreign seed partners for the purpose of testing/positioning and, when relevant, for the marketing of their existing cultivars in other countries characterized by specific growing conditions (breed locally - test globally);
- Larger companies whose breeding strategies aim at a European and/or a global scale (e.g. maize) and consist of breeding for a given Area Of Adaptation (AOA), which could be defined as an area where agro-climatic and plant growing conditions are uniform (breed globally – test locally).

ANNEX IX: SELECTED DATA REGARDING THE CURRENT EU COMMON CATALOGUES FOR VEGETABLE AND FIELD SPECIES

Figure 1: Number of registered agricultural varieties per Member State

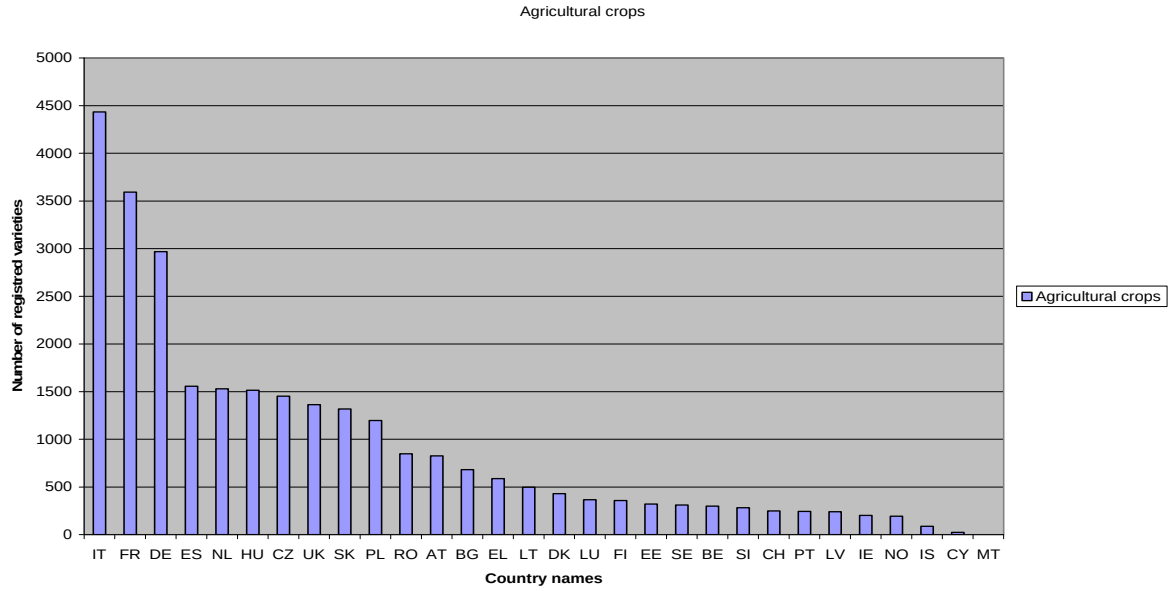
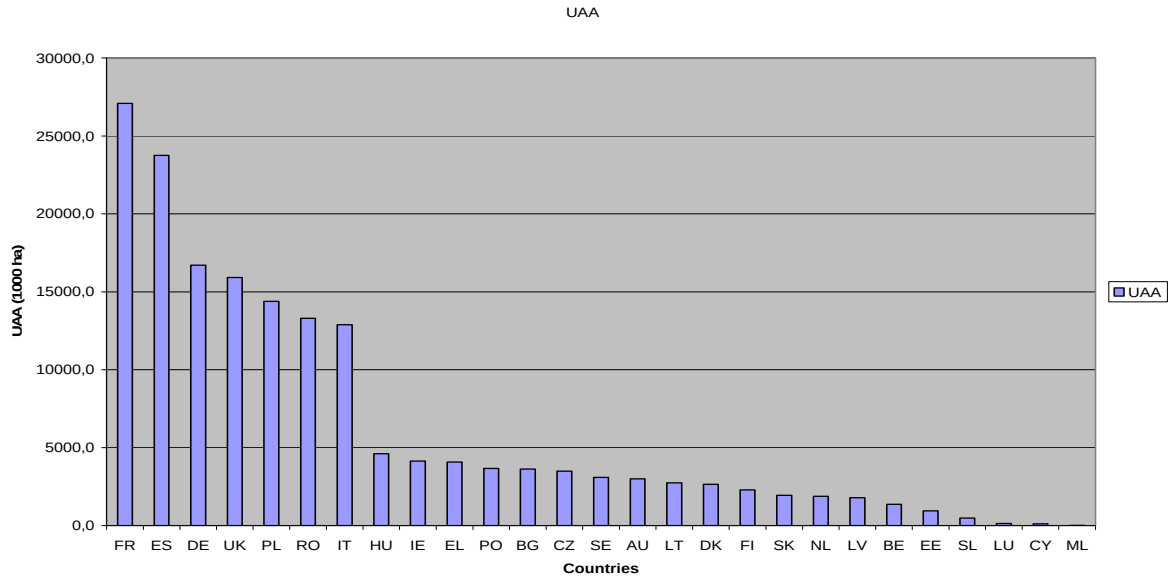


Figure 1 shows that the three main countries with regard to registration of agricultural varieties, i.e. Italy, France and Germany, each 3000 or more varieties on their national catalogue. Then 7 Member States (new or old ones) follow which have on their national list between 1000-1500 varieties, followed by another 4 with numbers of varieties ranging from 500-1000. The common catalogue lists also varieties from Iceland, Norway and Switzerland.

These data can be compared to the utilised agricultural area (UAA)[53]. In France, the UAA covers 27.1 million ha (16% of the total UAA of the EU27), followed by Spain with 23.8 million ha (14.0%), Germany 16.7 million ha (10%), the United Kingdom 15.9 million ha (10%), Poland 14.4 million ha (8.5%), Romania 13.3 million ha (7.8%) and Italy 12.9 million ha (7.6%). These seven Member States accounted for almost three quarters of the utilised agricultural area in the EU27 in 2010 (see the figure below).

[53] http://epp.eurostat.ec.europa.eu/cache/ITY_PUBLIC/5-11102011-AP/EN/5-11102011-AP-EN.PDF

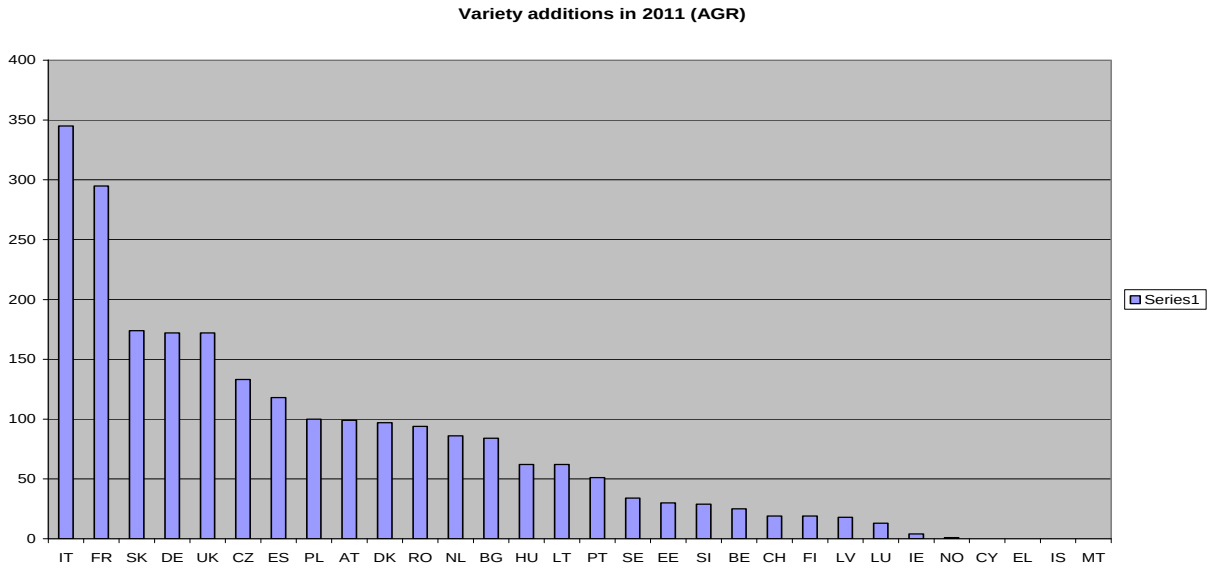
Figure 2: Utilised agricultural area in the EU Member States



Figures 1 and 2 show that more breeding companies are registering their varieties in Italy even though Italy is not the biggest agricultural country in terms of UAA. This could be partially explained by the diversity of agro-ecological situations and smaller costs for registration.

The situation in Romania can be understood by its relatively recent status as EU Member State. The big difference between the importance of variety registration in the Netherlands and other smaller Member States could be linked to important knowledge of this country with regards to technical examination (plant variety protection) and the number of seed companies based there (NL is the leading EU seed exporting country). Regarding the number of varieties listed in Slovakia, it could be link to a smaller cost for registration.

Figure 3: Number of agricultural varieties added per Member State in 2011



Regarding the most recent variety additions, Germany has registered fewer varieties than other large Member States such as Italy and France, while Slovakia and United Kingdom have been quite active compared to Germany.

Figure 4: Number of registered vegetable varieties per Member State

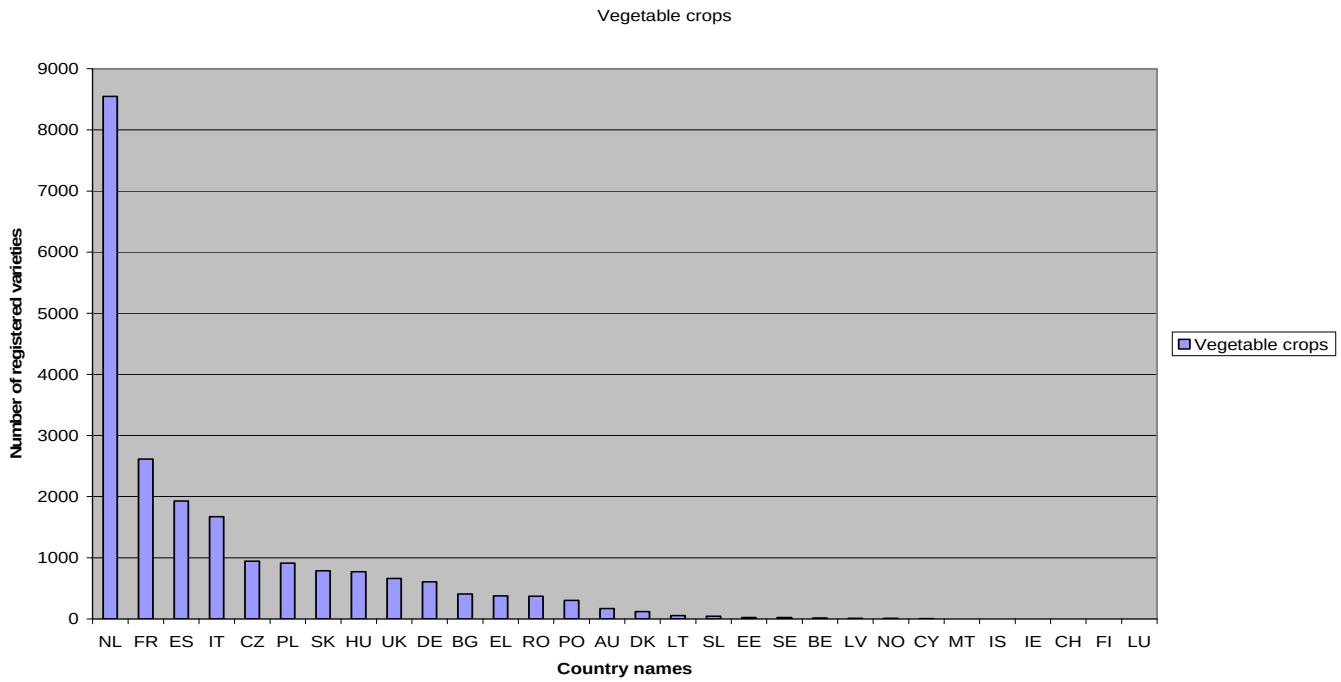
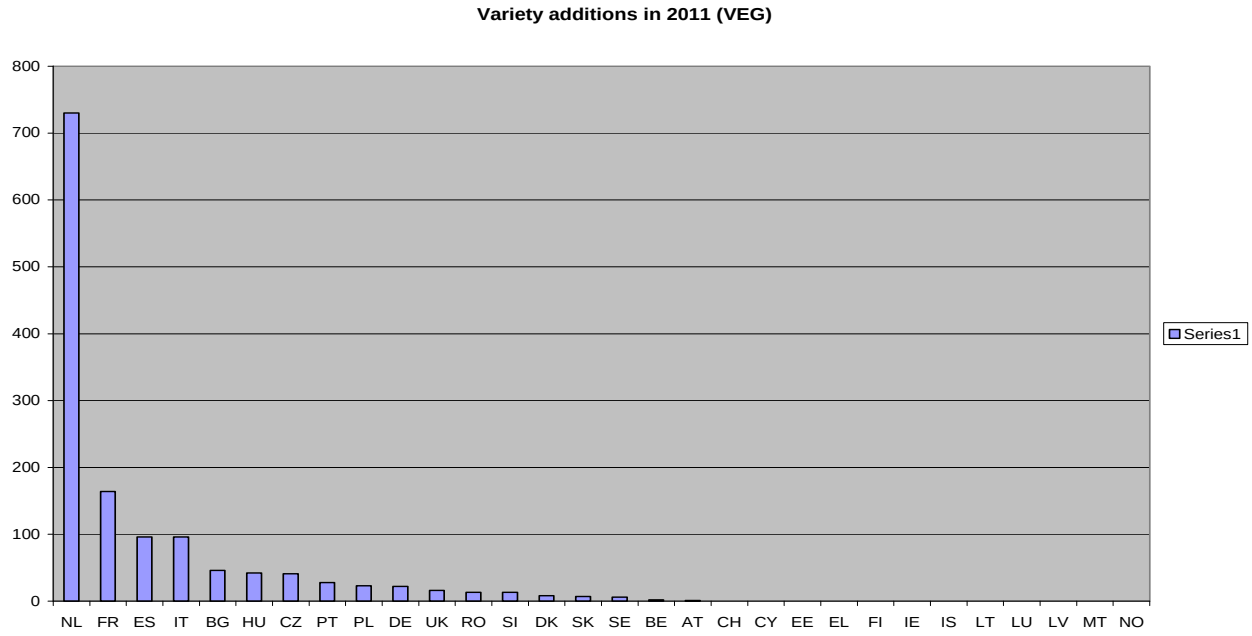


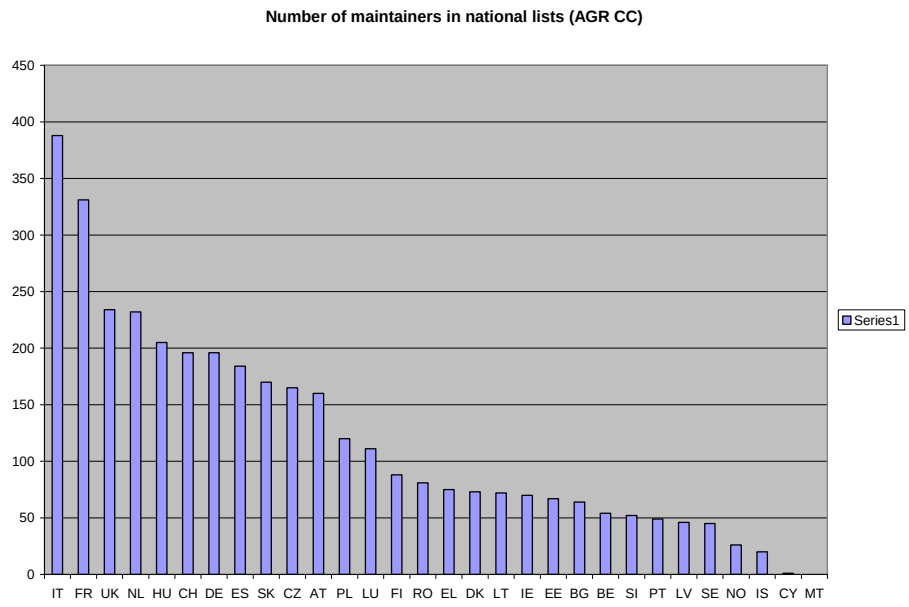
Figure 5: Number of vegetable varieties added per Member State in 2011



These two figures show the predominance of the Netherlands with regard to registration of vegetable varieties (8500); followed by France, Spain and Italy which have on their national

catalogues between 1600 and 2600 varieties. 8 countries have less than 60 vegetable varieties on their list and 6 have no varieties.

Figure 6: Number of maintainers for agricultural varieties in national lists

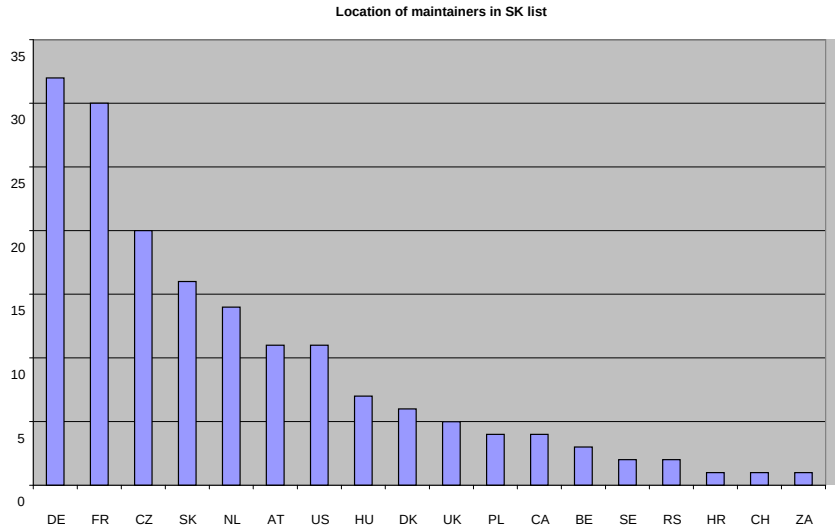


This figure shows that the number of maintainers of agricultural varieties by Member States mirrors the general situation with regard to variety registration. In countries where there is a significant number of varieties registered, they is also a high number of maintainers.

The following figures give indications on some national situations in order to see the origin of the varieties by studying the responsible maintainers.

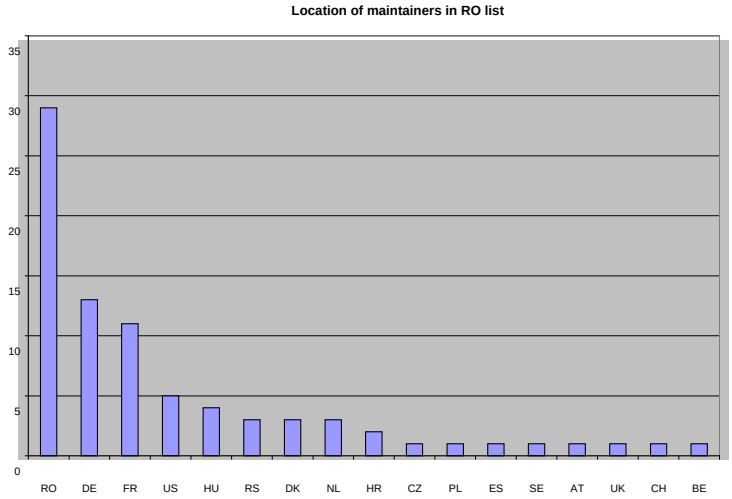
For agricultural crops:

Figure 7: Number and provenance of maintainers in the Slovakian national list



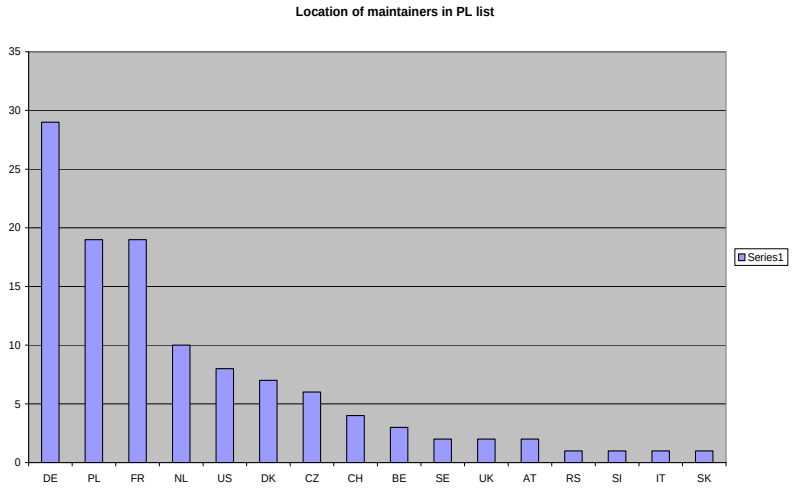
In Slovakia, 170 maintainers are listed. 80% of maintainers are coming from other countries, mainly from 3 EU Member States (48%): Italy, France and the Czech Republic. National maintainers represent 10%, which means that foreign operators are very interested in registering their varieties in Slovakia.

Figure 8: Number and provenance of maintainers in the Romanian national list



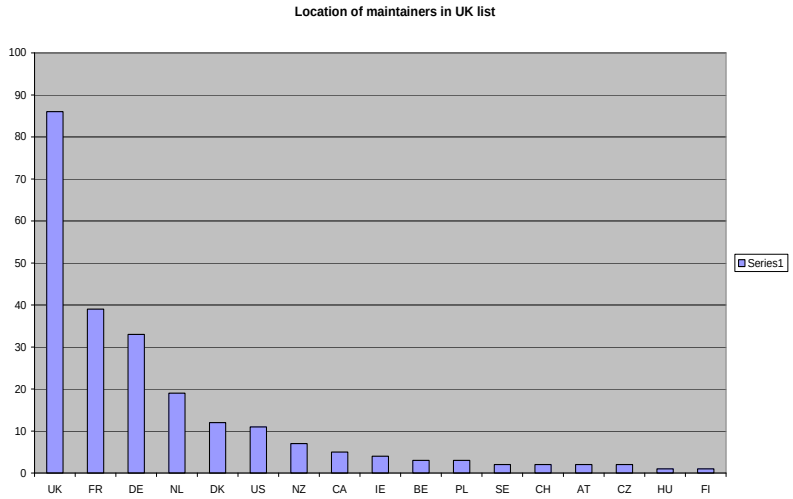
In Romania, 81 maintainers are listed. Local maintainers represent 35%. Maintainers coming from France and Germany represent around 30%. This figure indicates that a lot of local operators are active on this market.

Figure 9: Number and provenance of maintainers in the Polish national list



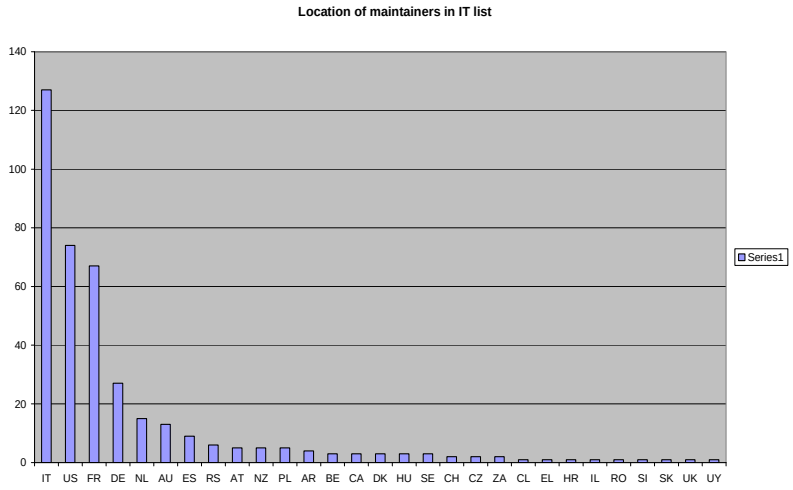
In Poland, 115 maintainers are listed. 25% of the maintainers are from Germany. Local and French maintainers represent 16.5% respectively.

Figure 10: Number and provenance of maintainers in the UK national list



In United Kingdom, more maintainers are registered (232); 37% are from UK and 31% from France and Germany.

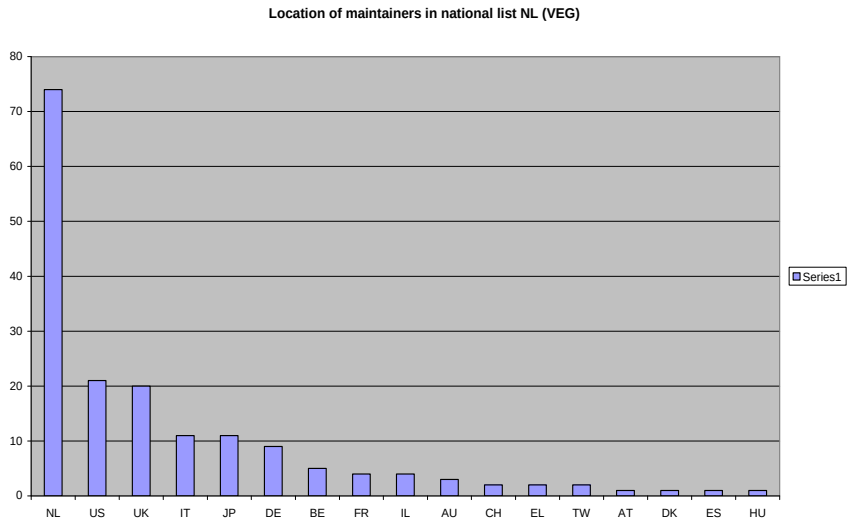
Figure 11: Number and provenance of maintainers in the Italian national list



In Italy, an important number of maintainers are registered (387); 33% are based in Italy. 19% are from US, 17% from France and 7% from Germany.

For vegetable crops:

Figure 12: Number and provenance of maintainers in the Dutch national list



In The Netherlands, with regards to vegetable variety maintainers, 43% are located in the Netherlands, 21% are coming from non EU countries (12% from US, 6% from Japan and also

Israel and Taiwan). This reflects the situation where a lot of vegetable seed companies are located in the Netherlands or have a subsidiary there.

ANNEX X: INSPECTION COSTS FOR FOREST REPRODUCTIVE MATERIAL

(Source : EFNA - European Forest Nurseries Association – summary of questionnaire results from AU, BE, CZ, DE, FR, HU, ES, NL, SE, UK participants)

*** Registration of new Selected Seed Stands or Qualified Seed Orchards:**

generally done by State authorities (except in DK)

FR, ES	No cost
AU	Cost: small fee
BE	For new Selected Seed Stands or Orchards, no cost for registration but an inspection is needed by the INBO (Institute of Nature and Forestry Research).
CZ	Costs for seed stand and qualified orchards: EUR 20/hour and travel costs. Registering of identified source is for free.
DE	Variable from Land to Land, e.g. EUR 150-200 in Lower Saxony.
HU	EUR 120/stand plus a sliding fee scale from EUR 10-100 depending on stand size
UK	£70 to inspect, no cost of registration
SE	EUR 1000/hour for registration

*** Inspections during collection**

	Number of inspections
DK, IE	1-2
AU, UK	1 – 3
CZ	Minimun two
FR	1 inspection at the collection. 1 inspection for certification
BE, ES	1 inspection every day of collection and per seed stand
DE	Some collections are controlled daily, some only as spot check. Before collection, the possibility of doing a collection should get checked.
NL	1-5 depending upon species and crop

HU	Not specified but they take place
SE	**Normally no inspection during collection**

	Cost for supervising seed collection
AU, CZ, ES, FR, IE, UK	No cost for nurseries
DE	Variable among Landers
HU	EUR 40 plus EUR 10 Euros for each specified quantity of seed collected / 1000 kg Quercus, 100 kg Robinia, 50 kg Fagus, 10 kg Salix, Populus, 1000 kg cones of any species.
NL	EUR 88/hour (accounted by half hours) for any inspection made EUR 96 plus travel if outside NL
SE	Included in the yearly fee
DK	EUR 300 Euro each number/origin

*** Master Certificate of provenance/origin for a seed lot**

AU, CZ, ES, FR, IE	No cost
BE	If the seeds are collected for own purpose and if they are sown out in own nursery (no trade), there is no additional cost. The only cost to be paid is EUR 10.5 € for every lot of FRM
DE	Variable among Landers: from EUR 15 to max EUR 300 per certificate
DK	EUR 500 in DK
HU	Sealing carried out by authorities at EUR 100 per batch
NL	basic cost : EUR 45/certificate + additional cost depending upon species and weight collected (Conifers EUR 15/kg, Oak/Sweet chestnut EUR 0.75/kg, Beech/other broadleaves collected green EUR 1.4/kg, Other broadleaves collected dry EUR 3.0/kg, Alder/Birch EUR 15/kg) If an FRM species is sown for non-forestry purposes a fee of EUR 45 is charged for the certificate “not for forestry use”
SE	inclusion in the annual fee

*** Inspection of seed companies, nurseries**

	Number of inspections
AU, CZ, DK, HU	Once a year
IE	One to two
BE	+/- 20 times a year
DE	Variable among Landers and upon the size of the enterprise: from several times a year until once every 5th year.
ES	Forest nurseries: minimum of 2 times/year
FR	Every 2 weeks
NL	1-5 depending upon crop
SE	Not every year
UK	Some every year some less frequently

	Cost for inspections
AU, CZ, DE, ES, FR[54], IE, UK	No cost
BE	Fixed cost of EUR 52.50 + EUR 105.00 for suppliers of FRM + EUR 10.5 for every lot of FRM (yearly cost)
DK	one for nursery and one for Seed company + EUR 100-125/hour according to number of FRM plants
HU	Annual charge EUR 40 plus sliding scale 50-100 (thousands of seedlings or transplants) EUR 90 100-200 -> EUR 100 700-800 -> EUR 300 200-300 -> EUR 130 800-900 -> EUR 330 300-400 -> EUR 170 900-1000 -> EUR 370

[54] FR: a fee is paid in the context of the deliverance of the phytosanitary passport

	400-500 -> EUR 200 1000-1500 -> EUR 420 500-600 -> EUR 230 1500-2000 -> EUR 470 600-700 -> EUR 270 2000-2500 -> EUR 570 above 2500 000 -> EUR 200/each million. For conifers you pay only the 50% of the amounts above.
NL[55]	Every business selling FRM has to pay a minimum fee of EUR 200 which includes the first 0.5ha of the nursery or first EUR 5000 of turnover. + sliding scale based which varies from EUR 1610/ha for nurseries 0.5-1 ha in size to a charge of EUR 1811.16 + EUR 490/ha for nurseries over 20 ha. Nurseries can choose to pay according to turn-over rather than area for three year periods; the rate is about 1.5% of gross turn-over. If a nursery has to be re-checked due to some irregularity, a levy of 96 Euros on top of the normal EUR 88 hourly rate is charged. Standard fee of EUR 17.5/ batch of FRM grown/inspected. + proposal for an additional inspection charge of EUR 0.20/1000 plants for nurseries with more than 10,000,000 plants to EUR 0.5/1000 plants up to one million plants
SE	Yearly fee: company who sells and/or produces more 10000 plants has to pay EUR 1428 (13000SEK); other EUR 493 (4500SEK) + EUR 659 (6000 SEK)/visit

	Proportion for document and stock looking
AU, SE, CZ	Variable
BE, IE	80% administration, 20% looking at stock
DE, UK	90% books; 10% field
DK, FR, ES	50 % of each

*** quantity of seed sown, number of plants produced and sold**

	Methods
AU	seed lot samples stored at the "Federal office of Forests" for comparison

[55] NL: charge per plant passport of 0,08€ and suppliers document of 7,50€

BE	seed lot number estimated according to seed viability and field germination
CZ.	Forest research institute: table with theoretically plant numbers produced from 1 kg of seed for forestry species. All batches should have analysis and every year every FRM nursery has to send stocktaking and amount of sold stock to Forest management institute.
DE	Germination % test from the seeds and % lost during production.
ES	number of plants in some samples during the growing season inspection
FR	Germination controlled once a year and surviving plants after transplanting; numbers of saleable plants are checked on beds before lifting.
SE	Correlation between the amount of seed sold per master certificate and of produced plants
UK	Audit trial
	Audit for seeds or plants sold over more than one year
AU, BE, CZ, DE, DK, FR, ES, SE, IE	Yes
AU	Notice to the authority, punishment
BE	no possibility to sell more plants than estimated once the field inspection took place
CZ	Fine up to EUR 40 000
DK	Added control / inspection and punishment by losing rights to sell FRM plants.
FR	Warning system: eventual destruction + legal action against the nurseryman
ES, SE, UK	?

The French Organisations for Forest Seeds and Nursery

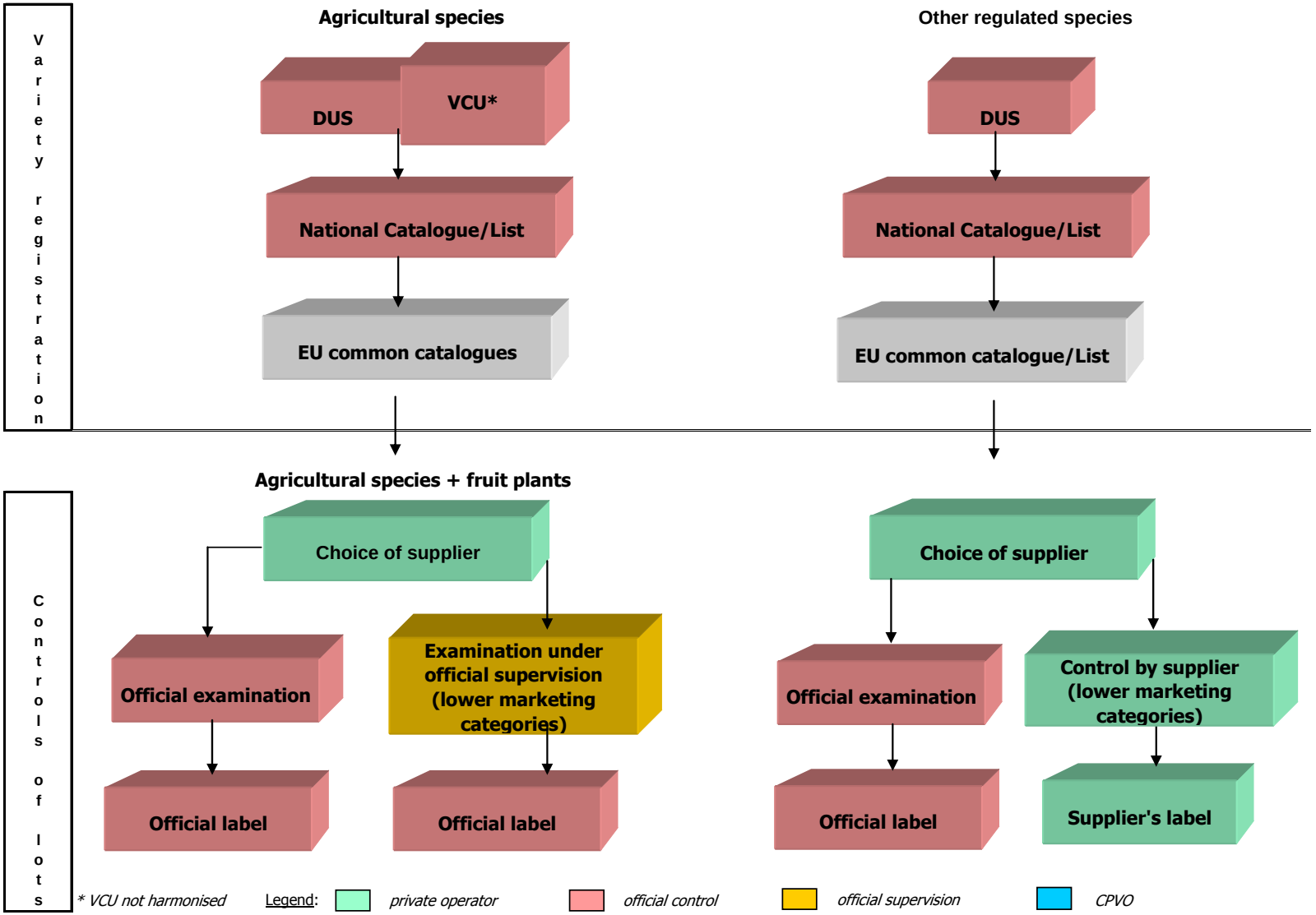
GIE Improved Forest Seeds: harvesting 1 ton of certified seed of seed orchards. It combines the Vilmorin private Company and the ‘’Office National des Forêts’’.

*French Forest Nursery (*nursery growers and poplar producers): 80% of French production of seedlings (60 million in 2008-2009).

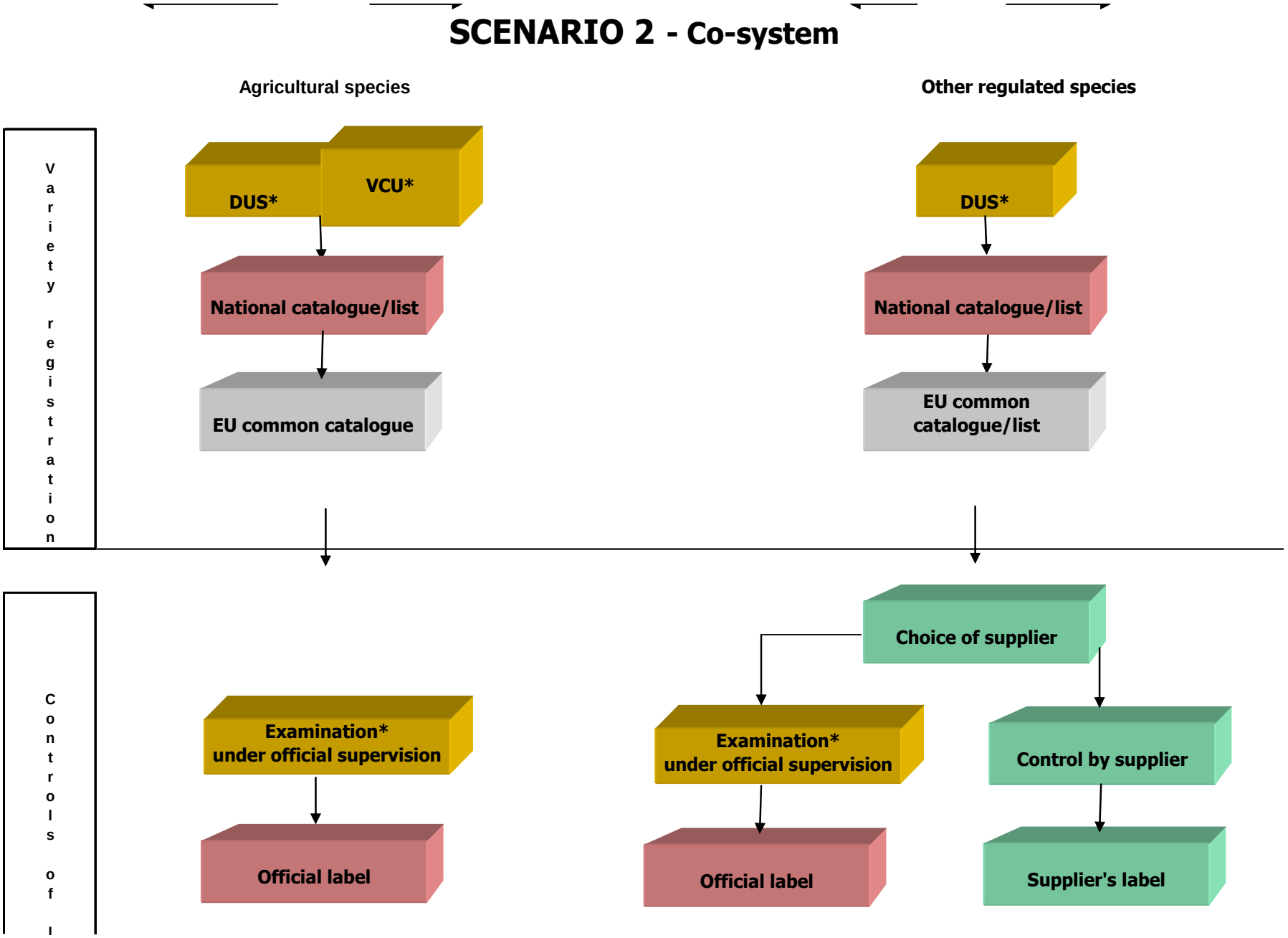
8. **THE FOREST NURSERY ASSOCIATION OF THE CZECH REPUBLIC: 76 MEMBERS MANAGING 1.400 HA OF FOREST NURSERIES, I.E. ABOUT 90% OF TOTAL CZECH FOREST SEEDLING PRODUCTION AREA.**

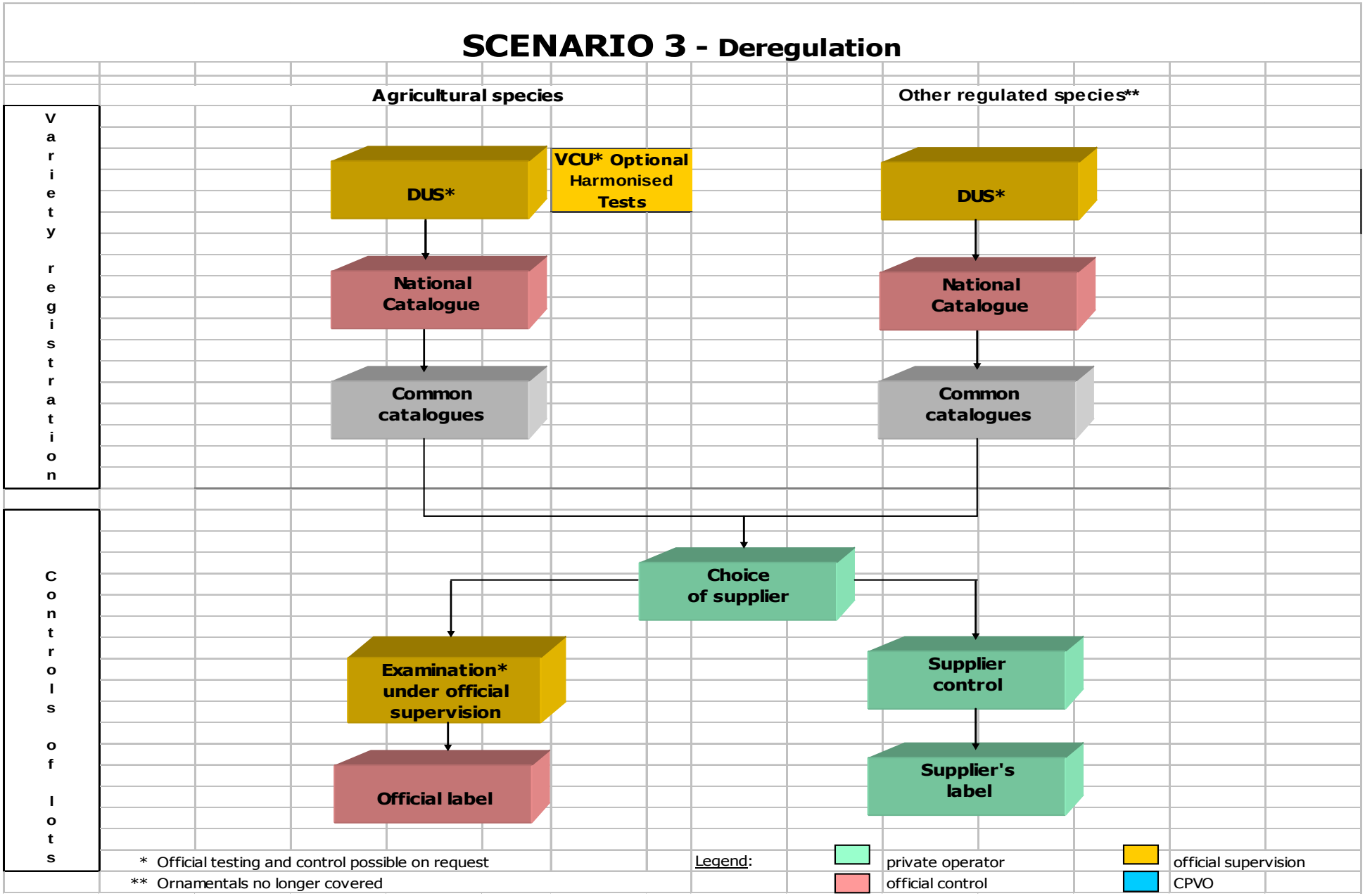
ANNEX XI: GRAPHICAL PRESENTATION OF THE FIVE SCENARIOS

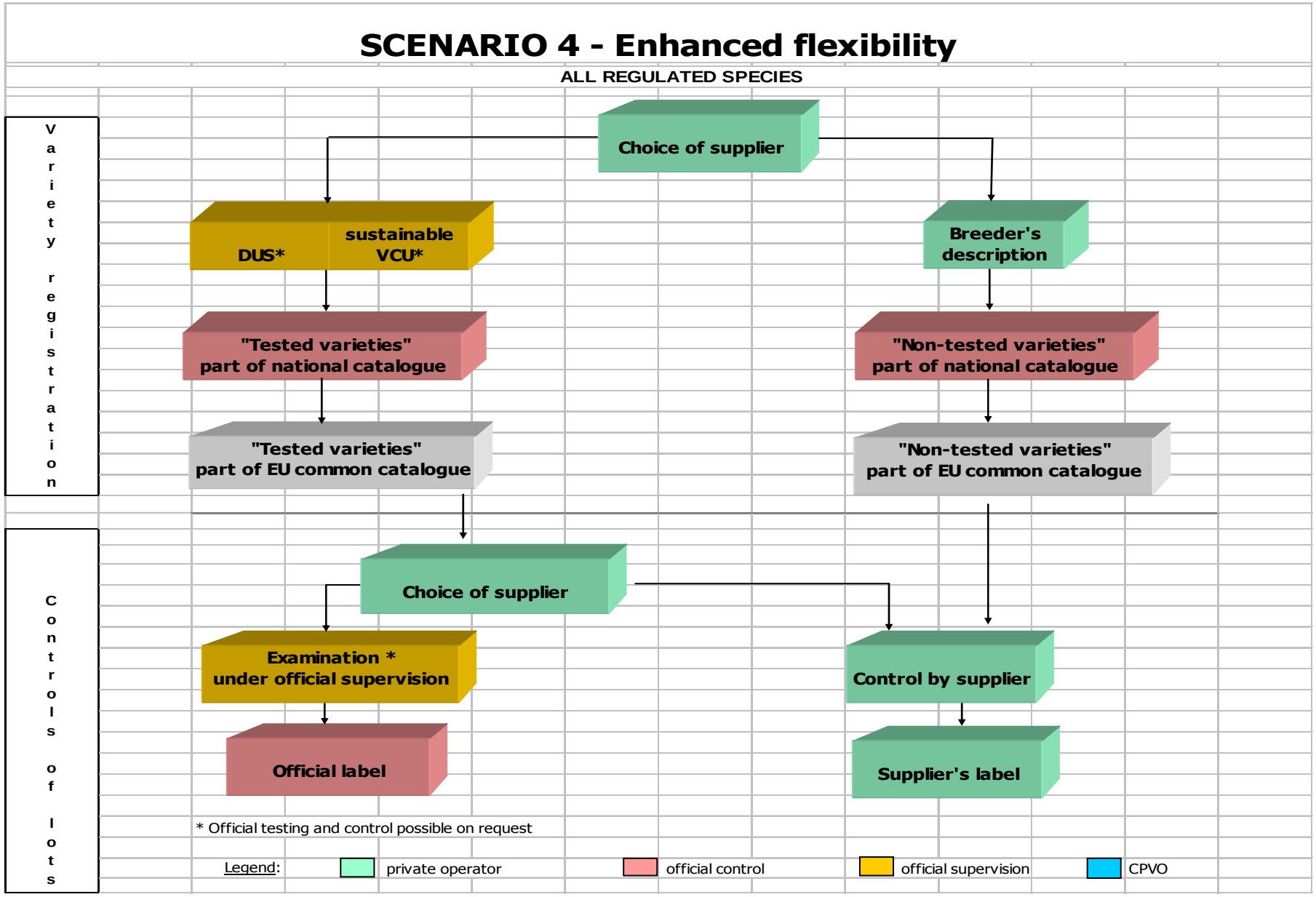
SCENARIO 1 - Cost recovery



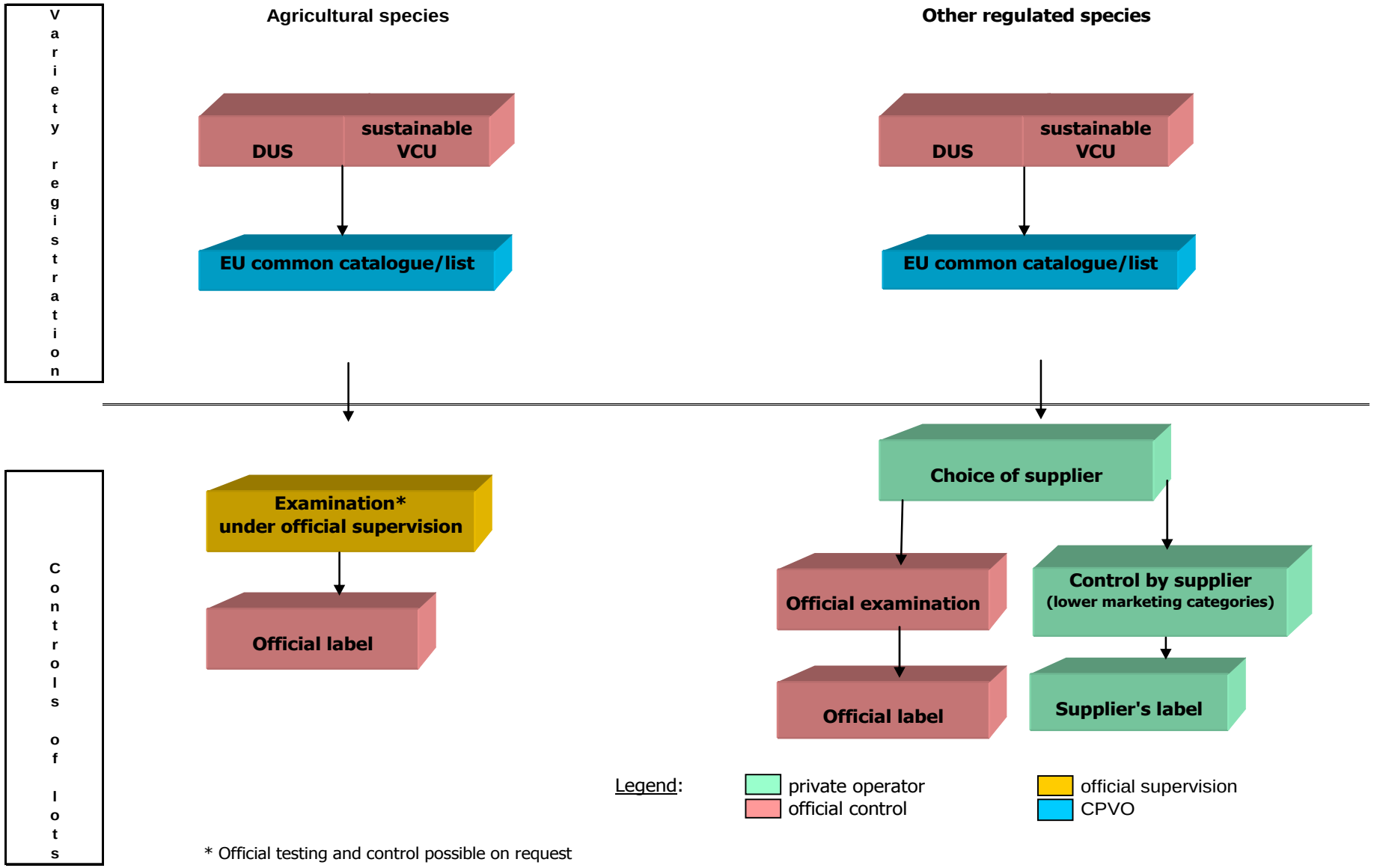
SCENARIO 2 - Co-system




SCENARIO 3 - Deregulation
Agricultural species
Other regulated species**
Variety registration
Controls of lots
DUS*
VCU* Optional Harmonised Tests
National Catalogue
Common catalogues
DUS*
National Catalogue
Common catalogues
Choice of supplier
Examination* under official supervision
Official label
Supplier control
Supplier's label
* Official testing and control possible on request
** Ornamentals no longer covered
Legend:
private operator
official control
official supervision
CPVO


SCENARIO 4 - Enhanced flexibility
ALL REGULATED SPECIES
Variety registration
Controls of lots
Choice of supplier
DUS*
sustainable VCU*
Breeder's description
"Tested varieties" part of national catalogue
"Non-tested varieties" part of national catalogue
"Tested varieties" part of EU common catalogue
"Non-tested varieties" part of EU common catalogue
Choice of supplier
Examination * under official supervision
Official label
Control by supplier
Supplier's label
* Official testing and control possible on request
Legend:
private operator
official control
official supervision
CPVO

SCENARIO 5 - Centralisation



* Official testing and control possible on request

ANNEX XII: VARIETY REGISTRATION AND SEED CERTIFICATION SYSTEMS IN MAJOR THIRD COUNTRIES

AUSTRALIA – Variety registration and seed certification

The Australian Seeds Authority (ASA) is responsible for supervising the implementation of both the OECD and the Australian Seed Certification Schemes in relation with harmonised technical standards and quality control procedures for the production, processing and labelling of certified seed. To meet this obligation ASA has commissioned the National Association of Testing Authorities (NATA), as an independent authority for the accreditation of inspection bodies, to implement a national accreditation scheme for certification agencies. NATA accreditation of Plant Laboratories requires compliance with the international quality management systems standard ISO/IEC 17020.

To be eligible for certification under the OECD or Australian Seed Certification Schemes a variety must be listed with ASA. ASA is responsible for maintaining and publishing a national list of varieties which have been accepted in Australia as eligible for certification in the OECD and Australian Seed Certification Schemes.

Additional information on the variety must accompany the application for listing. A statement detailing the origin and breeding history of the variety, a morphological description of the variety, a statement of authorisation from the breeder (if the applicant is not the breeder) to apply for certification and to multiply the variety in Australia, a brief statement of the expected agronomic value of the variety in Australia, and a maintenance plan indicating the number of generations and the number of harvests allowed for each generation, are required.

DUS: Evidence must be provided on the uniformity and stability of the variety having regard to the species concerned and the breeding system used. It must be indicated the period over which the generations of seed multiplication have been observed as being uniform and stable. If off-types have been observed, their frequency must be stated and a description of them supplied. A detailed morphological description of the variety is required. Comparative information with other varieties of the same species currently in use should be included.

VCU: There are no standards for agronomic value but applicants must indicate the anticipated agronomic value of the variety in Australian agriculture relative to other commonly grown varieties.

The applicant must provide details of the maintenance plan adopted for the production of Pre-Basic, Basic and Certified Seed. The Variety Maintainer is responsible for ensuring that multiplication of Breeders and Pre-Basic Seed is carried out in a satisfactory manner so that only authentic, uncontaminated seed of the variety is released for further multiplication under the certification schemes.

ASA must have access to all records of maintenance of varieties in the certification schemes. The Maintenance Plan should also indicate whether or not a certification agency will be overseeing and assisting with the production of Pre-Basic Seed; this collaboration is encouraged as it can often result in the identification and correction of any varietal purity issues prior to larger scale production of Certified Seed.

ASA also co-ordinates official Australian interaction with the International Seed Testing Association (ISTA) on international seed testing policy and practice, and has signed Authorisation Agreements with four ISTA-accredited laboratories to test certified seed prior to its final release as certified seed.

CANADA – Variety registration and seed certification

The Canadian Food Inspection Agency is responsible for the administration of the **Seeds Act** and **Regulations** to help to ensure that seeds sold in, imported into and exported from Canada meet established standards for quality and are labelled so that they are properly represented in the marketplace, and are registered prior to sale in Canada (most agricultural crop varieties). **In 2009,** amendments to the **Seeds Regulations** were introduced in order to increase the flexibility of the variety registration system. This is accomplished by dividing the list of all crop kinds that require variety registration, into three parts with three levels of registration requirements. For all parts, basic variety registration information continues to be required, including information demonstrating conformity with minimum health and safety standards, information confirming the identity of new varieties, information supporting the verification of claims, and information required for seed certification purposes.

Part I (**status quo**): The registration of new varieties requires pre-registration testing and merit assessment to determine whether the variety performs as well as or better than reference varieties (Merit assessment VCU). This part is intended for crop kinds for which there is a continuing need for government oversight to ensure that varieties meet standards.

Part II: The registration of new varieties requires pre-registration testing, but not merit assessment. This part is intended for crop kinds where official oversight to confirm the validity of pre-registration testing data is useful, but where merit assessment is burdensome.

Part III: New varieties are subject to only basic variety registration requirements.

Seed crop certification is a program of planned production, record keeping, inspections, and standards to ensure the production of high quality seed. Certified is labelled with an official blue certified tag (or bulk pedigreed certificate) and graded with a Canada pedigreed grade name when sold in Canada. The pedigreeing of seed ensures varietal purity. This is especially important to maintain yield, quality, disease resistance and the other distinguishing characteristics of a variety. There are 3 categories: (i) Breeder Seed from plant breeders of public research institutions and private companies, (ii) Foundation Seed produced from Breeder seed and rogued for off-types to meet variety descriptions and

purity standards, (iii) Certified Seed produced from Foundation seed by seed growers for sale to farmers to use in planting their commercial grain acreage. Seed certification is performed for seed growers and processors dedicated to taking the extra steps necessary in planting, harvesting, handling, storage, and conditioning to produce Certified seed.

NEW ZEALAND - Variety registration and seed certification

The New Zealand Seed Certification Scheme operates on a voluntary basis**.** The scheme aims at providing the consumer with seed of high varietal purity but gives no guarantee of this other than to certify that an acceptable procedure has been followed to attain this goal. It gives no warranty as to the germination of the seed but requires a minimum standard of physical purity.

There are four main classes in certification:

- Breeders Seed (Pre-Basic): Produced from nucleus material grown by the plant breeder.
- Basic Seed: Produced from areas sown with Breeders seed. It is produced by selected growers under the supervision of the breeder or his agent.
- Certified Seed 1st Generation: Produced from areas sown with Basic seed and is traded freely both in New Zealand and overseas.
- Certified Seed 2nd Generation: Produce from areas sown with certified seed 1st Generation and applies to certain arable crops only. (See under standards for varieties).

Any merchant, exporter and seed cleaning operator involved in seed certification must have a MAFB NZ approved organisation system detailing their operating procedures.

A grower must be registered with the SCB to be eligible to grow certified seed. Applications for certification of proprietary varieties cannot be accepted from growers who do not hold a contract or agreement with the owner of the variety.

A seed variety must be registered with the SCB for it to be eligible for certification.

The variety registration conditions for the Acceptance of Agricultural Varieties (Arable and Herbage) into the New Zealand Seed Certification Scheme) are the following:

DUS: Evidence must be provided of the uniformity and stability of the variety having regard to the species concerned and the breeding systems used. An acceptable way of providing this evidence would be to indicate the period over which the generations of seed multiplication have been observed as being uniform and stable. If off-types have been observed, state their frequency and supply a description of them. A morphological description of the variety is required. Comparative information with other varieties of the same species currently in use should be included.

VCU: There are no standards for agronomic value but applicants are required to indicate the anticipated use or place in New Zealand agriculture.

In addition, NZ puts strong regulation for the importation of seeds:

- Biosecurity Act 1993
- Hazardous Substances and New Organisms Act 1996 (HSNO Act 1996)
- MAF Biosecurity Standard PBC-NZ-TRA-PQCON: Specification for the Registration ofa Plant Quarantine or Containment Facility, and Operator.

UNITED STATES OF AMERICA - Variety registration and seed certification

Seed certification in the United States is the responsibility of each individual state; within each, there is an agency designated to certify seed.

Certification programs in the United States are generally non-profit programs, but must generate funds to cover salaries, overhead, and operating expenses.

A four generation scheme has been devised to do this:

1. **Breeder seed** is produced under the direct supervision or authorization by the plant breeder and represents the true pedigree of the variety.

2. **Foundation seed** is the first generation seed from breeder seed and is produced under contract by a foundation seed organization as authorized by the plant breeder. Foundation seed is also labelled with white certification tags.

3. **Registered seed** is the seed from foundation seed and is intended for the purpose of increasing seed another generation before the production of certified seed. Registered seed is not intended to be a commercial class of seed. In two states (Michigan and Wisconsin), all certified seed is the progeny of foundation seed, and no registered class is used.

4. **Certified seed** is produced from foundation or registered seed and represents the final product of the certification program.

Varietal Release

To be eligible for certification, a variety must be properly released, named, and described. Regardless of the releasing agency, a procedure must be available for evaluating potential varieties and recommending their release. When plant breeders have a candidate for release, they submit to the appropriate review board a description of their variety, its identifying characteristics, and performance data.

To help clarify this situation, an ad hoc committee representing the USDA, the Association of Official Seed Certifying Agencies, the American Society of Agronomy, and the

American Seed Trade Association[56], has developed a comprehensive consensus definition of different kinds of varieties.

Individual certification agencies are aided in determining the eligibility of varieties for certification by national variety review boards which have been established by AOSCA. Four review boards have been established representing alfalfa, grasses, soybeans, and small grains.

However, in actual practice, many individual agencies still require varieties to meet adaptability and performance standards established for their particular state.

[56] The Association of Official Seed Certifying Agencies (AOSCA) is an organization of certification agencies in the United States, Canada, and New Zealand. Its purposes are: (1) to establish minimum standards for genetic purity and recommend minimum standards for the classes of certified seed. (2) to standardize seed certification regulations and procedures. (3) to encourage cooperation with all individuals, agencies, groups, and organizations to accomplish these purposes, and (4) to assist its member agencies in seed promotion, production, and distribution.

ANNEX XIII: DETAILED PRESENTATION OF THE MEASURES INCLUDED IN THE PREFERRED OPTION

General principles

- Cost recovery for services carried out by competent authorities. Exemptions are possible depending on the degree of public interest in the respective variety's marketing. The latter exemption will mainly affect conservation varieties.

- Operators can carry out, under official supervision by the competent authority, as many activities as possible for themselves. Official examination or inspection services shall always be available in case that operators do not possess the resources to carry out these tasks.

- All operators have to be registered.

- Specific and strict obligations concerning registration and certification shall apply to a closed list of species. General minimum requirements shall apply to all other PRM on the market and shall cover labelling obligations and a provision of fitness for use.

- Inspections for plant health and certification shall be combined.

- Forest reproductive material: Following the Impact Assessment and the stakeholder consultation the basic approach on FRM identification and certification will not be changed and official controls will be maintained. A separate chapter in the proposed Regulation is dedicated to FRM.

Specific provisions

Variety registration: DUS technical examination

- CPVO holds a database with the description of all these varieties.

- CPVO audits the national examination offices for a full harmonisation of DUS examination.

- The possibility is offered to the private sector to carry out DUS and VCU technical examination.

- Support the extension of bilateral agreements in order to facilitate the flow of DUS reports in the EU.

- Have a same and unique DUS testing for registration of varieties with a view to market and for Community Plant Variety Rights protection (‘*one key- several doors’* approach).

- The registration of officially tested varieties in national and common registers shall be an option that is given to conservation and amateur varieties for reasons of public good. The listing of this latter group shall be based on an officially recognised description by the breeder.

- Quantitative restrictions for the marketing of conservation varieties shall be abolished.

- National catalogues shall continue to exist. Inclusion in the National catalogue will be the only precondition for the marketing throughout the EU for all crops.

- CPVO shall take over practical arrangements for the publication of the EU common catalogues as a database.

- CPVO verifies denominations for all applications.

- As an alternative to national registration, centralised variety registration by CPVO shall be offered for species that do require to undergo VCU-evaluation.

Variety registration: VCU evaluation

- VCU shall be maintained and shall be decided on a species-by species basis. VCU criteria shall focus more on public goods and become a “VCU for sustainability and health”.

- VCU shall be continuously improved as much as possible to take care of any evolution of public and private needs. Harmonisation of VCU protocols is most likely to be practical and useful across agro-ecological regions. Coordination between Member States of official observations and national decisions for VCU, possibly under bilateral agreements, should be encouraged.

- VCU should be a set of species-specific endorsed information made as widely available as possible to users of PRM.

- At the EU level, a high level group including all relevant stakeholers shall be established for providing policy guidance on variety registration.

Certification/inspection of lots

- Mandatory certification of lots of certain crops shall be maintained. The list of species that have to be covered by this obligation shall be determined on a crop-by crop basis to allow for future changes in, for example, health risks or economical importance.

- The examination under official supervision shall be widened to all species and all categories (i.e. basic and pre-basic crops).

- "Reference Certification Centres" shall be established to develop, harmonise and disseminate best practices in PRM certification.

ANNEX XIV: COST STRUCTURE OF REGISTRATION AND CERTIFICATION FOR SEED

Variety registration

The major costs centres identified are:

- Pre-registration costs: costs related to the production of preliminary data on the main characteristics of the variety and administrative costs for applications preparation and submission.

- Registration costs: DUS and VCU management costs, for each the following sub-costs centres:

- Technical and administrative management of demands
- Planning of experimentation
- Reception and disposal of materials
- Conducting of experimentation
- Networks management and co-ordination
- Trials approval including field visits
- Validation and treatment of data
- Maintenance of reference collections
- Costs related to the administrative management of approved varieties, i.e. denomination and publications

Post-registration costs:

- Costs for the examination of the maintenance of varieties.

Certification: The Seed Directives allow the sampling and testing of all categories of seed and the field inspection of certified seed to be carried out either officially (certification under official examination) or under official supervision (certification under official supervision). The structure of costs varies accordingly and the major costs centres identified are:

- Certification costs under official supervision
  - Registration of operators, testing laboratories and staff belonging to the operators or companies by certification authority
  - Field inspection by trained and competent staff
  - Seed lot sampling and seed sample testing by trained and competent staff
  - Labelling of packages, containers by trained and competent staff
- Certification costs under official examination
  - Registration of operators, testing laboratories by certification authority
  - Official inspection of production

- Official lot sampling and sample testing
- Official labelling packages, containers

- Post-labelling test
  - Official post-control examination of varietal identity and purity
  - Official recording of control by certification authority
  - Official control of marketing

- Other
  - Granting of equivalence for importation of PRM from third countries
  - Comparative trials

The total costs for the 8 Member States are estimated at around EUR 82.5 million per year. As these 8 Member States represent about 70% of the EU market value, by extrapolation to all Member States, the total registration and certification costs for competent authorities for the group **'Seed'** can reasonably be estimated to around EUR **120 million**[57] **per year** (in reality vary +/- 10%).

Table 1 - Total annual registration and certification costs – All seed crops

National Authorities	Variety registration costs					Certification costs				
MS	Pre-registration costs (K.EUR)	DUS costs (K.EUR)	VCU costs (K.EUR)	Post-registration costs (K.EUR)	Total variety registration costs (K.EUR)	Certification under official examination (K.EUR)	Certification under official supervision (K.EUR)	Post-certification costs (K.EUR)	Total certification costs (K.EUR)	Total costs (K.EUR)
AT	22	187	4.442	50	4.700	1.377	201	338	1.916	6.617
BE		30	700	80	810	1.250		400	1.650	2.460
DE		6.699	7.812	36	14.547	8.328	930	2.412	11.670	26.217
DK		716	730	92	1.538	4.004	694	450	5.148	6.687
FR		5.194	5.400		10.594	3.871	9.684	769	14.324	24.918
IT		597	801		1.398	5.534	98		5.632	7.030
SE	17	64	244	28	352	1.958	90	159	2.207	2.559
UK	383	1.153	145		1.681	2.842	1.078	467	4.387	6.068
Total	422	14.640	20.274	285	35.621	29.165	12.775	4.994	46.934	82.555

FP: Fodder Plant, C: Cereal, B: Beet, VG: Vegetable Seed, P: Potatoes, OF: Oil and Fibre plant.
A GBP/EUR conversion rate of 1,4187 (April 2007-March 2008) has been used for the costs estimated by UK

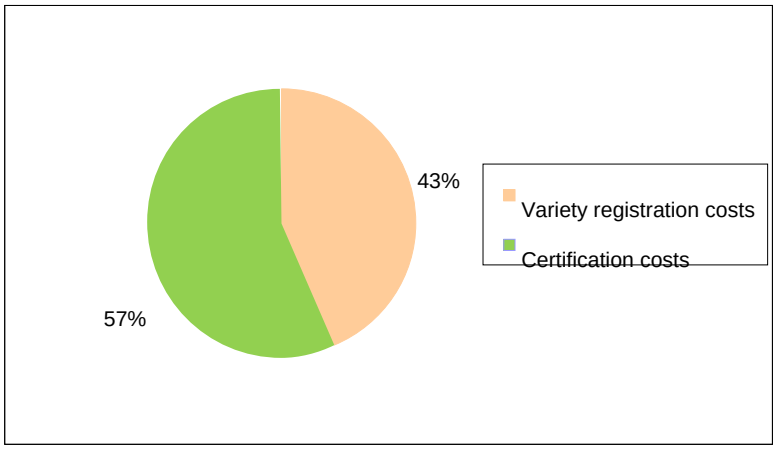
Based on the figures for the overall costs of implementation of the Community legislation and on the statistics addressing the domestic seed market value, a ratio Costs/Market Value has been calculated concluding that implementation of the Community legislation costs for

[57] 117.94 million EUR = 82.555 million EUR/0.7

competent authorities represents **2.8% of the domestic market value** (on average on the major seed markets in the EU, variability from e.g. IT just over 1% to e.g. AT nearly 7%)

The **registration and certification costs** respectively represent **43% and 57% of total annual costs** incurred by the national authorities of the 8 Member States considered for the analysis (caveat see above).

Graph 1 - Distribution between registration costs and certification costs for national authorities



Registration

Seed registration costs represent around **1.3%** of the sum of the values of the domestic commercial market for seed of 19 selected EU Member States (FR, DE, IT, UK, PL, ES, NL, HU, DK, SE, AT, CZ, GR, BE, SK, FI, IE, PT, SI). Some Member States have transferred totally or partially the registration costs to the industry.

Table 2 – Current distribution of seed registration costs between public and private bodies in the Member States

MS	Transfer of registration costs	Additional information
AT	-	Not available
BE	Yes	Partial transfer of costs (around 50% of DUS and VCU costs)
BG	No transfer of DUS costs, partial transfer of VCU costs	
CY	Yes	Partial transfer of costs (around 50% of DUS and VCU costs)
CZ	Yes	Partial transfer of costs (between 70% and 80% of DUS and VCU costs)

DE	Yes	Partial transfer of costs (around 50% of DUS and VCU costs)
DK	Yes	Full transfer of DUS and VCU costs (100%)
EE	Yes	Full transfer of DUS and VCU costs (100%)
ES	Yes	Partial transfer of costs
FI	Yes	Full transfer of DUS and VCU costs (100%)
FR	Yes	Partial transfer of costs (around 2/3 of DUS and VCU costs are transferred to the industry)
GR	Yes	Partial transfer of costs
HU	No	
IE	No	
IT	Yes	Full transfer of DUS and VCU costs (100%)
LT	No	
LU	Yes	Partial transfer of costs
LV	No	
MT	No	
NL	Yes	Full transfer of DUS and VCU costs (100%)
PL	Yes	Partial transfer of costs (around 25 to 30% of DUS and VCU costs)
PT	Yes	Partial transfer of costs
RO	No	
SE	Yes	Full transfer of DUS and VCU costs (100%)
SI	Almost no DUS testing performed in Slovenia, around 70% of VCU costs are transferred	
SK	Yes	Partial transfer of costs (around 70% of VCU costs)
UK	Yes	Full transfer of DUS and VCU costs (100%)

Source: compiled on the basis of the data provided in the qualitative and the cost questionnaire

Total variety registration costs

The total costs incurred by the national authorities vary in each Member State and can be grouped into 3 groups as regards the category 'all seed crops', by taking into consideration the annual number of DUS and VCU applications received as well as the estimated value of the domestic market share of each Member State:

Table 3 – Grouping of Member States by based on the total variety registration costs, the annual number of DUS and VCU applications received and the estimated value of the domestic market size

MS	Crops	Annual number of DUS applications received	Annual number of VCU applications received	Estimated value of the domestic market size (EUR million)	Total variety registration costs (K. EUR)
FR	All seed crops	1150	900	1396.1	10.594
DE	All seed crops	800	700	974.0	14.547
AT	All seed crops	546	675	97.4	4.700
IT	All seed crops	1790	1240	649.4	1.398
DK	All seed crops	300	317	162.3	1.553
UK	All seed crops	468	420	259.7	1.681
SE	All seed crops	115	111	155.8	352
BE	All seed crops	50	156	123.4	810

Cost per applicant

The following table presents the annual number of DUS and VCU applications received by the national authorities having responded to the costs questionnaire and the registration costs per application.

Table 4 –Annual number of DUS and VCU applications received by the national authorities

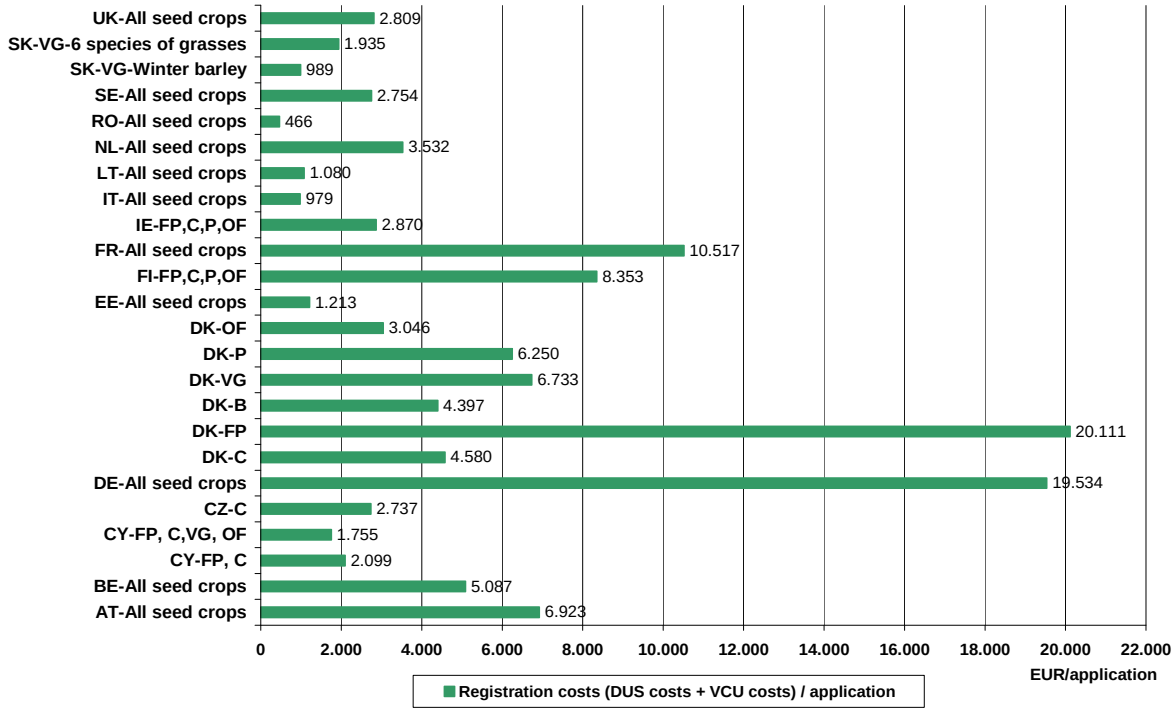
MS	Crops	Annual number of DUS application received	Annual number of DUS application received per country	Annual number of VCU application received	Annual number of VCU application received per country
AT	All seed crops	546	546	675	675
BE	All seed crops	50	50	156	156
CY	FP, C	8	19	8	16
CY	FP, C,VG, OF	11		8	
CZ	C	78	78	78	78
DE	All seed crops	800	800	700	700
DK	C	116	300	176	317
DK	FP	10		9	
DK	B	49		47	
DK	VG	6		0	
DK	P	0		4	
DK	OF	119		81	
EE	All seed crops	65	65	65	65
FI	FP,C,P,OF	54	54	110	110
FR	All seed crops	1150	1150	900	900
IE	FP,C,P,OF	6	6	307	307
IT	All seed crops	1790	1790	1240	1240
LT	All seed crops			200	200
NL	All seed crops	950	950	160	160
RO	All seed crops	854	854	516	516
SE	All seed crops	115	115	111	111
SK	VG-Winter barley	325	650	275	550
SK	VG-6 species of grasses	325		275	
UK	All seed crops	468	468	420	420

Total DUS 7895 ***Total VCU 6521***

FP: Fodder Plant, C: Cereal, B: Beet, VG: Vegetable Seed, P: Potatoes, OF: Oil and Fibre plant.

The registration costs per application for national authorities are (DUS and the VCU costs, without pre-and post-registration costs):

Graph 2- Registration costs per application for national authorities



FP: Fodder Plant, C: Cereal, B: Beet, VG: Vegetable Seed, P: Potatoes, OF: Oil and Fibre plant.

The annual **variety registration costs** estimated by associations of suppliers. These costs can concern one or several crops. These costs are not representative of the total costs for the private operators in the Member States concerned, as they are rough estimations not based on detailed accounting system.

Table 5 - Total annual variety registration costs per Member State and crop for private operators

MS	Crops	Annual budget figures	Pre-registration costs (K.EUR)	DUS cost (K.EUR)	VCU costs (K.EUR)	Post-Registration costs (K.EUR)	Total costs (K.EUR)
DK	C	2007	150	340	300	300	1.090
FR	VG	2007		993		507	1.500
FR	OF	2005/2006		450	550	150	1.150
FR	C	2007/2008	1.000	950	1.150	300	3.400
IT	All seed crops	2006/2007		620	780		1.400
PL	All seed crops	2007		190	238		428

FP: Fodder Plant, C: Cereal, B: Beet, VG: Vegetable Seed, P: Potatoes, OF: Oil and Fibre plant.

Certification

Seed certification costs represent between **1 and 2% of the total production costs**. Seeds produced in the EU have a high quality, so that the original '*quality*' objective of certification can be considered as largely achieved. Currently, in most of the Member States, the focus tends to be on reducing the certification costs while maintaining the same level of quality for seed.

Certification costs for **competent authorities represents 57% of the total costs** linked to the implementation of the Community legislation and represents about 1.7% of the sum of the sizes of the internal commercial market for seed of the 8 selected EU Member States (FR, DE, IT, UK, DK, SE, BE, and AT).

Table 6 – Current distribution of seed certification costs between public and private bodies in the Member States

MS	Certification costs are transferred to industry	Additional information
AT	Yes	Partial transfer of costs
BE	Yes	30% of costs are transferred to the industry
BG	Yes	Partial transfer of costs
CY	Yes	Partial transfer of costs
CZ	Yes	Partial transfer of costs
DE	Yes	Between 30% and 70% depending on the Federal Land concerned
DK	Yes	Full transfer of costs (100%)

EE	Yes	Partial transfer of costs
ES	Yes	Partial transfer of costs
FI	Yes	Full transfer of costs (100%)
FR	Yes	97% for seed, 65% for vine
GR	Yes	The fee = (reference price) x (certified quantity) x 3%. The rate of the reference price is fluctuating between the farmer's price and the final selling price of the seed.
HU	Yes	Full transfer of costs (100%)
IE	Yes	Partial transfer of costs
IT	Yes	Full transfer of costs (100%)
LT	Yes	8% is financed by private sector
LU	Certification is mostly financed by national authorities	
LV	Yes	Partial transfer of costs
MT	No	
NL	Yes	Full transfer of costs (100%)
PL	Yes	Full transfer of costs (100%)
PT	Yes	Full transfer of costs (100%)
RO	Yes	
SE	Yes	Full transfer of costs (100%)
SI	Yes	
SK	Yes	
UK	Yes	70-80 of costs transferred to the industry and target of 100%

Source: compiled on the base of the answers provided to the cost questionnaire and by official authorities to the preliminary questionnaire.

The annual certification costs incurred by the **national authorities** can concern one or several crops.

Table 7: Total annual certification costs per Member State and crop for national authorities

Countries and Crops	Annual budget figures	Costs of certification under official examination (K.EUR)	Costs of certification under official supervision (K.EUR)	Post-certification costs (K.EUR)	Total certification costs (K.EUR)
AT-All seed crops	2007-2008	1.377	201	338	1.916
BE-All seed crops	2007	1.250		400	1.650
CZ-C	2007	393	29	132	554
DE-All seed crops	2007	8.328	930	2.412	11.670
DK-FP,C,B,VG,OF	2007	2.873	626	450	3.948
DK-P	2007	1.131	69		1.200
EE-FP, C, VG, OF	2007	180	11	2	193
FI-FP,C,P,OF	2007	1.897	10	65	1.972
FR-FP, C, B, P, OF	2006-2007	3.871	9.684	769	14.324
IE-FP,C,P,OF	2007	3.040		207	3.248
IT-All seed crops	2008	5.534	98		5.632
LT-All seed crops	2007	64		26	90
SE-All seed crops	2008	1.958	90	159	2.207
SK-All seed crops	2007	610	22	32	664
UK-P	2007-2008	2.388			2.388
UK-FP, C, B, OF	2007-2008	455	1.078	467	2.000

FP: Fodder Plant, C: Cereal, B: Beet, VG: Vegetable Seed, P: Potatoes, OF: Oil and Fibre plant.

Four main cost centres have been considered per certification structure:

- Registration of companies and seed-testing laboratories;
- Official field inspection;
- Official seed lot sampling and testing;
- Official labelling of lots.

The following table presents the annual certification costs estimated by the responding associations of suppliers in the Member States. These costs can concern one or several crops. Each line of the table corresponds to the data provided by one association of suppliers in a Member State. These costs are not representative of the total costs for the private operators in the Member State concerned, as they are rough estimations not based on detailed accounting system.

Table 8 - Total annual certification costs per Member State and crop for private operators

MS and Crops	Annual budget figures	Costs for certification under official examination (K.EUR)	Costs for certification under official supervision (K.EUR)	Post-certification costs (K.EUR)	Total certification costs (K.EUR)
DK-C	2007	1.500	1.450	320	3.270
EE-FP,C,VG,OF	2007	21	6		28
FR-OF	2005/2006		900		900
FR-C	2007/2008		4.775	20	4.795
IT-All seed crops	2006/2007	6.200			6.200
PL-All seed crops	2007	1.850	1.314	310	3.474

FP: Fodder Plant, C: Cereal, B: Beet, VG: Vegetable Seed, P: Potatoes, OF: Oil and Fibre plant.

Total certification costs incurred by the private operators vary in each Member State (e.g.: in Poland: EUR 3.473 K and Italy: EUR 6.200 K).

Under certification under official examination, the two main costly activities for national authorities are seed lot sampling & analysis and field inspections. In most of the Member States, seed lot sampling and analysis represents more than 50% of the total certification costs. Field inspection costs represent in between 20-30% on average. **It should be highlighted that these ratios are quite similar for certification under official examination and certification under official supervision.**