Evaluation of the Community Plant Variety Right *Acquis* - Final Report

GHK Consulting with ADAS UK for

DG SANCO

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DG SANCO

A report submitted by GHK in association with ADAS UK

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Contents

Abbreviations

ABS	Access and benefit sharing
AIPH	International Association for Horticultural Producers
BIPO	Breeders' Intellectual Property Office
BR	CPVR Basic Regulation (EC) No 2100/94
BSPB	British Society of Plant Breeders
CAP	Common Agricultural Policy
CBD	Convention on Biological Diversity
COPA-COGECA	Committee of Professional Agricultural Organisations – General Confederation of Agricultural Cooperatives
CIOPORA	Communauté Internationale des Obtenteurs de Plantes Ornementales et fruitières de Reproduction Asexuée
CPVO	Community Plant Variety Office
CPVR	Community plant variety right
DG SANCO	Directorate General for Health and Consumer Affairs
DUS	Distinctness, uniformity, stability
ECJ	European Court of Justice
ED	Enforcement Directive
EFSA	European Food Safety Authority
EFTA	European Free Trade Association
EDV	Essentially derived variety
EPC	European Patent Convention (Convention on the Grant of European Patents)
EPO	European Patent Office
ESA	European Seed Association
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FSS	Farm saved seed
GATT	General Agreement on Tariffs and Trade
GEVES	Group d'Etude et de contrôle des Variétés et de Semences
GNIS	Groupement National Interprofessionnel des Semences et Plants
IP	Intellectual property
IPR	Intellectual property rights
ISF	International Seed Federation
ISTA	International Seed Testing Association
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
MS	Member States
NCA	National Competent Authority
NGO	Non-governmental organisation
OAPI	African Intellectual Property Organisation
OECD	Organization for Economic Co-operation and Development

PBR	Plant breeders' rights
PVR	Plant variety rights
RAC	Royalty Area Collection
S&PM	Seed and plant propagating material
SME	Small and medium-sized enterprises
SOP	Standard operating procedure
STV	Saatguttreuhandverwaltungs-GmbH
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UK	United Kingdom
UPOV	International Union for the Protection of New Varieties of Plants
UN	United Nations
VCU	Value for cultivation and use
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Summary of key messages

The CPVR *acquis* functions well and has met its objectives. Stakeholders are generally content with the system. There are some areas of weakness to be addressed, however, particularly the operation of the agriculture exemption and the ease with which rights' holders can enforce their rights.

The evaluation of the Community Plant Variety Right *acquis* covers the period that the CPVR legislation has been in effect (1995 - present). It assesses how well the CPVR *acquis* has met its original objectives as well as its current strengths and weaknesses. Options are proposed to resolve deficiencies identified in the system.

The evaluation indicates that the CPVR *acquis'* primary strengths are that:

1. The CPVR *acquis* provides uniform, harmonised EU-wide intellectual property protection for new plant varieties.
2. The *acquis* strikes a reasonable balance amongst stakeholders and can be considered an appropriate EU regime, enabling the granting of intellectual property rights and coexisting effectively with national plant variety rights systems.
3. The *acquis* incentivises breeders to invest in research and develop new plant varieties and meets sustainability objectives.
4. The breeders' exemption is the most important feature of the CPVR *acquis*. It facilitates innovation in variety development and encourages competition in the breeding industry.
5. The durations of protection for plant varieties are appropriate: they are set to balance incentives for innovation with ensuring opportunities for further experimentation.

There are also areas for improvement in the CPVR *acquis*:

1. Useful adjustments could be made where the *acquis* interacts with other EU legislative frameworks:
   - The Seed Marketing Directives - *implementing a 'one key, several doors'* approach, supervised by the CPVO, could create greater efficiencies and avoid duplication, where only one procedure is used to grant CPVR and to market agricultural and vegetable varieties.
   - The legislative framework for patents (Directive 98/44/EC) - *CPVO could provide more information regarding plant-related patents and their implications for particular plant varieties* to help breeders determine when a patent overlaps with plant variety rights.
   - The EU Enforcement Directive (2004/48/EC) - *Articles 94 and 97 could be amended so that the two frameworks are aligned on compensation, damages, and restitution, and to ensure that the language in the CPVR Regulation does not preclude use of Directive 2004/48/EC.*
2. The provision for essentially derived varieties (EDVs) is appropriate but EDV enforcement could be improved by developing standardised protocols for the most economically important species. *CPVO could play a greater role in assisting industry develop these protocols.*
3. Effective royalty collection arrangements for farm-saved seeds are absent in many Member States. Enforcement is constrained by European Court of Justice (ECJ) rulings that limit breeders' ability to request information from farmers about farm saved seed use. *Amending the CPVR Basic Regulation to obligate farmers to answer 'yes' or 'no' when asked whether they have used farm saved seed would relieve the burden on breeders to discover its use and is consistent with the ECJ decisions.*
4. Extending the CPVR *acquis* to EFTA countries would help to bring EU and EFTA trade polices into closer alignment and may improve EU breeding industry competitiveness.

Executive Summary

This final report of the evaluation of the Community Plant Variety Right (CPVR) *acquis* provides the analysis and conclusions to the evaluation questions set out in the project terms of reference. The report explores the extent to which the *acquis* has achieved its objectives, examines its current strengths and weaknesses, and considers options that would help to address deficiencies identified in the system and ensure that it is well equipped to meet future challenges.

This evaluation was launched by the Directorate-General for Health and Consumers in May 2010. The evaluation covers the period 1995 to present—the period during which the CPVR legislation has been in effect. The CPVR *acquis* is based on Council Regulation (EC) No 2100/94 and a set of implementing rules (hereafter, the Basic Regulation). The strategic objectives of the study were to:

- Assess whether the original objectives of the *acquis* have been met;
- Identify the strengths and weaknesses of the current system; and
- Identify options that would address future challenges for plant variety rights in the EU.

The consulting team was provided by GHK Consulting Ltd working with ADAS UK Ltd. The core team was supported by EU experts in plant variety rights and with particular experience of the CPVR system across a range of academic fields including agricultural economics, intellectual property law and plant breeding.

This study process involved:

- An initial phase of desk research to define the legislative framework, outline the current situation and develop a detailed schedule of the issues to be explored;
- A large scale consultative exercise with government representatives, industry, NGOs and others across the EU through a detailed questionnaire and in-depth interviews;
- A data gathering exercise that provided evidence to support the analysis;
- A second consultation exercise focused on individual plant breeders and growers to gather views on questions that were difficult to answer from the initial consultation;
- Formulation of conclusions to the evaluation questions; and
- Development of options to address identified problems.

The evaluation has concluded that the CPVR system functions well overall, that stakeholders are happy with it and that they wish to retain the system in its current form, albeit with some carefully targeted adjustments.

The *acquis* is achieving its principal strategic objectives. It provides voluntary, uniform, harmonised EU-wide intellectual property protection for new plant varieties which has been popular with the EU plant breeding industry. The evaluation suggests that it has, by and large, struck a fair balance between the interests of breeders and consumers, and as such supported the competitiveness of the EU's seed and propagating materials trade, breeding and agriculture industry. The CPVR *acquis* can be considered an appropriate EU regime, enabling the granting of intellectual property rights and coexisting peaceably with national plant variety rights systems. Moreover, the *acquis* incentivises breeders to invest in research and development of new plant varieties, enabling their exchange for breeding and experimentation. Environmental, social and economic sustainability objectives are generally met through a system that encourages the creation of new varieties. Overall, stakeholders are happy with the system and wish to retain it more or less in its current form.

The conclusions reached on the specific questions set for this evaluation are described below. These illustrate the strengths and weaknesses of the system, and describe the areas in which there is scope for further improvement.

Harmonisation: The CPVR *acquis* provides for a harmonised intellectual property regime for plant varieties at EU level, but enforcement varies widely in practice. This is considered to be one of the biggest problems inhibiting an effective EU-wide plant variety rights system.

Appropriateness and effectiveness: The CPVR *acquis* has enabled the granting of intellectual property rights valid throughout the EU. It coexists effectively with national plant variety rights regimes. The acts to which only CPVR holders are entitled and the rights conferred on CPVR holders

are appropriate in general, although there is scope to improve the provisions extending to harvested material in the case of unauthorised use.

The duration of protection is, in general, appropriate to the system's needs. CPVR protection durations are comparable to national plant variety rights systems in Member States. On average, a CPVR 'lifespan' is much shorter than the protection period provided under existing legislation. Nonetheless many breeders would still like to see the duration of protection extended to 30 years for all plant varieties.

The CPVR *acquis* provides an appropriate exemption for plant breeders. The breeders' exemption is the cornerstone of effective plant variety rights, and central to what makes plant variety rights an important and useful system of intellectual property protection.

The *acquis* also provides an exemption to growers, providing for payment of reduced fees for use of farm saved seed. Implementation of the 'agriculture exemption' has been problematic and stakeholders are widely dissatisfied with it. In particular, European Court of Justice rulings on the legal interpretation of farmers' obligation to report farm saved seed (FSS) use creates practical difficulties with royalty collection. The operation of this exemption could be improved and more effective royalty collection systems for FSS established across the EU.

The list of species covered by the agriculture exemption is generally satisfactory though some stakeholders indicated concern regarding phytosanitary risks arising from farm saved potatoes. The appropriate definition of a 'small farmer' is also contentious and there is disagreement about whether the provision should remain in Regulation (EC) No 1768/95. The 'own holding' definition could be clarified to better reflect farming practices, and there is scope to clarify the definition of 'equitable remuneration'.

The provision for 'essentially derived varieties' (EDVs) is appropriate, and helps to protect against plagiarism of plant varieties that are too similar to one another. The definition is unclear, however, both in the CPVR Basic Regulation and in UPOV, and there are few established protocols for making EDV determinations. Procedures to determine 'essential derivation' are not well-established, therefore technical determinations do not produce clear results. There is scope for improvement in this area.

A plant variety must be new, distinct, uniform and stable (i.e. conform to DUS criteria), and have an appropriate variety denomination to qualify for CPVR protection. The application of these criteria is generally appropriate and effective, though the quality of testing centres could be improved. DUS criteria examinations are generally satisfactory, but the criteria themselves could be more flexible. The variety denomination criteria and procedures are unsatisfactory and need to be changed.

***CPVO role and effectiveness*:** The Community Plant Variety Office (CPVO) is regarded as an effective institution. There is some scope for further improvement, including adjustments to the CPVR application process. The process for appointment of CPVO senior management as laid down in the Basic Regulation ought to be reviewed to ensure it is consistent with current best practice.

***Costs*:** The costs of the CPVR system are generally reasonable, but stakeholders expressed concerns about CPVR maintenance fees, DUS testing costs and enforcement costs. Breeders are generally satisfied with most costs associated with CPVR, but dissatisfied with the maintenance fee and believe that enforcement costs are too high. Plant growers are divided on whether the costs they incur in using CPVR are reasonable. Member State representatives believe that the costs they incur related to the CPVR system are generally reasonable, though some Member States argue that DUS testing fees do not adequately cover the actual testing costs and that reimbursement takes too long.

***Enforcement*:** Enforcement is probably the issue of greatest concern for stakeholders in the CPVR system. Overall they are satisfied with the principles of enforcement provisions but unhappy that these provisions have not been uniformly implemented by the Member States. Moreover, enforcement is considered to be ineffective in many Member States and in some cases dispute resolution mechanisms are not easily accessible. There are also some points of tension between the CPVR Basic Regulation and the Enforcement Directive.

***Effects on stakeholders*:** The CPVR *acquis* provides benefits to EU plant breeding, agriculture, the seed and propagating materials sector and biodiversity. The impacts of the CPVR *acquis* on small, medium-sized and large plant breeders and breeding companies are generally positive, though there are few data on this issue. The CPVR *acquis* is thought to have positive effects on small, medium-

sized and large farms, and for EU citizens and consumers, though data on these issues are also scarce.

***Stimulating tool*:** The CPVR *acquis* has stimulated breeding and development, and facilitated and improved the protection of new plant varieties in the EU as compared with the situation before 1994. CPVR applications and rights granted are increasing over time and plant breeders from all Member States apply for and most are granted CPVR across crop groups. Stakeholders indicate that the CPVR *acquis* facilitates EU protection of new plant varieties and stimulates plant breeding.

***Impact on EU biodiversity, agriculture and the seed and propagating materials sector*:** The CPVR *acquis* may have some positive and some negative impacts on the preservation and erosion of plant genetic resources in the EU. The evaluation indicates that minimum distances between plant varieties have decreased in recent years. This may contribute to the erosion of plant genetic resources. The EDV concept may help to reduce minimum distance problems, however, thus reducing this likelihood. There may be an intermediate link between CPVR and availability of genetic resources via two Directives on marketing varieties, but no positive or negative impacts could be determined as a result of this link. The CPVR *acquis*' contribution to the harmonious development of EU agriculture, and particularly the seed and propagating materials sector, is difficult to define.

***Interactions with national and international law, policy and instruments*:** The rules related to public access to documents are unclear. Council Regulation (EC) No 1049/2001 and the CPVR Basic Regulation (Article 33a) create one set of rules and routes of appeal while Article 88 of the Basic Regulation creates a second set for release of information held by CPVO.

The CPVR *acquis* is a significant addition to the EU's intellectual property systems. There are no particular issues arising from interaction of CPVR and trademarks or geographical indications, but stakeholders are highly concerned about overlap between CPVR and patents. The Biotechnology Directive provides some harmonisation between patent law and plant variety rights, but stakeholders are concerned that overlap between patents and plant variety rights could undermine the effectiveness of plant variety rights over time. Compulsory cross-licenses are unsatisfactory for dealing with the tension between overlapping patents and CPVR.

The CPVR *acquis* is coherent with EU consumer, environment, agriculture and trade policy; environment policy; agriculture policy; trade policy; and consumer policy. The objectives of the CPVR *acquis* support the objectives of EU programmes on the conservation, characterisation, collection and utilisation of genetic resources in agriculture though stakeholders are concerned that uniformity requirements may be too high.

National plant variety rights (PVR) systems can and do differ from the CPVR system but this not a matter of general concern. Stakeholders pointed to the stronger protection offered by the Dutch PVR system and to lower costs in some Member States. CPVR provide an advantage through EU-wide coverage. The costs of CPVR are lower than some national PVR systems, and higher than others. Some Member States have a wider scope of plant variety protection, which breeders appreciate. The relative 'market share' of CPVR and national rights varies among Member States, but overall there is a discernable trend toward use of the CPVR system over national PVRs.

The CPVR *acquis* may have indirect impacts on the legal systems of third countries but these are difficult to determine; a potential extension of the CPVR *acquis* to European Free Trade Association (EFTA) countries would be a positive development. There is a high degree of support amongst EU stakeholders for an extension of the CPVR *acquis* to EFTA countries.

The objectives of the CPVR *acquis* generally support the objectives of the UN Convention on Biological Diversity and the International Treaty on Plant Genetic Resources for Food and Agriculture, though some stakeholders would like to see disclosure of origin in CPVR applications and ensure that access to genetic resources is maintained.

Options that would help to address current weaknesses and future challenges have been identified and assessed

Options for improving the current system have been identified, drawing on the research conducted for the evaluation, ongoing European Commission initiatives, inputs from the stakeholder consultation, industry position papers and discussion, and third party research. The options recognise the

continuing development of the 'external' environment as defined by changes in Member State and international law and practice, bioscience and plant breeding developments, and user expectations.

Options have been developed for both primary (i.e. higher priority) and secondary (i.e. lower priority) issues. Primary issues are those where there are recognised deficiencies and/or challenges are concentrated and stakeholders expressed the most interest and support for improvements. Secondary issues are those where there are recognised deficiencies and/or challenges exist but are fewer or less extreme, and stakeholders expressed moderate interest and support for improvements. Options are assessed according to their: contribution to correcting a known deficiency in the CPVR system; feasibility of implementation; stakeholder support; administrative burdens and costs; and the wider consequences of implementing the option, including economic, environmental, social and international impacts.

Primary issues and options

Interaction with the Seed Marketing Directives: there are links between the Seed Marketing Directives and the CPVR *acquis* where DUS testing and variety denominations are required for listing and certification, and for plant variety protection. In some cases, these procedures are unnecessarily duplicated. A 'one key, several doors' approach, supervised by the CPVO, in which only one procedure is used for each purpose, would remedy this duplication.

Interaction with the patent system: The EU legislative framework for patents allows for overlap between patents and plant variety rights. A plant variety may receive CPVR protection, but may not be patented, while an invention related to plants may be patented so long as it is not confined to a particular plant variety. This is a major concern, particularly as patents become more prevalent in agricultural research. This is due to the lack of a breeders' exemption and limited research exemption for patents. Determining whether a plant variety may overlap with a patent can be difficult without sufficient legal and technical expertise. CPVO could help to inform breeders of these overlaps by assembling and publishing more information on plant-related patents and their implications for particular plant varieties. This could include a database of relevant patents, with commentary and discussion from CPVO regarding the potential impacts on plant varieties. Additional information (e.g. outside studies or CPVO-prepared analysis) could also be provided.

Interaction with the Enforcement Directive: There is a tension between the CPVR Basic Regulation on infringement procedures and the EU Enforcement Directive (2004/48/EC). There are a number of potential points of conflict. In particular, Articles 94 and 97 of the Basic Regulation have a high degree of conflict with the Enforcement Directive and should be amended.

***Extending the CPVR acquis to EFTA countries*:** The European Free Trade Association (EFTA) promotes free trade and economic integration for these countries and is linked to the EU through trade agreements. Extending the CPVR *acquis* to EFTA countries in order to harmonise their plant variety rights systems with that of the EU would benefit both the EU and EFTA countries.

***EDV determinations*:** There are no standardised protocols or thresholds developed by CPVO or Member States to determine essentially derived varieties (EDVs), though these instruments have been developed for a limited number of species by plant breeders' associations. Disagreements over EDV determinations can be difficult to resolve where there are no established procedures or thresholds, and industry would benefit from these, particularly in court procedures. The legislator could give CPVO an expanded role to assist industry develop standardised approaches to determining EDVs for the most economically important species.

***Reporting requirements on farm saved seed use*:** CPVR holders currently find it difficult to obtain royalties for farm saved seed use, in part due to European Court of Justice rulings that limit their ability to request information from farmers. Amending the Basic Regulation to obligate growers to declare whether they have used farm saved seed ('yes' or 'no') would address this issue while leaving the terms of license and payment collection obligations unchanged. A designated authority would be required to make the request on behalf of the breeders—either an organisation chosen by breeders or a Member State authority where an organisation is not designated.

Secondary issues and options:

Enforcement: Enforcement is a major concern for rights' holders and most courts in EU Member States are not adequately knowledgeable about CPVR issues to rule on CPVR cases. Designated competent courts in each Member State and/or an EU-level competent court for CPVR cases could make more informed decisions on CPVR-related cases and improve resolution of enforcement issues, though the feasibility and costs of such arrangements would need to be explored further.

Scope of protection for harvested materials: UPOV 1991 extends the breeder's ability to enforce rights against unauthorised multiplication of the protected variety. The scope of protection is extended in the same way in the CPVR Basic Regulation. The protection of harvested material is not sufficiently well-defined in the Basic Regulation, however, resulting in uncertainties and loopholes in the protection that a breeder can expect from a CPVR. This could be corrected by ensuring the language for harvested materials is identical in the Basic Regulation to that provided by UPOV.

Interaction with access to information legislation: The CPVO would like to have greater clarity on the rules regarding public access to documents and which of the available appeal procedures should be applied in a given case. Complexity arises as a result of the interplay between information access provisions in the CPVR Basic Regulation and the more recent Public Access Regulation (1049/2001/EC).

Capacity building: The CPVO could usefully be more involved in capacity-building for the CPVR system. There are two recommended areas for further involvement. First, breeders currently bank genetic material at testing centres on a small scale to provide a sample for use in enforcement claims. This could be encouraged on a wider scale or standardised for all plant variety rights granted. Second, CPVO could provide greater outreach to third countries in the development of their plant variety rights systems that conform to TRIPS and WTO obligations.

***Recruitment of senior management in the CPVO*:** The rules laid down in the Basic Regulation for the recruitment of senior management in CPVO no longer align with current Commission practices. The Basic Regulation could be amended to bring it into alignment.

Editorial errors in the Basic Regulation: There are some editorial errors in the Basic Regulation; any revision to the Regulation should consider correcting them. This could be done alongside any other potential revisions to the Basic Regulation.

1 Introduction

1.1 Background to the study

This is the final report of an evaluation of the European Union's legislative framework governing intellectual property rights for new plant varieties—Community Plant Variety Rights (CPVR). CPVRs are granted to breeders on request and the rights cover the entire territory of the European Union (EU). The CPVR system coexists with national plant variety rights systems in each of 23 Member States (MS).[1]

This evaluation was launched by the Directorate-General for Health and Consumers in May 2010. The evaluation covers the period 1995 to present—the period during which the CPVR legislation has been in effect. The CPVR *acquis* is based on Council Regulation (EC) No 2100/94 and a set of implementing rules (hereafter, the Basic Regulation)[2].

The consulting team was provided by GHK Consulting Ltd working with ADAS UK Ltd, GHK's partner in the framework contract (Lot 3: Food Chain) through which this project was procured. The core team was supported by EU experts in plant variety rights and with particular experience of the CPVR system across a range of academic fields including agricultural economics, intellectual property law and plant breeding.[3]

1.2 CPVR Evaluation – aims and objectives

The CPVR *acquis* has not been evaluated in the 15 years since it came into effect, therefore, this evaluation is a timely opportunity to assess:

- Whether the original objectives of the *acquis* have been met;
- Strengths and weaknesses of the current system; and
- Options to address future challenges for plant variety rights in the EU.

The CPVR *acquis* was designed to address specific issues and concerns related to plant breeding and property rights in the context of wider policy goals and societal needs. These wider goals and needs include increased innovation, the development of an efficient single market and improved economic, social and environmental sustainability. The evaluation assesses the achievements of the CPVR *acquis* in meeting the specific objectives for which it was designed in the context of wider strategic context and policy goals. The evaluation aims to provide insight into the operation of the CPVR system and assist the Commission's future policy design in respect of plant variety rights.

1.3 Purpose and Structure of the Final Report

The final report presents the evaluation conclusions and options to address deficiencies identified in the CPVR system. It comprises:

- A high-level overview of the CPVR *acquis;*
- A summary of the research method;
- Analysis and conclusions on the performance of the CPVR *acquis* in meeting its core objectives, and its current strengths and weaknesses;
- Options to address identified deficiencies in the CPVR system, and an assessment of each option, with a preferred set of options identified; and
- A set of annexes detailing the consultation results and analysis that underlies the evaluation results and options.

[1] Four Member States do not have a national plant variety rights system: Cyprus, Greece, Luxembourg and Malta.

[2] A complete list is provided in Annex 2.

[3] The expert advisors were: Dr Mike Adcock, Durham Law School, UK; Dr Paul van der Kooij, Leiden University, the Netherlands; Dr Robin Pistorius, Facts of Life, the Netherlands; and Dr Chittur Srinivasan, Reading University, UK.

2 A high level overview of the CPVR *acquis*

This chapter sets the context for the analysis that follows by briefly describing the objectives and structure of the CPVR system.

2.1 The design of the CPVR *acquis* was influenced by decisions taken on a series of framing issues

The CPVR *acquis* was designed to provide voluntary, uniform and harmonised EU-wide plant variety rights. It sets out rules for the application, testing and approval of new plant varieties, while satisfying TRIPS[4] and UPOV[5] requirements and providing plant variety protection that is effective in all Member States through a single application process.

The design of the CPVR system was informed by views taken on a set of important 'framing' issues, as set out in the terms of reference for this evaluation. Specifically:

- A '*sui generis*'[6] system with specific requirements and exemptions provides protection that complements other forms of intellectual property protection. Plant variety rights requirements include novelty, distinctness, uniformity and stability. By contrast, patents are granted for inventions that are new, inventive and industrially applicable. Plant variety rights and patents protect different forms of subject matter.
- Any EU-level PVR regime must comply with internationally recognised variety protection requirements. The EU is a party to the TRIPS Agreement, which requires all members to provide intellectual property protection for plants either by patents or by a *sui generis* system or a combination of both. The EU CPVR *acquis*, which is based on the 1991 UPOV Convention, satisfies this requirement. Therefore, any EU-level PVR system must conform to UPOV criteria.
- The CPVR system was designed to complement rather than replace national PVR protection. Member State PVR regimes were not harmonised at EU level when the CPVR system was established. Therefore, national PVR coexist with CPVR, but the same plant variety may not have simultaneous protection at national and EU level.
- The CPVR *acquis* needed to account for the latest plant breeding techniques, including advances in biotechnology, to ensure continued plant variety innovation, and as such required flexibility to accommodate these advances.
- Member States should not carry out the implementation and application of an EU-level PVR system. Rather, an EU agency with legal personality would be established for these purposes. The CPVO operates its own budget and is independent from EU Institutions.
- The *acquis* itself must be clearly defined, particularly regarding the rights of a CPVR holder, and CPVR duration, exemptions, derogations and coordination with other similar systems. A clearly defined system would thus not compete with but rather augment and complement other systems and *vice versa*. More importantly, it would address the needs of breeders, farmers and consumers, and ensure an effective single market, encourage innovation and balance environmental, economic and social sustainability. These basic societal needs must be accounted for by any such system operating across the EU.

2.2 The CPVR *acquis* was intended to achieve certain specific objectives

The CPVR *acquis* was designed to achieve a set of strategic objectives, principally to:

- Provide voluntary, uniform, harmonised EU-wide intellectual property protection for new plant varieties;

[4] TRIPS is the Agreement on Trade-Related Aspects of Intellectual Property Rights.

[5] UPOV is the International Union for the Protection of New Varieties of Plants.

[6] That is, a unique system designed specifically for plant variety rights, rather than use of systems designed for other forms of intellectual property.

- Maintain EU seed and propagating materials trade, breeding and agriculture industry competitiveness by striking a fair balance between breeders and consumer rights;
- Maintain and develop plant genetic resource diversity via effective plant variety rights;
- Incentivise breeders to invest in research and development of new plant varieties;
- Enable exchange of new varieties for breeding and experimentation while protecting against counterfeit and fraud; and
- Encourage the creation of new plant varieties that support a balance between environmental, social and economic sustainability.

These priorities were determined based on the framing issues detailed above.

2.3 The legislation clearly specifies the system and its intended operation

The CPVR *acquis* sets out the parameters and mechanisms by which the system should operate (outlined below).

The CPVR *acquis* defines the following:

- Scope of plant variety rights for the rights holder;
- Limits of CPVR effects;
- Derogations of the CPVR regime (breeder's exemption and farmer's exemption);
- Exhaustion of a right;
- Essentially derived varieties definition;
- Technical criteria and testing protocols to grant CPVRs;
- Fee levels to the CPVO by rights holders;
- Role and structure of the CPVO;
- Implementing rules for the CPVR regime;
- Procedural rules regarding proposal acceptance/refusal and for defining variety denomination requirements;
- Criteria regarding compulsory licensing;
- Duration of a CPVR; and
- Compliance with international requirements (e.g. UPOV).

The terms of reference for this evaluation assign a question to each of these parameters. The final report addresses each evaluation question, providing background information on each objective, relevant results of the stakeholder consultation, further analysis and, where possible, conclusions to the questions (Section 4). Conclusions to each evaluation question are provided in Annex 4. Options are identified where a perceived deficiency has been identified (Section 5). The intervention logic for the CPVR system is provided in Annex 1.

3 Description of the research method (*in brief*)

This chapter describes the approach and method for the evaluation in brief. A detailed description is provided in Annex 5.

3.1 Methodological approach

This study involved a combination of evaluation tools and included several phases:

- An initial phase of desk research to define the legislative framework, outline the current situation and develop a detailed schedule of the issues to be explored;
- A large scale consultative exercise with government representatives, industry, NGOs and others across the EU through a detailed questionnaire and in-depth interviews;
- A data gathering exercise that provided evidence to support the analysis;
- A second consultation exercise focused on individual plant breeders and growers to gather views on questions that were difficult to answer from the initial consultation;
- Formulation of conclusions to the evaluation questions where possible; and
- Development of options to address identified problems.

The overall project workflow is shown in Annex 6.

3.2 Desk research and analysis

The first phase of the evaluation involved a literature review. A non-exhaustive list of the literature consulted for this study is listed in Annex 19. Relevant literature and other materials reviewed included the following:

- EU legislation and other official documents, including memos and reports;
- Documents relating to court cases, including decisions from the European Court of Justice and national courts;
- CPVO reports and presentations;
- Stakeholder reports, memos, position papers, presentations and other sources; and
- Academic literature on the CPVR system and on plant variety rights more broadly.

Additional data were collected and analysed from a variety of sources, including:

- CPVO data on:
  - CPVRs, including comprehensive data on applications and rights granted from 1995-2011 for all plant varieties;
  - Costs, including:
    - Fees for applying for, obtaining and maintaining CPVRs;
    - Fees charged for variety testing and estimated costs to national testing centres for conducting the tests;
  - Technical reports sold by the CPVO to authorities in third countries; and
  - The number of court cases related to CPVRs in EU MS and in the European Court of Justice (incomplete data set);
- UPOV data at Member State (i.e. national PVRs) and EU level (i.e. CPVRs);
- FAO data on the trade in agricultural crops;
- Eurostat data on :
  - Size of farms in the EU; and
  - EU agricultural holdings by farm size and crop type.
- Data and statistics provided by industry, including estimates of the following:
  - Farm saved seed use across the EU and for various Member States;
  - Royalty collection levels in some Member States and for some species;
  - The number and extent of fraud cases and revenues foregone through fraudulent marketing and selling for some Member States; and
  - Value of the seed and propagating materials markets and trade in seeds and crops (international, EU and for specific Member States).

Overall, data availability and third party analysis on the CPVR system varies considerably. For some evaluation questions, the data is comprehensive and can be triangulated across several sources. For example, analysis of CPVR protection durations was facilitated by CPVR data on the dates of rights granted and terminated (to yield the 'lifespan' for different CPVR), views from stakeholders based on interview and questionnaire responses, and academic literature on the effects of different durations of protection. On other issues, however, the available data cannot be directly related to CPVR impacts (e.g. effects on consumers). Finally, for some questions, information is only available based on the stakeholder consultation – in these cases, the views of different stakeholder groups are triangulated to provide the most complete assessment possible of the CPVR system and potential options.

3.3 Stakeholder consultation

The evaluation attempts to accommodate the perspectives of the diverse stakeholders of the CPVR system.[7] Accordingly, the stakeholder consultation combines survey results with in-depth interviews covering each of the stakeholder groups as well as information from other relevant individuals and organisations (for a more detailed description of the research method, see Annex 5). The consultation involved:

- A detailed questionnaire: The research team prepared and distributed detailed questionnaires tailored to key stakeholder categories (plant breeders, plant growers and Member State representatives), as well as a survey intended to reach a broader range of other interested stakeholders. This approach was intended to lead to greater refinement of results, increased efficiency in analysis and increased convenience from the point of view of respondents (as certain questions were relevant only for specific groups of stakeholders).
- E-survey: An online version of the general questionnaire was also made available in the form of an electronic survey. It was offered in four languages – English, French, German and Spanish – in order to reach a wide range of stakeholders across the EU.
- In-depth interviews: In-depth interviews were conducted with a selected subset of key stakeholders across all stakeholder groups.
- Follow-up interviews/clarification and further explanation: Follow-up interviews were conducted with selected respondents to the questionnaires sent out as part of the initial consultation for the purposes of clarification and analysis of specific responses and observations at greater depth in order to obtain an enhanced understanding of various aspects of the CPVR system.
- Follow-up questionnaires and interviews with breeders and growers: Follow-up questionnaires were distributed to plant breeding companies, growers, and national representative organisations for breeders and growers.

The evaluators faced some challenges in seeking a comprehensive and balanced set of stakeholder views. While the evidence and viewpoints presented in this report are robust and provide a fair representation of views, the pattern of responses and manner in which they were obtained do limit the extent to which it is possible to present the views of each group in quantitative terms. In particular:

- ***The consultation response is imbalanced insofar as significantly more plant breeders responded to the consultation than plant growers***: Representative associations for the relevant stakeholder groups were asked to submit a survey for their organisation (representing the views of their collective membership) and also to distribute information about the consultation to their individual members. The same approach of engagement and distribution was adopted for breeders and growers. There was also an open opportunity for organisations from any sector across Europe to engage via the online survey. The plant breeding sector was much more responsive than plant growers to this invitation. In total, the research team received 205 completed surveys across the different stakeholder categories listed in Table A5.1 of Annex 5. Of

[7] These include Member State representatives on the relevant Standing Committees of the European Commission, technical liaison officers, private sector interests (including plant breeders, plant growers, seed marketers and traders, and foresters), the Community Plant Variety Office (CPVO), various European and international governmental organisations, non-governmental organisations (NGOs) and Commission services concerned with intellectual property rights and CPVR.

the private sector responses received, nearly 70% (110 out of 161) came from the plant breeding sector, from which many individual companies (79) responded as well as representative bodies (31). The second round of the consultation, conducted in January and February 2011, was directed at attaining a higher response rate from growers to ensure that growers' perspectives are adequately reflected in the overall analysis. Seven additional responses from representative organisations (for a total of 15) as well as 27 responses from individual farmers (in France, Germany and the UK) were obtained in this second consultation period, though response rates from growers were low during this phase as well.

- ***The plant breeding industry submitted a coordinated response to the consultation, limiting a quantitative assessment of their views***: A large proportion (67 out of 79) of the responses received from individual companies were nearly identical to the responses of two major representative associations for plant breeders, one operating at the European level and one in the Netherlands. These organisations also separately submitted completed questionnaires giving their institutional viewpoint. The fact that, on several matters, the views expressed in the representative association responses were reiterated by member companies in their own survey responses has been taken into account in the analysis and presentation of results. For breeder's responses a 'plant breeding industry view' is referenced in most cases when presenting the views of these stakeholders. Where appropriate, for example in cases where an individual company has changed or added to the narrative comments to survey questions, these nuances are highlighted in the analysis through direct quotation.
- ***Member State representatives responded to the survey in different ways—some with a centrally coordinated, single response, and others with two or more separate responses***: Member State representatives completed 44 surveys, with at least one survey returned from each of 26 Member States (except for Malta). In many cases, representatives of one Member State submitted one unified and coordinated survey response, while in others representatives submitted several individual surveys. Where individual survey responses from different officials in a given Member State were the same, a Member State 'view' is provided in the analysis. This was possible for the majority of such surveys. In cases where responses differed, responses are treated separately in our analysis and further consideration is given to what that divergence of views illustrates in a particular Member State. This is possible by analysing the narrative comments in the survey and in-depth interview discussions.

4 The performance of the CPVR *acquis* in achieving its core objectives and its current strengths and weaknesses

This Section provides analysis and conclusions on the performance of the CPVR *acquis* in achieving its core objectives, as well as the system's current strengths and weaknesses.

4.1 The CPVR *acquis* provides for a harmonised intellectual property regime for plant varieties at EU level, but enforcement varies widely in practice

4.1.1 There is a rationale to uniform application, granting and enforcement procedures for plant variety rights within the EU territory

Plant variety protection legislation was introduced in several European countries during the 1960s in response to increased private sector involvement in plant breeding (UPOV 1987; Queen Mary Institute 2004). A number of countries introduced limited rights to plant breeders prior to this period: in the United States through the Plant Patent Act (1930), in the Netherlands through the Breeders Ordinance of 1941, and in Germany through the Law on the Protection of Varieties and the Seeds of Cultivated Plants (1953). During this period, however, the criteria for grant of rights differed from country to country and even the concept of 'variety' was not uniformly defined or interpreted. Rights granted by a country to its nationals were not guaranteed to nationals of other countries.

Plant breeders' rights were recognised internationally for the first time in 1961 with the adoption of the International Convention for the Protection of New Varieties of Plants (*hereafter,* the UPOV Convention) (UPOV 1987). The UPOV Convention has since undergone two major revisions, in 1978 and 1991.

The UPOV Convention attempts to harmonise plant variety protection legislation among its member countries. It specifies three uniform criteria for protection: *distinctness, uniformity* and *stability*, which reflect the need to identify a variety as a prerequisite for intellectual property rights. The Convention requires members to treat nationals of other states as they do their own. Finally, it provides for 'right of priority' and for certain elements of reciprocity. Importantly, it defined the scope of breeders' rights, which extend to '*production for purposes of commercial marketing of the propagating material of the new plant variety*'.

Harmonised intellectual property protection for plant varieties was further supported by the Uruguay Round of GATT negotiations, which resulted in the Agreement on Trade-Related Aspects of Intellectual Property Rights (*hereafter*, the TRIPS Agreement) in 1994. The GATT negotiations explicitly defined intellectual property rights as a trade-related issue, and their harmonisation became embedded in the rules establishing the World Trade Organisation (WTO) in 1995.

The UPOV Convention facilitates introduction of relatively uniform plant variety protection standards in all member countries through the 'national treatment', 'right of priority' and 'reciprocity' provisions. It also facilitates cooperation agreements for testing which reduces the need for testing new varieties in each country where protection is sought.

Nonetheless, the UPOV Convention prescribes only *minimum* norms that must be met by national legislation. As a result, significant differences can exist among UPOV members with respect to important provisions including species coverage, protection duration and farm saved seed. Some of these differences are determined by whether the Member State adheres to the UPOV Convention of 1961, 1978 or 1991.[8]

Most importantly, harmonised plant variety rights under UPOV only provide protection to the plant breeder that can be exercised in the country of application. Multi-country protection requires that the plant breeder apply for and secure protection separately in each country. This entails transaction costs (for application, testing and renewal of protection) in each country where the breeder seeks protection.

[8] 23 of 27 Member States are UPOV members: four (Ireland, Italy, France and Portugal) are party to the 1978 Convention and Belgium is party to the 1961 Convention. The remaining 18 ratified the 1991 Convention.

Transaction costs that accumulate by obtaining protection in more than one jurisdiction could reduce the incentives for breeders to disseminate innovations beyond the country of origin and to develop plant varieties that are appropriate for several national markets. This poses significant barriers to the development and dissemination of plant variety innovations, which is evident from the low incidence of multi-country protection when only national PVR systems existed in the EU. For example, on average, less than 3% of plant variety rights (across key crops including wheat, maize and soyabean) were protected in three or more countries (Srinivasan, 2005).

Against this background, the introduction of the CPVR system provides a harmonised system of intellectual property rights for plant varieties that facilitates trade within the EU and also benefits trade beyond the EU.

4.1.2 The CPVR *acquis* provides for harmonised plant variety rights across the EU territory, but in practice enforcement is uneven across Member States

The CPVR *acquis* vests rights enforcement powers with Member States' judicial systems. Similarly, royalty collection systems for farm saved seed have been left to arrangements developed by rights' holders in individual Member States based on the enabling provisions contained in the CPVR legislation. This means that the feasibility, effectiveness and costs of enforcing rights may vary substantially across Member States depending on the coordination and capabilities of rights' holders to enforce their rights, and the technical expertise and knowledge relating to plant variety rights available with the judicial systems of Member States and their operational efficiency.

For example, Table A7.1 in Annex 7 illustrates the variance in farm saved seed (FSS) royalty collection systems across Member States. The system is considered to be well-functioning (effective) in only seven MS. Only 14 MS have a system in place, and in three Member States, a system is under discussion, but not implemented. Many breeders (68 out of 81) noted that the CPVR enforcement provisions constitute a good framework for the system, but emphasised that national arrangements should be more uniform to facilitate better implementation. These issues are discussed in greater detail in Section 4.2.10.

4.2 The CPVR *acquis* can be considered an appropriate EU regime overall – it has enabled the granting of intellectual property rights valid throughout the EU and coexists effectively with national plant variety rights regimes

4.2.1 The rights conferred on CPVR holders are appropriate in general, although there is scope to improve the provisions extending to harvested material

The CPVR Basic Regulation provides a set of acts to which only the CPVR holder is entitled. These include:

- Production and reproduction (multiplication);
- Conditioning for the purposes of propagation;
- Offering for sale and selling or other marketing;
- Importing and exporting; and
- Stocking for any of the above mentioned purposes.

These apply in the first instance to plant propagating material and in a more limited way to harvested materials.

Control over the act of production and reproduction is perhaps the most important right of the CPVR holder, particularly as this right cannot be exhausted through Article 16 of the Basic Regulation (Wurtenberger et al 2006). Moreover, conditioning for propagation (i.e. cleaning and grading seed) is viewed as a commercial activity that enables use of the material for commercial purposes, and the provision for sales is essential to the activities for which plant variety protection were introduced. Importing and exporting provisions provide CPVR holders with information concerning the movement of seed and propagating materials across EU boundaries. Stocking (i.e. storage) provisions are aimed at activities which ensure that protected material is ready for commercial release.

4.2.1.1 The scope and rights provided to the breeder are, in general, appropriate, proportionate and consistent with the objectives of the CPVR *acquis*

Stakeholders consulted in this evaluation are generally satisfied that the following acts require the authorisation of the rights' holder: production and reproduction, conditioning for propagation, offering for sale and selling, exporting and importing, and stocking.

Without exception, all responses to the breeders' survey indicated agreement with the above mentioned acts requiring the CPVR holder's authorisation. An overwhelming majority answered 'strongly agree' in this context. Growers' responses were more qualified, but the majority confirmed that these rights are appropriate so long as the intention of each activity is to engage in commercialisation and trade of the protected variety.

Member State representatives largely agree with these views. Representatives from 25 out of 26 MS agree that the CPVR holders' rights should include authorisation for production and reproduction, and for exporting and importing, representatives from 23 EU MS agree that holder's rights should include offering for sale and selling and 22 agree that they should include conditioning for propagation.

Member State responses were less aligned with respect to the stocking provisions: representatives from 19 MS agreed that the CPVR holder's rights should include stocking and three disagreed. Among those who disagreed, one suggested that the provision for 'stocking' could be combined with the provision for 'production and reproduction' in order to minimise bureaucratic delays, as these activities are usually performed together. Another indicated that the stocking provision is appropriate, though there may be problems in special cases such as preserving varieties in a gene bank.

Overall, the acts to which CPVR holders are entitled are appropriate to suit their intended purposes, where they apply to plant propagating materials.

4.2.1.2 The provisions extending to harvested material in the case of unauthorised use could be improved

Under the 1978 UPOV Convention, the minimum right that must be granted to a breeder relates to the commercial exploitation of the *propagating material* of the variety [Article 5(1)]. Prior to this, it was possible for material of a variety protected in Country A to be taken to Country B, where no protection existed, and to be multiplied and used there to produce the end product of the variety, which could then be exported back to Country A. Notwithstanding the protection right, the breeder could take no action in Country A to prevent this practice since the protection applied to the propagating material only and not to the end product. The breeder of the variety protected in Country A (and also licensed to producers in Country B) lost revenue. This problem was most extreme in the cut flower industry, where the lightweight end product is suitable for air freight and an important international industry has developed over the past 30-40 years. Recent examples of illegal propagation in the cut flower industry are provided by Royalty Administration International, an organisation dedicated to royalty collection issues in the cut flower industry.[9]

As this problem increased in intensity, it became necessary to consider whether the breeder's right should be extended to the end products derived from the protected variety. The agriculture sector in the EU was conscious, however, that the end products of many plant varieties are staple elements of the world food supply and they were not willing to grant to plant breeders a right that could be exercised at the breeder's discretion either over, for example, wheat seed or the end product, the grain. Accordingly, Article 14(2) of the 1991 Convention extends the minimum right of the breeder to the harvested material of his protected variety but only if the harvested material is:

- Obtained through unauthorized use of protected propagating material, and provided that
- The breeder had no reasonable opportunity to exercise his right over the propagating material.

The 1991 UPOV Convention thus attempts to significantly extend the breeder's ability to enforce rights against unauthorised multiplication of the protected variety.

The scope of protection is extended in the same way in the CPVR Basic Regulation. The protection of harvested material is not sufficiently well-defined in the legislation, however, resulting in uncertainties and loopholes in the protection that a breeder can expect from a CPVR. An international plant breeders' association provided the example of cut roses detailed below to illustrate the problem.

[9] Royalty Administration International: http://www.rai-worldwide.com/htm/indexEN.html (viewed 30 March 2011)

Case Study 1: Cut roses - an example of loopholes in the provision extending to harvested material

A Dutch breeder of a CPVR-protected cut rose variety delivers 500 elite plants of his variety to a German propagator. He grants the propagator a license to produce 50,000 rose plants from this elite material and sell them within the EU. The breeder receives license fees for production of the 50,000 plants. The contract between the parties explicitly forbids export out of the EU.

The German propagator produces 50,000 plants and sells them to a grower in France. The French grower plants 25,000 of these and sells 25,000 plants to a grower in Brazil, who assures him that he wants to use the plants only for producing cut roses. Although Brazil has granted plant variety protection for roses for some years, the variety concerned did not obtain protection in Brazil because it did not meet the novelty criterion.

On receipt of the rose plants, the Brazilian grower changes his mind and propagates another 45,000 rose plants. He exports to the EU the cut roses harvested from the 25,000 plants received from the French grower and from the 45,000 plants he propagated himself.

According to Article 16 of the CPVR-Regulation the holder's right is exhausted for the 50,000 rose plants (= propagating material) produced by the German propagator, because the plants were sold with the consent of the breeder in the EU. Article 16 (b) is not applicable, because Brazil provides for plant variety rights for roses. Article 16 (a) is also not applicable at the time of export, because no further propagation is involved when the export takes place.

Because the CPVR is exhausted, no authorisation is required for these acts. Thus, the title holder cannot exert his right on the cut roses harvested from the newly propagated 45,000 rose plants, particularly not if the cut roses qualify as harvested material and not as 'variety constituents'.

Hypothetical example provided by an international plant breeders' association

The plant breeding industry strongly supports including authorisation from users of seed and propagating materials who stock harvested material among the title holder's rights. Such a provision is in line with UPOV 1991 guidelines (UPOV Act of 1991, Article 14, Chapter V). Extending the scope of holders' rights to harvested material would enable holders to earn royalties on harvested material that is not brought to market (such as material stored for use in animal feed).

The holder's rights could also be extended to the transfer or 'transit' of propagating material. 'Transit' refers to a customs procedure for goods that are moved to, from or through EU Member States but are not in free circulation (DG TAXUD 2010). For these goods, customs duties have not been paid and import formalities have not been fulfilled. Seed and propagating materials might be imported into an MS for 'transit' purposes and then distributed to and commercialised in non-EU markets. There is strong support for this extension within the plant breeding industry, which would allow rights' holders to collect royalties on transited materials where they were unable to exercise their right with respect to the propagating material.

Options to improve the CPVR system in regard to harvested materials are discussed in Section 5. Each option is assessed in Annex 16 (Option I).

4.2.2 The duration of protection can be considered appropriate to fulfil the needs it aims to satisfy

The durations of protection for CPVRs are particularly important for this evaluation. The duration criteria are set to maintain a balance between incentivising innovation (by providing adequate time to recuperate returns on investment) and ensuring that CPVR duration does not hinder further experimentation and variety development by others.

The protection durations provided by the legislation vary by plant species. Council Regulation (EC) No 2470/96 extends the duration terms for potatoes, as these plants are recognised to require greater expenditure on research activities and take longer to realise commercial value. The duration of protection for CPVRs is 25 years for most plant varieties, and 30 years for trees, vines and potatoes.

There is a link between the prescribed duration and the time taken to develop and produce new varieties (e.g. trees and vines have longer protection duration than other plants). In practice, the time required for cost recovery varies greatly. It depends on the initial costs for the breeding programmes,

which may accrue over a 5 to 12 year period, as well as the popularity of the new cultivar and the duration of that popularity. Case Study 2: provides one example of the potential variance in costs and returns, taking the example of wheat breeding programmes in the UK.

Case Study 2: UK wheat breeding

A competitive UK commercial wheat breeding programme is currently estimated to cost €1.1-1.7 million per annum (£1-1.5 million) to maintain. These costs may rise in the future through the use of increasingly sophisticated breeding technologies.

The UK wheat breeding industry collects €16.5-17.7 million (£14-15 million per annum) in royalties, but this amount is not evenly distributed among all wheat breeders. At the extremes, one successful breeder could recoup the entire investment in the breeding programme within a couple of years if the varieties capture 100% market share, while an unsuccessful breeder may never achieve market share. Alternately, a small breeder of ornamental plants may face much lower costs than a wheat breeder (i.e. less than €57,000 per annum) and also have a much wider market for its plant variety (i.e. EU-wide, rather than primarily UK).

Information taken from: British Society of Plant Breeders 2010

Tree and vine species take longer to commercialise because traditional production methods require that genetic material is clonally propagated and grafted onto a rootstock after the initial period of breeding and variety testing and before supply to the market. This process can add five years to the time period before which appreciable revenues accrue. The duration of protection for trees and vines is set at 30 years on this basis.

The market equivalence of varieties is another factor to consider in protection duration. For example, most barley varieties are used for feed, but some varieties are acceptable for feed and malting, expanding their market range. Therefore, all barley cannot be considered equivalent when estimating the potential returns for this species. In other cases, market sector demands change slowly: some potato varieties remain popular and are grown commercially for more than 30 years.

4.2.2.1 CPVR protection durations are comparable to national plant variety rights systems in MS

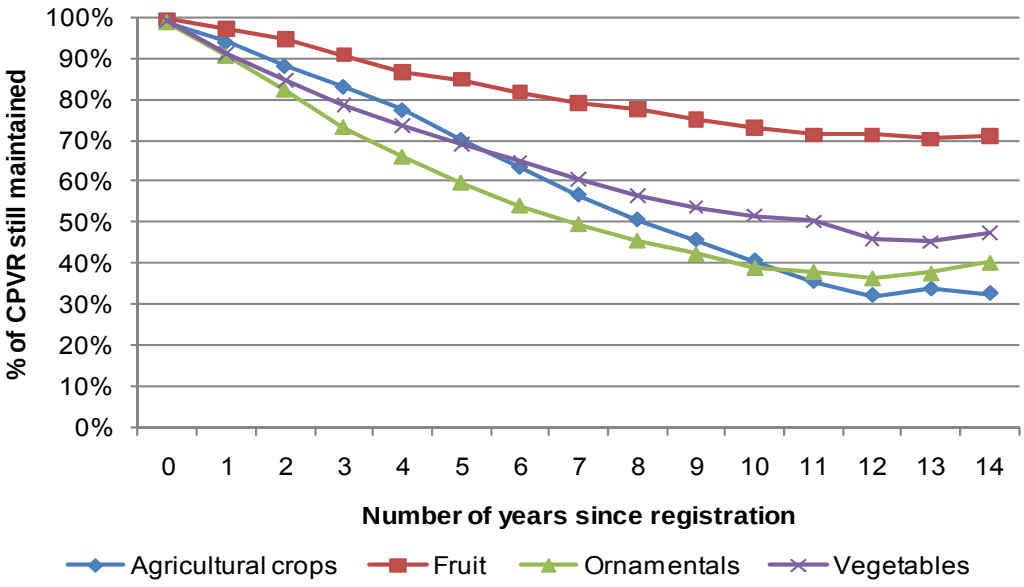
Most national plant variety rights systems have a similar duration of protection to the CPVR system. This is one indication that the duration of protection is satisfactory, because each Member State with a national system can change the duration of protection. The Netherlands has extended the duration of protection to 30 years for some species that were previously only protected for 25 years. The plant breeding industry indicated that this increased level of protection should be considered for the CPVR system as well.

4.2.2.2 On average, a CPVR 'lifespan' is much shorter than the protection period provided under existing legislation

Many CPVRs are terminated by the rights holder long before the end of the legal protection provided to them by the legislation. Many are terminated after only a few years. On the basis of experience to date, around 75% of CPVRs for fruit varieties are still maintained after 10 years but only about 40% of CPVRs granted for ornamental and agricultural crops (Figure 4.1). Terminated CPVRs to date have been, on average, between three and five years old when discontinued (Figure 4.2).

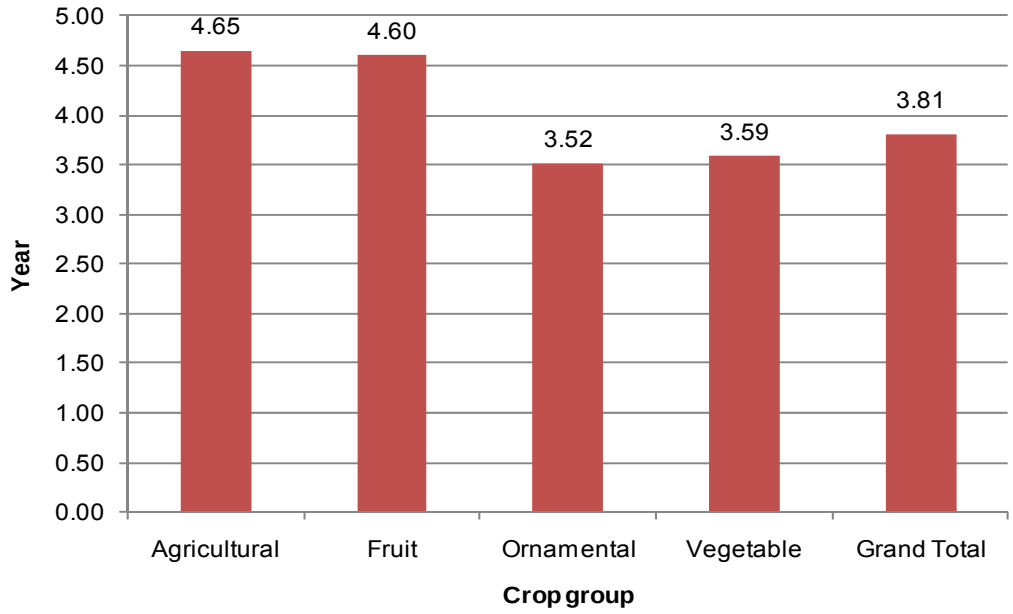
In effect, these data show that 'life expectancy' at registration is higher for some plant varieties than for others. Fruit trees, certain cereals, and potatoes have a higher expected lifespan than other varieties. The CPVR lifespan for vegetable varieties exhibits a large variance: certain varieties tend to be terminated after a relatively short period, whilst other varieties are protected for significantly longer periods, and include some of the longest lasting varieties, such as beans, peas, and some herbs.

Figure 4.1 CPVR titles awarded to fruit varietals are maintained longer than other varietals, while ornamental CPVR tend to be the shortest lived



Source: GHK analysis based on CPVO data for 1996-2009

Figure 4.2 Terminated CPVRs have been, on average, three to five years old when discontinued[10]



Source: GHK analysis based on CPVO data, January 1995-July 2010

A small number of species account for a large proportion of the population of older rights (i.e. rights that were maintained for at least ten years) (Table 4.1). For agricultural and fruit varieties, more than 60% of the oldest CPVR (i.e. CPVR maintained for 10 or more years) belong to only three species; for ornamentals and vegetables, approximately 40% of the oldest CPVR belong to three species.

[10] The CPVR granted in the 1996-2009 period that were in force at least as at July 2010 have no known termination date, and could therefore not be analysed. For this reason, the analysis is based only on titles that were both granted and terminated in the 1996-2009 period.

Table 4.1Concentration ratio and species of the oldest IPRs in the market

Crop group	3 species with highest shares of CPVR enforced for 10 years or longer	Concentration ratio (leading 3 species as % of overall number of CPVR enforced for ≥10 years)
Rights still in force (granted at least 10 years ago)		
Agricultural	Potato, Corn, Wheat (Soft)	61.27%
Fruit	Apples, Peaches, Strawberries	61.25%
Ornamental	Rose, Geranium, Chrysanthemum	40.41%
Vegetable	Lettuce, Cabbage, Common bean	37.03%
Rights not currently in force (but were in force for at least 10 years)		
Agricultural	Potato, Corn, Wheat (Soft)	54.91%
Fruit	Peaches, Strawberries[11]	80.95%
Ornamental	Rose, Geranium, Chrysanthemum	47.41%
Vegetable	Lettuce, Peas, Common bean	62.22%

Source: CPVO data, January 1995 - July 2010

A comparison of the average duration of protection across the four major crop categories, comparing CPVR terminated with those still in operation, indicates that on average, titles granted to vegetable varieties are the oldest active IPRs in the EU[12]. Annex 7 figures (A7.11 - A7.14) provide an alternative profile of CPVR duration patterns, showing more uniform behaviour for fruits and agricultural crops.

The CPVR system itself is still too new for any rights to have been maintained to the maximum enforcement limit (25 or 30 years). Taking an arbitrary recent cut-off date (1 July 2010), the data indicate that of the 1,436 CPVR granted in 1996, only 179 agricultural, 39 fruit, 268 ornamental, and 79 vegetable CPVR are still maintained (or approximately 40% of all titles awarded in 1996). It is unclear how long they may be maintained and so it may be premature to reach a definitive judgement on the functional utility of changes to duration. The available evidence, however, suggests that the current maximum length of protection (i.e. 25-30 years) is likely to be sufficient for most purposes.

4.2.2.3 Breeders would like to see an extension to the duration of protection.

The majority of plant breeders believe that the current duration of protection for plant varieties, other than trees, vines and potatoes (25 years), is inadequate. Most favour a 30 year duration. Two breeders commented that the protection duration was adequate for most varieties because their commercial life is often significantly shorter than the duration of protection granted (a proposition corroborated by the data shown above). Nonetheless, these stakeholders argued for an extension of protection duration for specific varieties (particularly flower bulbs, strawberry, alstroemeria, anthurium, bromeliaceae, orchids and calathea) that yield returns over a longer time period.

Growers indicated that the current durations of protection are sufficient, with a few indicating that it is already excessive relative to the lifespans of plant variety rights. Representatives of most (18 of 26) Member States agreed that a 25 year protection duration is appropriate for plant varieties other than trees, vines and potato varieties. One Member States' representatives disagreed, arguing that a protection period of 20 years would be sufficient and better encourage new variety development. Representatives from 20 Member States also agreed that the duration of protection is satisfactory for trees and vines (30 years) and for potato (30 years) varieties.

[11] In this category, peach (*Prunus persica* (L.) Batsch) and strawberry (*Fragaria x ananassa* Duch.) species represent 17 of the 21 CPVR awarded; the remaining four were awarded to four different fruit varieties: walnut (*Juglans regia* L.), apple (*Malus domestica* Borkh.), cherry (*Prunus avium* L.) and pear (*Pyrus communis* L.).

[12] These figures are underestimates: for analytical purposes the termination date for all CPVR granted in the 1996-2009 period and still in force as at July 2010 was assumed to be 1 July 2010 across all crop categories for consistency (so as to be able to compute protection duration for these rights). Considering that some of these titles might continue to be in force for an undefined duration, the average figures arrived at in this context are less than the true averages, but do yield interesting conclusions, as discussed above.

The possibility to extend the duration of protection is discussed in Section 5; an assessment is provided in Annex 16 (Option F).

4.2.3 The exemptions provided in the CPVR *acquis* are appropriate. The breeders' exemption is the cornerstone of effective plant variety rights. EDVs are a useful addition to the system. Implementing the agriculture exemption is problematic, however. There is scope for change in this area.

Plant variety rights have emerged as a distinct form of intellectual property right for plant varieties mainly through adaptation of industrial property rights concepts to the specificities of plant varieties (see Annex 2). These adaptations from patent law concepts played only a facilitating role in this process. The primary impetus for plant breeders' rights arose from efforts to regulate the European trade in seed and propagating materials since the early 20th century (UPOV 1987). Growth in the trade created a need for regulation to prevent the exploitation of farmers through unscrupulous trade practices, such as sale of poor quality seed, false claims, and use of deceptive or false denominations. European trade regulations involved one or more of the following elements:

- *Registration regulations,* stipulating that only registered varieties could be offered for sale.
- *Denomination regulations,* stipulating that varieties be sold under the proper variety name, and labelled by variety and producer. The breeder owns the registered variety name.
- *Certification regulations,* which controlled variety quality (physical and genetic purity) through field inspections at different production stages. (Certification eventually became mandatory in most European countries).

Providing farmers with quality seed and propagating materials required giving breeders some degree of control over the multiplication of their varieties. These regulations were intended to prevent malpractice in the production and marketing of varieties, but it was a short step to a system of plant breeders' rights. Berlan and Lewontin (1986) argue that *registration* and *certification* conferred *de facto* IPRs on breeders in European countries before formal PVR systems were introduced.

While the key objective of plant variety rights is to encourage plant breeding innovation, this adaptation has entailed two significant departures from patent law. These include:

- *Agriculture exemption*, which acknowledges the farmers' right to use farm saved seed. The breeders' right extends only to seed produced for commercial marketing. Consequently, farm saved seed use is outside the purview of the breeders' right.
- *Breeders' exemption*, which provides that use of a new (protected) variety as the initial source of variation for creating further new varieties and marketing them does not require the breeder's authorisation.

The breeders' exemption recognises cumulative plant variety innovation (i.e. the dependence of new varieties on existing varieties) and seeks to preserve incentives for future innovation within the framework of an IPR regime. Without this exemption, variety protection could completely foreclose development of further varieties based on the initial protected variety. This idea runs contrary to the basic objective of stimulating innovation. The breeders' exemption allows for a protected variety to be freely used to develop new varieties.

Moreover, plant variety protection was developed to stimulate creation of new varieties, not to confer breeders with ownership of the underlying genetic resources. Accordingly, CPVR do not grant the plant breeder any rights in the genes contained in the new variety.

An important implication of the breeders' exemption is that a variety that is only marginally different[13] from a protected variety could qualify for protection as a new variety. Production of such 'mimic' varieties could deprive the original breeder of royalties from the protected variety. The 'essentially derived variety' provision in UPOV and repeated in the CPVR Basic Regulation is an attempt to reduce the problems with imitation that can result from the breeders' exemption.

[13] It could also facilitate 'cosmetic breeding'.

4.2.3.1 The breeders' exemption is appropriate and satisfactory—the exemption is central to what makes plant variety rights an important and useful system of intellectual property protection

The breeders' exemption is widely viewed as the most important feature of the CPVR system. The exemption encourages competition in the breeding industry and facilitates rapid advancement in genetics by encouraging innovation in variety development (see Section 4.4.1). Stakeholders support the breeders' exemption in the CPVR *acquis*.

> 'The breeders' exemption is a cornerstone in the continuous and steady improving of varieties. This open access system secures competitive breeding and prevents monopoly.'
>
> *Selected comment of a small, private-sector breeding company*
>
> '[The breeders' exemption] has been shown to increase breeding activity and offers opportunities for new breeders to come into the market place with their creativity.'
>
> *Selected comment of an international plant growers' association*
>
> 'This exemption is an important part of plant breeding and facilitates development of new varieties.'
>
> *Selected comment of Member State representative*

The scope of the plant breeders' exemption can be considered appropriate in its current form. A study by Eaton and Van Tongeren (2005) concludes that any reduction in the scope of the breeders' exemption will lead to increased profits for the dominant seed and propagating materials breeding firms while decreasing profits in the farming sector due to increased costs for new varieties and increasing costs for varietal development as a result of more restricted access to new varieties for research purposes. Decreased farming profits and increased costs for varietal development could result. Thus the breeder's exemption is crucial for the development of innovation in plant breeding (Louwaars et al 2009).

4.2.4 The agriculture exemption is satisfactory in principle, but is difficult to implement. There is scope to improve this exemption to facilitate effective FSS systems in EU Member States

Article 5(1) of the 1978 UPOV Convention stipulates that the prior authorization of the breeder is necessary for production of the reproductive or vegetative propagating material of a protected variety for purposes of commercial marketing. Seed and propagating materials fall outside the scope of the breeder's right if, for instance, produced for re-sowing on the farmer's own land rather than for commercial marketing. This feature of UPOV 1978 implicitly creates the agriculture exemption.

Agriculture exemption provisions under UPOV 1978 specify only the minimum scope of protection that must be granted to the breeder. Individual UPOV signatories may grant a wider scope of protection, if they choose. Difficulties with the UPOV 1978 provisions were encountered in practice in specific situations. For example, the provision applied not only to seeds that farmers regularly save but also to fruit and plantation crops and cut flowers. An individual could buy one fruit tree, propagate it and plant an orchard with no remuneration to the breeder, claiming to exercise his or her agriculture exemption. The modern techniques of tissue culture multiplied opportunities for circumventing breeders' rights.

When the Convention was revised in 1991, the breeder's minimum right in relation to propagating material was extended to all 'production or reproduction (multiplication)' without the addition of the words 'for the purposes of commercial marketing only' [Article 14(1)]. If this were all, the effect would have been to completely eliminate farmers' rights to save seed of protected varieties.

This would have been unacceptable for a large majority of UPOV members. Therefore, Article 15(2) permits UPOV members, if they so wish, to restrict breeders' rights within 'reasonable limits' in order to permit farmers to save or re-sow seed on their own farms. In doing so, they must 'safeguard' the legitimate interests of breeders. The 1991 Convention thus replaces a provision in which the breeders' right did not cover seed saved on the farm with a provision that does cover such seed but leaves each country free to make appropriate exceptions based on national circumstances.

UPOV signatories have applied the revised provisions in different ways. The United States has accorded an unconditional agriculture exemption to all growers of sexually propagated species for which protection is provided under the Plant Variety Protection Act (1970). The European Union, on

the other hand, chose to limit the exemption with the intent to 'safeguard the legitimate interests' of both the breeder and the farmer (Regulation (EC) No 1768/95). In particular, only certain fodder plants and potatoes are exempted, small farmers growing these fodder plants and potatoes are exempt based on the area required to produce a specified tonnage per harvest, and larger farmers may save seed for the same set of fodder plants and potatoes provided they pay an appropriate royalty ('equitable remuneration') to the rights' holder. The revised provisions clearly indicate a systematic effort to improve breeders' rights, while acknowledging the importance of the seed saving tradition amongst farmers.

4.2.4.1 Stakeholders are widely dissatisfied with the agriculture exemption, but for different reasons

The majority of plant breeders are opposed to the agriculture exemption. The industry view is that the special provisions governing payment of royalties on farm saved seed (FSS) were introduced initially in order to assist the agricultural sector, but that this assistance is no longer necessary in the EU context. They argue that the exemption now operates against the interests of the breeding industry, creating incentives for farmers to evade reporting use of protected varieties. In particular, breeders indicate that in Member States where enforcement is lax, the FSS provision poses a serious impediment to breeders' ability to reinvest in variety development. For example, a European plant breeders' association estimates that FSS use currently represents:

- Approximately 40% of agricultural crop production, such as winter wheat, winter barley and rye in Belgium, France, Germany, Hungary and the United Kingdom;
- Approximately 70-80% of agricultural crop production in Poland, Finland and Hungary;
- As much as 94% of potato production in Poland.

Evasion of FSS royalty payments is estimated to represent €65 million in losses to breeders across the EU (estimate based on price levels in 2005).

Conversely, growers argue that the FSS exemption is essential to the CPVR system. Plant grower association representatives emphasised the significance of FSS in:

- Striking a balance between breeders' and farmers' interests;
- Preventing breeders from gaining an unfair advantage over plant variety development;
- Contributing to greater biodiversity by encouraging variety adaptation for local conditions;
- Reducing reliance on chemical inputs and improving resilience of agricultural systems to climate change in the long term.

Member State representatives also view the FSS exemption as an essential aspect of plant variety protection (23 out of 26). Similar to the growers' responses, Member State representatives indicate that FSS is important for ensuring a fair balance between the interests of farmers and breeders. A few stressed the significance of the FSS exemption for small and subsistence farmers.

4.2.4.2 Dissatisfaction with the agriculture exemption is focused on royalty collection

Rights' holders in each Member State are free under the CPVR legislation to develop their own royalty collection systems for farm saved seed. Most commonly this takes the form of self-declaration by the farmer, whereby the farmer indicates the level and types of farm saved seed used. Breeders charge a levy on this use, which serves as remuneration to the breeder for the farmer's use of a protected variety. Regulation (EC) No 2100/94 states that monitoring compliance for the above processes is the exclusive responsibility of the rights holders and there are no provisions for assistance from official bodies. This part of the Basic Regulation is thus enforced by the beneficiary, and in the case of avoidance or non-payment, the plaintiff.

The biggest problem cited with this approach is the high level of false or undeclared FSS use. Rights' holders have therefore developed a variety of systems to enhance their ability to collect remuneration on farm saved seed. Such systems are in place in 16 Member States for cereals and 13 Member States for potatoes, though with wide variance in royalty collection capabilities amongst breeders and levels of agreement between breeders and farmers (Table A7.1 in Annex 7 provides an overview of the systems in place across EU Member States and the extent to which they have been implemented and are considered to be operating well). Annex 9 provides case studies describing the royalty collection systems operating in the Czech Republic, France, Germany and the United Kingdom.

The system of self-policing used by rights holders for FSS payments is not typical of practice in the seed supply industry as whole. The evaluation of the Seed and Propagating Materials Directives (2010) indicates that the seed sector itself believes it needs public supervision to guarantee quality.

4.2.4.3 Legal interpretation of FSS users' obligation to report creates practical difficulties with royalty collection

The plant breeding industry reports problems in obtaining information on FSS use, and contact details for farmers. Complaints are linked to three decisions by the European Court of Justice, which have restricted breeders' ability to collect information regarding FSS:

- *Schulin v Saatgut* (C-305/00, 2003) established that a breeder could not request information from a farmer regarding FSS use without prior evidence of such use;
- *Schulin v Jäger* (C-182/01, 2004) confirmed the 2003 ruling; and
- *Saatgut v Brangewitz* (C-336/02, 2004) established that, similar to the *Schulin* ruling, information could not be obtained from a registered seed processor regarding a farmer's use of protected varieties without prior evidence that the contractor had processed protected varieties.

These cases have increased the difficulties with the enforceability of farm saved seed provisions. Voluntary declaration systems arose from this practical difficulty in requesting information from farmers without evidence of use. A Working Group on Farm Saved Seed comprising representatives from the breeders, farmers, seed processors and the European Commission was created in 2009 to analyse the situation. The findings of this Working Group and from the stakeholder consultation for this evaluation indicate that:

- The CPVR Basic Regulation could be amended to require that farmers declare ('yes' or 'no') whether they have used farmed saved seed, regardless of indication of use, and that this amendment is within the meaning of the ECJ rulings;
- Where a farmer indicates 'no' to the use of FSS, prior evidence is still required for a breeder to request information from the farmer regarding FSS use, within the meaning of the ECJ rulings;
- Stakeholders prefer a flexible approach: in cases where a system is in place, and considered to work well (e.g. in the UK), nothing needs to be done;
- Involvement of national authorities should be limited in order to avoid any additional administrative burdens;
- The request as to whether or not FSS has been used should be made by a representative organisation of rights' holders or by the national authorities, if there is no appropriate organisation to designate;
- The Single Farm Payment form could serve as an opportunity to collect information if the parties in a Member State agree to this measure. Such a system is already in place in some Member States, such as Finland.

Effective communication is viewed by all stakeholders as a critical component to effective royalty collection systems, regardless of their form. An option to improve the CPVR system in regard to information collection on farm saved seed is discussed in Section 5. The option is assessed in Annex 16 (Option G1).

4.2.4.4 The list of species that apply to the FSS exemption is generally satisfactory, though specific concerns were raised regarding phytosanitary risks from farm saved potatoes

The farm saved seed exemption only applies to a specified list of plant species in the following categories: fodder plants, cereals, potatoes, and oil and fibre plants. There is some debate about whether the farm saved seed exemption should continue to apply for particular categories, though in general, the stakeholder consultation indicated that this issue is not a high priority. The one exception is for potatoes, which are considered to be a specific problem due to phytosanitary risks arising from use of uncertified potatoes (i.e. farm saved seed potatoes). Some stakeholders, including some Member State representatives, breeders and growers indicated that potatoes should not be included in the farm saved seed provisions for this reason. The phytosanitary risks arising from the use of farm saved seed potatoes could be further investigated.

4.2.4.5 The appropriate definition of a 'small farmer' is contentious and there is disagreement as to whether the provision should remain in the Basic Regulation

'Small farmers' are exempt from the requirement to pay royalties on farm saved seed. Commission Regulation (EC) No 1768/1995 defines a small farmer as a producer with fewer than 92 tonnes of annual cereal production or less than 185 tonnes of potatoes.

The small farmer exemption has been criticised by both the breeding industry and some farming groups, but for different reasons. Both cite lack of cooperation from public authorities in establishing appropriate guidelines and enforcement procedures. Small farmer thresholds differ significantly across MS and national PVR systems, making regime harmonisation difficult. The European Commission acknowledges that national authorities no longer record nor calculate the size of 'small farmer' holdings and the definition of 'small farmers' set out in Regulation (EC) No 1768/95 is no longer in use.. Stakeholders did not suggest that the differences in thresholds were creating competition distortions among small farms from different Member States but the current situation is clearly unsatisfactory.

Breeders and some Member State representatives have suggested that the small farmer exemption should be removed from the CPVR legislation. Breeders believe that their right to collect revenue for FSS should extend across all growers, and state that the extent to which that right would be exercised would be determined by the balance between the cost of collection and the fee income. There is still strong support for this exemption amongst growers and the majority of Member State representatives.

Options to improve the CPVR system in regard to the small farmer exemption are discussed in Section 5. The options are assessed in Annex 16 (Options G2 and G3).

4.2.4.6 The 'own holding' definition could be clarified to better reflect farming practices, and there is scope to clarify the definition of 'equitable remuneration'

The 1991 UPOV Convention allows farmers to sow farm saved seeds of particular protected varieties on their 'own holding' if they pay 'equitable remuneration' to the rights holder each year.

Both growers and breeders cite dissatisfaction with the definition of 'own holding'. The main concern is lack of a harmonised definition. They indicate that the definition of 'own holding' set out in Article 4(2) of Regulation (EC) 1768/95 is too vague which creates uncertainties regarding its interpretation. For example, at one end of the spectrum, it could be considered to include only the contiguous area designated as a 'holding' by CAP legislation (and therefore would not cover any other holdings owned by the same farmer). At the other, it could include the area covered by a cooperative of farmers. Breeders prefer a narrow definition and growers a more expansive one. Growers' organisations argue in particular that the 'own holding' definition does not reflect modern farming practices - that the definition is too strict and does not encapsulate the current variation in farming practices ('holding' types) throughout the EU.

The CPVR Basic Regulation defines 'equitable' as remuneration which is 'sensibly lower' than the charge for equivalent certified seed (i.e. 'of the same variety in the same area'). The original language in the Basic Regulation provides flexibility for the definition of 'equitable' to change over time. A European Court of Justice ruling, however, found that 80% charged by a rights' holder does not constitute 'equitable'. Subsequently, Regulation (EC) 1768/95 further defines 'equitable remuneration' and provides for two situations: one in which the rights holder and the grower agree to a remuneration level and one in which the parties cannot agree (whereby the remuneration level is fixed at 50% of the cost for licensing propagating material).

Breeders who expressed dissatisfaction with the definition of 'equitable remuneration' cited the following issues:

- The definition goes beyond what UPOV requires for the farm saved seed exemption (i.e. the words 'sensibly lower' and the 50% default rule); and
- The default payment rate of 50% creates an artificial market distortion preventing market led pricing policies for farm saved seed use.

Options to improve the CPVR system in regard to the definitions of 'own holding' and 'equitable remuneration' are discussed in Section 5. The options are assessed in Annex 16 (Options G4 and G5).

4.2.5 The EDV provision is appropriate but the definition is unclear and there are few established protocols for making EDV determinations. There is scope for improvement in this area.

The CPVR system follows UPOV 1991 in providing protection for 'essentially derived varieties' (EDVs). The Basic Regulation considers a variety to be essentially derived when:

- It is predominantly derived from the initial variety, or from a variety that is itself predominantly derived from the initial variety;
- It is distinct from the initial variety in accordance with the provisions for distinctness set out in the Basic Regulation; and
- Except for differences which result from the act of derivation, it conforms essentially to the initial variety in the expression of the characteristics that result from the genotype or combination of genotypes of the initial variety.

When these conditions are met, the derived variety is considered to be related closely enough to the initial variety that the CPVR holder for the initial variety is also deemed to be the rights holder of the EDV. EDVs were introduced to plant variety legislation in order to protect against variety plagiarism.

4.2.5.1 The EDV definition is unclear, both in the CPVR Basic Regulation and in UPOV

The EDV concept is considered to be a useful and important part of the CPVR *acquis.* Most respondents to the stakeholder consultation, for example, emphasised that the EDV provision discourages 'plagiarism' of varieties and facilitates research and investment in breeding activity. A majority of respondents to the breeders' survey (75%) also commented, however, that there is scope for further clarity on the EDV definition in the CPVR regulations and that the definition set out in UPOV could be clarified as well[14].

4.2.5.2 Procedures to determine 'essential derivation' are not well-established, therefore technical determinations do not produce clear results

There are no standardised protocols or thresholds developed by the CPVO or by Member States to determine EDVs, though these instruments have been developed by ISF and CIOPORA for a few species, such as lettuce, maize, and ryegrass, (ISF 2004, 2005; CIOPORA 2008). An ISF protocol on sunflowers is forthcoming in mid-2011 (ISF 2011). Disagreements over EDV determinations are ultimately resolved by national courts in each Member State. In these cases, different courts have interpreted similar cases differently, illustrating that EDV decisions may reflect the courts understanding of competing studies and what constitutes sufficient evidence.

[14] This is outside the scope of the current evaluation; any changes to the EDV definition must be taken at UPOV-level before amending the CPVR legislation.

Case Study 3: EDV court cases

A brief examination of two cases in the same jurisdiction which use similar evidence to determine whether a variety is an EDV illustrate how key differences in the courts interpretation of scientific evidence impacts the decision making process.

In the case of Van Zanten Plants (2008) the court relied on a comparative genetic study conducted using AFLP technology and calculation of the Jaccard index. The court observed that "a DNA study can be an important indication that there is (essential) derivation". The court accepted the study results (presented by the claimant) which showed 100% homology and held the variety to be an EDV. The defendant did not produce a counter study which was a crucial factor in the acceptance of the claimant's evidence.

In the case of Danziger "Dan" Flower Farm (2009), the claimant also submitted a DNA study using similar evidence (AFLP technology) presented in the previous case. The study showed a high Jaccard index. The defendant presented competing reports which showed a lower Jaccard index (below the threshold similarity) and challenged the appropriateness of AFLP technology. The court in this case favoured the defendant's view that AFLP was an inappropriate technology. In light of the conflicting reports, the court held that the claimant's evidence did not prove essential derivation.

These decisions show that absent uniformly established tests and criteria for identifying EDV, court decisions in similar cases might vary significantly due to methodological uncertainties and counter evidence.

A significant proportion of respondents to the breeders' survey (69 out of 84) favour using a combination of genotypic and phenotypic parameters to determine whether a variety is essentially derived, with a fixed protocol specifying the procedure to be followed for different species. Growers are also concerned about the imprecise definition and determinations for EDVs (16 out of 23 respondents were uncertain as to whether the procedure used in EDV determination was satisfactory, with comments indicating that this uncertainty is due to the lack of established procedures to determine whether a variety is 'essentially derived'). Member State representative responses indicate similar concerns, though they insist that setting EDV thresholds and making determinations are issues for the industry itself to resolve. CPVO could provide support to the development of protocols.

Uniform protocols can help to reduce the variance in technical determination methods that to date have yielded different results. Established thresholds can be used to trigger a reversal of the burden of proof in disputes. Thresholds must be adjusted for different species, and set to catch deliberate plagiarism but avoid spurious cases. Rapid innovation in the methods and techniques associated with EDV determinations (e.g. molecular marker technology) require regular reviews of any protocols or thresholds that are established.

An option to improve the CPVR system in regard to protocol development for EDV determinations is discussed in Section 5. The option is assessed in Annex 16 (Option E).

4.2.6 The application of CPVR protection criteria is generally appropriate and effective, though the quality of testing centres and variety denomination criteria could be improved

CPVR technical examinations are conducted by official testing centres designated by the CPVO Administrative Council, which operate in different EU Member States. There are currently 20 such 'Competent Examination Offices' located throughout the EU. The CPVO is responsible for developing the criteria on which technical examinations are based. Competent examination offices apply these criteria to each application.

Additionally, an appropriate variety denomination must be proposed by the applicant. Variety denomination is the only identifier of a plant variety so it must be the same in all MS. Applicants must ensure that the variety denomination:

- Is not being utilised by a third party;
- Does not create recognition difficulties;
- Is different from and may not be confused with another variety or with other goods; and
- Is not misleading with respect to the variety's characteristics or other features.

The CPVO is responsible for checking and approving the candidate variety denomination.

4.2.6.1 CPVR technical examination procedures are generally satisfactory, but the quality of DUS testing in some MS could be improved

Technical examinations for CPVR applications are conducted through national testing centres entrusted by the CPVO Administrative Council. For certain species, particularly ornamentals, there is only one entrusted examination centre (i.e. 'centralised testing'). Conversely, agricultural species have several competent examination offices. If more than one examination office is entrusted for the same species, CPVO may consider criteria such as the climate, the breeder's domicile and breeder requests to determine the testing centre. When CPVO receives an application for a variety for which there is no entrusted testing centre, CPVO will make a call for tender. If none of the entrusted offices makes an offer, the CPVO may request an examination office outside the EU to conduct the test.

Most breeders expressed satisfaction with the supporting infrastructure in place for the CPVR regime (e.g. testing facilities in MS and reference collection maintenance). A few are concerned about the quality of testing centres, and particularly that some examination centres lack the appropriate infrastructure to conduct the required tests.

Further, a more pragmatic approach to DUS testing for varieties of common knowledge could involve increased consultation with applicants to help identify the most important reference varieties of commercial relevance. In France, GEVES involves breeders in DUS testing, allowing them to supply the first year of data, which are prepared under GEVES supervision. The system reduces costs, improves application quality, and reduces national examination office workloads. In some MS, companies have been authorised to perform the testing for one DUS cycle for National Listing and this could be considered for CPVR as well.

The CPVO has recently implemented an audit and entrustment process to assess the capabilities of all current and potential testing centres across the EU. This system was implemented in order to introduce greater transparency in the entrustment process and ensure a minimum level of quality that is consistent across all testing facilities. This may improve DUS testing in the future, but at this stage audits are still underway and no information is available regarding the impacts of this new system.

An option to improve the CPVR system in regard to official licensing for DUS testing is discussed in Section 5. The option is assessed in Annex 16 (Option K5).

4.2.6.2 DUS criteria examinations are generally satisfactory, but the criteria themselves could be more flexible

The CPVR system relies on varieties being new, distinct, uniform and stable and having an appropriate denomination. The CPVO Administrative Council adopts protocols specifying the conduct of tests and reporting, which are based on the relevant UPOV guidelines where a species is covered by UPOV protocols. If no CPVO or UPOV protocol has been adopted for a plant species, examination offices may apply national protocols. Examination offices determine whether the variety fulfils the DUS criteria based on the protocols.

Breeders raised specific concerns about the use of genetic testing for DUS examinations. While breeders generally support the use of molecular markers and DNA-based testing, the majority of respondents indicated that genetic testing approaches should not replace morphological testing procedures, and that any additional costs should be borne by breeders who stood to benefit from the use of genetic techniques, rather than incorporated into the overall costs for granting CPVR.

Growers largely agreed that DUS criteria examinations are satisfactory (17 out of 24 respondents, six of whom 'strongly agreed'), but two respondents indicated that the system could better reflect varieties adapted to local conditions and that this would promote greater diversity and improved conservation (see Section 4.3.3).

Representatives from 25 out of 26 Member States agreed or strongly agreed that DUS criteria examinations are satisfactory. Two respondents stressed the importance of maintaining a balance between (i) having harmonised examination criteria and procedures and (ii) giving MS authorities the flexibility to adapt the regulations to unique circumstances or significant species in their Member State. Several plant breeders and MS representatives indicated that the use of 'additional characteristics' is important where two varieties are obviously distinct, but where the established protocols do not provide for consideration of these characteristics. Additional characteristics may be critical for determining that varieties which are obviously distinct are eligible for CPVR protection. This is very important where characteristics such as disease resistance are central to breeding developments for a

particular species (e.g. lettuce varieties) and a key feature of their agricultural significance. For these reasons, DUS criteria could be more flexible.

The CPVO Administrative Council adopts protocols based on UPOV guidelines. The CPVO President is empowered to add characteristics to the current guidelines, but will only act when it has been thoroughly examined at UPOV level. Changes are unlikely without an initiative by UPOV in this matter, which is outside the scope of this evaluation.

An option to improve the CPVR system in regard to adjusting testing protocols to accommodate additional characteristics is discussed in Section 5. The option is assessed in Annex 16 (Option K1).

4.2.6.3 Variety denomination criteria and procedures are unsatisfactory; there is scope to improve in this area.

The stakeholder consultation identified three main issues in the variety denomination criteria and procedures for CPVR:

- Procedural delays resulting in slower approvals than for national listing, which then delays market introductions for new varieties;
- CPVO rejection of denominations that were previously approved by national systems—in some cases after varieties have been commercially released at national level and where the name must subsequently be changed for marketing purposes; and
- Maximum limits for codenames are too restrictive.

A similar finding was reported in the recent evaluation of the Seed Marketing Directives, which concluded in July 2009. The evaluation indicated that there is a need to minimise inconsistencies between national level denominations and those approved by CPVO.

The CPVO has recently taken steps to improve coordination on variety denominations at EU and national level with a searchable, online database of known variety denominations which enables Member States to check potential names against those already in existence. The current database contains more than 500,000 denominations (as of 2008).[15] Some stakeholders noted during interviews that not all Member States are actively using the CPVO database, which reduces its usefulness. Furthermore, the database does not resolve all cases where a national denomination is rejected by CPVR (e.g. where a new name is accepted by national authorities after consulting the database, but that name is not accepted by CPVO).

An option to improve the CPVR system for variety denominations through a 'one key, several doors' approach to testing is discussed in Section 5. The option is assessed in Annex 16 (Option A).

4.2.7 The CPVO is an effective institution, but stakeholders suggest there is scope for improvement, particularly with the application process

The CPVO is an EU agency—one of more than 20 such bodies governed by public law that operate as independent legal entities and are financially independent from EU Institutions. The CPVO has an Administrative Council which comprises one representative from the Commission and one from each Member State. The Administrative Council did not include breeders' representatives in the past, but recent changes will allow a selection of representative organisations to participate in Administrative Council proceedings starting in 2010. The Administrative Council is primarily responsible for advising, issuing guidelines and rules and authorising the CPVO budget. Within the Administrative Council, the Commission has one representative and no vote. The Administrative Council does not take decisions on CPVR applications.

The CPVO is managed by its President, with the assistance of a Vice-President. The President and Vice-President are appointed by the European Council. The term for each of these offices is limited to five years and is renewable for additional terms. The President is responsible for personnel and financial management, advising the Administrative Council and implementing the budget. All CPVO decisions fall under the authority of the President.

[15] CPVO variety denomination database: http://www.cpvoextranet.cpvo.europa.eu/WD150AWP/WD150AWP.exe/CONNECT/ClientExtranet (viewed 30 March 2011).

The CPVO also provides an independent Board of Appeal (or multiple Boards of Appeal).[16] To date, only one Board has been established due to the low number of appeals. While the Board may be convened as necessary, in practice it has met between two and four times per year (Wertenberger 2006). The Board is composed of a Chairman and two other members, which are selected by the Chairman. Board decisions are based on a majority opinion.

A CPVR application must undergo three different examination procedures before its acceptance (i.e. a CPVR is granted) or rejection. The first two, formal and substantive examinations, are undertaken by the CPVO itself.

A recent evaluation of the CPVO (2010) found that CPVO functioning is generally satisfactory: CPVO maintains its independence, has a clear and well-structured strategic framework, a transparent decision-making process, and operates within its budget. Stakeholders consulted for the current evaluation largely agree with these findings, and the breeding industry is generally satisfied with CPVO's operation. The industry did, however, express reservations on specific details related to costs (discussed in Section 4.2.9) and to potential efficiency gains in the application process and information exchange requirements between applicants and the examination centres (see Section 4.2.7).

4.2.7.1 The application process could be further improved through minor changes in the CPVO's operations

A majority of breeder respondents indicated that the CPVR application could be improved, particularly regarding what are considered to be overly burdensome information requirements for submitting an application. Issues cited include:

- Difficulties contacting the CPVO to resolve issues: particularly, lengthy response times to inquiries and requests by applicants;
- Information requirements to submit a new application are too extensive and some requirements are unnecessary to determine whether a CPVR should be granted;
- Duplicate requirements within the application;
- Unnecessary administrative burdens where CPVO requires that all correspondence be included between the applicant and the examination office when it takes over DUS reports from national authorities; and
- Additional burdens due to variations between national PVR application procedures and CPVR procedures, where a national application is made prior to a CPVR.

The 2010 CPVO evaluation also identified issues with communication to resolve issues, time delays in processing applications and other similar issues outlined above.

Respondents favour further development and expansion of the online application procedures that were recently initiated in order to improve efficiency and reduce costs. Currently, the online procedure is available in English for 90 of the most common species (e.g. roses and wheat). Additional languages (Dutch, German and French) will be available by the end of 2011. Additional varieties are being added regularly.[17]

Most of the issues cited in this area can be improved by removing inefficiencies in the CPVO's daily operations, without large-scale changes in the CPVO. An option to improve the CPVR with respect to CPVO taking over DUS test reports is discussed in Section 5. The option is assessed in Annex 16 (Option K2).

4.2.7.2 The CPVO Board of Appeal fulfils its role

The CPVO also comprises an independent Board of Appeal (or multiple Boards of Appeal). To date, only one Board has been established due to the relatively low number of appeals. While the Board may convene as necessary, in practice it has met between two and four times per year.

A majority of breeder respondents are satisfied with the functioning of the Board of Appeal. Most breeders observed that provisions relating to appeal periods and payment requirements could be

[16] The following decisions of the CPVO may be appealed: nullification/cancellation of a CPVR; objections; refusal/grant of a CPVR; acceptability/amendment of variety denominations; fees charged; apportionment of costs; entering information in the register of the Office; and public inspections of registers (see also Article 67(3)).

[17] See CPVO website: http://www.cpvo.europa.eu/main/en/home/filing-an-application/online-applications (viewed 21 March 2011).

made more stringent. One 'micro' enterprise also suggested that the appealing party be required to pay for extending yearly cultivation fees of the variety in question in the event of an appeal not proving successful. Breeders must currently bear the additional burden of these fees over and above legal costs incurred in defence against the appeal, and this is a particular problem for small businesses.

4.2.8 The process to appoint senior management in the CPVO laid down in the BR is not aligned with current Commission practices and process in other EU agencies

Articles 43 and 47 of the Basic Regulation indicate the process that should be undertaken to appoint senior management in the CPVO. These procedures, however, no longer conform to current Commission practices for hiring senior management, as they are undertaken in some other EU agencies. The CPVR Basic Regulation, and thus the rules for hiring, predates the formation of some other EU agencies. The Basic Regulation should be amended to conform to current practices to reduce the administration burdens currently encountered for hiring. An option to improve the CPVR system regarding hiring procedures for CPVR senior management is discussed in Section 5. The option is assessed in Annex 16 (Option M).

4.2.9 The costs related to the CPVR system are generally reasonable, but stakeholders expressed concerns about CPVR maintenance fees, DUS testing costs and enforcement costs

4.2.9.1 Breeders are generally satisfied with most costs associated with CPVR, though they are dissatisfied with the maintenance fee and indicate that enforcement costs are too high

Breeders making use of the CPVR system incur:

- Administrative charges levied by the CPVO; and
- Administrative costs associated with collecting FSS fees, licensing fees, and enforcement costs.

In general, breeders regard the costs of *obtaining* CPVR as a reasonable proportion of overall innovation costs, particularly for major crops with marketing potential in multiple EU Member States. A few respondents indicated that affordability is more of an issue with respect to:

- Minor crops, with less wide marketing potential,
- Varieties with highly segmented markets;
- Varieties with very short shelf lives; and
- Small companies, where the costs are relatively much higher to obtain CPVR.

Most plant breeders also agreed that CPVR costs are reasonable in comparison with costs incurred through national PVR procedures. Member State representatives indicated during interviews, however, that plant breeders in some countries consider the costs of the CPVR system to be too high for them to use it. This is particularly the case in some new Member States, where national PVR costs are very low compared to those of the CPVR system.

While a majority of breeders believe that the application costs are appropriate overall, they do not view the annual maintenance costs as proportionate. The industry suggested that maintenance costs should either be lowered or decrease over time so as to better reflect true administrative costs to CPVO for maintaining the right. The CPVO has stated that it works to keep costs as low as possible for applicants. It has reduced maintenance fees in past years, in line with reducing budget surpluses.

Consultations indicate that, whatever the balance between the charges and costs of annual maintenance, these annual fees are effective at ensuring that plant varieties that are no longer viable on the market are removed from protection and made fully available to other users. This issue is discussed in the section on duration of protection (Section 4.2.2).

Overall, the existing charging structure (including a maintenance fee element) is appropriate. Fees should reflect costs, and costs should be based on application of best practice procedures and efficient operation of the institution as a whole.

Breeders believe there is scope for greater cost efficiencies in their interactions with the CPVO. A majority of breeder respondents did not agree that CPVR applications are processed in a cost-effective manner. Improved communication between breeders and CPVO staff was also highlighted as having the potential to lead to cost efficiencies by way of reduced testing expenses. Some breeders advocate licensing breeders' organisations to conduct DUS tests and analysis. The use of

molecular tools was also raised an opportunity for greater cost efficiencies. Options to improve the CPVR system in these areas are discussed in Section 5. The options are assessed in Annex 16 (Options K3, K5, and L1).

A majority of breeder respondents (87 out of 97) believe that enforcement costs for CPVR are disproportionately high in relation to the benefits they derive from the right. Most 'strongly disagreed' (72 respondents) when asked if these costs were reasonable. Enforcement costs are particularly high where enforcement is less effective. Costs for legal procedures are too high in general (e.g. costs of legal support, evidence gathering and court expenses). Where enforcement difficulties are perceived to outweigh financial returns, breeders are deterred from attempting to enforce their rights at all. Options to improve the CPVR system with regard to enforcement are discussed in Section 5. The option is assessed in Annex 16 (Options C and H).

The majority of breeder respondents (72 out of 79) indicated that the costs of operating fee collection systems for FSS are too high. This was attributed to difficulties in the requirements for information provision by farmers and inefficiencies in fee collection regimes across several MS. Some respondents indicated that costs could be lowered if farmers were obliged to indicate whether or not they had used FSS on request. An option to improve the CPVR system with regard to royalty collection on FSS is discussed in Section 5. The option is assessed in Annex 16 (Option G1).

4.2.9.2 Plant growers are divided on whether the costs they incur in using CPVR are reasonable

Plant growers incur costs where they pay royalties and license fees to use protected varieties. Growers are divided on the issue of costs, with 11 out of 22 respondents indicating that these costs are excessively high and eight indicating that they are reasonable. One suggested that the royalties earned by rights' holders for 'high value added' varieties of fruit and vegetables were unreasonably high. Growers were largely uncertain as regards other types of costs related to CPVR, such as dispute resolution and reconciliation costs and equitable remuneration for FSS. Given the limited response from growers and uncertainty about the basis of claims of excessive cost there is insufficient evidence to conclude that the CPVR system imposes unreasonable costs on growers.

4.2.9.3 Member State representatives believe that the costs they incur related to the CPVR system are generally 'reasonable', though some Member States argue that DUS testing fees do not adequately cover the actual testing costs

Member States incur the following costs related to the CPVR system:

- DUS testing for technical determinations;
- Reference collections maintenance; and
- Providing expertise and inputs to the CPVR system beyond that for DUS testing.

Costs involved in the CPVR *acquis* for examination offices vary widely by Member State; some examination offices argue that the DUS examination fees do not cover the costs of testing. Representatives from 17 out of 26 Member States agreed that the costs they incur maintaining the CPVR system are 'reasonable'. Representatives in only two Member States disagreed. In one Member State, representatives argue that the cost of providing expertise is not recovered through CPVR fees. In another Member State, representatives indicated that because the CPVO only pays the examination offices for DUS testing after two years, the offices must absorb an unnecessary burden by pre-financing the tests. Further research into this issue could be undertaken, but is not a priority concern. In general, the overall costs to EU Member States appear to be reasonable. An option to improve the CPVR system with regard to the fee payment lag is discussed in Section 5. The option is assessed in Annex 16 (Option K4).

Representatives of 15 Member States agreed that the costs for DUS testing are reasonable. Twelve of those 15 also agreed that the overall costs are reasonable. Representatives of four indicated that DUS testing costs are too high, for reasons that included the cross-subsidisation of testing across Member States through CPVO testing fees[18]. Other MS representatives cited overly prescriptive DUS protocols and an inflexible approach to testing which is further discussed in Section 4.2.6.

[18] Some Member States cannot recover the DUS testing costs through CPVO fees, while others receive more compensation than the tests actually cost.

Representatives from eight out of 26 Member States agree that the costs for maintaining reference collections are reasonable. Eleven disagreed. These respondents indicated that costs are high for certain crop species (e.g. those which are vegetatively propagated, such as many trees and shrubs). Others suggested that the DUS testing fees are inadequate for maintaining the appropriate reference collections. Nonetheless, reference collections are used for a number of purposes, only one of which is to conduct DUS tests for CPVRs. For this reason, the costs of maintaining reference collections should not be a priority consideration for reform in the CPVR *acquis*, but rather an issue to be addressed at Member State level.

4.2.10 Enforcement is viewed as one of the greatest concerns for the CPVR system

4.2.10.1 Stakeholders are satisfied with the enforcement provisions in principle, but unhappy that they have not been uniformly implemented in each Member State

The plant breeding industry is dissatisfied with the implementation of CPVR enforcement provisions. Several respondents observed that the enforcement provisions provide an adequate framework for the system, but emphasised that national regimes should be harmonised to facilitate better implementation. One grower respondent reiterated the plant breeding industry view, indicating that enforcement issues are related to implementation in Member States, rather than a problem with the CPVR legislation, itself.

4.2.10.2 Enforcement is considered to be ineffective in many Member States and in some cases dispute resolution mechanisms are not easily accessible

Most plant breeders disagreed, some strongly, with the proposition that CPVR enforcement is effective across all EU MS. Respondents raised particular concerns about fraudulent marketing, illegal planting of protected varieties and failure to pay fees for farm saved seed.

Fraudulent marketing can take two forms:

- Marketing a protected variety as an unprotected variety; and
- Plagiarism – that is, marketing a variety using a variety denomination of a protected variety, but where the variety itself is not the variety named.

Fraudulent marketing is cited as a problem:

- Generally across the EU for vegetable seeds, where the value of seed is high and the volumes involved are small. A plant breeding company estimates that plagiarised vegetable seeds may reach 10% for the most important crops.
- To a lesser extent for ornamentals;
- Increasingly in Sweden; and
- Particularly in Hungary for agricultural varieties.

Illegal sale of protected varieties, without authorisation from the right's holder:

- Is cited as a general problem across Southern and Eastern Europe, and particularly for cereals.
  - An ISF (2005) presentation to UPOV estimates that illegal wheat planting occurs across the EU, and represented 30% of wheat planting in Poland, 23% in Finland, 20% in the Czech Republic and 18% in the United Kingdom during 2005.
  - A plant breeding company estimates illegal propagation currently occurs for 50% of cloned orchard crops in Spain (personal communication).
- Occurs across all EU Member States for potatoes, where only 50-60% of the ware crop is planted with certified seed potatoes (with the exception of the Netherlands where seed and ware potatoes[19] are legally differentiated) (personal communication from a potato growers cooperative association).
- Occurs for hybrid varieties (as farm saved seed), which is forbidden under CPVR legislation (personal communication from multiple plant breeding companies and representative associations):

[19] Ware potatoes are those grown for human consumption; seed potatoes are grown for further propagation.

  - For F1 and F2 hybrid tomatoes in Spain;
  - For F2 hybrid onions in Poland;
  - For F2 hybrid spinach in Italy; and
  - For F2 hybrid watermelon in Hungary.
- Is concentrated in particular market segments; for example:
  - A plant breeding company estimates that 90% of baby lettuce marketed in Italy is illegally reproduced and sold (personal communication); and
  - Another company estimates that 20-25% of hybrid tomatoes are illegally reproduced in Spain (personal communication).
- Is a particular problem for the cut flower and fruit industries regarding propagation in third countries, where illegal products are imported into the EU (this issue is described in greater detail in Section 4.2.1).

Failure to pay royalties for farm saved seed:

- Occurs widely for agricultural varieties, particularly where farmers share seed with one another:
  - In Germany, a national plant breeders association estimates that 50% of FSS remuneration is estimated to be lost annually (representing approximately €7 million per year) (personal communication);
  - In France, a national plant breeders' organisation estimates annual losses at €25 million per year (personal communication);
  - In the Netherlands, a national plant breeders' association estimates that for cereals, between 25-30% of royalties are not paid to breeders (personal communication).
- Occurs widely for potatoes across the EU: a potato seed distributor estimates that for their breeders, estimated losses from evasion of royalty payments is approximately 25% (personal communication).

Under these circumstances, plant breeders have a range of options to choose from in order to facilitate plant variety rights enforcement:

- Private negotiation with plant growers to obtain royalty payments.
- Contractual agreements with plant growers regarding FSS use and required royalty payments.
- Facilitated royalty collection for FSS and other varieties through organisations representing plant breeders in different EU Member States. These include: the British Society of Plant Breeders (BSPB) in the UK, Geslive in Spain, SICASOV in France, and Bundesverband Deutscher Pflanzenzuchter (BDP) in Germany. This option is limited where royalty collection systems are not present in Member States, and no organisation has been designated to assist with royalty collection.
- Advance payment for FSS, which occurs, for example, with respect to potatoes in the Netherlands.
- Customs actions in collaboration with DG Taxation and Customs for illegal imports from third countries.
- Court cases, which are considered to be a 'last resort' measure where other opportunities are not feasible. Court cases are costly and stakeholders indicated that cases often lead to different results for similar cases.

There are a number of reasons why breeders indicate enforcement is problematic:

- Evidence is very difficult to collect:
  - Particularly for FSS, where the current legislation and ECJ rulings make it difficult to ascertain who is using FSS at all; and
  - Due to variance in procedures in many MS, and particularly where obtaining permission to collect samples from a potentially infringing premise is difficult or impossible to obtain.
- Royalty collection on imports of illegally produced materials from third countries is hindered by:
  - Loopholes in the legislation for harvested materials (see Section 4.2.1.2); and
  - Customs actions that are hindered by Article 11 of Regulation 1383/2003 (the anti-piracy customs regulation), which provides only three days to judge whether suspected products infringe CPVR holders' right. Determining PVR infringements requires time consuming

procedures that are difficult and in some cases impossible to conduct in only three days (personal communication from a national plant breeders' representative association).

- National authorities are unwilling to assist with infringement cases, particularly in Southern Europe (personal communication from several plant breeding companies and a national plant breeders' association)
- Variance in national enforcement norms and procedures, and particularly with variance in implementation of the EU Enforcement Directive (personal communication from several plant breeding companies and plant breeders' representative associations);
- Infringement cases are expensive to bring to court and the outcomes are highly uncertain, which reduces the perceived usefulness of this option (see Section 4.2.9).

Growers cite the following issues with enforcement procedures:

- Dispute resolution mechanisms not easily accessible (survey results and personal communication);
- Distrust of breeders' representative organisations in some MS (personal communication);
- Insufficient farmer representation in decision making forums at national, EU and UPOV levels (personal communication);
- A lack of transparency and harmonisation on enforcement rules and procedures across EU MS (personal communication).

Options to improve the CPVR system for enforcement-related concerns are discussed in Section 5. The options are assessed in Annex 16 (Options C, G1, H, I, L1, L2).

4.2.10.3 There are points of tension between the CPVR Basic Regulation and Enforcement Directive

There is a tension between Article 97(3) of the Basic Regulation on infringement procedures and the EU Enforcement Directive (2004/48/EC).The Directive was adopted after the Basic Regulation and places an obligation on Member States to adopt legal tools and remedies to enforce plant variety rights. Article 97(3) of the Basic Regulation, however, states that 'in all other respects the effects of CPVR shall be determined solely in accordance with this Regulation'. This could be interpreted to include enforcement, so that the Enforcement Directive would not apply to the CPVR *acquis*. A court case has already considered this issue, hearing the argument that Article 97(3) would prevent a national judge from applying the national enforcement rules laid out in the Directive. There are other potential points of conflict between the Directive and the Basic Regulation, outlined in Table 4.2. These issues are described in greater detail in Annex 10. An option to improve the CPVR system to resolve these tensions is discussed in Section 5. The option is assessed in Annex 16 (Option C).

Table 4.2 Points of tension between the Enforcement Directive and CPVR Basic Regulation

Regulation (EC) No 2100/94	Directive (EC) No 2004/48	Conflict	Comment
Article 94 entitles the complainant to 'reasonable compensation' and 'further damage'.	Article 13 entitles the rights' holder not to 'reasonable compensation' but to 'damages appropriate to the actual prejudice suffered'.	High	The CPVR could be amended to include provisions similar to the Enforcement Directive (ED).
Article 94(2) provides that in cases of slight negligence claims may be reduced.	Article 13(2) does not reduce claims but directs the judicial authority to order profit recovery or pre-established damage payments	High	The CPVR could be amended to include provisions similar to the ED
Article 97(3) states 'In all other respects the effects of Community plant variety rights shall be determined solely in accordance with this Regulation.'	(N/A)	High	The Basic Regulation (BR) could be construed to preclude the use of ED in its entirety. Article 97(3) needs to be deleted or amended accordingly.
Article 97 refers to application of national laws for Restitution.	Article 13 goes much beyond restitution.	Moderate	The BR is silent on applicability of national laws for issues other than restitution (e.g. damages). The BR needs to be amended to harmonize these concepts.

Article 104 entitles the holder and any person enjoying the right to bring an enforcement action. Art 104 is exhaustive and can be interpreted to exclude any other entity as having standing to bring an action.	Article 4 specifically includes collective action by certain recognized bodies.	Moderate	The CPVR can be amended to include this category more specifically as breeders association etc.
Does not make any reference to issues or recall, removal and destruction.	Article 10 expressly refers to corrective measures of recall, removal and destruction.	Low	The ED provides important corrective tools. Although there is no conflict between the CPVR and ED on this issue, explicit reference would better enable the courts. The BR could be amended to clarify applicability of national laws.
Article 94 read with Articles 13(2), 17(1), 17(2) and 18(3) include a set of violators who could be sued, but does not include intermediaries.	Article 9 and 11 make specific reference to intermediaries.	Low	The BR could be amended to include intermediaries as a violator and should go beyond the ED in broadly defining intermediary.

4.3 The CPVR *acquis* is generally beneficial for users of protected varieties, though data are limited in this area

4.3.1 The impacts of the CPVR *acquis* on small, medium-sized and large plant breeders and breeding companies are generally positive, but data are limited on this issue

Small and medium-sized enterprises (SMEs) represent 99% of all businesses in the EU. They are central to economic growth, innovation, employment and social integration[20]. The World Intellectual Property Organization has noted that UPOV membership provides benefits to SMEs in the plant breeding sector, including:[21]

- Lower 'barriers to entry' in the breeding sector (particularly through the 'breeder's exemption');
- A simplified and harmonised application system (which lowers costs and reduces administrative burdens to applicants); and ultimately,
- Intellectual property protection that allows SMEs to reinforce their market presence and ensure sufficient return on investment from developing new plant varieties.

The CPVR system conforms to UPOV, so these benefits should accrue to SMEs who use this system. There is, in principle, an additional benefit from CPVR over national PVR protection because the CPVR system provides EU-wide protection for new plant varieties.

4.3.1.1 Small, medium-sized and large plant breeders apply for and are granted CPVR

SMEs are important to the plant breeding industry. A well-functioning CPVR system should support SMEs' ability to apply for, receive and enforce PVRs. Data on SME representation among all CPVR rights holders are not available, but the survey used for this evaluation collected information on the business size of each respondent. Among the 79 plant breeder companies who submitted a survey, 61 enterprises classified themselves as an SME.

Large companies that responded to the evaluation survey account for approximately 85% of total rights granted (1995-2010) to all survey respondents (Table 4.3). Medium-sized companies represent approximately 11% of rights granted, and small and 'micro' sized companies together represent less than 5% of rights granted to respondents. In total, SME survey respondents represent approximately 15% of rights granted. If this pattern is representative of all plant breeders that use the CPVR system, the result suggests that SMEs participate in the CPVR system to a modest but significant extent.

[20] DG Enterprise and Industry, 'Small and medium-sized enterprises (SMEs)', http://ec.europa.eu/enterprise/policies/sme/index_en.htm (viewed 19 November 2010).

[21] World Intellectual Property Organisation (WIPO), Program Activities, 'Getting the Most out of your New Plant Variety', http://www.wipo.int/sme/en/documents/upov_plant_variety.htm (viewed 18 November 2010).

Table 4.3 CPVR distribution among evaluation consultation respondents by company size

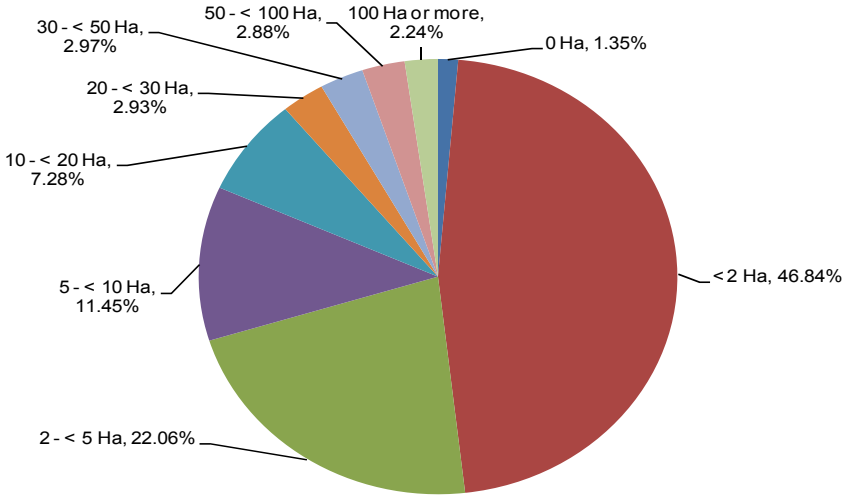
Company Size *(number of employees)*	**Number of breeding company respondents**	**Number of CPVR titles granted to respondents[22]**	**% of total CPVR granted to respondents**
Large *(more than 250)*	19	6,954	84.90
Medium *(50-250)*	20	889	10.85
Small *(10-50)*	22	229	2.80
Micro *(fewer than 10)*	18	119	1.45
Total		**8,191**	

Source: GHK analysis of CPVO data (titles granted from January 1995 to July 2010)

4.3.2 The relative impacts of the CPVR *acquis* on small, medium-sized and large farms are difficult to determine because there are limited data available on this issue

European farms are diverse and vary widely in size. There is currently no universally recognised definition of small and medium farms in the European Union and farm size cannot easily be compared to other SMEs. For the purposes of this study, small, medium, and large farms are defined based on the Eurostat classification of farm sizes as: small where their size is between 0-5 hectares (ha), medium where farm size is between 5-30 ha, and large where farm size is >30ha[23]. Farms of less than five hectares represent 70% of farms in the EU (Figure 4.3). Smaller-sized agricultural holdings are mostly located in small and Eastern European countries (Figure A7.1 in Annex 7).[24]

Figure 4.3 Approximately 70% of EU farms are small operations of less than five hectares



Source: Eurostat (2007 data)

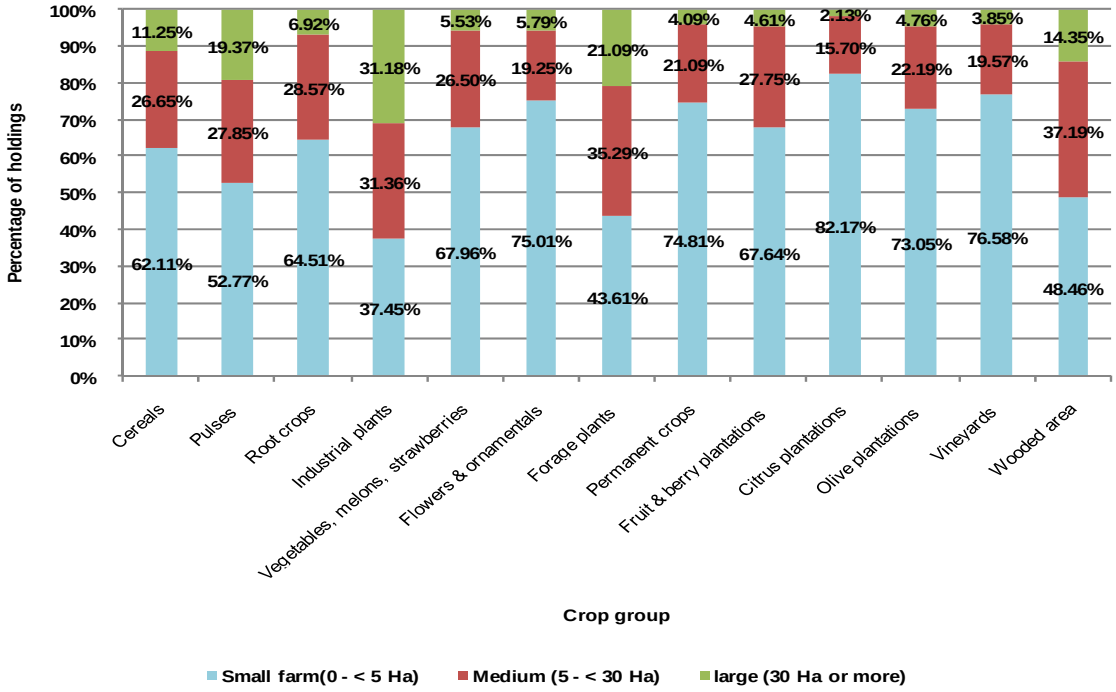
Farm sizes differ by crop type: cereals, forage plants and pulses tend to be correspond with larger farms. Vegetable, flower and fruit production corresponds with smaller (<5 ha) holdings (Figure 4.4).

[22] This refers to the total number of CPVR granted to respondent companies in the period analysed.

[23] Eurostat farm size classifications: 0, 0-2, 2-5, 5-10, 10-20, 20-30, 30-50,50-100, more than 100 hectares.

[24] These figures include properties claimed as farms but may not actually be farms; these data cannot be separated in the analysis due to missing information.

Figure 4.4 Percentage of total number of agricultural holdings by farm size and crop type



Source: Eurostat (2007 data)

Ornamental growers have registered the largest number of CPVR applications, and ornamentals are mostly grown on small farms (Figure 4.4). These data suggest that small farmers will accrue the most benefit from new plant varieties in the ornamental sector.

Agricultural crops are also widely planted on small farms (Figure 4.4), particularly in southern and eastern EU Member States. The CPVR system includes a 'small farmer exemption' which provides benefits to small farmers as they do not have to pay royalties on farm saved seed, thus increasing their returns on investment (see Section 4.2.4.5). No data have been located that would explain the impacts of the small farmer provision on EU farms.

The current data do not contain information on the quantity of usage (e.g. a small number of grants could cover a large harvested area). It is difficult to make definitive conclusions about the relationship between the economic welfare of small farm businesses and the CPVR system due to limitations in the available information.

4.3.3 The consequences of the CPVR *acquis* on EU citizens and consumers are generally thought to be positive, though limited data are available on this issue

The CPVR *acquis* may have positive impacts on EU citizens and consumers where the system incentivises development of new varieties which are:

- Higher yielding (i.e. producing more food on less land);
- More sustainable (e.g. require fewer inputs such as pesticides and fertilisers);
- Better adapted to climatic conditions (e.g. adaptation to climate change); and/or
- More nutritious (i.e. produced to have a higher nutrient content).

As a result, EU citizens and consumers may directly or indirectly see the following benefits:

- Directly, through foods that are lower priced, higher quality, and healthier; and
- Indirectly, through greater: European competitiveness in the agricultural sector, benefiting the EU economy; food security; and environmental sustainability.

Stakeholder consultation results support these perceived impacts and benefits.

While the majority of growers (15 out of 24) agreed that the CPVR system upheld the interests of the wider public, four respondents pointed to some potential drawbacks for EU citizens and consumers:

- Reduced access to diversified food options, because the CPVR system favours standardised varieties for industrial agricultural production over traditional varieties;
- Reduced environmental benefits, because those varieties that are best adapted to organic or low-input agriculture often do not conform to the CPVR criteria; and
- Reduced biodiversity, because the CPVR criteria are a barrier to cultivation and commercialisation of traditional varieties.

No evidence could be obtained demonstrating direct consequences of the CPVR system on EU citizens and consumers.

4.4 The CPVR *acquis* provides benefits to EU plant breeding, agriculture and biodiversity

4.4.1 The CPVR *acquis* has stimulated breeding and development, and facilitated and improved the protection of new plant varieties in the EU as compared with the situation before 1994

The development of new crop varieties is widely considered to have made a very significant contribution to growth in agricultural productivity, particularly in the last century. A distinguishing feature of contemporary plant breeding is the planned incorporation of specific desirable traits in new varieties, using the range of techniques and information available to plant breeders (OECD 1993). Accordingly, the transformation of plant breeding into an organised scientific activity raises the issue of how to provide incentives for research, and in particular whether intellectual property rights for plant varieties encourage innovation.

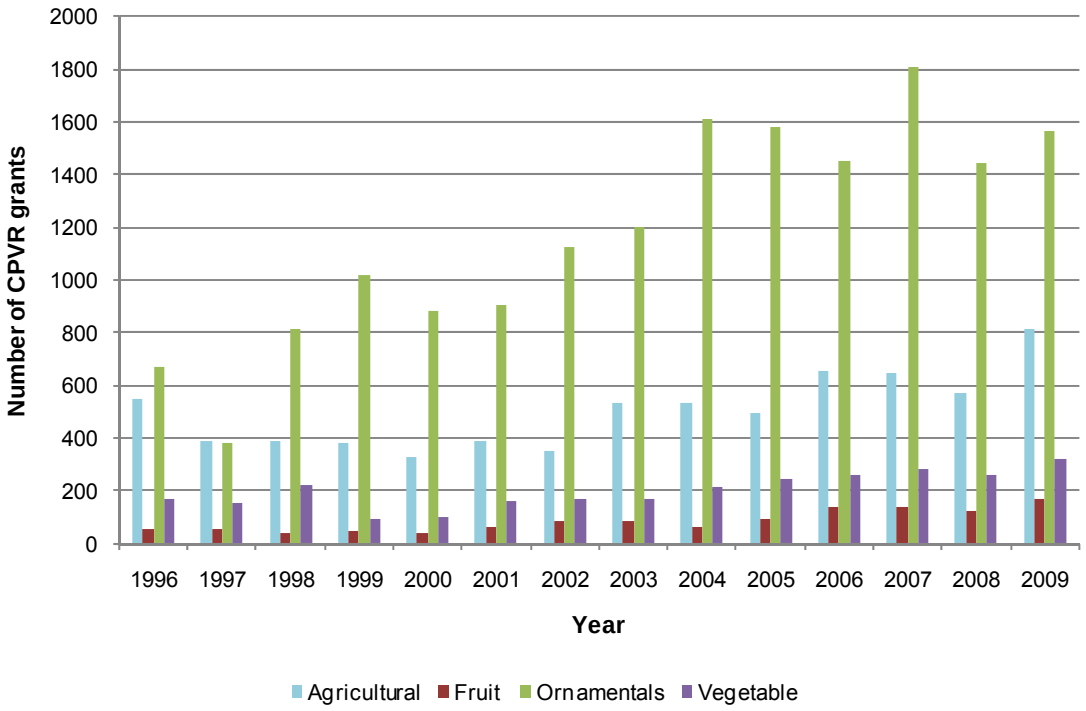
4.4.1.1 CPVR applications and rights granted are increasing over time

A straightforward way to assess whether the CPVR *acquis* can be considered to 'stimulate' plant breeding and variety development is to determine whether it has facilitated the protection of new plant varieties in the EU.

The number of CPVR applications and CPVR awarded has steadily increased since the regime came into force in 1995. New varieties must meet novelty criteria in order to be granted. During the first five years of the CPVR system (1995-2000), the number of titles granted fluctuated, averaging 1,400 per year. Since 2000, the number of rights granted has more than doubled. In 2009, 2,866 titles were granted. A similar trend can be found in the number of CPVR applications over time: 1,348 were received in 1996 compared to 2,956 in 2009. This suggests that not only is there increased interest and perceived usefulness in the system (i.e. applications increase over time) but also that there are an increasing number of 'new' varieties being developed (i.e. rights granted increase over time).

Some fluctuation can be seen in the number of CPVR granted annually across crop categories. The number of CPVR awarded under the agricultural category, for example, has varied over time, but the overall trend is toward an increasing number of rights granted per year (discounting the effect of a large number of rights granted when the system was introduced in 1996) (Figure 4.5).

Figure 4.5 The number of CPVR granted to varieties under the four major categories has risen overall since 2000



Source: GHK analysis of CPVO data (1996-2009)

The number of rights granted across all four crop groups has risen since the system was implemented suggesting that decline in a particular year does not mark a structural shift in the system. A similar effect can be seen for CPVR applications (Annex 7, Figure A7.9).

4.4.1.2 Stakeholders indicate that the CPVR *acquis* facilitates EU protection of new plant varieties and stimulates plant breeding

All plant breeders, without exception, expressed satisfaction that the CPVR *acquis* facilitates the protection of new plant varieties in the EU. Breeders indicated that the CPVR *acquis* aligns all EU MS with the 1991 UPOV Convention by providing an EU-wide plant variety protection system, thus ensuring better protection for new varieties. Representatives from 25 out of 26 Member States also believe that the CPVR *acquis* plays a significant role in ensuring the protection of new plant varieties in the EU.

Representatives of all 26 Member States also agreed that the CPVR *acquis* encourages plant breeding activity. Most Member State respondent comments emphasised the regime's effectiveness in securing returns on breeders' investment in variety development research. Similarly, the plant breeding industry view is that the CPVR *acquis* stimulates plant breeding. Most breeders also indicated that the CPVR system facilitates continual investment and reinvestment in new variety development.

Most growers (21 out of 24) also agreed that the *acquis* encourages plant breeding. Two respondents disagreed, however, arguing that the regime favours commercial variety breeding without adequately encouraging locally adapted variety cultivation by farmers. A national growers' association argued that the system does not adequately support innovation for marginal or 'orphan' species.

There is no direct evidence that the CPVR *acquis* stimulates innovation, though Ghijsen (2009), Eaton and Van Tongeren (2005) and Louwaars et al (2009), indicate that the breeders' exemption acts as strong stimulus for innovation. Louwaars et al (2009) further argue that the CPVR increases innovation by maintaining access to protected varieties thereby decreasing market entry barriers and increasing competition (although no quantitative data are provided to directly support this claim).

4.4.1.3 Plant breeders from all MS apply for and most are granted CPVR across crop groups

Another way to assess whether the CPVR *acquis* 'stimulates' plant breeding is to examine the pattern of distribution of CPVRs amongst plant breeders. The data indicate that at least one CPVR title was awarded to applicants based in 25 of the EU 27 MS from 1995-2010[25]. One application listing Latvia (LV) as the country of origin was rejected in this period, while no applications were received from applicants based in Lithuania (LT). In total, EU Member States account for nearly 80% of all CPVR grants (23,290 of a total of 29,294) awarded in this period.

Far more CPVRs have been granted to breeders in some MS than in others. Only three countries account for more than 60% of all CPVRs (i.e. the Netherlands, Germany and France). The Netherlands (NL) accounts for 32% of all CPVR grants from 1995-2010, and Germany (DE) and France (FR) together account for 30%. The distribution of CPVR titles also varies across the four major crop varietal groups. Breeders from the Netherlands hold the most rights across the ornamental and vegetable categories, and France and Germany together account for more than 50% of all CPVR grants awarded to agricultural varieties. France, Italy and Spain together account for more than 50% of all titles granted to fruit varieties. The cost of obtaining CPVR may be much higher than the cost of using national PVR in some MS, reducing its appeal. This issue is discussed in greater detail in Section 4.2.9.1.

4.4.2 The CPVR *acquis* has some impacts on preservation and erosion of plant genetic resources in the EU

There is some evidence to support the idea that agricultural biodiversity is being reduced over time (UNEP 1999). Many older, less popular varieties or those that have been superseded by newer varieties are not grown anymore, resulting in reduced agricultural diversity and genetic erosion. The extent of this reduction has not been well-documented. Furthermore, the meaning of 'genetic erosion' is also unclear. Genetic erosion may be reflected in the reduction of allelic evenness and richness, but must be viewed in conjunction with variety-level differences (e.g. mutants).

A study by the Over Seas Development Institute (1999) indicates that agricultural biodiversity is being eroded because industrial agricultural systems increase the risk of on-farm genetic erosion through ecosystem simplification and reduction of species and varieties. The study observes, however, that agricultural biodiversity is difficult to measure, as the most common means of assessing erosion is by counting named varieties, which do not directly correspond to genetic diversity. Little evidence, however, has been found to link the loss in agricultural biodiversity to the availability of plant variety rights. This section analyses arguments that link the availability of plant variety rights to the availability of plant genetic resources to determine whether the available evidence supports these claims:

- One view of the interaction between plant variety rights and plant genetic resources is that the availability of plant variety rights results in companies only promoting protected varieties, resulting in fewer varieties being grown and therefore loss in agricultural biodiversity.
- A second view of this interaction is that the availability of plant variety rights provides the incentive to breed new varieties and thus increases genetic diversity.

The 'minimum distance' between plant varieties may also provide an indication of a change in biodiversity. This is the third indicator discussed in this section.

Finally, there is an intermediate link between the CPVR system and availability of plant genetic resources via two EU Directives (2008/62/EC and 2009/145/EC). These Directives attempt to address losses in agricultural biodiversity that occur through marketing limitations for plant varieties through National Listing and the common catalogue. This is the fourth and final indicator discussed in this section.

4.4.2.1 One view of the interaction between plant variety rights and plant genetic resources is that the availability of plant variety rights results in companies only promoting protected varieties, resulting in fewer varieties grown and therefore a loss in agricultural biodiversity

Following expiration or termination of a plant variety right, the genetic materials are in theory freely available for further research and development of new varieties, but this is not always the case as illustrated through an example from potato breeding.

[25] As at 1 July 2010

Case Study 4: Biodiversity loss in potato breeding

Amongst potato breeders there is a practice commonly referred to as 'burying' a variety. Essentially, a potato breeder uses a variety right and obtains a return on investment for the protected variety (i.e. via royalty collection), until it has outlived the duration of protection (i.e. 30 years). At this point, the plant breeder removes the variety from the National List (i.e. it can no longer be marketed). The plant breeder then removes the variety from the pool of available genetic resources by destroying the propagating material or ensuring that it is inaccessible to other breeders.

Breeders are able to continue this practice due to biological specificities of potatoes - potato propagating materials are difficult to produce in sufficient quantities to grow a new variety at commercial scale. The breeder then promotes a new variety through National Listing and with protection from a new plant variety right instead of the 'buried' variety.

In these cases, potato varieties that are popular among growers and/or consumers may no longer be available for further propagation once the plant variety right has been terminated or the period of protection has otherwise ended (i.e. 30 years are reached). Stakeholders in several Member States referred to popular potato varieties that are no longer cultivated for these reasons. The Rettet Linda variety, originally developed in Germany, is one of the most well-known cases.

The stakeholder consultation indicated that this issue is a problem for potato varieties, but no similar issues were raised for other varieties. Potatoes may therefore be an exceptional case. National Listing may have a stronger effect in cases like those demonstrated for potatoes, where removal from the list restricts their production to non-marketable purposes (such as research or hobby farming).

4.4.2.2 A second view of the interaction between plant variety rights and plant genetic resources is that the availability of plant variety rights provides the incentive to breed new varieties and thus increases genetic diversity

The returns obtained from exploiting a plant variety right could result in increased revenue for breeders, thus encouraging and financing new breeding programmes. Under this scenario, an increasing number of varieties may be available for farmers to plant and for other breeders to build upon in developing further new varieties. The result would be a positive effect on agricultural biodiversity. This indirect link, however, has never been formally investigated. Moreover, this argument does not necessarily suggest that the availability of plant variety rights assists in the *preservation* of plant genetic resources (e.g. for potato varieties)—only that it encourages breeding programmes for *new* varieties.

Nonetheless, a study by Van der Wouw *et al* (2009) investigated the impact on genetic variation through the replacement of landraces by modern cultivars. Van der Wouw *et al* conducted a meta-analysis of 44 publications in Europe and North America. The results suggest an increase in genetic variation at the allele level, but a decrease in the number of marketed plant varieties.

The analysis covers only the twentieth century, so does not include the period during which the CPVR system has been operational. But plant variety protection systems have been in place in Germany and the Netherlands since 1940 and UPOV-based plant variety rights systems have been in place since the 1960s. Therefore, one could conclude that plant variety rights do not necessarily have a *negative* impact on genetic variation at the allele level, but equally no *positive* effect can be discerned either.

4.4.2.3 Minimum distances between plant varieties have decreased in recent years; this may contribute to the erosion of plant genetic resources

There are indications that the minimum distance between plant varieties has decreased significantly over time. Minimum distance refers to the measurable distance between two plant varieties that is necessary for those varieties to be considered 'distinct' under CPVR DUS rules. The minimum distance provision in the Basic Regulation is intended to ensure that breeders can protect their rights against copies and too-close derivations. It is directly related to provisions concerning essentially derived varieties (EDVs), which are discussed in greater detail in Section 4.2.5.

One potential outcome of decreasing minimum distances between plant varieties is a reduction in the genetic diversity of available plant materials and ultimately a reduction in plant genetic resources.

Representatives from several Member States and plant breeding associations indicated during interviews that a sufficiently large minimum distance is necessary between plant varieties to encourage the development of varieties that are not too closely related. An appropriate minimum distance may help promote increased biodiversity in EU plant breeding and agriculture. The EDV concept, therefore, may contribute to increased genetic diversity through relatively wide minimum distance requirements.

4.4.2.4 CPVR may be linked to the availability of genetic resources via EU Directives 2008/62/EC and 2009/145/EC on marketing varieties

As discussed, there are few data to suggest that plant variety protection in general, or CPVR specifically, are directly responsible for the preservation or erosion of plant genetic resources. An intermediate link, however, exists via two recent Directives (2008/62/EC and 2009/145/EC[26]) which attempt to address losses in agricultural biodiversity that occur due to restrictions on National Listing and the common catalogue.

Only plant varieties on a National List or in the common catalogue may be marketed (sold, exchanged or given away). National listing requires that a plant variety conform to DUS criteria. Traditionally grown varieties and landraces[27] do not conform to DUS criteria and therefore cannot be listed and subsequently marketed within the EU.

The primary derogation of Directives 2008/62/EC and 2009/145/EC provides for agricultural and vegetable landraces and varieties to be marketed without official examination if they meet some minimum standards. For those species with a DUS testing protocol published by the CPVO, the minimum characteristics for National Listing will be required based on the relevant technical questionnaire for that species, and specifically based on the main variety characteristics. Any changes to the CPVO DUS testing protocols will impact on a registrant's ability to pursue National Listing for landraces and traditionally grown varieties where DUS testing protocols are available for that species.

No current issues are known related to the connection between the CPVO testing protocols and the Directives on landraces and traditionally grown varieties. But these links should be considered if and when CPVO testing protocols are changed in order to maintain coherence between EU and international policy objectives related to preservation and erosion of plant genetic resources and the CPVR *acquis*.

4.4.3 The CVPR *acquis*' contribution to the development of EU agriculture is difficult to define

There is little evidence that directly links the CPVR *acquis* to the development of EU agriculture. Determining the current condition of the seed sector itself is a challenge due to inconsistent data sources and different views on trends across sectors. These issues are described in greater detail in the final report from an evaluation of the EU seed marketing and plant propagating material (S&PM) *acquis* (2008). The following data indicate the value of the global and EU seed markets and where there are alignments between the seed sector and the CPVR system.

International Seed Federation (ISF) data indicate that the value of the global seed trade:

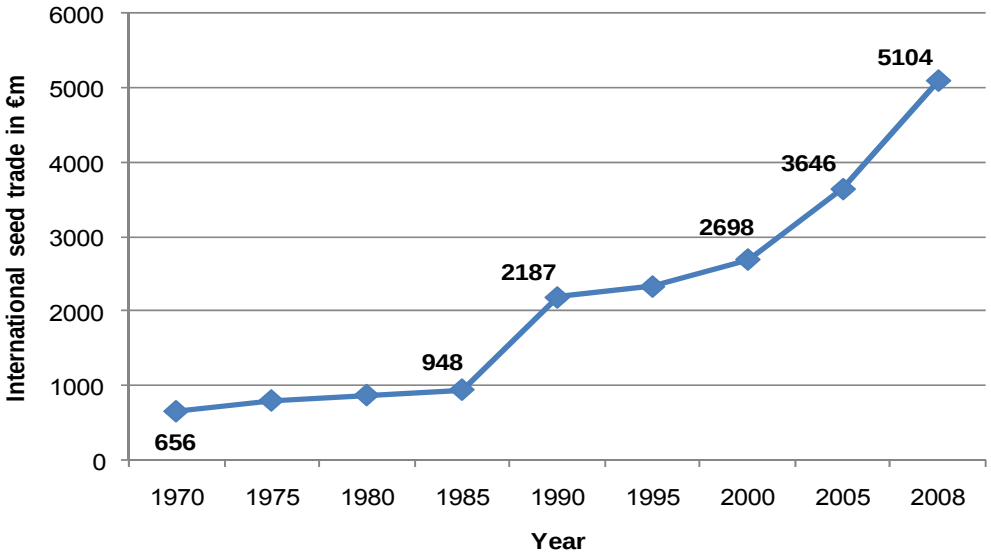
- Has risen steadily since the 1970s -- from about €650m in 1970 to over €5bn in 2008[28].
- The increase was particularly marked in the period from 1985-1990 during which the global seed trade doubled in value, from about €950m in 1985 to nearly €2.2bn in 1990.
- The value of the international seed trade in 2008 (roughly €5.1bn) was almost twice the corresponding figure for 2000 (about €2.7bn).

[26] Commission Directive 2008/62/EC of 20 June 2008 providing for certain derogations for acceptance of agricultural landraces and varieties which are naturally adapted to the local and regional conditions and threatened by genetic erosion and for marketing of seed and seed potatoes of those landraces and varieties; Commission Directive 2009/145/EC of 26 November 2009 providing for certain derogations, for acceptance of vegetable landraces and varieties which have been traditionally grown in particular localities and regions and are threatened by genetic erosion and of vegetable varieties with no intrinsic value for commercial crop production but developed for growing under particular conditions and for marketing of seed of those landraces and varieties

[27] A landrace is defined by the UN FAO as 'an early, cultivated form of a crop species, evolved from a wild population'. See Zaid et al (1999).

[28] ISF website: Seed Statistics (see http://www.worldseed.org/isf/seed_statistics.html)

Figure 4.6 The global seed trade has grown in value since 1970, with notable growth in the periods 1985-1990 and 2000-2008



Source: International Seed Federation[29]

The European Seed Association (ESA) estimates that the EU seed market was worth €6.8bn in 2010[30]. This corresponds with ISF estimates of the total value of the domestic seed markets in 21 EU Member States of approximately **€**6.4bn. ISF figures suggest that the EU seed market accounted for about a quarter (25%) of the international seed market in 2010[31].

ISF also provides data pertaining to seed exports and imports for the majority of the EU Member States in 2009, at an aggregate level as well as for two crop categories – field crops and vegetable crops (Table 4.4 below and Table A7.2 in Annex 7).

These data indicate that:

- EU MS with the largest number of CPVR granted – the Netherlands, France and Germany – account for a significant proportion of total EU crop exports (67%) and imports (46%).
- France is the largest EU exporter (32%) and importer (21%) of field crop seeds and Germany the second largest exporter (16%) and importer (16%). Combined, these two countries account for 53% of exports and over 35% of imports for EU field crop seed. The domestic seed markets of these two countries (valued at €3.15bn) account for nearly 50% of the EU market (about €6.4bn) (see Figure A7.2 in Annex 7). These two countries also account for 56% of all CPVR granted for agricultural crops.
- Similarly, France and Germany are leading EU exporters of major agricultural crops such as wheat, maize, barley and rapeseed and also account for large shares of CPVR titles for these crops (Table 4.4). The Netherlands is a leading potato exporter and accounts for more CPVR grants awarded to potato varieties than any other country.
- In contrast, Hungary and Romania are also leading exporters of major agricultural crops, but represent a very small proportion of CPVR granted for these species (applicants based in Hungary accounted for only 0.2% of CPVR awarded to agricultural varieties in the 1996-2009 period, while Romania did not account for any). This may be due in part to the fact that these two countries are both new EU Member States (Hungary joined in 2004 and Romania in 2007), and uptake of the CPVR system has thus far been minimal.

[29] Exchange rate (€1 = USD 1.37) sourced using www.xe.com as at 31 January 2011.

[30] ESA (2010): 'ESA Facts and Figures'

[31] ISF website: Seed Statistics (see http://www.worldseed.org/isf/seed_statistics.html)

Table 4.4 Leading EU exporters of selected agricultural crops and number of CPVR awarded to each Member State

Crop	Leading exporter (*quantity exported in '000 tonnes*)	Number of CPVR awarded (*% of total for each crop*)
Maize	France *(6,138)* Hungary *(3,372)* Germany *(685)*	France: 994 *(42%)* Hungary: 0 (*0%*) Germany: 396 *(17%)*
Wheat	France *(16,293)* Germany *(7,038)* Hungary *(2,113)*	France: 378 *(44%)* Germany: 158 *(18%)* Hungary: 5 (*0.6%*)
Barley	France *(5,025)* Germany *(1,663)* Romania *(645)*	France: 254 *(38%)* Germany: 172 *(26%)* Romania: 0 (*0%*)
Rapeseed	France *(2,102)* Romania *(564)*, Hungary *(430)* Germany *(430)*	France: 216 *(36%)* Romania: 0 (*0%*) Hungary: 0 (*0%*) Germany: 165 *(28%)*
Potato	France *(1,890)* Netherlands *(1,488)* Germany *(1,397)*	Netherlands: 333 *(34%)* Germany: 294 *(30%)* France: 135 *(14%)*

Sources: UN FAO (2008) and GHK analysis of CPVO data (1996-2009)

4.5 Interactions with national and international law, policy and instruments

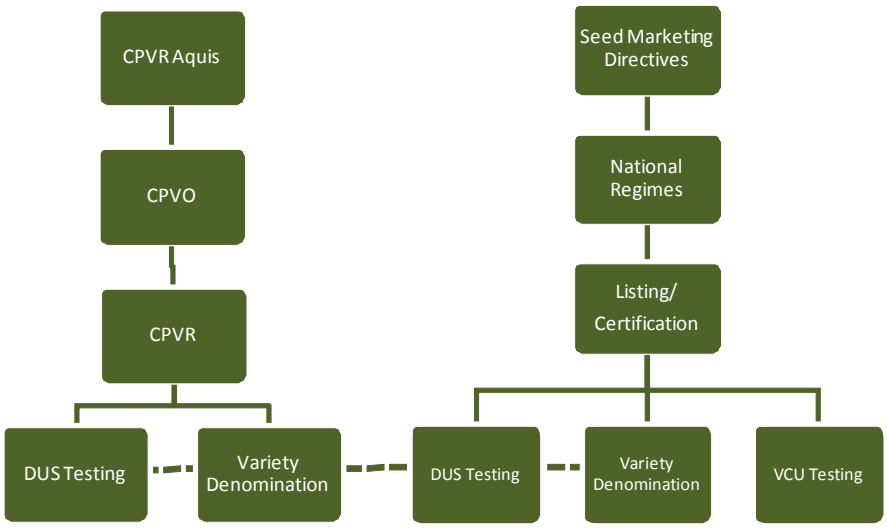
4.5.1 Technical links between the Seed Marketing Directives and the CPVR *acquis* impact both systems, but efforts are already underway to resolve issues that arise as a result of these links

There are links between the Seed Marketing Directives and the CPVR *acquis* where DUS testing and variety denomination are required for listing and certification (under the Seed Marketing Directives) and for plant variety protection (under the CPVR *acquis*). These are discussed in greater detail in Annex 11.

Independent from CPVR, agricultural plant and vegetable species must also comply with *inter alia* the DUS requirements for market authorisation. National authorities are responsible for these market authorizations. Authorised varieties are entered into a national list. The Commission compiles national lists to form the common catalogue. In principle, the DUS criteria are equally applied under both systems and cross reference is made from the applicable directives to the CPVR legislation.

The implementing measures and DUS test guidelines for agricultural plant and vegetable species are set out in Directives 2003/90/EC and 2003/91/EC. The annexes to the Directives stipulate that certain species must comply with either CPVO or UPOV guidelines and species not listed in the Annexes comply with individual MS legislation. Under certain conditions, the CPVO may use DUS reports already issued in a national listing procedure as the basis for a variety DUS determination.

Figure 4.7 The CPVR *acquis* and the Seed Marketing Directives are linked through DUS and variety denomination requirements



Source: GHK analysis

A 2008 evaluation of the Seed Marketing Directives ('Evaluation for the Community *acquis* on the marketing of seed and plant propagating material) for DG SANCO concluded that it is unclear why two sets of DUS tests and variety denomination procedures should be required where a variety may be both protected by CPVR and nationally listed. One recommendation put forward in this evaluation to remedy the duplication is the 'one key, several doors' approach:

- A single DUS test is conducted by CPVO-appointed testing centres for CPVR and MS variety listings; and
- CPVO is responsible for variety denominations across the EU to streamline procedures.

The stakeholder consultation for this evaluation revealed a high level of support for a 'one key, several doors' approach to DUS testing and variety denomination procedures. This would also reduce costs, streamline procedures and resolve variety denomination problems described in Section 4.2.6.

The Action Plan that emerged from the 2008 evaluation proposes a work programme to create a single horizontal legal framework for marketing of seed and propagating materials, harmonise implementation of legislation in Member States, reduce administrative costs and ensure consistency with other EU policies. The Action Plan also mentions the possible extension of the CPVO's role to the seed and propagating materials marketing sector. The Commission is currently considering changes to the Seed Marketing Directives, which may help to harmonise the duplication via this recommendation.

An option to improve the CPVR system to resolve these tensions is discussed in Section 5. The option is assessed in Annex 16 (Option A).

4.5.2 The rules related to public access to documents are unclear

The CPVO would like to have greater clarity on the rules regarding public access to documents and which of the available appeal procedures should be applied in a given case. Complexity arises as a result of the interplay between information access provisions in the original Basic Regulation that established the CPVR system and the more recent Public Access Regulation (Council Regulation (EC) No 1049/2001[32]).

[32] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents.

Article 88 of the CPVR Basic Regulation states that in cases of *legitimate interest*, documents relating to CPVR applications and to CPVR already granted shall be open to inspection. Exceptionally, a CPVR applicant can request that all data related to parent lines of varieties may be withheld. Article 67 of the Basic Regulation refers appeals related to decisions concerning public inspection pursuant to Article 88 to the Board of Appeal.

All documents held by the CPVO are subject to the Public Access Regulation. The *legitimate interest* requirement is not present in Regulation 1049/2001. Access can be only denied if an exception in Article 4 applies, which may include access to parent lines of varieties, which are commercially sensitive information[33]. Article 33a of Regulation (EC) No 2100/94[34] states that CPVO decisions not to provide document access may form the subject of a complaint to the Ombudsman or an action before the European Court of Justice. When Article 33(a) was introduced into the Basic Regulation, the Commission advised the CPVO that the Basic Regulation should be interpreted in light of Regulation (EC) No 1049/2001, overruling Article 88 and the requirement of *legitimate interest.* The CPVO currently applies this interpretation.

Figure 4.8 The CPVR Basic Regulation (Article 33a) and the Council Regulation (EC) No 1049/2001 (Article 88) create two different sets of rules and routes of appeal in relation to the release of information held by CPVO

Source: CPVO (adapted by GHK)

Article 88 thus is *lex specialis* such that some documents in the application procedure may not be covered by Article 33(a) and therefore refer to a different complaints/appeals procedure. An option to improve the CPVR system to resolve these tensions is discussed in Section 5. The option is assessed in Annex 16 (Option J).

4.5.3 The CPVR *acquis* is a significant addition to the intellectual property systems available in the EU; there are no issues related to points of connection between CPVR and trademarks or geographical indications, but stakeholders are highly concerned about overlap between CPVR and patents

Stakeholders consulted for this evaluation indicated that the CPVR *acquis* has been a significant addition overall to the EU's intellectual property systems. They emphasise the value of a uniform, EU-wide protection regime and the cost efficiency possible through economies of scale.

[33] These relate to public security; defence and military matters; international relations; individual privacy; commercial interests, including IPR; court proceedings and legal advice; and inspections and audits.

[34] Introduced through the adoption of Council Regulation (EC) No 1650/2003 of 18 June 2003 amending Regulation (EC) No 2100/94 on Community plant variety rights, OJ L245, 29.9.2003, p. 28

The CPVR *acquis* operates alongside several other intellectual property rights systems in the EU. These include patents, trademarks, copyright and geographical indications. This section analyses the connections between the CPVR *acquis* and these other IPR systems.

4.5.3.1 The Biotechnology Directive (98/44/EC) goes some way towards harmonising patent law and plant variety rights, but stakeholders are concerned that overlap between patents and plant variety rights could undermine the effectiveness of plant variety rights over time

Plant variety rights are most closely related to patents as a form of intellectual property. In particular, 'identifiability' is essential to determining whether a plant variety may receive intellectual property rights protection. The four criteria to identify a new variety (novelty, distinctness, uniformity and stability) are adapted from the four criteria required under patent law (inventive step, utility, novelty and disclosure).

Article 27(1) of the TRIPS Agreement requires all WTO Members to provide patent protection for inventions across all fields of technology, subject to the provisions of paragraphs 2 and 3 (the so-called 'optional exclusions').[35] Article 27(3)(b) allows Members to exclude plants and animals but requires that plant varieties are protected either by patents or by an effective *sui generis* system (including CPVR) or any combination thereof.

The European Parliament and the Council adopted Directive 98/44/EC on 6 July 1998 (the 'Biotechnology Directive') specifies the conditions under which a patent may be granted for a biotechnological invention.

The EU legislative framework (as defined by Directive 98/48/EC) does not, however, eliminate or reduce the possibility of overlap between patents and plant varieties (see Annex 12 for a detailed explanation). A plant variety may receive CPVR protection, but may not be patented, while an invention related to plants may be patented so long as it is not confined to a particular plant variety. As a result, plant-related patents (e.g. on a particular trait, such as flowering time) can cover a plant variety, without applying directly to that plant variety.

The Biotechnology Directive brings greater coherence between patent law and CPVR by aligning some of the provisions and exemptions between the two. In particular, it directly references the agriculture exemption as it is defined under the CPVR Basic Regulation. On other issues, however, the two sets of legislation are less clearly aligned. For example, the EU Patent Convention provides for the right to use patented materials for research purposes (Article 25-28), including acts regarded as private, non-commercial and experimental. Member States implement this right inconsistently: the distinction between permissible and non-permissible acts varies by Member State (though all commercial acts are seen to be infringing). This creates a high degree of uncertainty for the users of protected material as to the activities that may be considered infringing in this regard.

France and Germany have integrated a research exemption for breeders into patent law via the patent law research exemption (and the Netherlands will include a research exemption in the near future), which allows for the use of biological materials for the purpose of breeding, or discovering and developing a new plant variety. Nonetheless, French and German law does not extend this research exemption to commercialisation. Many plant breeders pointed out that a similar research exemption in European patent law would be of limited value as it would still prevent commercialisation without a license from the patent holder and therefore create too much uncertainty with respect to return on investment for a breeding programme if a license cannot be obtained at the commercialisation stage. Some plant breeders are concerned about the lack of a breeders' exemption under the patent system.

[35] Article 27(2): 'Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such an exclusion is not made merely because the exploitation is prohibited by their law'.

Article 27(3): 'Members may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, *Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof*...' [Emphasis added].

An option to improve the CPVR system with respect to tensions between plant variety rights and patents is discussed in Section 5. The option is assessed in Annex 16 (Option B).

4.5.3.2 Compulsory cross-licenses are unsatisfactory for dealing with the tension between overlapping patents and CPVR

Compulsory licenses are granted on the grounds of sufficient public interest, including protection of life or health of humans, animals or plants. If the rights holder sufficiently supplies the market through licenses, then compulsory licenses will not be required. Individual interests (e.g. a particular grower or group of growers) are also unlikely to be successful at obtaining compulsory licenses. In principle, compulsory licenses for plant variety rights can only be granted in cases of abuse of a dominant market position.

An overwhelming majority of plant breeders strongly disagreed with the proposition that the use of compulsory cross-licenses was satisfactory in areas of overlap between CPVR and patents. Stakeholders believe that a cross-license has been impossible to obtain due to excessively stringent requirements for proving that a protected variety demonstrates sufficient technical advancement and potential economic viability. There are no known cases of compulsory cross-licenses being sought to date. One national breeders' association suggested that this issue could gain increased significance in the near future as plant patents and genetically modified (GM) crops gain commercial importance in the EU.

4.5.3.3 There are no significant interactions between the CPVR *acquis* and development of geographical indications

Geographical indications are a type of intellectual property identifying a product as originating in a particular region or locality. Examples include champagne, Roquefort cheese and Parma ham. There are three conditions for recognition as a geographical indication:

- It relates to a good (though in some countries, it may relate to a service);
- The good must originate from a defined area; and
- The good must have qualities, reputations or other characteristics that are clearly linked to the geographical origin of the good[36]

No significant positive or negative impacts have been discerned in the CPVR *acquis*' interactions with geographical indications. They coexist peacefully where variety denomination testing is conducted appropriately and there is no confusion or overlap between a denomination and a geographical indication.

4.5.3.4 There are no significant interactions between the CPVR *acquis* and the trademark system

Plant variety names may be protected by trademarks, but also must have their own denomination under the CPVR system. Trademarks may be protected at EU level, similarly to CPVR. They are also administered by a single office, similar to CPVO and require a single application. Trademarks are granted for an initial period of ten years, and may be extended for additional ten years periods and may be renewed indefinitely so long as the trademark meets certain criteria, including 'genuine use' within a period of five continuous years. The evaluation found no significant points of interaction between CPVR and trademarks, though the United Kingdom Intellectual Property Office (UKIPO) offers some relevant guidance on UKIPO's examination practices with respect to the application of trademarks that consist of varietal names: 'Varietal names will no longer face an objection on absolute grounds at the *prima facie* stage, but trademarks consisting of varietal names are liable to be declared invalid if the name was generic at the date of the application'.

4.5.4 The CPVR *acquis* is coherent with EU consumer, environment, agriculture and trade policy

Overall, the CPVR *acquis* can be considered coherent with other related EU policies. There are few, if any direct links with these other policy areas, but indirect links suggest coherence.

[36] See European Commission, DG Trade, 'Intellectual property: Geographical indications', http://ec.europa.eu/trade/creating-opportunities/trade-topics/intellectual-property/geographical-indications/ (viewed 18 November 2010).

4.5.4.1 The CPVR *acquis* is consistent with EU environment policy

EU environment policy aims to improve the quality of water, reduce air and noise pollution, assure chemical safety, set standards for waste disposal and protect the EU's native wildlife and plants. Environmental objectives are integrated into EU policy-making across all relevant areas and issues (e.g. agriculture and trade). EU environment policy should cohere with the objectives and outcomes of the CPVR system in this regard.

No *direct* effects have been observed on environmental policy objectives stemming from the CPVR system. There are some potential *indirect* connections, mainly in relation to protection of the EU's native plants. The CPVR system is connected to EU policies on the conservation of plant genetic diversity though there is little evidence on the indirect links between preserving plant genetic diversity and CPVR system effects, as discussed in Section 4.4.2.

A further indirect connection may occur through the EU's commitment to producing 20% of its energy through renewable sources by 2020. Biofuel production is considered to be an important factor in reaching this target. Some plant varieties[37] are regularly used for biofuel production. Increasingly, tree varieties are also being produced for this purpose.[38] A plant variety protection system that supports and encourages production of new plant varieties such as these to meet the needs of biofuel production more efficiently and with lower environmental impact, is consistent with EU energy and environmental policy. No evidence that would substantiate this connection has been located.

4.5.4.2 The CPVR *acquis* is consistent with EU agriculture policy

EU agriculture policy is focused on ensuring competitive, sustainable and diverse food production that meets consumer demands.[39] The CPVR system is aligned with the EU common agricultural policy (CAP). No direct effects of the CPVR system on CAP have been observed. Many stakeholders, however, commented that the CAP subsidy and support system provides sufficient protection to farmers and that therefore, the farm saved seed exemption has become less important for protecting agricultural production than it may have been in the past.

Supporting rural communities is another aim of EU agriculture policy. No direct effects, whether positive or negative, of the CPVR system on rural communities have been observed. There may be indirect effects through the farm saved seed exemption. One Member State representative noted that cross-compliance should be specified in the Rural Development policy.

4.5.4.3 The CPVR *acquis* is consistent with EU trade policy

The CPVR system supports the functioning of the European single market by providing one plant variety right that is effective across all Member States. In principle, this allows plant breeders to develop, license and sell their protected varieties in any Member State and to enforce their rights across the EU.

EU trade policy is based on agreements and obligations set out by the WTO, of which EU countries were founding members. Maintaining coherence with the WTO system is therefore another important component of EU trade policy. In this regard, EU trade policy is intended to increase fair and transparent trading opportunities with other countries, worldwide.

One important component of a fair and transparent global trading system is an effective intellectual property rights regime governing traded goods, including plant varieties. The TRIPS Agreement is the multilateral mechanism for ensuring effective IPR systems under the WTO. The TRIPS Agreement requires that where a signatory's national patent system does not cover plant varieties, a *sui generis* (i.e. unique) system must be created to conform to this obligation. The EU is a member of UPOV, and the CPVR *acquis* conforms with UPOV 1991, thus fulfilling this requirement.

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[37] Particularly wheat (Genus *Triticum*), maize (*Zea mays*), sugar beet (*Beta vulgaris*), sugar cane (Genus *Saccharum*)

[38] including poplar (Genus *Populus*), willow (Genus *Salix*), black locust (*Robinia pseudoacacia*) and eucalyptus (Genus *Eucalyptus*)

[39] DG Agriculture and Rural Development, Rural Development policy 2007-2013, http://ec.europa.eu/agriculture/rurdev/index_en.htm (viewed 25 November 2010).

A second important component of a fair and transparent global trading system is a set of import practices for goods entering the EU to ensure that imports are traded at fair prices and do not cause unfair damage to European companies and their workers. In this regard, import practices for protected plant varieties do not always ensure fair compensation (royalty payments) to plant breeders. The Basic Regulation does not grant unqualified protection to the harvested material of CPVR-protected varieties, which limits the right holders' ability to enforce illegal propagation in third countries of materials that are imported back into the EU. This issue is discussed in Section 4.2.1.2.

4.5.4.4 The CPVR *acquis* is consistent with EU consumer policy

EU consumer policy is designed to protect consumer health, safety and economic well-being. This includes maintaining an effective single market to promote consumer confidence in cross-border transactions and clear legal rights pertaining to the effective implementation of those transactions. EU consumer policy can be considered coherent with the CPVR system to the extent that the CPVR system supports an effective single market system and enforcement of consumer rights.

4.5.5 The objectives of the CPVR *acquis* support the objectives of EU programme on the conservation, characterisation, collection and utilisation of genetic resources in agriculture but stakeholders are concerned that uniformity requirements may be too high

The EU programme on the conservation, characterisation, collection and utilisation of genetic resources in agriculture was established by Council Regulation (EC) No 870/2004. It promotes genetic diversity and information exchange between Member States and the European Commission for the conservation and sustainable use of genetic resources in agriculture. It is meant to ensure sustainable agricultural production and sustainable development of rural areas. It is also meant to align and support undertakings in these areas under a variety of EU and international initiatives[40]. Seventeen actions are currently being undertaken within the framework of the programme. Twelve of these actions relate to plants and therefore may be impacted by the CPVR system.[41]

Representatives from six Member States indicated that there may be some tensions between the EU programmes and the CPVR *acquis*, particularly regarding transfers of plant genetic resources between different stakeholders and overly stringent uniformity requirements. Nonetheless, the 2010 FAO 'State of the World Report' indicates that the conservation, characterisation, collection and utilisation of genetic resources in agriculture are particularly strong in the EU with respect to plant variety rights.

4.5.6 National PVR systems can and do differ from the CPVR system but this not a matter of general concern; stakeholders pointed to the stronger protection offered by the Dutch PVR system and to lower costs in some Member States

Each MS may provide its own plant variety rights regime, for which rights are granted only within the border of the particular state. There are 23 such PVR systems operating within the EU. Cyprus, Greece, Luxembourg and Malta have not developed or implemented national PVR legislation.[42]

National PVR systems are independent of the CPVR system. A breeder may choose whether to apply for national or EU-wide protection but may not simultaneously hold national and EU rights per Article 92 of the Basic Regulation. A breeder may, however, seek CPVR protection before the expiration of a national right, and if granted, place the national rights 'on hold' until the expiration of the CPVR.

[40] For example: CBD, EU biodiversity strategy, ITPGRFA; and FAO's Global Plan of Action for the Conservation and Sustainable Utilisation of Plant Genetic Resources for Food and Agriculture.

[41] These programmes include: leafy vegetables (001), grapevine (008), forest (009), saffron and allies (Crocus spp.) (018), European small berries (036), rice (049), vegetative allium (garlic and others) (050), crop biodiversity *in situ* (057), oats (061), artichokes (063), nuts and almonds (068), and currants and gooseberry (071). DG Agriculture and Rural Development, 'The 17 Actions on genetic resources in agriculture', http://ec.europa.eu/agriculture/genetic-resources/actions/index_en.htm (viewed 20 November 2010).

[42] With the exception of Law No 1564 'Organisation of Production and Marketing of propagating Material of Plant Species', which provides for PVR protection in Greece, but does not appear to be in force.

4.5.6.1 CPVR provide an advantage through EU-wide coverage. In some cases, the costs of CPVR are lower than national PVR systems, but in other cases they are higher. Some Member States have a wider scope of PVR protection, which breeders appreciate

National plant variety rights systems differ among Member States. In particular, 23 of 27 Member States are UPOV members, and of those 23, four (Ireland, Italy, France and Portugal) are party to the 1978 Convention; Belgium is party to the 1961 Convention. The remaining 18 ratified the 1991 Convention, which is also the basis for the CPVR *acquis*.

Table 4.5 Differences between the 1961, 1978 and 1991 UPOV Conventions and impacts on Member State PVR systems

Issue	Convention	CPVR	Impact
Species coverage	**1961** - Does not require that members provide protection for all species; specifies that five species should be provided for initially and a minimum of 24 after eight years	Provides protection for all species	Belgium - a new variety may not be protected by national PVR because the species is not covered
Duration of protection	**1978** - Provides minimum protection durations of 18 years for trees and vines and 15 years for other plants **1991**- provides 25 years for trees and vines, and 20 years for other plants	Provides maximum protection durations of 30 years for trees, vines and potatoes; 25 years for all other species	National PVR systems in some Member States have higher or lower protection durations than for CPVR
Agriculture exemption	**1978** – Implicitly created by exempting re-sown seed from scope of breeders' right; UPOV members may widen the scope of protection **1991** - Extends minimum breeders' rights to all production and reproduction activities; permits UPOV members to restrict breeders' rights to allow farm saved seed	Limits exemption to a particular list of species; requires 'equitable remuneration' for FSS use; exempts 'small farmers'	France - does not provide for the 'farmer's exemption' Different UPOV members have applied this option in different ways.
Harvested materials	**1978** - Extends minimum right to the propagating material of the variety, but not to the end product **1991** - Extends minimum right to harvested material of a protected variety under certain conditions	Should conform to UPOV 1991, but there are differences in the provisions	The harvested materials provision is different between the CPVR *acquis* and UPOV 1991
EDVs	**1978** - Provides for variety protection if it is 'clearly distinguishable by one or more important characteristics from any other known variety'; in practice, small variations could be protected **1991** - EDV concept was introduced to balance rights for protected varieties with introduction of new varieties representing only a small change	Conforms with the definition in UPOV 1991	National PVR systems under UPOV 1978 do not provide for EDVs

Source: GHK analysis

Differences between national PVR systems and the CPVR system could lead to inconsistencies between national PVR legislation based on the 1961 and 1978 UPOV Conventions and CPVR, and between CPVR and national systems which are based on UPOV 1991, but where national systems differ beyond minimum requirements.

EU-wide protection is the main advantage to the breeder of CPVR over national rights. Most breeders also agreed that the CPVR technical examination process was similar to its national-level counterparts, and emphasised that uniform examination criteria was an advantage enjoyed by the CPVR system over national systems.

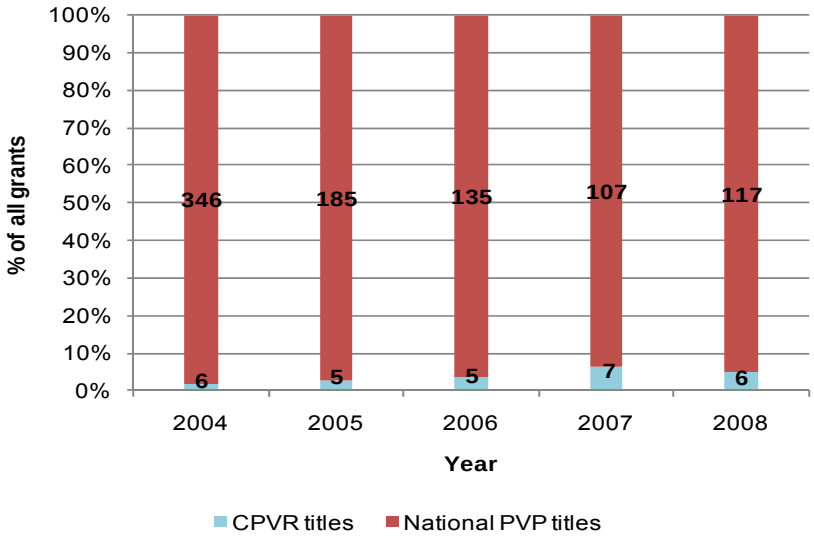
Some stakeholders advocate the wider scope of protection offered by the national PVR system in the Netherlands and want to see this extended to the CPVR system. Plant variety rights legislation in the Netherlands currently offers stronger protection than the CPVR system on several dimensions such as longer duration of protection for some species (e.g. 30 years for varieties such as anthurium and

strawberry), stricter FSS enforcement and better information provisions related to FSS use. Some breeders noted that Italian PVR law contains a provision regarding reversal of the burden of proof that could be incorporated in CPVR legislation to improve enforcement for harvested materials.

The majority of growers (16 out of 24) also agreed that the CPVR system held advantages over national PVR systems, with EU-wide protection and marketability cited as specific advantages by four respondents. Two growers, however, argued that the CPVR regime favours industrial-scale varieties over low input or organic varieties better adapted to climate change over the long term.

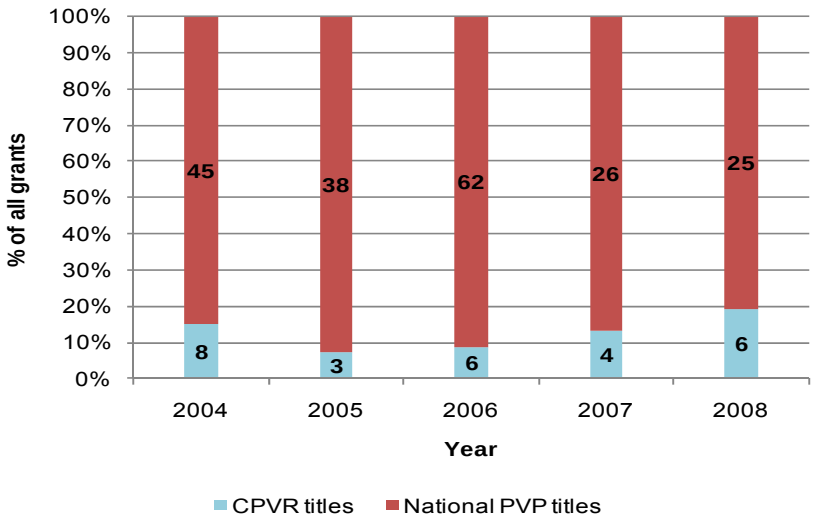
Member State representatives are divided as to whether CPVR have advantages over national PVR. Representatives from 13 MS agreed with this statement and 5 disagreed. Among those who disagreed, a few indicated that their national PVR regimes offer better protection. Others argue that breeders enjoy similar privileges under national PVR and CPVR. National application, testing and maintenance fees in some MS are significantly lower than those required for CPVR. Cost differences are significant enough in some MS that breeders apply for national PVR far more often than for CPVR.

Figure 4.9 Plant breeders in Poland are granted more national PVR than CPVR



Source: CPVO and UPOV data (2004-2008)

Figure 4.10 Plant breeders in Hungary are granted more national PVR than CPVR



Source: CPVO and UPOV data (2004-2008)

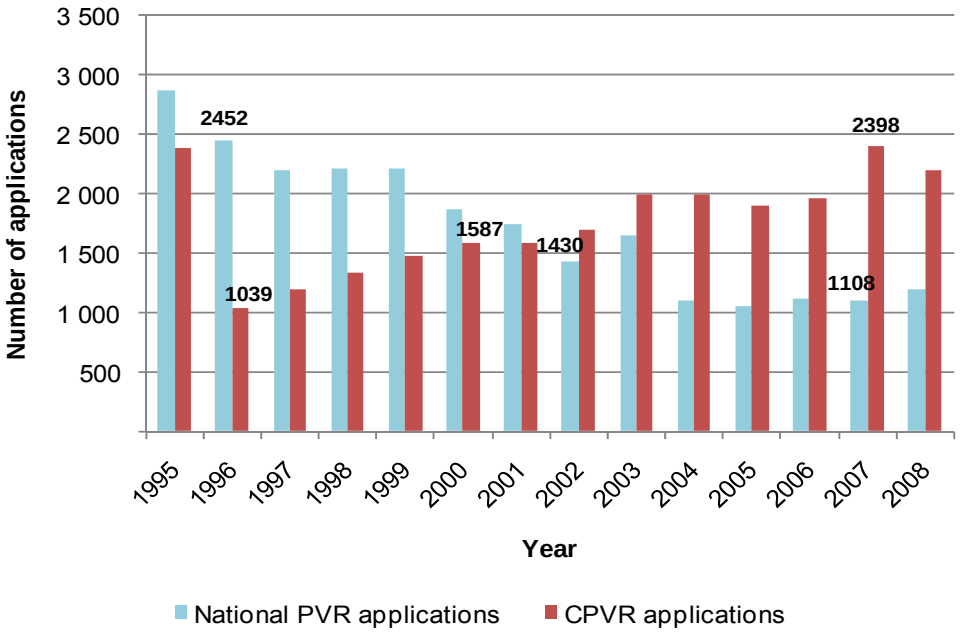
CPVO and UPOV data on rights granted from 2004-2008 demonstrate that more plant breeders in Poland and Hungary apply for national PVR than CPVR (Figure 4.9 and Figure 4.10).

4.5.6.2 Market share between CPVR and national rights varies among Member States, but there is a discernable trend toward use of the CPVR system over national PVR overall

The evaluators have compared national PVRs in nine Member States across the time period 1995-2010, for which UPOV and CPVO data are both available. Individually, the EU 27 display a range of trends: some Member States use the CPVR system almost to the exclusion of the associated national system. This is evident for Belgium (Annex 7, Figure A7.3). In other Member States, the reverse is true. Romanian plant breeders have been granted no rights under the CPVR system, but between 20 and 35 national PVR were granted each year from 2004-2008. A similar result is evident for Poland and Hungary as described above.

Other Member States range between these extremes in their use of the CPVR against national PVR systems, though in many cases the trend is towards greater CPVR use over national systems. This is best illustrated by looking at the top five countries for CPVR rights granted, which together account for 72% of all rights granted (CPVO data for 1996-2009).

Figure 4.11 CPVR are gaining market share over national PVR in the top 5 countries in which CPVR are granted



Source: CPVO, UPOV and World Intellectual Property Organisation (WIPO) data (1995-2008)

Here, a discernible trend indicates that the CPVR system is increasingly favoured over national rights for these five countries (i.e. Denmark, France, Germany, Netherlands, and the United Kingdom).

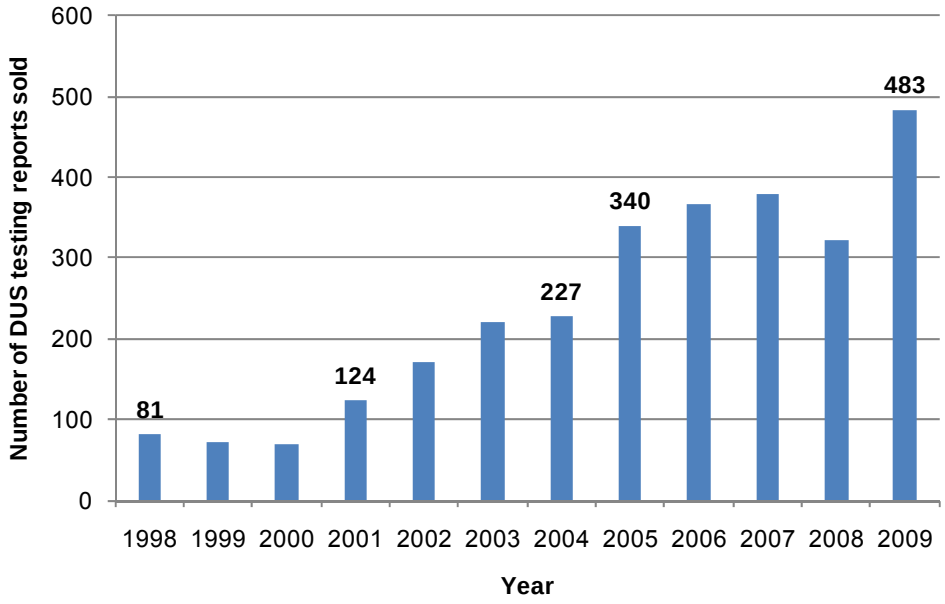
4.5.7 The CPVR *acquis* may have indirect impacts on the legal systems of third countries but these are difficult to determine; a potential extension of the CPVR *acquis* to EFTA countries would be a positive development

During interviews, stakeholders indicated that CPVO shares information and experience on the operation of the CPVR system with third countries. Moreover, the CPVR system provides a model for third countries with respect to developing their own *sui generis* system for plant variety protection to comply with TRIPS Agreement. For example, in 2006, 16 countries in West and central Africa have joined to form the African Intellectual Property Organisation (OAPI). The OAPI Act includes plant variety rights provisions based on UPOV 1991. The OAPI plant variety rights are similar to CPVR in that they seek to harmonise regional plant variety protection systems and ultimately create a single enforceable regime across all member countries.

The extent of impact in this regard, however, is unknown. Some Member State representatives indicated that CPVO could do more to promote the CPVR system at international level, and particularly in fora such as WIPO, CBD and ITPGRFA. The CPVO already makes its technical

examination reports available to authorities in third countries to facilitate international coordination in decision making on applications for plant variety rights. In the period 1998-2009, the CPVO sold 2,854 reports to authorities in 36 countries[43]. As indicated in Figure 4.12 below, the number of DUS reports sold annually has increased steadily, rising nearly six-fold from 81 in 1998 to 483 in 2009.

Figure 4.12 DUS testing reports sold by CPVO have risen significantly from 1998-2009



Source: Recreated by GHK from Community Plant Variety Office (2009)

Figure A7.15 in Annex 7 depicts the most important countries in terms of these sales. While Israel purchases the largest number of reports (approximately 15% of reports sold in the 1998-2009 period), there has been a significant rise in the number of reports requested by Latin American countries such as Ecuador, Brazil and Colombia in recent years, in particular for ornamental varieties. The number of reports sold to authorities in Kenya has also registered a sharp increase in recent years, especially as regards reports focusing on rose varieties.

4.5.7.1 The CPVR *acquis* may impact third countries, but the impacts cannot be directly ascertained

Intellectual property rights protection for plant varieties pose different sets of issues for industrialized countries and for developing countries but the effects of plant variety rights and plant patent regimes are difficult to estimate for developing economies. Baseline data are often unavailable or inadequate, and analysis is complicated by the fact that plant breeding industries have developed in countries such as India in the absence of plant variety rights systems (Eaton et al 2007).

No evidence has been located of direct or indirect effects of the CPVR on outcomes in third countries, though several studies have attempted to assess the impact of plant variety rights systems in general on developing country economies. Findings from a range of sources indicating these more general effects from a developing economy perspective include:

- WTO members are required to implement minimum intellectual property rights standards across several sectors, including agriculture, under the TRIPS Agreement. Plant breeding is accorded a high degree of flexibility in how these standards are set in each country to accommodate concerns with protecting local farmers and local seed trading arrangements. Nonetheless, evidence suggests that developing countries are pressured under bilateral and multilateral trade agreements to exceed these minimum requirements (Eaton et al 2006; Morris et al 2006). For example, the 1999 Cooperation Agreement between the EU and Bangladesh (C143/9) requires Bangladesh to 'endeavour to accede' to the UPOV 1991 Convention.

[43] Community Plant Variety Office, 2009. Annual Report

- The agriculture exemption is viewed as a critical component to prevent risks to the local seed supply and to rural livelihoods (Eaton et al 2006, 2007). In many developing countries, farm saved seed accounts for more than 80% of all seed use. As a result, some developing countries have implemented UPOV 1978 requirements, but many have not adopted UPOV 1991 because of the more restrictive conditions on farm saved seed use. No country in sub-Saharan Africa, South and Southeast Asia (excluding Singapore) or Latin America has implemented UPOV 1991. Colombia is one of the few developing countries to limit FSS use by prohibiting the practice on farms larger than five hectares.
- Furthermore, while farmers' rights are not formally included in the Convention on Biological Diversity, they are considered to be a related part of the debate on access to genetic resources and were first formulated as such by FAO in 1989 (Resolution 5/89). Many developing countries have resisted plant variety rights protection over agricultural crops (Rai 1994). A World Bank report from 2006 emphasises the usefulness of '*sui generis*' plant variety rights systems in developing countries in order to increase flexibility and account for the interests of local plant growing communities.
- Small and subsistence farmers comprise a large percentage of the farming population in developing countries. They are at risk of being 'squeezed out' of the innovation process under plant variety rights systems which incentivise innovation for medium and large-scale growers who have greater resources to invest in research and development and in the measures required to protect their new varieties (Das 2011).
- Increased strength of plant variety protection systems in developing countries has resulted in increased privatisation in the seed and propagating materials sector and corresponding decrease in public sector breeding activities. A 2006 study by Morris et al indicate that public investment in agricultural research across 119 developing countries has declined from 4.6% (during the period from 1976-1981) to 1.9% (during the period from 1991-1996).

While UPOV 1991 may not be appropriate for developing countries in all respects Eaton et al (2006) argue that the DUS testing criteria introduced through the 1991 Convention may facilitate the introduction of a harmonised approach to testing, allowing developing countries to accept test reports from other countries. This could reduce the costs of regional testing and application processing, shorten the approval process and facilitate the trade in seed and propagating materials.

An option to improve the CPVR system whereby CPVO supports outreach to third countries is discussed in Section 5. The option is assessed in Annex 16 (Option L3).

4.5.7.2 There is a high degree of support amongst EU stakeholders for an extension of the CPVR *acquis* to EFTA countries

The European Free Trade Association (EFTA) comprises four countries—Iceland, Liechtenstein, Norway and Switzerland. EFTA promotes free trade and economic integration for these countries and is linked to the EU through trade agreements. This evaluation has considered whether the CPVR *acquis* might be extended to EFTA countries. Doing so would harmonise plant variety rights between the EU and EFTA countries, therefore bringing their trade policies closer into alignment. An extension is in line with the current CPVR *acquis*, but would require changes to the legislation to implement the extension. The extension is also consistent with the application of EU seed marketing legislation, which is already in use in EFTA countries.

Potential positive impacts from an extension include:

- One CPVR covers a larger number of countries, resulting in greater efficiencies for plant breeders, particularly an extended area of protection through a single application;
- Many breeders operating at EU level already have close economic contacts with EFTA countries, particularly with Norway and Switzerland, and the extension offers additional opportunities to strengthen EU economic ties with EFTA countries;
- Additional financial revenue to the CPVO, and to the EU, through wider membership;
- Administrative impacts to CPVO are likely to be minimal.

Potential challenges to the extension include:

- EFTA countries will need to amend their relevant legislation to include all EU Regulations and Directives related to plant variety rights;

- Three of the four EFTA members are UPOV members (Iceland, Norway and Switzerland), but Liechtenstein is not: Liechtenstein will be required to join the UPOV Convention;
- CPVO will need to consider how to accommodate the transfer of national EFTA-country plant variety rights to CPVR during a transitional period.

Overall, EU stakeholders support the possible extension to EFTA countries. A possible extension of the CPVR *acquis* to Switzerland has been considered recently in the context of negotiations concerning a free trade agreement for foodstuffs. Any extension would need to consider particular concerns, for example, maintaining the agriculture exemption. An option to extend the CPVR system to EFTA countries is discussed in Section 5. The option is assessed in Annex 16 (Option D).

4.5.8 The objectives of the CPVR *acquis* generally support the objectives of the UN Convention on Biological Diversity and the International Treaty on Plant Genetic Resources for Food and Agriculture, though some stakeholders would like to see disclosure of origin in CPVR applications and ensure that access to genetic resources is maintained

The Convention on Biological Diversity (CBD) is an international treaty signed by 150 government leaders in 1992. The CBD is meant to be a practical means of implementing the ideals set out in Agenda 21—a comprehensive action plan related to human impacts on the environment. The CBD sets goals and actions to achieve the objectives set out in Agenda 21, and organises related technical and financial cooperation. Achieving the goals set out in the CBD, however, rests on its members, including the EU.

Access and benefit sharing (ABS) provisions are a major component of the CBD, arising out of a commitment to fair and equitable benefit sharing for the use of genetic resources. The Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of the Benefits Arising out of their Utilisation[44] were adopted by the parties to the CBD in 2002. These guidelines provide a flexible framework on access and benefit sharing, setting out a series of aims, ideals or key features for the practical implementation of an ABS system that can be used by contracting parties to introduce national legislation.

Though the Bonn Guidelines are not legally binding, they encourage countries to take measures to encourage disclosure of the country of origin for genetic resources in applications for intellectual property rights, including CPVR. CPVR Technical Questionnaires thus include an optional question regarding the origin of a new variety's parents and the geographical origin of the variety itself as part of the application process.

The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) was adopted by the UN Food and Agriculture Organization (FAO) Conference in November 2001. It is a legally binding treaty for all signatories, which includes the EU, and covers all plant genetic resources relevant for food and agriculture. The Treaty is harmonised with the Convention on Biological Diversity. The main objectives of the Treaty are:

- Conservation and sustainable use of plant genetic resources for food and agriculture;
- Fair and equitable sharing of the benefits derived from the use of these resources.

These objectives are to be met through the Multilateral System for Access and Benefit-Sharing where parties to the treaty agree to establish an efficient, effective and transparent multilateral system to facilitate access to plant genetic resources for food and agriculture and to share the benefits in a fair and equitable way.

Among the small number of respondents to the stakeholder consultation who believe there is a conflict between the objectives of the CBD and the CPVR *acquis,* the primary concern relates to a lack of disclosure of origin *requirements* in the CPVR application. Such a requirement (rather than a voluntary measure) would likely necessitate changes at UPOV level, which would then be taken up by the CPVR system. Changes to the CPVR *acquis* prior to UPOV actions may mean that the *acquis* no longer conforms to the UPOV 1991 Convention, under which the CPVR system is bound.

[44] The Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of Their Utilisation, http://www.cbd/int/doc/publications/cbd-bonn-gdls-en.pdf (viewed 18 November 2010).

One respondent raised the issue of transfers of plant genetic resources to farmers as a problem, but several others emphasised that the CPVR regime had been recognised as an exception to the ITPGRFA transfer rules in this context.

4.6 Other issues

4.6.1 There are some editorial errors in the Basic Regulation; any revision to the Regulation should consider correcting them

CPVO has indicated that there are some errors in the text of the Basic Regulation. The language of the Basic Regulation could be amended alongside any potential revisions to correct these errors. A list of errors can be provided on request to the CPVO.

An option to improve the CPVR system by correcting these errors is discussed in Section 5. The option is assessed in Annex 16 (Option N).

5 Options for the future

This evaluation has assessed the CPVR *acquis* in terms of how well it has met its objectives and its current strengths and weaknesses. Based on this assessment, the evaluators have identified a set of deficiencies and assessed potential options for improving the system. This section explains the options, and the process of their development and appraisal.

5.1 Option identification

Options have been developed to address:

- Primary issues: that is, areas where:
  - Recognised deficiencies and/or challenges are concentrated; and
  - Stakeholders have expressed the most interest and support for improvements.
- Secondary issues: that is, areas where:
  - Recognised deficiencies and/or challenges exist but are fewer or less extreme; and
  - Stakeholders have expressed moderate interest and support for improvements.

Options were identified directly from the evaluation results, from ongoing European Commission initiatives, inputs from the stakeholder consultation, industry position papers and discussions, and third party research. A total of 36 options were subjected to an initial screening, at which stage six were eliminated. The remaining options are presented in Table 5.7 and Table 5.8 according to the issue they are intended to address, rather than the schedule of evaluation questions specified in the project terms of reference (with more detail in Annex 15 and 16). Where more than one issue could be resolved with the same option they have been combined so that the option is assessed once.

5.2 Option assessment

Each option has been assessed according to the following criteria, as defined in the evaluation terms of reference:

- Contribution to correcting a known deficiency in the CPVR system;
- Feasibility of implementing the option;
- Stakeholder support levels amongst the following three stakeholder categories:
  - Plant breeders;
  - Plant growers;
  - Member State representatives;
- Administrative burdens that may result from implementing the option, including the associated costs; and
- The wider consequences of implementing the option, including economic, environmental, social and international impacts.

Each criterion is scored for each option. Expected impacts are scored based on a qualitative assessment and assigned a rating according to the expected magnitude of the impact, with a seven point scale applied for these purposes (Table 5.6).

Table 5.6 Options assessment rating

Rating	Rating description
---	May have a major negative impact
--	May have a significant negative impact
-	May have a slight negative impact
0	May have no/negligible impact
+	May have a slight positive impact
++	May have a significant positive impact
+++	May have a major positive impact
(+)/(-)	Impacts uncertain – potential positive and negative impacts

Ratings are assigned on the basis of the expected percentage change rather than absolute change, to provide some equivalence of impact across the assessment categories.

Options have been assessed with reference to a baseline scenario which involves no changes to the specification of the CPVR system. The options recognise the continuing development of the 'external' environment as defined by changes in Member State and international law and practice, bioscience and plant breeding developments, and user expectations among other issues.

The option assessment scorecard in Table 5.9 provides ratings for each criterion and an overall rating for each option. In order to compare the options, the ratings are each assigned equal weighting. Thus, the options with a net positive rating are recommended for further consideration and those with a net negative rating are not. Those options with a net positive rating are then categorised according to their initial priority ranking (primary or secondary).

Table 5.7 Category I: Policy options to address primary issues

		Issue	Option
A		Interaction with the S&PM Directives results in multiple DUS testing and variety denomination requirements for plant varieties (see Sections **Error! Reference source not found.** and **Error! Reference source not found.**)	Implement the 'one key, several doors' approach to DUS testing and variety denominations
B		Interaction with the patent system results in overlapping protection for some plant varieties and patents. This creates uncertainty for plant breeders and potential conflicts where the provisions of the CPVR *acquis* (particularly the breeders' exemption) are not available under patent legislation (see Section **Error! Reference source not found.**)	Improve information provision for protected varieties (led by CPVO)
C		Interaction with the Enforcement Directive (see Sections 4.2.9.1, and 4.2.10)	Amend Basic Regulation (BR) to accommodate Enforcement Directive
D		Consider whether to extend the CPVR *aquis* to EFTA countries (see Section **Error! Reference source not found.**)	Extend the CPVR *acquis* to EFTA countries
E		There are no official protocols or standards for determining whether a plant variety is 'essentially derived', resulting in uncertainty for breeders in conducting their research programmes and court cases using similar evidence but resulting in different judgments. (see Section 4.2.5)	CPVO plays a greater role in supporting protocol and EDV threshold development, in collaboration with the plant breeding industry
F		The duration of protection may not be adequate to ensure that plant breeders can obtain a return on investment where breeding programmes and variety development are particularly long (see Section **Error! Reference source not found.**)	Extend the duration of protection on a case-by-case basis
G	G1	Legal interpretation of FSS users' obligation to report creates practical difficulties with royalty collection (see Sections **Error! Reference source not found.** and 4.2.9.1)	Amend the CPVR BR to obligate growers to report 'yes' or 'no' upon request whether they have used farm saved seed
	G2	The appropriate definition of a 'small farmer' is contentious and the current definition is no longer in use (see Section 4.2.4.5)	Amend Regulation (EC) No 1768/95 to redefine a 'small farmer'
	G3	The 'small farmer' exemption is contentious and could be removed from Regulation (EC) No 1768/95 (see Section 4.2.4.5)	Change Regulation (EC) No 1768/95 to remove the 'small farmer' exemption
	G4	The 'own holding' definition could be clarified to better reflect farming practices (see Section **Error! Reference source not found.**)	Amend Regulation (EC) No 1768/95 to redefine the 'own holding' definition
	G5	There is scope to clarify the definition of 'equitable remuneration' (see Section **Error! Reference source not found.**)	Amend Regulation (EC) No 1768/95 to redefine the 'equitable

				remuneration' definition

Table 5.8 Category II: Policy options to address secondary issues

		Issue	Option
H	H1	Courts in many MS do not have enough knowledge of CPVR-related issues to make informed judgements; similar court cases have different results (see Sections 4.2.9.1 and 4.2.10)	Develop a system of specialised national courts with knowledge of issues related to PVR
	H2	Courts in many MS do not have enough knowledge of CPVR-related issues to make informed judgements; similar court cases have different results (see Sections 4.2.9.1 and 4.2.10)	Develop a specialised EU-level court with knowledge of issues related to PVR
I	I1	There are differences between the UPOV 1991 definition of 'harvested materials' and that provided in the CPVR BR, which creates loopholes that prevent CPVR rights' holders from enforcing their rights in some cases (see Sections **Error! Reference source not found.** and 4.2.10)	Amend the Basic Regulation to provide unqualified protection for harvested materials
	I2	There is scope to expand the protection for harvested materials to the products made from harvested materials (see Sections **Error! Reference source not found.** and 4.2.10)	Extend scope of protection to products of harvested materials
	I3	There is scope to expand the protection for harvested materials to the transit of harvested materials (see Sections **Error! Reference source not found.** and 4.2.10)	Extend scope of protection to the transit of harvested materials
J		There are interactions between access to information legislation and the CPVR BR which require clarification for the CPVO (see Section **Error! Reference source not found.**)	Clarify procedures regarding access to information in cases of *lex specialis* with regarding to Article 88 pertaining to CPVR applications.
K	K1	DUS testing protocols do not include some important additional characteristics, which prevent varieties which are obviously distinct from obtaining CPVR protection (see Sections **Error! Reference source not found.** and **Error! Reference source not found.**)	Adjust the testing protocols to account for additional characteristics
	K2	The information requirements where CPVO takes over a DUS report from a national PVR system are considered to be too burdensome (see Section **Error! Reference source not found.**)	Reduce the information requirements where a DUS test report is taken over by CPVO from a national system
	K3	Communication between breeders, CPVO and testing centres could be improved to reduce the time lag between application and receipt of the grant (or rejection) and to improve the overall test results (e.g. reducing errors) (see Section 4.2.9.1)	CPVO facilitates better communication between applicants/rights' holders and the CPVO, as well as the national testing centres
	K4	A fee payment lag has been identified for at least some testing centres, which creates a financial burden for testing centres (see Section **Error! Reference source not found.**)	Assess the fee payment lag for national testing centres
	K5	Official licensing could be used to improve DUS testing results and reduce the costs (see Sections **Error! Reference source not found.** and 4.2.9.1)	Consider official licensing for private companies to participate in DUS testing
L	L1	CPVO could further support the use of molecular markers for infringement cases (see Sections 4.2.9.1 and 4.2.10)	CPVO-led support for molecular marker use in infringement cases
	L2	CPVO could further support sample banking of genetic materials (see Section 4.2.10)	CPVO-led support for sample banking of genetic materials
	L3	CPVO could further support outreach efforts to third countries (see Section **Error! Reference source not found.**)	CPVO-led outreach to third countries
M		There are difficulties with the procedures to hire senior management in the CPVO (see Section **Error! Reference source not found.**)	Amend the Basic Regulation to align hiring procedures with current Commission practices
N		There are some editorial errors in the Basic Regulation (see Section **Error! Reference source not found.**)	Amend the Basic Regulation to correct any errors

Table 5.9Option Assessment Scorecard

		Issue	Option	Parameter/Score								Net rating	Recommend? (Y/N)
				Contribution	Feasibility	Stakeholder support			Admin burdens/ costs	Coherence with other policies	Wider impacts		
						Breeders	Growers	MS Reps					
A		Interaction w/ S&PM Directives	Implement 'one key, several doors' approach	+++	+	++	++	++	(+)/(-)	++	++	**++**	**Y**
B		Interaction w/ patent system	Improve information provision for protected varieties	+	++	++	0	++	-	+	++	++	**Y**
C		Interaction with the Enforcement Directive	Amend BR to accommodate Enforcement Directive	+	+++	+++	++	+++	0	+++	+	++	**Y**
D		EFTA extension	Extend CPVR *acquis* to EFTA countries	+	++	++	++	++	+	+++	++	**++**	**Y**
E		EDV determinations	CPVO-led support for protocol & threshold development	++	++	++	0	0	--	++	+	**++**	**Y**
F		Protection duration	Case-by-case extensions	+	+	+++	--	0	-	--	(+)/(-)	(+)/(-)	**N**
G	G1	Reporting obligation	Amend CPVR BR to obligate growers to report 'yes' or 'no' whether they have used FSS	++	+	++	++	++	-	++	+	**++**	**Y**
	G2	'Small farmer exemption'	Amend Regulation (EC) No 1768/95 to redefine a 'small farmer'	++	-	+	+	+	-	++	+	**+**	**N**
	G3	'Small farmer	Change Regulation (EC)	+	--	++	--	--	(+)/(-)	+	--	**--**	**N**

		Issue	Option	Parameter/Score								Net rating	Recommend? (Y/N)
				Contribution	Feasibility	Stakeholder support			Admin burdens/ costs	Coherence with other policies	Wider impacts		
						Breeders	Growers	MS Reps					
		exemption	No 1768/95 to eliminate the 'small farmer' exemption										
	G4	'Own holding definition'	Amend Regulation (EC) No 1768/95 to redefine the 'own holding' definition	+	-	+	+	0	+	+	(+)/(-)	**+**	**N**
	G5	'Equitable remuneration' definition	Amend Regulation (EC) No 1768/95 to redefine the 'equitable remuneration' definition	+	+	+	+	0	-	+	+	**+**	**N**
H	H1	Specialised courts	National specialised courts	+	++	++	0	0	(+)/(-)	++	++	**++**	**Y**
	H2		EU-level specialised court	++	+	++	0	0	(+)/(-)	+	++	**++**	**Y**
I	I1	Harvested materials	Amend CPVR BR to provide unqualified protection for harvested materials	++	+++	++	-	0	(+)/(-)	+++	++	**++**	**Y**
	I2		Extend scope of protection to products of harvested materials	+	--	+	---	0	(+)/(-)	+	--	**-**	**N**
	I3		Extend scope of protection to transited	+	--	+	---	0	(+)/(-)	+	-	**-**	**N**

		Issue	Option	Parameter/Score								Net rating	Recommend? (Y/N)
				Contribution	Feasibility	Stakeholder support			Admin burdens/ costs	Coherence with other policies	Wider impacts		
						Breeders	Growers	MS Reps					
			harvested materials										
J		Interaction with access to information legislation	Clarify procedures with CPVO	+	++	+	0	0	++	++	0	**++**	**Y**
K	K1	Applications & examinations	Adjust testing protocols for additional characteristics	+	--	+	0	+	(+)/(-)	(+)/(-)	++	**+**	**N**
	K2		Reduce info requirements	(+)/(-)	++	+	0	0	+	N/A	N/A	**+**	**N**
	K3		Facilitate communication	+	+	+	0	0	-	N/A	N/A	**+**	**N**
	K4		Assess fee payment lag for testing centres	+	(+)/(-)	0	0	+	+	N/A	N/A	**+**	**N**
	K5		Official licensing for testing	+	-	+	0	0	-	N/A	N/A	**(+)/(-)**	**N**
L	L1	Capacity building	CPVO-led support for molecular markers	+	--	+	0	+	(+)/(-)	N/A	+	**+**	**N**
	L2		CPVO-led support for sample banking of genetic materials	++	-	(+)/(-)	0	0	(+)/(-)	++	+	**++**	**Y**
	L3		CPVO-led outreach to third countries	+	+	(+)/(-)	0	0	-	++	++	**++**	**Y**

	Issue	Option	Parameter/Score								Net rating	Recommend? (Y/N)
			Contribution	Feasibility	Stakeholder support			Admin burdens/ costs	Coherence with other policies	Wider impacts		
					Breeders	Growers	MS Reps					
M	Hiring senior management in CPVO	Amend BR to align practices with Commission policies	+	+++	+	0	0	+	+++	N/A	++	Y
N	Errors in the Basic Regulation	Amend BR to correct errors	+++	++	+	N/A	N/A	0	N/A	N/A	++	Y

5.3 Recommendations

The results of this evaluation indicate that the CPVR system functions well overall, and that stakeholders are happy with and wish to retain the system more or less in its current form. Nevertheless, improvement is possible in some areas, which have been detailed in this evaluation. Where options exist to resolve deficiencies, these have been assessed and proposed to form a package of potential changes to the *status quo* scenario. The conclusions of the option appraisal are summarised in Table 5.10 and Table 5.11. The complete assessment is provided in Annex 16.

Where the issue is of primary importance to the evaluation and the option is expected to have a significantly positive impact (i.e. with a net ranking of '++'), it is recommended that the option is taken forward. Where the issue is of secondary importance to the evaluation, and the option is expected to have a significantly positive impact (i.e. with a net ranking of '++') it is recommended for further consideration.

Table 5.10 Primary Issues - Recommended options

	Primary Issues	**Recommended Options**
A	Interaction with S&PM Directives results in multiple DUS testing and variety denomination requirements for plant varieties	Implement the 'one key, several doors' approach to DUS testing and variety denominations
B	Interaction with the patent system may create conflicts where patents and CPVR overlap. Determining whether a plant variety may overlap with a patent can be difficult without sufficient legal and technical expertise.	Improve information provision for protected varieties, led by CPVO
C	Interaction with the Enforcement Directive creates conflicts where the Directive does not align with the BR on infringement procedures, particularly in Articles 94 and 97 of the BR.	Amend the Basic Regulation to accommodate the Enforcement Directive
D	Extending the CPVR *acquis* to EFTA countries could benefit the EU and EFTA countries. Trade policies would be brought into closer alignment, cover a larger number of countries with one CPVR, and may improve EU breeding industry competitiveness.	Extend the CPVR *acquis* to EFTA countries
E	EDV determinations are currently problematic, so disagreements are more difficult to resolve. There are no standardised protocols, but industry has developed protocols and thresholds for some varieties, which can be used as evidence in EDV cases.	CPVO supports industry protocol and threshold development for EDVs
G1	Current reporting requirements on FSS use create barriers to well-functioning FSS systems. In particular, ECJ rulings limit breeders' ability to request information on FSS use which makes it more difficult for breeder to exercise their rights to collect royalties.	Amend the BR to obligate growers to report 'yes' or 'no' whether they have used FSS

Table 5.11 Secondary Issues – Recommended options

	Secondary Issues	Recommended Options
H1	Enforcement is a major concern for rights' holders and most courts in MS are not adequately knowledgeable about CPVR issues to rule on CPVR cases	Require MS to designate competent courts that can make more informed decisions on CPVR-related cases
H2		Develop an EU-level competent court for CPVR cases, ideally combined with an EU patent court
I1	Rights' holders have difficulties obtaining royalty payments on harvested materials where royalties are not obtainable for propagating materials. The definition in the BR is not clear enough to ensure that royalties may be obtained for harvested materials.	Amend the BR to provide unqualified protection for harvested materials
J	Interaction with access to information legislation creates uncertainty for CPVO	Clarify procedures with CPVO
L2	CPVO could be more involved in capacity-building for the CPVR system	CPVO could provide additional support for sample banking of genetic materials
L3		CPVO could provide more outreach to third countries
M	There are problems in the procedures to hire senior management in CPVO	Amend Basic Regulation to align practices with current Commission policies
N	There are some editorial errors in the Basic Regulation	Amend Basic Regulation to correct errors

In summary, the evaluation found a number of primary issues that require further consideration and/or potential remedy. These can be broadly grouped into three areas:

- Interaction with other EU policy areas and legislative frameworks (S&PM Directives, patent system, and Enforcement Directive);
- Problems with the derogations offered through the CPVR Regulation (EC) No 2100/94 (EDVs and the agriculture exemption); and
- Opportunities to extend the CPVR *acquis* beyond the EU-27, particularly to EFTA countries.

Secondary issues are those where opportunities to implement significant change may be less or where stakeholders view the issues as less urgent than those identified above. These, too, may be grouped into three areas:

- Concerns about rights' holders ability to enforce CPVR effectively;
- Opportunities for CPVO to engage in capacity-building for better CPVR functioning and to clarify its role and procedures; and

Additionally, there are some editorial errors in the Basic Regulation that could easily be amended. In each case, there are options that may be able to address these issues to support and encourage more efficient and effective operation of what is widely viewed to be a useful and effective system of plant variety rights for the EU. This study aimed to evaluate the CPVR *acquis* in terms of its ability to meet its original objectives as well as to ascertain its current strengths and weaknesses. The policy options recommended here are set out to help meet the challenges observed in the system.

ANNEXES

Annex 1 Intervention Logic

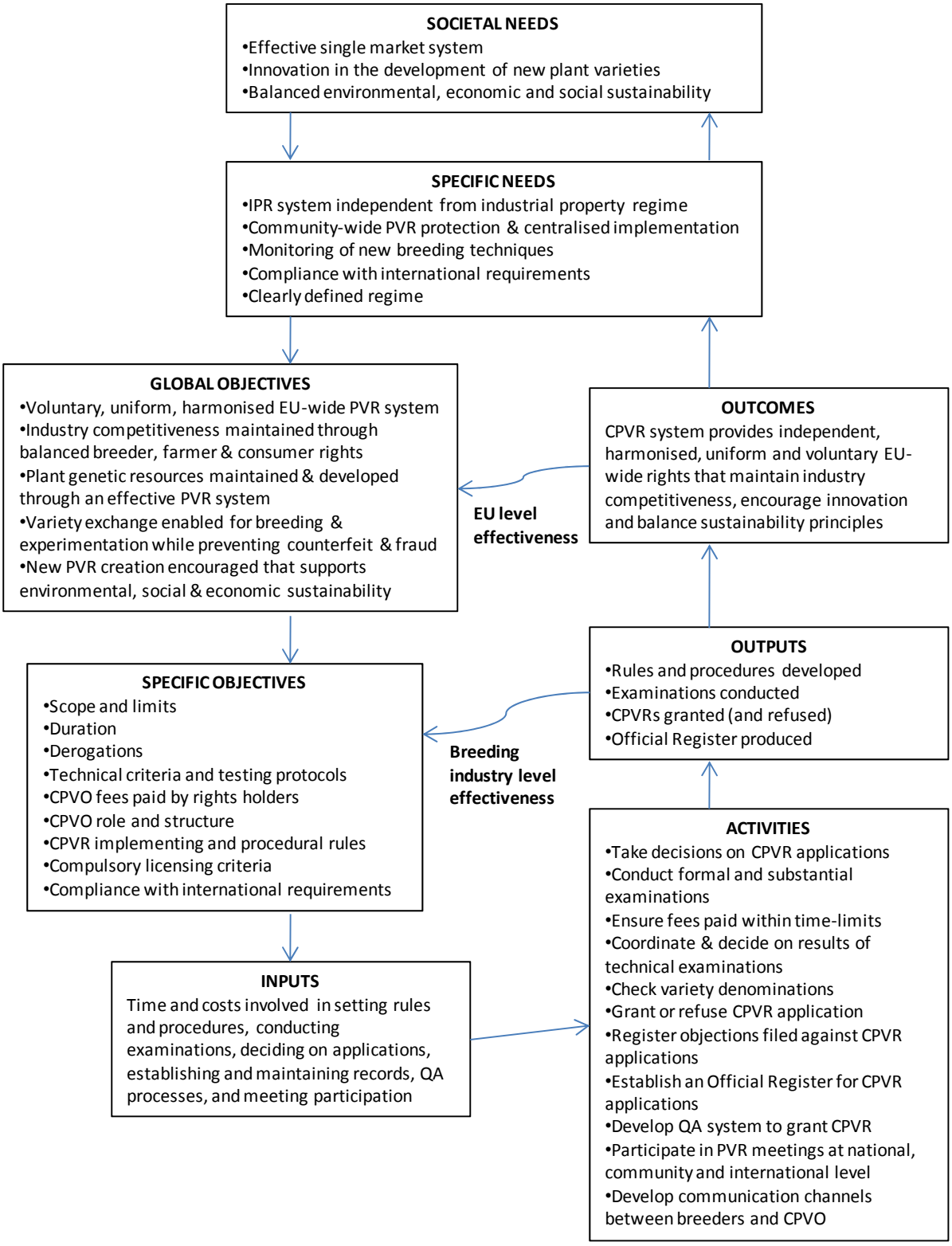
This evaluation aimed to assess how well the CPVR system functions after 15 years of operation both in relation to its original goals and how well it will respond to future developments and challenges. Evaluation success depends on a firm understanding of the system's rationale, purpose and intended impacts from the outset. Intervention logics aid in illustrating how a system like the CPVR regime should theoretically achieve its own objectives and what factors contribute to successful operation of the system.

The CPVR regime was designed to address specific issues and concerns related to plant breeding and property rights in the context of wider policy goals and societal needs. These wider goals and needs include increased innovation, the development of an efficient single market system and improved economic, social and environmental sustainability. Within the regime, specific objectives were set to address broader strategic and policy goals. Rules, procedures and activities were designed and undertaken to implement the regime and achieve the desired goals.

An intervention logic was therefore developed to help guide the CPVR evaluation by describing the system and its theory of change, highlighting the implicit links between the different elements of the policy and how they are intended to operate in practice. The intervention logic modelled the CPVR system by framing the regime's objectives in relation to its inputs (resources), outputs (products and services delivered) and outcomes (results). It served as an evaluation tool to help focus the study.

The intervention logic maps the regime's strategic objectives in relation to specific objectives and implementation activities. These activities in turn produce results and impacts, which can be measured and assessed in relation to the system's objectives and activities. The intervention logic was developed from information provided in the terms of reference and from the initial policy and document review. It was further refined throughout the evaluation as additional information and understanding guided understanding of the system's operation.

Figure A1.1 CPVR *acquis* Intervention Logic[45]



[45] CPVO = Community Plant Variety Office, IPR = intellectual property right, PVR = plant variety right, QA = quality assurance

Annex 2 Council Regulation (EC) No 2100/94 and implementing rules

Council Regulations

Council Regulation (EC) Nº 2100/94 of 27 July 1994 on Community Plant Variety Rights [Official Journal L 227, 01/09/1994 p. 0001-0030]

Corrigendum of Council Regulation (EC) Nº 2100/94 of 27 July on Community Plant Variety Rights [Official Journal L 111, 20/04/2001 p. 0031-0031 (F, FI, NL only)]

Council Regulation (EC) Nº 2506/95 of 25 October 1995 amending Regulation (EC) Nº 2100/94 on Community Plant Variety Rights [Official Journal L 258, 28/10/1995 p. 0003-0004]

Rectification, Official Journal L 111, 20/04/2001 p. 31

Council Regulation (EC) Nº 807/2003 of 14 April 2003 adapting to Decision 1999/468/EC the provisions relating to Committees which assist the Commission in the exercise of its implementing powers laid down in Council instruments adopted in accordance with the consultation procedure (unanimity) [Official Journal L 122, 15/05/2003 p. 0036-0062]

Council Regulation (EC) Nº 1650/2003 of 18 June 2003 amending Regulation (EC) Nº 2100/94 on Community Plant Variety Rights [Official Journal L 245, 29/09/2003 p. 0028-0029]

Council Regulation (EC) Nº 873/2004 of 29 April 2004 amending Regulation (EC) Nº2100/94 on Community Plant Variety Rights [Official Journal L 162, 30/04/2004 p. 0038-0039]

Council Regulation (EC) Nº 15/2008 of 20 December 2007 amending Regulation (EC) Nº2100/94 on Community Plant Variety Rights [Official Journal L 8, 11/01/2008 p. 2]

Act concerning the conditions of accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic and the adjustments to the Treaties on which the European Union is founded [Official Journal L 236, 23/09/2003 p. 840 (derogation for the Republic of Lithuania]

Council Regulation (EC) Nº 2470/94 of 17 December 1996 providing for an extension of the terms of a Community Plant Variety Right in respect of potatoes [Official Journal L 335, 24/12/1996 p. 0010-0010]

Commission Implementing Measures

Commission Regulation (EC) Nº 1238/95 of 31 May 1995 establishing implementing rules for the application of Council Regulation (EC) Nº 2100/94 as regards the fees payable to the Community Plant Variety Office [Official Journal L 121, 01/06/1995 p. 0031-0036]

Commission Regulation (EC) Nº 329/2000 of 11 February 2000 amending Regulation (EC) Nº 1238/95 as regards the fees payable to the Community Plant Variety Office [Official Journal L 037, 12/02/2000 p. 0019-0020]

Commission Regulation (EC) Nº 569/2003 of 28 March 2003 amending Regulation (EC) Nº 1238/95 establishing implementing rules for the application of Council Regulation (EC) Nº 2100/94 as regards the fees payable to the Community Plant Variety Office [Official Journal L 082, 29/03/2003 p. 0013-0016]

Commission Regulation (EC) Nº 1177/2005 of 20 July 2005 amending Regulation (EC) Nº 1238/95 establishing implementing rules for the application of Council Regulation (EC) Nº 2100/94 as regards the fees payable to the Community Plant Variety Office [Official Journal L 189, 21/07/2005 p. 26-27]

Commission Regulation (EC) Nº 2039/2005 of 14 December 2005 amending Regulation (EC) Nº 1238/95 establishing implementing rules for the application of Council Regulation (EC) Nº 2100/94 as regards the fees payable to the Community Plant Variety Office [Official Journal L 328, 15/12/2005 p. 33]

Commission Regulation (EC) Nº 572/2008 of 19 June 2008 amending Regulation (EC) Nº 1238/95 as regards the level of the annual fee and the fees relating to the technical examination, payable to the Community Plant Variety Office and the manner of payment [Official Journal L 161, 20/06/2008 p. 7-10]

Commission Regulation (EC) Nº 874/2009 of 17 September 2009 establishing implementing rules for the application of Council Regulation (EC) Nº 2100/94 as regards proceedings before the Community Plant Variety Office (recast) [Official Journal L 251, 24/09/2009 p. 3-28]

Commission Regulation (EC) Nº 1768/95 of 24 July 1995, establishing implementing rules on the agricultural exemption, provided for in Article 14(3) of Council Regulation (EC) Nº 2100/94 on Community Plant Variety Rights [Official Journal L 173, 25/07/1995 p. 14-21]

Commission Regulation (EC) Nº 2605/98 of 3 December 1998, amending Regulation (EC) Nº 1768/95, establishing implementing rules on the agricultural exemption provided for in Article 14(3) of Council Regulation (EC) Nº 2100/94 on Community Plant Variety Rights [Official Journal L 328, 04/12/1998 p. 6-7]

1.

Annex 3 Evaluation Matrix

This evaluation matrix sets out the questions for the evaluation, the judgement criteria, indicators identified and the data sources used. Annex 4 provides the conclusions reached in response to each question.

Evaluation Question (EQ)/Sub-Question (SQ)	Related Article from the Basic Regulation	Discussion of Issue/Judgement Criteria	Indicators	Data sources	Stakeholder Questions (reference numbers in draft survey)
Evaluation Objective 1: Past performance - the general 'Acquis' framework					
EQ 1: (Harmonisation) To what extent has the CPVR 'acquis' harmonised industrial property regimes for plant varieties at EU level?	Article 2: *Uniform effect of CPVR*				
SQ1: To what extent has the CPVR "acquis" had a uniform effect within the EU territory with regard to granting industrial property rights valid throughout the community, and by means of uniform application procedures?		CPVR are granted uniformly across Member States	1. CPVR application procedures are consistently applied by CPVO; 2. CPVR holders enjoy the same privileges across all Member States	Stakeholder surveys & interviews; Application statistics from CPVO or other sources	1
SQ2: To what extent has the enforcement of the CPVR "acquis" been uniform across EU Member States?		CPVR infringements are treated uniformly across Member States	1. Infringement law suits have consistent outcomes across all Member States	Stakeholder surveys & interviews; Court cases	2,3
EQ 2: (Appropriateness) To what extent can the CPVR 'acquis' be considered an appropriate EU regime which, although co-existing with national regimes, has allowed for the grant of industrial property rights valid throughout the EU?	Entire Council Regulation (EC) No. 2100/94				
Sub-Question 1: Protection - conditions, scope, limitations, duration					
SQ1a: How appropriate and effective is the application of CPVR protection criteria (e.g. application of DUS requirements and the need to designate a variety denomination as set out in the 'UPOV' Convention)?	Articles 5 – 10 (Part Two, Chapter 1: *Conditions Governing the Grant of CPVR*); Article 63: *Variety Denomination*	CPVR protection criteria match needs of the small, medium-sized and large plant-breeding industry; CPVR protection criteria match the latest scientific understanding of plant varieties and facilitate the work of the examination offices	1. Stakeholder satisfaction with CPVR protection criteria is high across all industry levels and Member States; 2. Scientific research on plant varieties corroborates CPVR protection criteria	Stakeholder surveys & interviews; interviews with scientists; academic literature (botanical)	29, 33,34
SQ1b: Are the rights conferred on CPVR holders and their limitations and exceptions appropriate?	Articles 13 – 18 (Part Two, Chapter III: *Effects of CPVR*)	CPVR stimulate innovation at all levels of the breeding industry, without impeding growth at any level of the agricultural sector (small, medium-sized and large farms); CPVR contribute to the enhancement of agricultural genetic diversity	1. Stakeholder satisfaction with rights and privileges conferred on CPVR holders is high; 2. Increasing numbers of plant varieties on the market; 3. Increasing numbers of plant varieties grown on farms 4. Plant breeding industry includes firms of all sizes	Stakeholder survey & interviews; Market surveys; Statistics from Farmers' Associations or other sources; Statistics from Plant Breeders' Industrial Associations	12

SQ1c: Are the derogations from the CPVR regime ('agriculture exemption' or 'farm-saved seed exemption') and the 'breeder's exemption' appropriate and satisfactory? What are the possible ways forward to enhance the system in this regard?	Article 14: *Derogation from CPVR* ; Article 15: *Limitation of the effects of CPVR*	The derogations from CPVR facilitate growth at all levels of the in the agricultural sector, without hindering innovation at all levels of the breeding industry; The derogations from CPVR contribute to the enhancement of agricultural genetic diversity	1. Stakeholder satisfaction with the derogations from CPVR is high; 2. Farms of all sizes have or can obtain sufficient 'freedom to operate' with regard to propagating material needed for their production processes	Stakeholder survey & interviews;	15-21
SQ1d: Is the duration of protection appropriate in order to fulfil the needs it aims to satisfy? What criteria should the legislator take into account when establishing the duration?	Articles 19 – 21 (Part Two, Chapter IV: *Duration and Termination of CPVR*)	CPVR duration stimulates innovation at all levels of the breeding industry; CPVR duration allows for adequate recuperation of breeder's investments, while striking the right balance between public and private interest	1. Stakeholder satisfaction with the duration of protection is high; 2. Increasing numbers of plant varieties on the market; 3. Statistics show breeders' investments in developing new varieties generally lower than economic benefits received from CPVR throughout its duration; 4. Duration of	Stakeholder survey & interviews; Market surveys; Statistics from Plant Breeders' Industrial Associations; Evaluations of other intellectual property regimes	35-37
Sub-Question 2: CPVO role and effectiveness					
SQ2a: To what extent is a system where the implementation and application of the CPVR "acquis" is not carried out by the authorities of the Member States but by a Union Office with legal personality, the "Community Plant Variety Office" effective?	Entire Council Regulation (EC) No. 2100/94	CPVR granted effectively by CPVO; CPVR granted by CPVO are recognised throughout EU territory; Only few, if any, administrative functions are entrusted to national agencies by CPVO (cf. Art. 30.4)	1. Numbers of CPVR granted are rising; 2. Stakeholder satisfaction with functioning of CPVO is high; 3. Stakeholders interact directly with CPVO rather than through national authorities	Statistics from CPVO; Stakeholder survey & interviews	41,43
SQ2b: To what extent does the Community Plant Variety Office (CPVO) "play its role", as defined in the CPVR Regulation, both in terms of the procedure for the granting of a CPVR as well as in terms of technical criteria (DUS) used for deciding to grant a CPVR?	Articles 30 – 48 (Part Three: *The Community Plant Variety Office*)	CPVO successfully executes formal and substantive examination of applications for CPVR; CPVO successfully arranges for technical examination of plant material and samples related to applications for CPVR; Examination Offices effectively carry out DUS tests	1. Numbers of applications for CPVR are rising; 2. Numbers of CPVR granted are rising; 3. Stakeholder satisfaction with the operations of CPVO and Examination Offices is high	Statistics from CPVO; Statistics from Court of Auditors of the European Communities; Stakeholder survey & interviews	29,31,43,44,48, 49
SQ2c: Do the proceedings before the CPVO for the breeders fulfil their role?	Articles 49 – 91 (Part Four: *Proceedings before the Office*)	Examination of application for CPVR, grant and maintenance of CPVR, as well as appeals to decisions made are carried out by CPVO to satisfaction of the small, medium-sized and large plant breeding industry	1. Breeders' satisfaction with CPVO proceedings is high; 2. Comparatively few complaints or appeals filed pursuant to CPVO proceedings or decisions	Stakeholder survey & interviews; Statistics from CPVO Board of Appeal	29,31,40,43,44
SQ2d: Does the Board of Appeal of the CPVO fulfil its role?	Articles 45 – 48 (Part Three, Chapter IV: *The Boards of Appeal*)	Appeals brought before the Board of Appeal are treated impartially	1. Stakeholder satisfaction with the CPVO Board of Appeal is high; 2. Few, if any, actions against decisions of the Board of Appeal are brought before the Court of Justice; 3. Decisions of the Board of Appeal do not consistently	Stakeholder survey & interviews; Statistics and decisions taken from CPVO Board of Appeal; Court cases	50

Sub-Question 3: Enforcement					
SQ3a: Is the EU legislation on the enforcement of CPVR appropriate and how has the legislation been applied by national courts?	Articles 94 – 107 (Part Six: *Civil Law Claims, Infringements, Jurisdiction*)	Enforcement of CPVR is effective and uniform across EU Member States	1. Stakeholder satisfaction with enforcement of CPVR is high across Member States; 2. Legal actions regarding infringements have similar outcomes across Member States	Stakeholder survey & interviews; Data from court cases	51-53
EQ 3: (Effects on stakeholders) To what extent is the CPVR "acquis" beneficial for all users of varieties protected at EU level?	Entire Council Regulation (EC) No. 2100/94				
SQ1: What are the consequences of the CPVR "acquis" on the small, medium-sized and large plant breeding industry?		Is the industry vibrant and diverse? How has the CPVR "acquis" changed small, medium-sized and large breeders' industrial practices and economic situation?	1. Plant breeding industry includes firms of various sizes; 2. Breeders' economic situation has changed in response to CPVR "acquis"	Statistics from Plant Breeders' Industrial Associations; Stakeholder survey & interviews	4,6,12
SQ2: What are the consequences of the CPVR "acquis" on small, medium-sized and large farms?		Is the agricultural sector vibrant and diverse? Do farms of all sizes continue to function across Member States? How has CPVR "acquis" changed their practices, production and economic situation?	1. Agricultural sector includes farms of all sizes; 2. Farmers' economic situation has changed in response to CPVR "acquis"	Statistics from Farmers' Associations and other sources; Stakeholder survey & interviews	5,6,12
SQ3: What are the consequences of the CPVR "acquis" on EU citizens and consumers?		Are there more or fewer plant varieties available to end consumers? How has public research been affected by the CPVR "acquis"?	1. Increasing numbers of plant varieties on the market; 2. Public research into plant varieties has changed in response to CPVR "acquis"	EU market surveys; University & governmental data on public research; Stakeholder survey & interviews	8, 9,11
EQ 4: (Stimulating tool) To what extent has the CPVR "acquis" proven to be a stimulating tool for EU breeders?					
SQ1: To what extent has the CPVR "acquis" facilitated the protection of new varieties of plants in the EU?		Have the numbers of plants protected in the EU increased (by application numbers and by PVR granted) since 1994? What is the ratio of National PVR vs. CPVR?	1. Rising numbers of PVR applications (total of applications to CPVO and National Authorities); 2. Rising numbers of PVR granted (total of applications to CPVO and National Authorities)	Statistics from CPVO; Statistics from National Plant Variety Protection Authorities; Stakeholder survey & interviews	7
SQ2: To what extent has the CPVR "acquis" stimulated the breeding and development of new varieties?		Does the promise of protection incentivise breeding and development of new plant varieties? Does expanded scope of protection further incentivise innovation?	1. Increasing numbers of plant varieties on market; 2. Increasing numbers of plant varieties grown in fields; 3. Expanding plant breeding industry since 1994	EU market surveys; Statistics from Farmers' Associations; Statistics from Plant Breeders' Industrial Associations	
SQ3: To what extent has the CPVR "acquis" improved protection compared with the situation before 1994 for all plant breeders, without, however, unjustifiably impairing access to protection generally or in the case of certain breeding techniques?		Is the CPVR "acquis" partial to particular breeding techniques? Does the CPVR "acquis" impair access to other forms of industrial protection? Is the CPVR "acquis" less accessible to certain breeders (e.g. small breeders)?	1. Plant varieties developed through a particular breeding technique receive consistently more protection than those developed through other techniques; 2. Small, medium-sized and large breeding firms have equal access to protection under CPVR "acquis"	Statistics from CPVO; Stakeholder survey & interviews	7,434

EQ 5: (Impact on EU biodiversity, agriculture and seed sector)					
SQ1: What is the impact of the CPVR "acquis" on the preservation and the erosion of plant genetic resources in the EU?		Does the CPVR “acquis” facilitate or hinder the preservation of plant genetic resources? Is it partial to particular forms of preservation (e.g. ex situ vs. in situ)? Does it enhance or erode genetic diversity in the EU?	1. Agricultural genetic diversity is stable or has increased since 1994; 2. CPVR “acquis” has changed practices of preservation of plant genetic resources	Statistics from conservation organisations; Statistics from Farmers’ Associations; Stakeholder survey & interviews	9,10
SQ2: To what extent has the CPVR "acquis" contributed to a harmonious development of the EU agriculture including in particular the EU seed sector?		Has the EU agricultural sector developed evenly across Member States? Is the number of small, medium-sized and large farms increasing, stable, or declining? Has the EU seed sector developed evenly across Member States? What is the contribution of the CPVR “acquis” in these developments?	1. EU Agricultural sector includes farms of all sizes in all Member States; 2. EU seed sector existing and vibrant in all Member States	Statistics from Farmers’ Associations; Statistics from Industrial Associations (seed sector)	
SQ3: What is the impact of technical links between the seed marketing Directives and the CPVR "acquis"?		Have the technical links between the Seed Marketing Directives and the CPVR “acquis” impacted on the EU seed sector? Have they had any other impact on EU agriculture?	1. EU Seed sector has changed practices or otherwise developed in response to technical links between Seed Marketing Directives and CPVR “Acquis”	Statistics from Industrial Associations (seed sector); Stakeholder survey & interviews	59
EQ 6: (Interactions with National and International law)					
SQ1: To what extent does the CPVR "acquis" impact on the protection of new varieties of plants at National level?		Has legislation regarding PVR at the national level changed since 1994? Have Member States adopted provisions of the CPVR “acquis” into their national legislation regarding plant variety protection?	1. National legislation regarding PVR has changed since 1994; 2. Provisions of CPVR “acquis” have influenced change in National legislation	Texts of National legislations regarding PVR; Text of CPVR Regulation;	
SQ2: What is the impact of the CPVR "acquis" at the international level, in particular, on the legal systems of third countries?		Has legislation regarding PVR in countries outside the EU changed since 1994? Have other countries (or other regions) adopted provisions of the CPVR “acquis” into their national (or regional) legislations regarding plant variety protection?	1. National legislation regarding PVR outside the EU has changed since 1994; 2. Regional legislation regarding PVR outside the EU has changed since 1994; 3. Provisions of CPVR “acquis” have been replicated in National and/ or Regional legislation outside the EU	Texts of National and Regional legislations regarding PVR outside EU; Text of CPVR Regulation;	

Evaluation Objective 2: Current performance - strengths & weaknesses of the current 'Acquis'					
EQ 7: (Impact on stakeholders) To what extent does the CPVR "acquis" strike a fair balance with regard to the interests of the various EU stakeholders' groups?	Entire Council Regulation (EC) No. 2100/94				
SQ1: Holder's rights					
SQ1a: What are the strengths and weaknesses of the CPVR provisions regarding the rights of the holder?	Article 13: Rights of the holder of a CPVR and prohibited acts; Article 29: *Compulsory licensing*	Are all the rights (Art. 13.2 (a) – (g)) conferred appropriate? Are there disputes about any particular right or privilege?	1. Stakeholder satisfaction with holder's rights is high	Stakeholder survey & interviews	13
SQ1b: Is the concept of "Essentially Derived Variety" useful in this context? What are its strengths and weaknesses?		Concept of "essentially derived variety" expands CPVR to variety predominantly derived from variety initially protected – does this expand or constrain scope of CPVR too much? Is EDV a disputed category (i.e. can what is an EDV and what is not be unambiguously established?)	1. Stakeholder satisfaction with concept of EDV is high; 2. Scientific opinion concurs with definition of EDV	Stakeholder survey & interviews; Scientific literature	14,38,39
SQ1c: What are the strengths and weaknesses of the CPVR provisions regarding the limitations of the rights of the holder?		Are there disputes regarding Art. 13.3 and 13.4?	1. Stakeholder satisfaction with holder's rights, including their limitations is high;	Stakeholder survey & interviews	13
SQ2: Breeder's and agriculture exemptions					
SQ2a: What are the strengths and weaknesses of the breeder's exemption?	Article 15: *Limitations of the effects of*	Does it stimulate innovation or restrict CPVR too much?	1. Plant breeding industry is vibrant and diverse; 2. Stakeholder satisfaction with breeder's exemption is high	Statistics from Plant breeders' Industrial Associations; Stakeholder survey & interviews	15,16
SQ2b: What are the strengths and weaknesses of the agriculture exemption with regard to fodder plants?	Article 14: *Derogation from CPVR* , Paragraph 2(a)	Is the derogation with regard to fodder plants necessary? Should more or fewer varieties be included in the list of fodder plants?	1. Stakeholder satisfaction (especially of farmers growing fodder plants, and breeders breeding fodder plants) is high	Stakeholder survey & interviews	17
SQ2c: What are the strengths and weaknesses of the agriculture exemption with regard to cereals?	Article 14: *Derogation from CPVR* , Paragraph 2(b)	Is the derogation with regard to cereals necessary? Should more or fewer varieties be included in the list of cereals?	1. Stakeholder satisfaction (especially of farmers growing cereals, and breeders breeding cereals) is high	Stakeholder survey & interviews	18
SQ2d: What are the strengths and weaknesses of the agriculture exemption with regard to potatoes?	Article 14: *Derogation from CPVR* , Paragraph 2(c)	Is the derogation with regard to potatoes necessary? Should more or fewer varieties be included in the list of potatoes?	1. Stakeholder satisfaction (especially of farmers growing potatoes, and breeders breeding potatoes) is high	Stakeholder survey & interviews	19
SQ2e: What are the strengths and weaknesses of the agriculture exemption with regard to oil and fibre plants?	Article 14: *Derogation from CPVR* , Paragraph 2(d)	Is the derogation with regard to oil and fiber plants necessary? Should more or fewer varieties be included in the list of oil and fiber plants?	1. Stakeholder satisfaction (especially of farmers growing oil and fiber plants, and breeders breeding oil and fiber plants) is high	Stakeholder survey & interviews	20

SQ2f: Is the definition of "small farmers" useful in this context? What are its strengths and weaknesses?	Article 14: *Derogation from CPVR* , Paragraph 3	Should small farmers be exempt from paying "equitable remuneration"? Is the definition of "small farmers" as laid down in Council Regulation EEC 1765/92 appropriate?	1. Stakeholder satisfaction with use and definition of "small farmers" notion is high; 2. Farmers' Associations concur with definition of "small farmers" as laid down in EEC 1765/92	Stakeholder survey & interviews	21,22
SQ2h: Is the notion of "own holding" useful in this context? What are its strengths and weaknesses?	Article 14: *Derogation from CPVR* , Paragraph 1	Does the notion of "own holding" restrict or expand the agricultural exemption too much? Can a farmer's own holding always be unambiguously identified?	1. Stakeholder satisfaction with use and definition of "own holding" concept is high	Stakeholder survey & interviews	25
SQ2g: Is the definition of "equitable remuneration" useful in this context? How do stakeholders and Member States perceive this notion? How do farmers' and breeders' associations determine the level of this remuneration and the way to collect royalties?	Article 14: *Derogation from CPVR* , Paragraph 3	Should equitable remuneration be further specified by CPVO?	1. Stakeholder satisfaction with definition of "equitable remuneration" is high; 2. Few, if any, disputes arise with regard to the level of this remuneration	Stakeholder survey & interviews; Data from court cases and CPVO	26,27
SQ2i: How effective is the information system between farmers using protected farm saved seed (FSS) and the holder of a right, in order for the latter to recuperate their legitimate and "equitable remuneration" from farmers using FSS? What is the role of National Authorities in the provision of this information?	Article 14: *Derogation from CPVR* ; Articles 87 – 91 (Part Four, Chapter VIII: *Registers*)	Is communication between farmers and CPVR holders functioning? Is information readily available to farms of all sizes?	1. Few, if any, disputes between farmers and CPVR holders make reference to insufficient information available; 2. Stakeholder satisfaction with information system is high	Data from court cases and CPVO Stakeholder survey & interviews	23,24,75
SQ2j: In which ways and how effectively has the "agriculture exemption" been implemented in the different Member States?	Article 14: *Derogation from CPVR*	Have all Member States enacted legislation to uphold the agricultural exemption? Have they implemented the exemption by other means? What is most effective form of implementation?	1. "Agricultural exemption" is effectively implemented in all Member States; 2. Stakeholder satisfaction with implementation of agricultural exemption is high	Texts of National legislations; Data from Court cases; Stakeholder survey & interviews	28
SQ3: Costs					
SQ3a: Are the costs involved in the CPVR "acquis" reasonable and proportionate for breeders, taking into account that there are administrative costs (fees to CPVO), technical and experimental costs of plant breeding per se, and practical costs regarding the recuperation of the equitable remuneration due from farmers using the protected product?	Articles 83 – 86 (Part Four, Chapter VII: *Fees, Settlement of Costs*); Article 113: *Fees regulation*	Are the costs proportionate for breeders of the small, medium-sized and large breeding industry?	1. Stakeholder satisfaction with costs is high	Stakeholder survey & interviews	42,68-72
SQ3b: Are the costs involved in the CPVR "acquis" reasonable and proportionate for farmers?	Article 14: *Derogation from CPVR*	Are usual license fees proportionate for all farmers? Is the equitable remuneration proportionate for all farmers?	1. Stakeholder satisfaction with license fees and equitable remuneration is high; 2. Farms do not go out of business due to too high costs involved in CPVR "acquis"	Stakeholder survey & interviews; Data from Farmers' Associations	42,74,77,78

SQ3c: Are the costs involved in the CPVR "acquis" reasonable and proportionate for examination offices? How cost effective is their functioning?	Article 108: *Budget*	Do the examination offices operate within their budget? Do they have an appropriate income from examination fees?	1. Examination Offices operate within their budget; 2. Income from examination fees covers examination costs; 3. Stakeholder satisfaction with Examination Offices performance and	Statistics from individual examination offices; Statistics from Court of Auditors of the European Communities; Stakeholder survey & interviews	42,73
SQ3d: Are the costs involved in the CPVR "acquis" reasonable and proportionate for Member States?		To what extent does the CPVR "acquis" constitute an additional cost to Member States?	1. Stakeholder satisfaction with costs to Member States is high	Stakeholder survey & interviews	42,47,76
SQ3e: Are the costs involved in the CPVR "acquis" reasonable and proportionate for the CPVO? Does the cost effectiveness of CPVO functioning differ with regard to different plant species		Does the CPVO operate within its budget? Applications with regard to which plant species are most cost effective, which are least cost-effective?	1. CPVO operates within its budget; 2. Applications with regard to all plant species are cost-effective; 3. Stakeholder satisfaction with CPVO performance and cost-effectiveness is high	Statistics from CPVO; Statistics from Court of Auditors of the European Communities; Stakeholder survey & interviews	42,45,46
SQ4: Implementation and enforcement					
SQ4a: What are the strengths and weaknesses of the implementation of the CPVR "acquis"?	Article 114: *Other implementing rules*	To what extent has implementation achieved the objectives set out in provisions of CPVR "acquis"?	1. Implementation of CPVR "acquis" has made uniform application of CPVR procedures possible; 2. Stakeholder satisfaction with implementation is high	Stakeholder survey & interviews; Texts of Implementation Rules	3, 55,56
SQ4b: What are the strengths and weaknesses of the enforcement of the CPVR "acquis" by the right holders vis-à-vis the users of protected varieties?	Articles 94 – 107 (Part Six: *Civil Law Claims, Infringements, Jurisdiction*)	Is either party advantaged or disadvantaged by the enforcement mechanisms currently in place?	1. Stakeholder satisfaction with enforcement mechanisms is high;	Stakeholder survey & interviews	51
SQ4c: What are the strengths and weaknesses of the enforcement of the CPVR "acquis" by the National Courts?		To what extent do legal actions relating to civil law claims treated in National Courts facilitate the enforcement of the CPVR "acquis"?	1. Stakeholder satisfaction with enforcement by National Courts is high	Stakeholder survey & interviews	53,54
SQ5: CPVR regime compared with National PVR systems					
SQ5a: What are the strengths of the CPVR regime compared with the National PVR systems of Member States as perceived by the different stakeholders?	Entire Council Regulation (EC) No. 2100/94	What are the strengths of the CPVR regime across Member States?	1. Stakeholders emphasise various strengths of CPVR regime compared with National plant variety protection	Stakeholder survey & interviews	30,32,57
SQ5b: What are the weaknesses of the CPVR regime compared with the National PVR systems of Member States as perceived by the different stakeholders?		What are the weaknesses of the CPVR regime as compared to national protection?	1. Stakeholders emphasise various weaknesses of CPVR regime compared with National plant variety protection	Stakeholder survey & interviews	30,32,57

EQ 8: (Impact on EU and Member States) To what extent can we consider that the CPVR "acquis" satisfies the need of the Union and the Member States and what is the interaction between the CPVR and other national IP protection systems?	Entire Council Regulation (EC) No. 2100/94				
SQ1: What is the added value of the CPVR "acquis" compared with the European patent system, the trademark system, and other *sui generis* intellectual property systems?		Which aspects of plant breeding does the CPVR "acquis" address that are not or could not be met by other IP protection regimes?	1. CPVR "acquis" addresses aspects of plant breeding that are not met by other IP protection regimes	Stakeholder survey & interviews; Text of CPVR Regulation; Text of relevant IP protection regimes	58
SQ2: What is the impact of the CPVR "acquis" on the National Plant Variety Rights systems of the EU Member States?	Article 3: *National property rights for plant varieties*; Articles 92 – 93 (Part Five: Impact on other Laws)	Does the CPVR "acquis" interfere with National PVR systems or other national IP systems? Do they duplicate or complement each other?	1. The CPVR "acquis" complements National Plant Variety Protection regimes	Stakeholder survey & interviews; Text of CPVR Regulation; Text of relevant IP protection regimes	58
EQ 9: (Interaction with other EU policies) To what extent is the CPVR "acquis" coherent or overlapping with the EU's policies as managed by DG SANCO and other relevant DGs?	Entire Council Regulation (EC) No. 2100/94				
SQ1: To what extent is the CPVR "acquis" coherent or overlapping with EU consumer policy?		Does the CPVR "acquis" complement EU consumer policy, or does it conflict with it?	1. CPVR "acquis" complements EU consumer policy	Stakeholder survey & interviews; Policy texts	66
SQ2: To what extent is the CPVR "acquis" coherent or overlapping with EU environmental policy?		Does the CPVR "acquis" complement EU environmental policy, or does it conflict with it?	1. CPVR "acquis" complements EU environmental policy	Stakeholder survey & interviews; Policy texts	66
SQ3: To what extent is the CPVR "acquis" coherent or overlapping with EU agriculture policy?		Does the CPVR "acquis" complement EU agriculture policy, or does it conflict with it?	1. CPVR "acquis" complements EU agriculture policy	Stakeholder survey & interviews; Policy texts	66
SQ4: To what extent is the CPVR "acquis" coherent or overlapping with EU trade policy?		Does the CPVR "acquis" complement EU trade policy, or does it conflict with it?	1. CPVR "acquis" complements EU trade policy	Stakeholder survey & interviews; Policy texts	66

EQ 10: (Interaction with other international instruments) To what extent do the intervention's objectives support or contradict those of other related interventions?	Entire Council Regulation (EC) No. 2100/94; including objectives outlined in its Preamble, and Article 1: *CPVR*				
SQ1: To what extent do the objectives of the CPVR system support or contradict the objectives of the UN Convention on Biological Diversity?		The objectives of the Convention on Biological Diversity are to promote the conservation of biological diversity, the sustainable use of the components of biological diversity, and the fair and equitable sharing of benefits arising from genetic resources	1. The CPVR "acquis" contributes to the conservation of biological diversity; 2. The CPVR "acquis" contributes to the sustainable use of the components of biological diversity; 3. The CPVR "acquis" contributes to the fair and euquitable sharing of benefits arising from the use of genetic resources	Text of Convention on Biological Diversity; Stakeholder survey & interviews	61
SQ2: To what extent do the objectives of the CPVR system support or contradict the objectives of the International Treaty on Plant Genetic Resources for Food and Agriculture?		The objectives of the International Plant Treaty on PGRFA are to establish a global system to provide farmers, plant breeders and scientists with access to plant genetic materials, and to ensure that recipients share benefits they derive from the use of these genetic materials with the countries where they have been originated.	1. The CPVR "acquis" contributes to the facilitation of access to plant genetic materials for farmers, plant breeders, and scientists	Text of International Treaty on PGRFA; Stakeholder survey & interviews	62
SQ3: To what extent do the objectives of the CPVR system support or contradict the objectives of the EU programmes on the conservation, characterisation, collection and utilisation of genetic resources in agriculture?		The objectives of the Council Regulation EC 870/2004 are to promote the conservation, characterisation, collection of biological and genetic diversity in agriculture, and to promote the sustainable use of the potential of that diversity in order to promote the aims of the common agricultural policy (CAP).	1. The CPVR "acquis" contributes to the conservation, characterisation, collection of biological and genetic diversity in agriculture; 2. The CPVR "acquis" contributes to the sustainable use of bio-genetic diversity	Text of Council Regulation EC 870/2004; Stakeholder survey& interviews	63
SQ4: To what extent do the objectives of the CPVR system support or contradict the objectives of the EU programmes on the legal protection of biotechnological inventions?		The objectives of the EU Directive 98/44/EC are to maintain and encourage investments in the field of biotechnology, and to harmonise laws of Member States regarding the protection of biotechnological inventions in order not to create barriers to trade.	1. The CPVR "acquis" encourages investments in the field of biotechnology; 2. The CPVR "acquis" contributes to the harmonisation of laws of Member States regardign the protection of biotechnological inventions	Text of EU Directive 98/44/EC; Stakeholder survey & interviews	64
SQ5: To what extent do the objectives of the CPVR system support or contradict the objectives of the EU Seed Marketing Directives?		DUS examination and variety denomination procedures are required under both the CPVR legislation and the Seed Marketing Directives	1. The CPVR legislation and Seed Marketing Directives provide harmonious DUS testing procedures and variety denominations	Texts of EU Seed Marketing Directives; Stakeholder survey & interviews	59,60
SQ6: To what extent do the objectives of the CPVR system support or contradict the objectives of EU market organisations?		The EU market organisations aim at the creation and maintenance of a unified market in their respective fields	1. The CPVR "acquis" supports the creation and maintenance of a unified market	Data from EU market organisations; Stakeholder survey & interviews	66

SQ7: To what extent do the objectives of the CPVR system support or contradict the objectives of EU trade policy?	Entire Council Regulation (EC) No. 2100/94; including objectives outlined in its Preamble, and Article 1: *CPVR*	The EU trade policy has as objective "to make the EU the strongest, most competitive single economy in the world".	1. The CPVR "acquis" contributes to the strengthening of the EU economy	Relevant documents on EU trade policy; Stakeholder survey & interviews	66
SQ8: To what extent do the objectives of the CPVR system support or contradict the objectives of the development of geographical indications?		The objectives of the Council Regulation EC 510/2006 are to encourage diversification of agricultural production in order to achieve a better balance between supply and demand on the markets, and to ensure best possible information reaches the consumer.	1. The CPVR "acquis" contributes to the diversification of agricultural production; 2. The CPVR "acquis" contributes to the reliability of information which reaches the consumer	Text of Council Regulation EC 510/2006; Stakeholder survey & interviews	65
Evaluation Objective 3: Future options - sustainability of the regime					
EQ 11: (Options for the future to address problem areas and new challenges) What are the possible different options for the future to address the problem areas identified and the EU's new challenges?	Entire Council Regulation (EC) No. 2100/94				
SQ1: What would be the relevance and implication of keeping the current CPVR regime as it is? Is there stakeholder support for keeping the status quo? What would the economical, environmental, social and international consequences of keeping the status quo be?		Which stakeholders benefit from keeping the current CPVR regime as it is?	1. Stakeholders emphasise the importance of keeping the current CPVR regime as it is	Stakeholder survey & interviews	79-84
SQ2: What would be the relevance and the implications of amending the current CPVR regime? What would such amendments involve? Is there stakeholder support for the proposed amendments? What would the economical, environmental, social and international consequences of the proposed amendments be?		Which stakeholders would benefit from which potential amendments to the current CPVR regime?	1. Stakeholders emphasise the importance of amending the current CPVR regime	Stakeholder survey & interviews	79-84

Annex 4 Evaluation Questions and Conclusions

This annex explains the conclusions reached for each evaluation question according to the framework set up in Annex 3.

Evaluation Question (EQ)/Sub-Question (SQ)	Discussion of Issue/Judgement Criteria	Evaluation Conclusions
EQ 1: (Harmonisation) To what extent has the CPVR 'acquis' harmonised industrial property regimes for plant varieties at EU level?		
SQ1: To what extent has the CPVR *acquis* had a uniform effect within the EU territory with regard to granting industrial property rights valid throughout the EU, and by means of uniform application procedures?	CPVR are granted uniformly across Member States	CPVR are granted through a uniform application process
SQ2: To what extent has the enforcement of the CPVR *acquis* been uniform across EU Member States?	CPVR infringements are treated uniformly across Member States	The CPVR *acquis* provides for harmonised plant variety rights across the EU territory, but in practice enforcement is uneven across Member States
EQ 2: (Appropriateness) To what extent can the CPVR 'acquis' be considered an appropriate EU regime which, although co-existing with national regimes, has allowed for the grant of industrial property rights valid throughout the EU?		
SQ1: Protection - conditions, scope, limitations, duration		
SQ1a: How appropriate and effective is the application of CPVR protection criteria (e.g. application of DUS requirements and the need to designate a variety denomination as set out in the 'UPOV' Convention)?	CPVR protection criteria match the needs of the small, medium-sized and large plant-breeding industry; CPVR protection criteria match the latest scientific understanding of plant varieties and facilitate the work of the examination offices	The application of CPVR protection criteria are generally appropriate and effective, though the quality of testing centres and variety denomination criteria could be improved
SQ1b: Are the rights conferred on CPVR holders and their limitations and exceptions appropriate?	CPVR stimulate innovation at all levels of the breeding industry, without impeding growth at any level of the agricultural sector (small, medium-sized and large farms); CPVR contribute to the enhancement of agricultural genetic diversity	The rights conferred on CPVR holders are appropriate in general, although there is scope to improve the provisions extending to harvested material
SQ1c: Are the derogations from the CPVR regime ('agriculture exemption' or 'farm saved seed exemption') and the 'breeder's exemption' appropriate and satisfactory? What are the possible ways forward to enhance the system in this regard?	The derogations from CPVR facilitate growth at all levels of the in the agricultural sector, without hindering innovation at all levels of the breeding industry; The derogations from CPVR contribute to the enhancement of agricultural genetic diversity	The exemptions provided in the CPVR *acquis* are appropriate. The breeders' exemption is the cornerstone of effective plant variety rights. EDVs are a useful addition to plant variety rights. The agriculture exemption is problematic to implement, however, and there is scope for change in this area.

Evaluation Question (EQ)/Sub-Question (SQ)	Discussion of Issue/Judgement Criteria	Evaluation Conclusions
SQ1d: Is the duration of protection appropriate in order to fulfil the needs it aims to satisfy? What criteria should the legislator take into account when establishing the duration?	CPVR duration stimulates innovation at all levels of the breeding industry; CPVR duration allows for adequate recuperation of breeder's investments, while striking the right balance between public and private interest	The duration of protection can be considered appropriate to fulfil the needs it aims to satisfy
SQ2: CPVO role and effectiveness		
SQ2a: To what extent is a system where the implementation and application of the CPVR *acquis* is not carried out by the authorities of the Member States but by a Union Office with legal personality, the "Community Plant Variety Office" effective?	CPVR granted effectively by CPVO; CPVR granted by CPVO are recognised throughout EU territory; Only few, if any, administrative functions are entrusted to national agencies by CPVO (cf. Art. 30.4)	CPVO functioning is generally satisfactory; the application process could be further improved through minor changes in the CPVO's operations
SQ2b: To what extent does the Community Plant Variety Office (CPVO) "play its role", as defined in the CPVR Regulation, both in terms of the procedure for the granting of a CPVR as well as in terms of technical criteria (DUS) used for deciding to grant a CPVR?	CPVO successfully executes formal and substantive examination of applications for CPVR; CPVO successfully arranges for technical examination of plant material and samples related to applications for CPVR; Examination Offices effectively carry out DUS tests	
SQ2c: Do the proceedings before the CPVO for the breeders fulfil their role?	Examination of application for CPVR, grant and maintenance of CPVR, as well as appeals to decisions made are carried out by CPVO to satisfaction of the small, medium-sized and large plant breeding industry	
SQ2d: Does the Board of Appeal of the CPVO fulfil its role?	Appeals brought before the Board of Appeal are treated impartially	The CPVO Board of Appeals fulfils its role
SQ3: Enforcement		
SQ3a: Is the EU legislation on the enforcement of CPVR appropriate and how has the legislation been applied by national courts?	Enforcement of CPVR is effective and uniform across EU Member States	Stakeholders are satisfied with the enforcement provisions in principle, but unhappy that they not been uniformly implemented in each Member State; enforcement is considered to be ineffective in many Member States and in some cases dispute resolution mechanisms are not easily accessible
SQ3b: To what extent are the Jurisdiction and procedure in legal actions, relative to civil law claims, appropriate and reasonable?	Jurisdiction and procedure in legal actions relating to civil law claims facilitates effective enforcement of CPVR	

Evaluation Question (EQ)/Sub-Question (SQ)	Discussion of Issue/Judgement Criteria	Evaluation Conclusions
SQ3c: Is there coherence between the sanctions laid down in the CPVR Regulation and the enforcement Directive 2004/48?	Sanctions of CPVR Regulation cohere with sanctions laid down in the EU Directive on the enforcement of intellectual property rights 2004/48; Criticism of Directive 2004/48 do not apply to CPVR Regulation	There are points of tension between the CPVR Basic Regulation and the Enforcement Directive (Directive 2004/48)
EQ 3: (Effects on stakeholders) To what extent is the CPVR *acquis* beneficial for all users of varieties protected at EU level?		
SQ1: What are the consequences of the CPVR *acquis* on the small, medium-sized and large plant breeding industry?	Is the industry vibrant and diverse? How has the CPVR *acquis* changed small, medium-sized and large breeders' industrial practices and economic situation?	The impacts of the CPVR *acquis* on small, medium-sized and large plant breeders and breeding companies are generally positive, but data are limited on this issue
SQ2: What are the consequences of the CPVR *acquis* on small, medium-sized and large farms?	Is the agricultural sector vibrant and diverse? Do farms of all sizes continue to function across Member States? How has CPVR *acquis* changed their practices, production and economic situation?	The relative impacts of the CPVR *acquis* on small, medium-sized and large farms are difficult to determine because there are limited data available on this issue
SQ3: What are the consequences of the CPVR *acquis* on EU citizens and consumers?	Are there more or fewer plant varieties available to end consumers? How has public research been affected by the CPVR *acquis*?	The consequences of the CPVR *acquis* on EU citizens and consumers are generally thought to be positive, though limited data are available on this issue
EQ 4: (Stimulating tool) To what extent has the CPVR *acquis* proven to be a stimulating tool for EU breeders?		
SQ1: To what extent has the CPVR *acquis* facilitated the protection of new varieties of plants in the EU?	Have the numbers of plants protected in the EU increased (by application numbers and by PVR granted) since 1994? What is the ratio of National PVR vs. CPVR?	The CPVR *acquis* has facilitated the protection of new plant varieties in the EU - stakeholders indicate this and, further, CPVR application as well as grant numbers are increasing over time
SQ2: To what extent has the CPVR *acquis* stimulated the breeding and development of new varieties?	Does the promise of protection incentivise breeding and development of new plant varieties? Does expanded scope of protection further incentivise innovation?	The CPVR *acquis* has stimulated the breeding and development of new varieties, though determining the extent to which it has stimulated breeding and development is difficult to measure
SQ3: To what extent has the CPVR *acquis* improved protection compared with the situation before 1994 for all plant breeders, without, however, unjustifiably impairing access to protection generally or in the case of certain breeding techniques?	Is the CPVR *acquis* partial to particular breeding techniques? Does the CPVR *acquis* impair access to other forms of industrial protection? Is the CPVR *acquis* less accessible to certain breeders (e.g. small breeders)?	The CPVR *acquis* has improved protection compared with the situation before 1994 for plant breeders, though small breeders and breeders in particular Member States have more limited access to protection than other breeders for economic

Evaluation Question (EQ)/Sub-Question (SQ)	Discussion of Issue/Judgement Criteria	Evaluation Conclusions
		reasons
EQ 5: (Impact on EU biodiversity and agriculture)		
SQ1: What is the impact of the CPVR *acquis* on the preservation and the erosion of plant genetic resources in the EU?	Does the CPVR *acquis* facilitate or hinder the preservation of plant genetic resources? Is it partial to particular forms of preservation (e.g. ex situ vs. in situ)? Does it enhance or erode genetic diversity in the EU?	One view of the interaction between plant variety rights and plant genetic resources is that the availability of PVRs results in companies only promoting protected varieties, resulting in fewer varieties grown and therefore a loss in agricultural biodiversity; another suggests that the availability of PVRs provides the incentive to breed new varieties and thus increases genetic diversity. Minimum distances between plant varieties have decreased in recent years; this may contribute to the erosion of plant genetic resources though data on this issue is limited. Further, there may be an intermediate link between CPVR and availability of genetic resources via two Directives on marketing varieties.
SQ2: To what extent has the CPVR *acquis* contributed to a harmonious development of EU agriculture including in particular the EU seed and propagating materials sector?	Has the EU agricultural sector developed evenly across Member States? Is the number of small, medium-sized and large farms increasing, stable, or declining? Has the EU seed and propagating materials sector developed evenly across Member States? What is the contribution of the CPVR *acquis* in these developments?	The contribution of the CVPR *acquis* to the harmonious development of EU agriculture, and particularly the seed and propagating materials sector, is difficult to define
SQ3: What is the impact of technical links between the Seed Marketing Directives and the CPVR *acquis*?	Have the technical links between the Seed Marketing Directives and the CPVR *acquis* impacted on the EU seed sector? Have they had any other impact on EU agriculture?	Technical links between the Seed Marketing Directives and the CPVR *acquis* impact both systems, but efforts are already underway to resolve issues that arise as a result of these links
EQ 6: (Interactions with National and International law)		
SQ1: To what extent does the CPVR *acquis* impact on the protection of new varieties of plants at National level?	Has legislation regarding PVR at the national level changed since 1994? Have Member States adopted provisions of the CPVR *acquis* into their national legislation regarding plant variety protection?	Market share between CPVR and national rights varies among Member States, but there is a discernable trend toward use of the CPVR system over national PVR overall

Evaluation Question (EQ)/Sub-Question (SQ)	Discussion of Issue/Judgement Criteria	Evaluation Conclusions
SQ2: What is the impact of the CPVR *acquis* at the international level, in particular, on the legal systems of third countries?	Has legislation regarding PVR in countries outside the EU changed since 1994? Have other countries (or other regions) adopted provisions of the CPVR *acquis* into their national (or regional) legislations regarding plant variety protection?	The CPVR *acquis* may have indirect impacts on the legal systems of third countries but these are difficult to determine; a potential extension of the CPVR acquis to EFTA countries would be a positive development
EQ 7: (Impact on stakeholders) To what extent does the CPVR *acquis* strike a fair balance with regard to the interests of the various EU stakeholders' groups?		
SQ1: Holder's rights		
SQ1a: What are the strengths and weaknesses of the CPVR provisions regarding the rights of the holder?	Are all the rights (Art. 13.2 (a) – (g)) conferred appropriate? Are there disputes about any particular right or privilege?	The rights conferred on CPVR holders, and their limitations and exceptions, are generally appropriate, but growers indicated that the scope of protection may be too extensive
SQ1b: Is the concept of "Essentially Derived Variety" useful in this context? What are its strengths and weaknesses?	Concept of "essentially derived variety" expands CPVR to variety predominantly derived from variety initially protected – does this expand or constrain scope of CPVR too much? Is EDV a disputed category (i.e. can what is an EDV and what is not be unambiguously established?)	The EDV provision is appropriate but the definition is unclear and there are few established protocols for making EDV determinations. There is scope for improvement in this area.
SQ1c: What are the strengths and weaknesses of the CPVR provisions regarding the limitations of the rights of the holder?	Are there disputes regarding Art. 13.3 and 13.4?	There is scope to improve the provisions extending to harvested material in the case of unauthorised use
SQ2: Breeder's and agriculture exemptions		
SQ2a: What are the strengths and weaknesses of the breeder's exemption?	Does it stimulate innovation or restrict CPVR too much?	The breeder's exemption is appropriate and satisfactory — the exemption is central to what makes plant variety rights an important and useful system of intellectual property protection, and is uniformly supported by stakeholders
SQ2b: What are the strengths and weaknesses of the agriculture exemption with regard to fodder plants?	Is the derogation with regard to fodder plants necessary? Should more or fewer varieties be included in the list of fodder plants?	Plant breeders are widely dissatisfied with the agriculture exemption - this dissatisfaction is focused on royalty collection; growers and Member State representatives view the exemption as an essential aspect of plant variety protection.
SQ2c: What are the strengths and weaknesses of	Is the derogation with regard to cereals necessary?	

Evaluation Question (EQ)/Sub-Question (SQ)	Discussion of Issue/Judgement Criteria	Evaluation Conclusions
the agriculture exemption with regard to cereals?	Should more or fewer varieties be included in the list of cereals?	The list of species that apply to the FSS exemption is generally satisfactory, though specific concerns were raised by some stakeholders regarding phytosanitary risks from farm saved potatoes.
SQ2d: What are the strengths and weaknesses of the agriculture exemption with regard to potatoes?	Is the derogation with regard to potatoes necessary? Should more or fewer varieties be included in the list of potatoes?	
SQ2e: What are the strengths and weaknesses of the agriculture exemption with regard to oil and fibre plants?	Is the derogation with regard to oil and fibre plants necessary? Should more or fewer varieties be included in the list of oil and fibre plants?	
SQ2f: Is the definition of "small farmers" useful in this context? What are its strengths and weaknesses?	Should small farmers be exempt from paying "equitable remuneration"? Is the definition of "small farmers" as laid down in Council Regulation EEC 1765/92 appropriate?	The appropriate definition of a 'small farmer' is contentious and there is disagreement as to whether the provision should remain in the Basic Regulation
SQ2h: Is the notion of "own holding" useful in this context? What are its strengths and weaknesses?	Does the notion of "own holding" restrict or expand the agricultural exemption too much? Can a farmer's own holding always be unambiguously identified?	The 'own holding' definition could be clarified to better reflect farming practices, and there is scope to clarify the definition of 'equitable remuneration'
SQ2g: Is the definition of "equitable remuneration" useful in this context? How do stakeholders and Member States perceive this notion? How do farmers' and breeders' associations determine the remuneration levels and the way to collect royalties?	Should equitable remuneration be further specified by CPVO?	
SQ2i: How effective is the information system between farmers using protected farm saved seed (FSS) and the holder of a right, in order for the latter to recuperate their legitimate and "equitable remuneration" from farmers using FSS? What is the role of National Authorities in the provision of this information?	Is communication between farmers and CPVR holders functioning? Is information readily available to farms of all sizes?	Royalty collection systems for FSS are not operating in many MS and are poorly functioning in others. Dissatisfaction is focussed on the provision of information requirements.
SQ2j: In which ways and how effectively has the "agriculture exemption" been implemented in the different Member States?	Have all Member States enacted legislation to uphold the agricultural exemption? Have they implemented the exemption by other means? What is most effective form of implementation?	The agriculture exemption is problematic to implement, and there is scope for change in this area.
SQ3: Costs		

Evaluation Question (EQ)/Sub-Question (SQ)	Discussion of Issue/Judgement Criteria	Evaluation Conclusions
SQ3a: Are the costs involved in the CPVR *acquis* reasonable and proportionate for breeders, taking into account that there are administrative costs (fees to CPVO), technical and experimental costs of plant breeding per se, and practical costs regarding the recuperation of the equitable remuneration due from farmers using the protected product?	Are the costs proportionate for breeders of the small, medium-sized and large breeding industry?	Breeders are generally satisfied with most costs associated with CPVR, though they are dissatisfied with the maintenance fee and indicate that enforcement costs are too high
SQ3b: Are the costs involved in the CPVR *acquis* reasonable and proportionate for farmers?	Are usual license fees proportionate for all farmers? Is the equitable remuneration proportionate for all farmers?	Farmers are divided on whether the costs they incur in using CPVR are reasonable
SQ3c: Are the costs involved in the CPVR *acquis* reasonable and proportionate for examination offices? How cost effective is their functioning?	Do the examination offices operate within their budget? Do they have an appropriate income from examination fees?	Costs involved in the CPVR *acquis* for examination offices vary widely by Member State; some examination offices argue that the DUS examination fees do not cover the costs of testing.
SQ3d: Are the costs involved in the CPVR *acquis* reasonable and proportionate for Member States?	To what extent does the CPVR *acquis* constitute an additional cost to Member States?	Member State representatives believe that the costs they incur related to the CPVR system are generally 'reasonable', though some Member States argue that DUS testing fees do not adequately cover the actual testing costs
SQ3e: Are the costs involved in the CPVR *acquis* reasonable and proportionate for the CPVO? Does the cost effectiveness of CPVO functioning differ with regard to different plant species?	Does the CPVO operate within its budget? Applications with regard to which plant species are most cost effective, which are least cost-effective?	CPVO costs are reasonable and proportionate. The CPVO operates within its budget.
SQ4: Implementation and enforcement		
SQ4a: What are the strengths and weaknesses of the implementation of the CPVR *acquis*?	To what extent has implementation achieved the objectives set out in provisions of CPVR *acquis*?	Enforcement is considered to be uneven; it is perceived to be ineffective in many Member States and in some cases dispute resolution mechanisms are not easily accessible
SQ4b: What are the strengths and weaknesses of the enforcement of the CPVR *acquis* by the right holders vis-à-vis the users of protected varieties?	Is either party advantaged or disadvantaged by the enforcement mechanisms currently in place?	The CPVR *acquis* is generally beneficial for users of protected varieties, though data are limited in this area
SQ4c: What are the strengths and weaknesses of	To what extent do legal actions relating to civil law	Stakeholders perceive that CPVR infringement

Evaluation Question (EQ)/Sub-Question (SQ)	Discussion of Issue/Judgement Criteria	Evaluation Conclusions
the enforcement of the CPVR *acquis* by the National Courts?	claims treated in National Courts facilitate the enforcement of the CPVR *acquis*?	cases in different countries do not have consistent outcomes
SQ5: CPVR regime compared with National PVR systems		
SQ5a: What are the strengths of the CPVR regime compared with the National PVR systems of Member States as perceived by the different stakeholders?	What are the strengths of the CPVR regime across Member States?	CPVR provide an advantage through EU-wide coverage. In some cases, the costs of CPVR are lower than national PVR systems. Market share between CPVR and national rights varies among Member States, but there is a discernible trend toward use of the CPVR system over national PVR overall
SQ5b: What are the weaknesses of the CPVR regime compared with the National PVR systems of Member States as perceived by the different stakeholders?	What are the weaknesses of the CPVR regime as compared to national protection?	Stakeholders pointed to the stronger protection offered by the Dutch PVR system and to lower costs in some Member States
EQ 8: (Impact on EU and Member States) To what extent can we consider that the CPVR *acquis* satisfies the need of the Union and the Member States and what is the interaction between the CPVR and other national intellectual property protection systems?		
SQ1: What is the added value of the CPVR *acquis* compared with the European patent system, the trademark system, and other sui generis intellectual property systems?	Which aspects of plant breeding does the CPVR *acquis* address that are not or could not be met by other intellectual property protection regimes?	The CPVR *acquis* is a significant addition to the EU's intellectual property systems; there are no issues related to points of connection between CPVR and trademarks or geographical indications, but stakeholders are highly concerned about overlap between CPVR and patents
SQ2: What is the impact of the CPVR *acquis* on the National Plant Variety Rights systems of the EU Member States?	Does the CPVR *acquis* interfere with National PVR systems or other national intellectual property systems? Do they duplicate or complement each other?	Discernible trend toward use of the CPVR system over national PVR overall
EQ 9: (Interaction with other EU policies) To what extent is the CPVR *acquis* coherent or overlapping with the EU's policies as managed by DG SANCO and other relevant DGs?		
SQ1: To what extent is the CPVR *acquis* coherent or overlapping with EU consumer policy?	Does the CPVR *acquis* complement EU consumer policy, or does it conflict with it?	The CPVR *acquis* is consistent with EU consumer policy
SQ2: To what extent is the CPVR *acquis* coherent or	Does the CPVR *acquis* complement EU	The CPVR *acquis* is consistent with EU environment

Evaluation Question (EQ)/Sub-Question (SQ)	Discussion of Issue/Judgement Criteria	Evaluation Conclusions
overlapping with EU environmental policy?	environmental policy, or does it conflict with it?	policy
The CPVR *acquis* is consistent with EU environment policy	Does the CPVR *acquis* complement EU agriculture policy, or does it conflict with it?	The CPVR *acquis* is consistent with EU agriculture policy
The CPVR *acquis* is consistent with EU agriculture policy	Does the CPVR *acquis* complement EU trade policy, or does it conflict with it?	The CPVR *acquis* is consistent with EU trade policy
EQ 10: (Interaction with other international instruments) To what extent do the intervention's objectives support or contradict those of other related interventions?		
SQ1: To what extent do the objectives of the CPVR system support or contradict the objectives of the UN Convention on Biological Diversity?	The objectives of the Convention on Biological Diversity are to promote the conservation of biological diversity, the sustainable use of the components of biological diversity, and the fair and equitable sharing of benefits arising from genetic resources	The objectives of the CPVR *acquis* generally support the objectives of the UN Convention on Biological Diversity and the International Treaty on Plant Genetic Resources for Food and Agriculture, though some stakeholders would like to see disclosure of origin in CPVR applications and ensure that access to genetic resources is maintained
SQ2: To what extent do the objectives of the CPVR system support or contradict the objectives of the International Treaty on Plant Genetic Resources for Food and Agriculture?	The objectives of the International Plant Treaty on PGRFA are to establish a global system to provide farmers, plant breeders and scientists with access to plant genetic materials, and to ensure that recipients share benefits they derive from the use of these genetic materials with the countries where they have been originated.	
SQ3: To what extent do the objectives of the CPVR system support or contradict the objectives of the EU programmes on the conservation, characterisation, collection and utilisation of genetic resources in agriculture?	The objectives of the Council Regulation EC 870/2004 are to promote the conservation, characterisation, collection of biological and genetic diversity in agriculture, and to promote the sustainable use of the potential of that diversity in order to promote the aims of the common agricultural policy (CAP).	The objectives of the CPVR *acquis* support the objectives of EU programme on the conservation, characterisation, collection and utilisation of genetic resources in agriculture but stakeholders are concerned that uniformity requirements may be too high
SQ4: To what extent do the objectives of the CPVR system support or contradict the objectives of the EU programmes on the legal protection of biotechnological inventions?	The objectives of the EU Directive 98/44/EC are to maintain and encourage investments in the field of biotechnology, and to harmonise laws of Member States regarding the protection of biotechnological inventions in order not to create barriers to trade.	The objectives of the CPVR *acquis* generally cohere with the objectives of the EU programmes on the legal protection of biotechnological inventions, but stakeholders are concerned about the overlap between patent protection and plant variety rights

Evaluation Question (EQ)/Sub-Question (SQ)	Discussion of Issue/Judgement Criteria	Evaluation Conclusions
The objectives of the CPVR *acquis* generally cohere with the objectives of the EU programmes on the legal protection of biotechnological inventions, but stakeholders are concerned about the overlap between patent protection and plant variety rights	DUS examination and variety denomination procedures are required under both the CPVR legislation and the Seed Marketing Directives	Technical links between the Seed Marketing Directives and the CPVR acquis impact both systems, but efforts are already underway to resolve issues that arise as a result of these links
SQ6: To what extent do the objectives of the CPVR system support or contradict the objectives of EU market organisations?	The EU market organisations aim at the creation and maintenance of a unified market in their respective fields	The CPVR *acquis* contributes to effective EU market functioning
SQ7: To what extent do the objectives of the CPVR system support or contradict the objectives of EU trade policy?	The EU trade policy has as objective "to make the EU the strongest, most competitive single economy in the world".	The CPVR *acquis* is consistent with EU trade policy
SQ8: To what extent do the objectives of the CPVR system support or contradict the objectives of the development of geographical indications?	The objectives of the Council Regulation EC 510/2006 are to encourage diversification of agricultural production in order to achieve a better balance between supply and demand on the markets, and to ensure best possible information reaches the consumer.	There are no significant interactions between the CPVR *acquis* and development of geographical indications
EQ 11: (Options for the future to address problem areas and new challenges) What are the possible different options for the future to address the problem areas identified and the EU's new challenges?		
SQ1: What would be the relevance and implication of keeping the current CPVR regime as it is? Is there stakeholder support for keeping the status quo? What would the economical, environmental, social and international consequences of keeping the status quo be?	Which stakeholders benefit from keeping the current CPVR regime as it is?	The current system generally operates well. Where there are recognised deficiencies, options have been identified to address shortcomings. Stakeholder support is considered for each option. Relevance and implications for these options have been assessed according to economic, environmental, social and international consequences.
SQ2: What would be the relevance and the implications of amending the current CPVR regime? What would such amendments involve? Is there stakeholder support for the proposed amendments? What would the economical, environmental, social and international consequences of the proposed amendments be?	Which stakeholders would benefit from which potential amendments to the current CPVR regime?	The current system generally operates well. Where there are recognised deficiencies, options have been identified to address shortcomings. Stakeholder support is considered for each option. Relevance and implications for the options have been assessed according to economic, environmental, social and international consequences.

Annex 5 Research Method (*in detail*)

Desk research and analysis

The research team first conducted a literature review of currently available information on the CPVR system. This included the relevant academic literature as well as reports, position papers and other secondary sources produced by the Commission, national governments, and a variety of stakeholders, including representative organisations at international, EU and national levels.

The first phase of the evaluation involved a literature review. A non-exhaustive list of the literature consulted for this study is listed in Annex 19Annex 18. Relevant literature and other materials reviewed included the following:

- EU legislation and other official documents, including memos and reports;
- Documents relating to court cases, including decisions from the European Court of Justice and national courts;
- CPVO reports and presentations;
- Stakeholder reports, memos, position papers, presentations and other sources; and
- Academic literature on the CPVR system and on plant variety rights more broadly.

Supporting background information and analysis was developed by each expert on our research team, covering the most current state of knowledge on the CPVR system across legal, economic, social and scientific dimensions of the evaluation.

Additional data were collected and analysed. For example, CPVO provided comprehensive time-series data on the applications and rights granted for CPVRs from 1995-2010—the entire period of the CPVR system's operation. National government representatives provided data for PVR applications and rights granted at Member State-level in a few cases, though this data was only available for a limited number of years and is not comprehensive across the EU. Additional data were collected and analysed from a variety of sources, including:

- CPVO data on:
  - CPVRs, including comprehensive data on applications and rights granted from 1995-2011 for all plant varieties;
  - Costs, including:
    - Fees for applying for, obtaining and maintaining CPVRs;
    - Fees charged for variety testing and estimated costs to national testing centres for conducting the tests;
  - Technical reports sold by the CPVO to authorities in third countries; and
  - The number of court cases related to CPVRs in EU MS and in the European Court of Justice (incomplete data set);
- UPOV data at Member State (i.e. national PVRs) and EU level (i.e. CPVRs);
- FAO data on the trade in agricultural crops;
- Eurostat data on :
  - Size of farms in the EU; and
  - EU agricultural holdings by farm size and crop type.
- Data and statistics provided by industry, including estimates of the following:
  - Farm saved seed use across the EU and for various Member States;
  - Royalty collection levels in some Member States and for some species;
  - The number and extent of fraud cases and revenues foregone through fraudulent marketing and selling for some Member States; and
  - Value of the seed and propagating materials markets and trade in seeds and crops (international, EU and for specific Member States)

Overall, however, the availability of data and third party analysis on the CPVR system varies considerably across the 'system'. For example, the evaluation has benefited from comprehensive data on the applications for CPVRs submitted to the CPVO. This has allowed for detailed analysis of the population of CPVRs. Data are less readily available (or non-existent) to support other issues relevant to the evaluation questions. For example, information is available regarding the percentages of small and medium-sized

(SME) businesses in the EU. But there is no universally recognised definition of small and medium *farms*, and we do not know what percentage of SMEs are farm businesses. Farm size data is available from Eurostat, but this is not directly comparable to SME information. Regardless, we do not have any information on the number of protected varieties grown on farms across the EU and therefore cannot draw conclusions about the effects of the CPVR system on SME farmers as a result.

This report integrates information from the literature review, expert inputs, available data sources and stakeholder consultation results where possible.

Stakeholder consultation approach

Our approach needed to accommodate the diverse stakeholders of the CPVR system

This report draws on the survey responses (both answers to 'scaled questions'[46] and supplementary information provided by survey respondents) as well as contextual information obtained through in-depth interviews. Interviews elicited a high level of detail concerning the operation of the CPVR system and the effects of the system on stakeholders. This information is integrated throughout the report.

Stakeholders in the CPVR system include:

- The governments of the 27 Member States as represented by:
  - The officials who participate in five different European Commission Standing Committees;[47] and
  - The technical liaison officers who coordinate DUS[48] testing and other CPVR-related matters between the Community Plant Variety Office and the respective MS;
- Various private sector interests, specifically
  - Plant breeders;
  - Growers;
  - Marketers of seed and propagating materials;
  - Traders; and
  - Foresters.
- The Community Plant Variety Office;
- Various international and European governmental organisations;[49]
- Non-governmental organisations (NGOs); and
- European Commission services concerned with intellectual property rights and CPVR.

Private sector interests are also important. The consultation focused first on the EU representative organisations of each sector but contacts have also been made with national-level representative associations and individual companies (many of which belong to the EU and international associations).

For many of the evaluation questions, responses from the EU and international level representative associations are sufficient. But in some areas there is a diversity of views within their membership which makes it more difficult for the representative organisation to formulate a coordinated message. And for a subset of technical and financial questions, representative bodies are not equipped to answer on behalf of their members. This is particularly an issue for questions relating to costs and the application and testing procedures for granting CPVR. For these reasons, the evaluation must also reach national associations and individual businesses to document better how the CPVR system operates.

[46] Many of the survey questions asked respondents to indicate their response against a scale from (for instance) 'strongly agree' to 'strongly disagree'. We refer to these as 'scaled questions'.

[47] These Standing Committees are: CPVR, Seeds, Fruit Genera and Species, Ornamental Plants and Forestry.

[48] 'DUS' refers to distinct ('D'), uniform ('U') and stable ('S'). These are three technical requirements that must be met in order to be granted plant variety rights. That is, a new variety must be: clearly distinguishable from all other existing varieties (i.e. distinct); uniform during propagation (i.e. uniform); and stable in its characteristics during repeated propagation (i.e. stable).

[49] These include: UPOV, OECD, WTO, EPO, EFSA, ISTA and FAO.

Accordingly, the stakeholder consultation was designed to combine survey results with in-depth interviews covering each of the stakeholder groups as well as information from other relevant individuals and organisations

The consultation involved:

- A survey distributed to Member State representatives on the five Standing Committees and their technical liaison officers, industry representative associations, and NGOs;
- A survey distributed by representative associations to their members, including national associations and individual companies; and
- In-depth interviews with a selected subset of these stakeholders and other organisations.

A complete list of interviewees is provided in Annex 6.

Stakeholder consultation results

Two stakeholder consultations were consulted; the research team received 205 completed surveys and conducted in-depth interviews with stakeholders from across the EU

The first round of consultation was initiated at the beginning of September 2010 and ran for eight weeks, concluding on 31 October 2010. A second consultation was conducted from January-February 2011, following presentation of interim findings, in order to obtain a higher response rate with respect to plant growers. The survey was completed by: Member State (MS) representatives; plant breeding companies; growers; EU-level and MS-level representative organisations of the seed, plant breeding, trade, processing and farming sectors; and NGOs.

Representative associations for the relevant stakeholder groups were asked to submit a survey for their organisation (representing the views of their collective membership) and also to distribute information about the consultation to their individual members. The same approach of engagement and distribution was adopted for breeders and growers. There was also an open opportunity for organisations from any sector across Europe to engage via the online survey. The plant breeding sector was more responsive than plant growers to this invitation. In total, the research team received 205 completed surveys across the different stakeholder categories listed Table A5.1 below. Of the private sector responses received, a strong majority (110 out of 161) came from the plant breeding sector, from which many individual companies responded as well as representative bodies. Additional work was undertaken in the post-interim phase of the evaluation to ensure that growers' perspectives are adequately reflected in the overall analysis, though response rates from growers were low during this phase as well.

Table A5.1 Survey responses by category

Category	Surveys received
Member State representatives*	44
Plant breeders – representative associations**	31
Plant growers – representative associations**	15
Plant breeders – individual companies	79
Plant growers – individuals/ individual enterprises	27
Other***	9
Total	**205**

* Includes Technical Liaison Office contact points for Member States

** Includes international, EU-level and national associations.

*** Includes NGOs and other relevant national and international organisations (listed in Annex 13)

In-depth interviews were conducted with a wide range of stakeholders and experts at EU and international level. These included representatives of the Community Plant Variety Office (CPVO), European Patent Office (EPO), and the relevant Directorates-General of the European Commission. A selection of those stakeholders who submitted surveys were also interviewed.

44 surveys were received from officials of 26 Member States

Member State representatives completed 44 surveys, with at least one survey returned from each of 26 Member States. Only Malta did not complete the survey, indicating that it would not respond due to its limited experience with the CPVR system and the fact that no DUS testing is currently being undertaken in the country[50].

In many cases, representatives of one Member State submitted one unified and coordinated survey response, while in others representatives submitted several individual surveys. Where individual survey responses from different officials in a given Member State were the same, a Member State 'view' is provided in the analysis. This was possible for the majority of such surveys.

In cases where responses differed, responses are treated separately in our analysis and further consideration is given to what that divergence of views illustrates in a particular Member State. This is possible by analysing the narrative comments in the survey and in-depth interview discussions. Where appropriate, we have also analysed the 23 responses received from technical liaison officers separately to that of other officials to highlight matters of particular relevance from their perspective.

Annex 13 elaborates on the number of in-depth interviews conducted, surveys received and stakeholders reached (directly and indirectly) across the 27 EU MS, highlighting the nine 'priority MS' specified by the Commission in the evaluation terms of reference.

Plant breeders, including individual companies and national, EU-level and international plant breeding associations returned 110 surveys

Survey responses were received from plant breeding organisations across Europe. These include the largest plant breeder representative organisations at EU and international level, as well as seven national plant 'breeders' associations. Individual companies of varied size also returned 79 surveys. These included several of the largest multinational companies and a number of small and medium-sized enterprises. [51] Approximately half of the 79 responses received from individual enterprises came from large and medium-sized enterprises, and approximately half were from companies that classified themselves as 'small' or 'micro' breeders, as indicated in Table A5.2 below:

Table A5.2 Breeders' survey - distribution of company responses by company size

Company Size *(number of employees)*	**Number of companies responding to survey**	**% of companies responding to survey in each category**
Large *(more than 250)*	19	24%
Medium *(50-250)*	20	25%
Small *(10-50)*	22	28%
Micro *(fewer than 10)*	18	23%
Total	**79**	

A large proportion (67 out of 79) of the responses received from individual companies were nearly identical to the responses of two major representative associations for plant breeders, one operating at the European level and one in the Netherlands. These organisations also separately submitted completed questionnaires giving their institutional viewpoint. The fact that, on several matters, the views expressed in

[50] As per information received by GHK Consulting via email from Ms. Paula Calamatta (Agricultural Attache – Phytosanitary), Permanent Representation of Malta to the European Union, on 10 September 2010.

[51] As per SME definition specified in Commission Recommendation 2003/361/EC: 'Micro' enterprises are defined as having fewer than 10 employees; small enterprises are defined as having 10-49 employees; medium-sized enterprises are defined as having 50-250 employees; and large businesses are defined as having more than 250 employees. Complete information can be found on the SME webpage of DG Enterprise and Industry: 'SME definition', http://ec.europa.eu/enterprise/policies/sme/facts-figures-analysis/sme-definition/index_en.htm (viewed 20 November 2010).

the representative association responses were reiterated by member companies in their own survey responses has been taken into account in the analysis and presentation of results.

For breeder's responses a 'plant breeding industry view' is referenced in most cases when presenting the views of these stakeholders. Where appropriate, for example in cases where an individual company has changed or added to the narrative comments to survey questions, these nuances are highlighted in the analysis through direct quotation.

Growers, including national and EU-level representative associations returned 43 surveys

Survey results from COPA-COGECA were received in mid-December. This association represents 76 agricultural organisations across the EU 27 Member States, as well as 36 partner associations from other European countries, including Switzerland and Norway. [52] It is widely acknowledged to be the major representative organisation for the European agricultural sector, and its membership covers general as well as specific interest groups in the sector.

Further, survey responses were received from five national plant grower organisations and an EU-level organisation representing a range of national and regional associations of farmers in the first consultation round.

The second round of the consultation, conducted in January and February 2011, was directed at attaining a higher response rate from plant growers, and yielded seven additional responses from representative organisations as well as 27 responses from individual farmers.

Representative associations that cover plant breeders, traders and producers at national, European and international levels returned 6 surveys

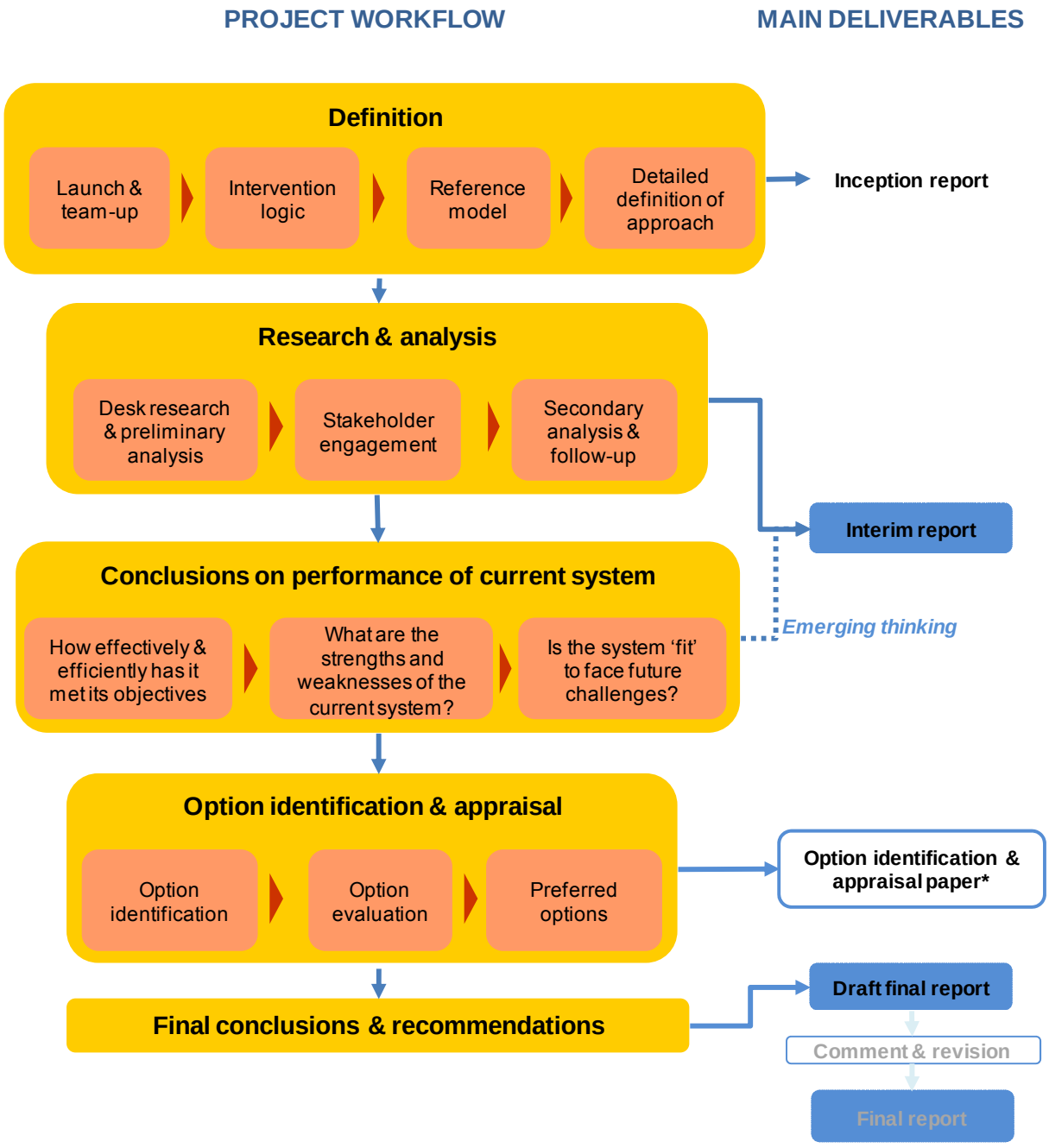
These organisations' responses are given special consideration as they represent multiple stakeholder perspectives and cannot easily be categorised as representing only breeders or growers of protected varieties. Three responses were also received from non-governmental organisations (NGOs). These associations are listed in Annex 13.

[52] COPA-COGECA, 'History', http://www.copa-cogeca.be/Main.aspx?page=CopaHistory&lang=en and http://www.copa-cogeca.be/Main.aspx?page=CogecaHistory&lang=en (viewed 20 November 2010).

Annex 6 Project Workflow

The position of the draft final report within the overall project is shown in Figure A6.1 below.

Figure A6.1 The position of the draft final report in the evaluation workflow



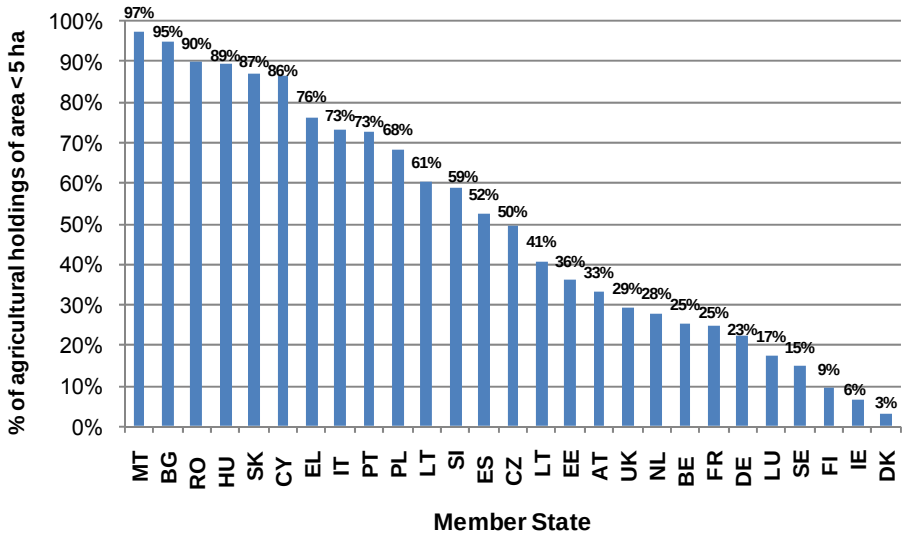
Annex 7 Additional Tables and Figures

Table A7.1 FSS Royalty Collection Systems in EU MS

FSS royalty collection system: (Member State)	System functions well	System functions well only for some crops	System recently established	System functions poorly	System does not function	System under discussion but not yet established
Belgium					✓	
Bulgaria						✓
Czech Republic	✓					
Denmark	✓					
Estonia			✓			
Finland	✓					
France		✓				
Germany				✓		
Hungary			✓			
Latvia			✓			
Lithuania			✓			
Netherlands	✓					
Poland			✓			
Slovenia	✓					
Spain						✓
Sweden	✓					
United Kingdom	✓					

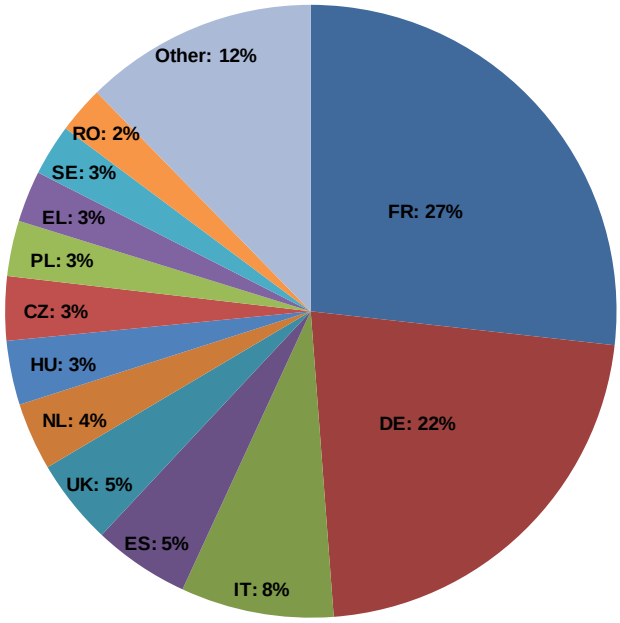
Source: Adapted from Scholte 2009 and supplemented by stakeholder consultation results from this evaluation

Figure A7.1 Percentage of agricultural holdings less than 5 ha in area, by EU Member State



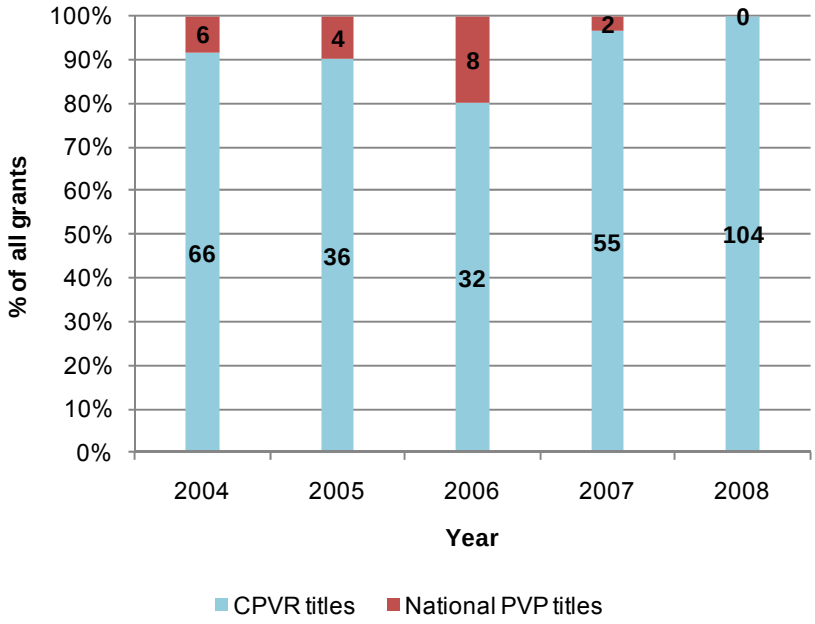
Source: Eurostat database. Retrieved on the 23/11/2010 on http://epp.eurostat.ec.europa.eu/portal/page/portal/statistics/search_database

Figure A7.2 France and Germany together represent approximately 50% of the EU seed market



Source: International Seed Federation (2010). This information refers specifically to the seed sector, and not to all plant propagating materials.

Figure A7.3 Plant breeders in Belgium are granted more CPVR than national PVR



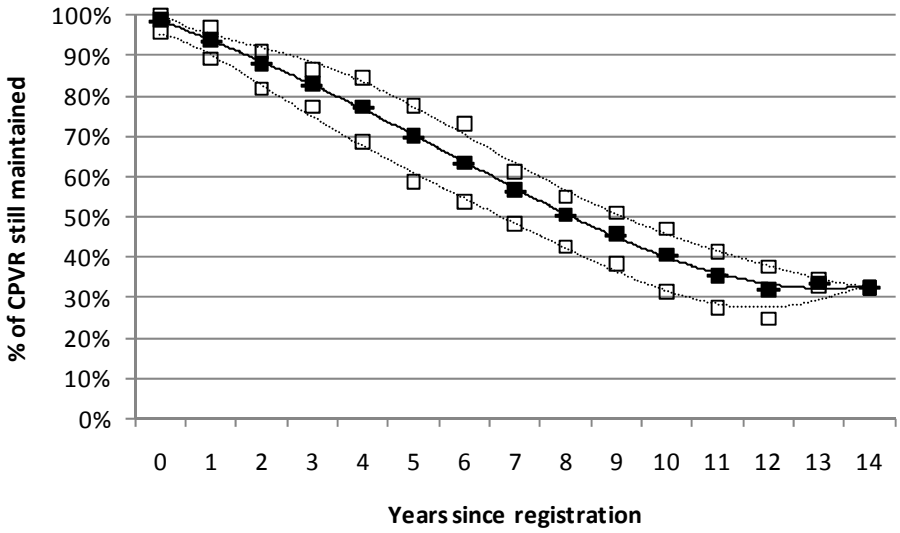
Source: CPVO and UPOV data (2004-2008)

Table A7.2 Leading EU exporters of selected vegetable crops and number of CPVR awarded to each Member State

Crop	**Leading exporter (*quantity exported in '000 tonnes*)**	**Number of CPVR awarded (*% of total for each crop*)**
Lettuce	Spain *(558)* Netherlands *(108)* Italy *(106)*	Netherlands: 531 *(67%)* France: 101 *(13%)* Germany: 10 *(1%)*
French beans	France *(54)* Netherlands *(42)* Spain *(29)*	Netherlands: 147 *(46%)* France: 63 *(20%)* Italy: 18 *(6%)*
Tomato	Spain *(939)* Netherlands *(921)* Belgium *(189)* France *(180)*	Netherlands: 93 *(42%)* France: 16 *(7%)*
Peas	France *(27)* Netherlands *(15)* Belgium *(6)*	France: 116 *(26%)* Netherlands: 77 *(18%)* Germany: 71 *(16%)*

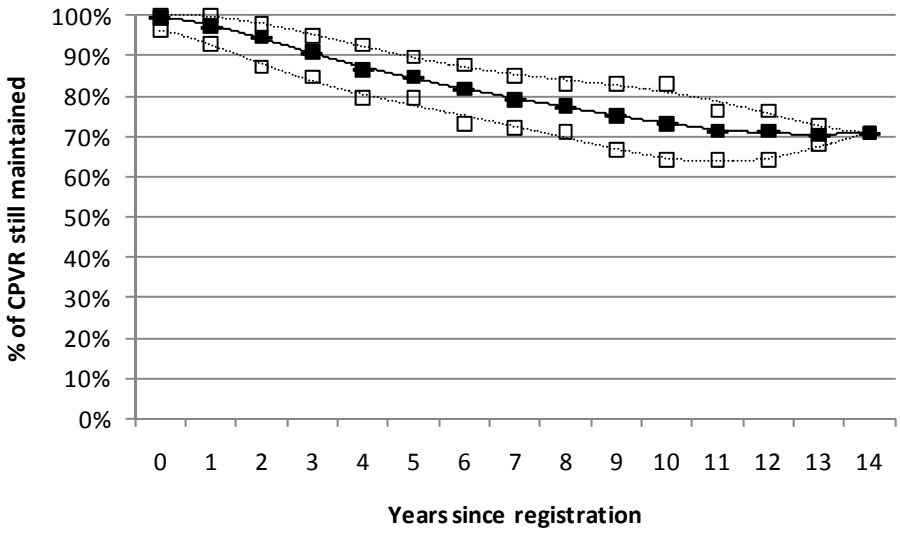
Sources: UN FAO (2008) and GHK analysis of CPVO data (1996-2009)

Figure A7.4 Half of the rights awarded for agricultural crops are terminated within eight years of their registration, and only 30% are maintained after 14 years



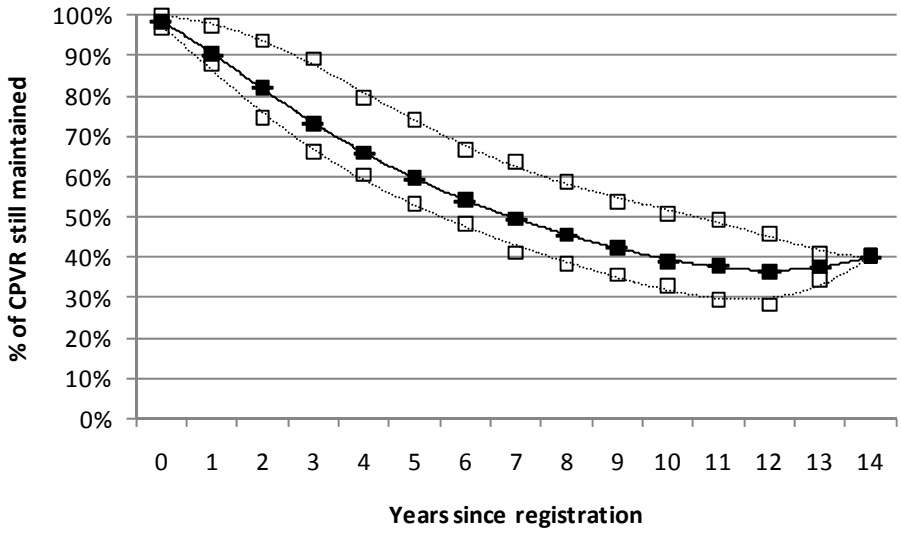
Source: GHK analysis based on CPVO data for 1996-2009. The black line is a 'best fit' curve for all years' data. White boxes indicate the upper and lower ranges of extant registrations. There is a larger number of observations for years to the left of the chart than for years to the right.

Figure A7.5 Comparatively few CPVRs are awarded for fruit species but they tend to be maintained for longer than those of other plant types – 70% are maintained to 14 years



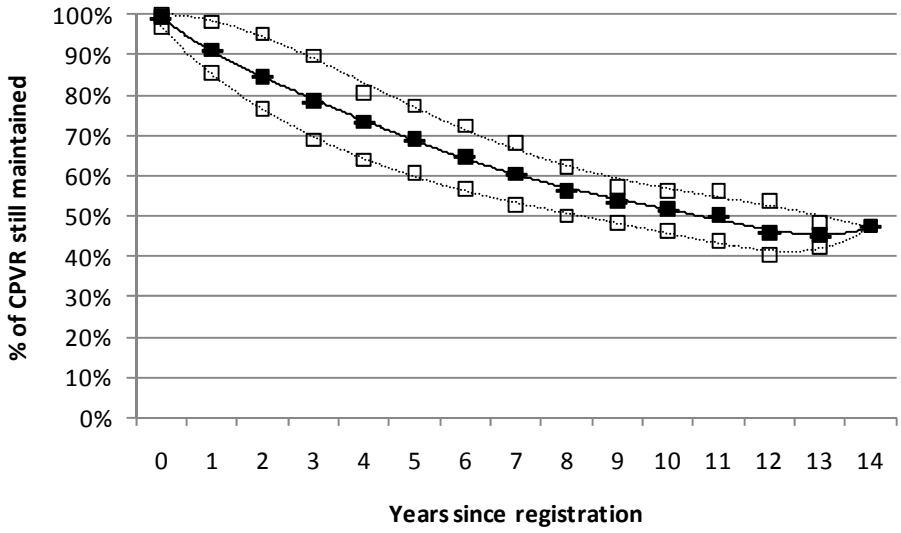
Source: GHK analysis based on CPVO data for 1996-2009. The black line is a 'best fit' curve for all years' data. White boxes indicate the upper and lower ranges of extant registrations. There is a larger number of observations for years to the left of the chart than for years to the right.

Figure A7.6There is a more rapid decline in the proportion of extant ornamental CPVRs than that of other varietals, with only 50% maintained after 7 years



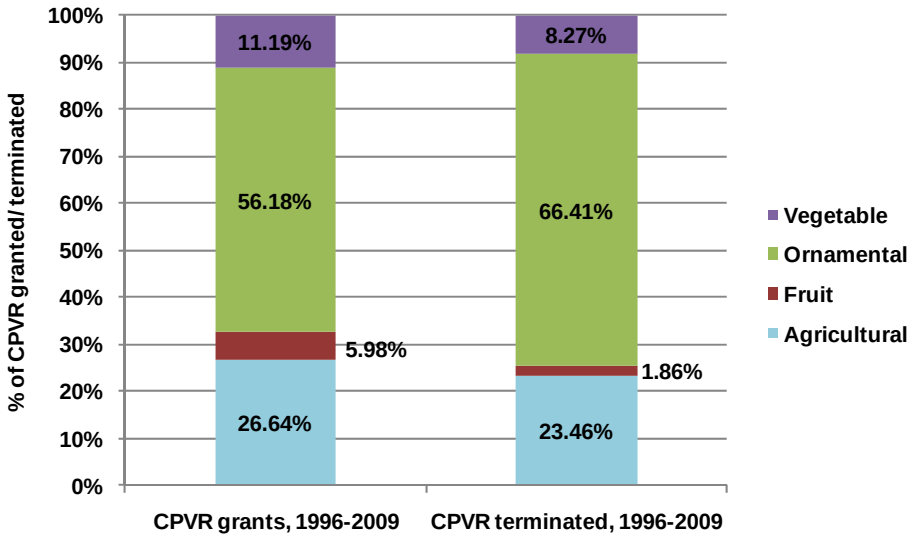
Source: GHK analysis based on CPVO data for 1996-2009. The black line is a 'best fit' curve for all years' data. White boxes indicate the upper and lower ranges of extant registrations. There is a larger number of observations for years to the left of the chart than for years to the right. The increase in extant CPVRs at age 13 / 14 is a consequence of this effect – there being comparatively few observations from the early years of the CPVR regime.

Figure A7.7 Vegetable CPVRs decline more slowly, with 50% of vegetable CPVRs maintained for at least 10 years



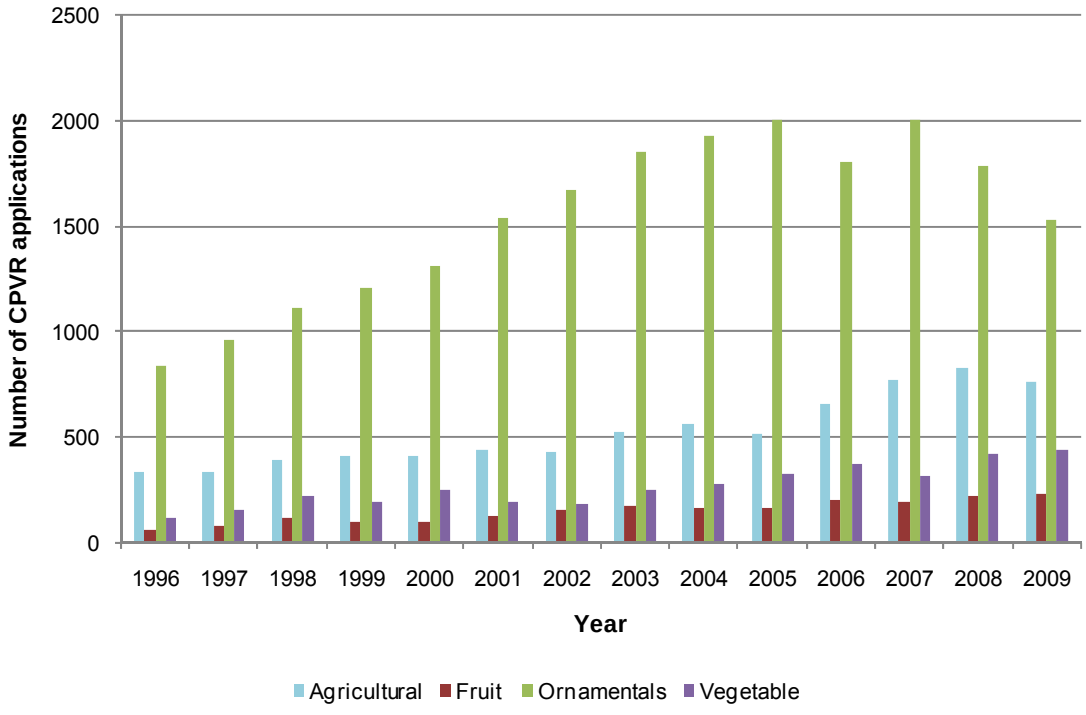
Source: GHK analysis based on CPVO data for 1996-2009. The black line is a 'best fit' curve for all years' data. White boxes indicate the upper and lower ranges of extant registrations. There is a larger number of observations for years to the left of the chart than for years to the right. The increase in extant CPVRs at age 13 / 14 is a consequence of this effect – there being comparatively few observations from the early years of the CPVR regime.

Figure A7.8 Ornamentals account for over half of all CPVR granted in the period 1996-2009 and for two-thirds of all CPVR terminated over the same period owing to the shorter average enforcement duration of CPVR under this varietal category



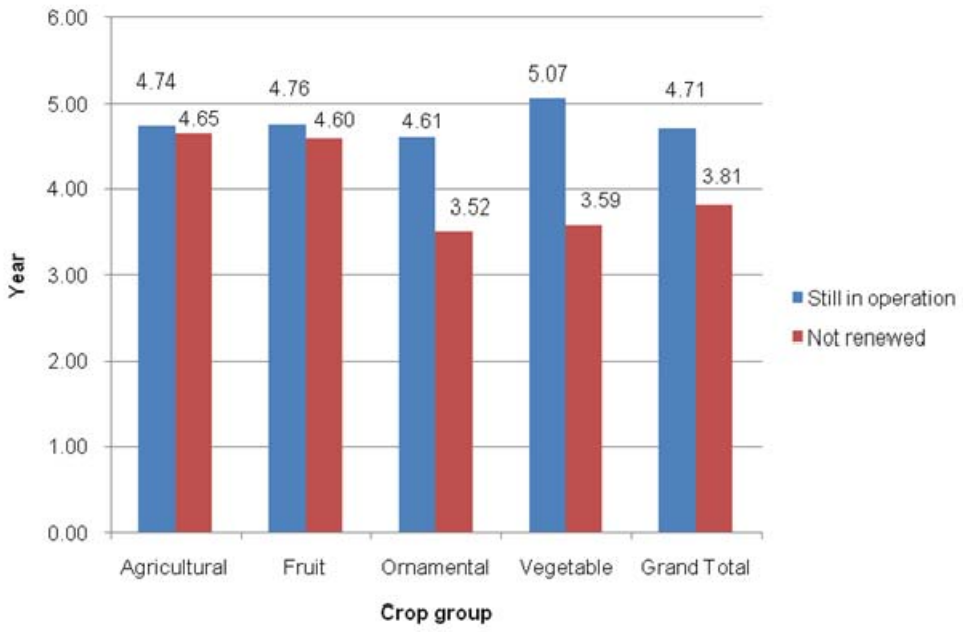
Source: GHK analysis of CPVO data, January 1995-July 2010

Figure A7.9 Applications for CPVR have risen annually for all group varietals in the 1996-2009 period; ornamental varieties have consistently accounted for the highest share of applications



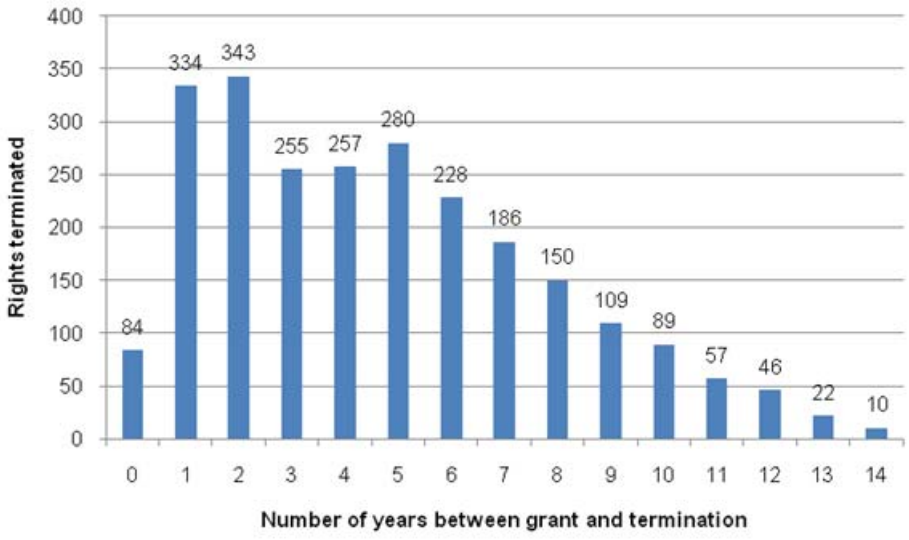
Source: GHK analysis of CPVO data (1996-2009)

Figure A7.10 Vegetables (and ornamental) varieties tend to 'die' faster (with ornamental) or 'live' longer than other types of crops on the CPVR register



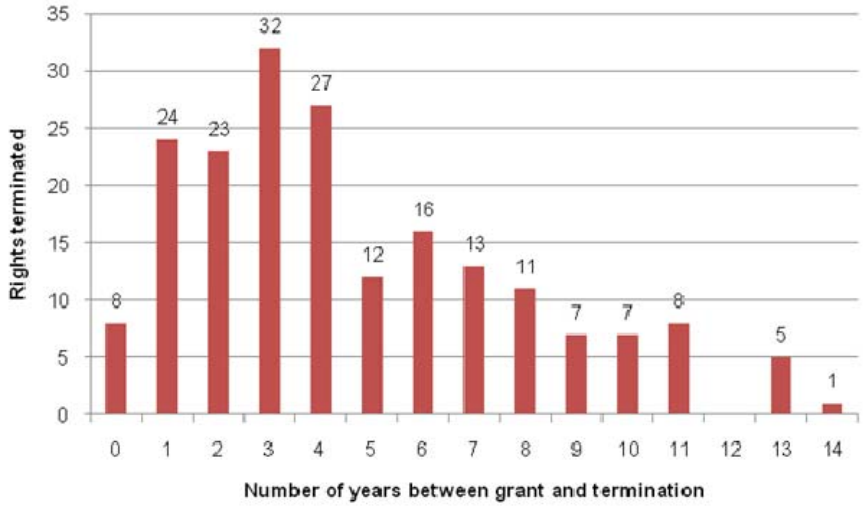
Source: CPVO data, January 1995-July 2010. Red columns (i.e. columns on the right) show average age of the right at time of termination. Blue columns (i.e. columns on the left) show average of extant rights.

Figure A7.11 Protection duration in Agricultural crops



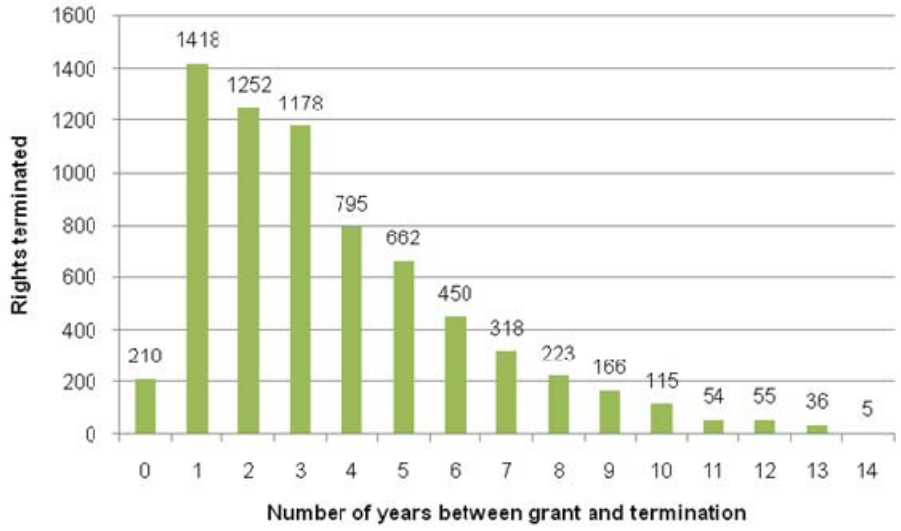
Source: CPVO data, January 1995 - July 2010

Figure A7.12 Protection duration in Fruit crops



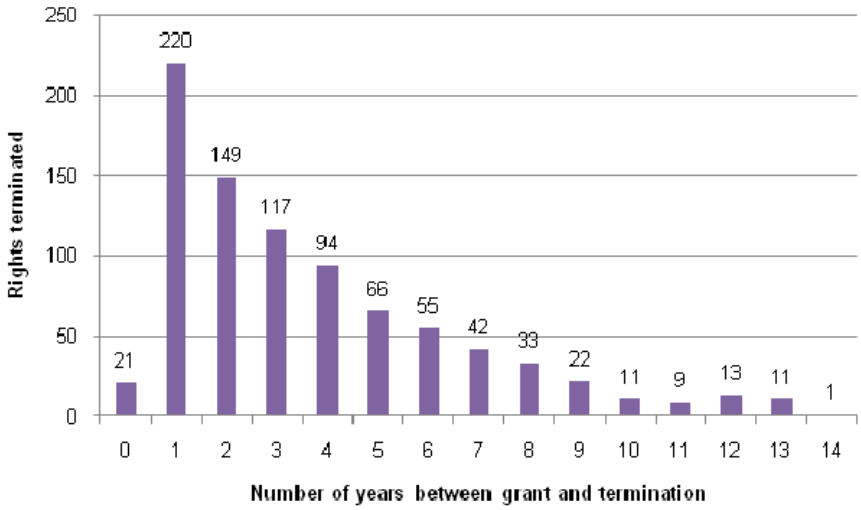
Source: CPVO data, January 1995 - July 2010

Figure A7.13 Protection duration in Ornamental crops



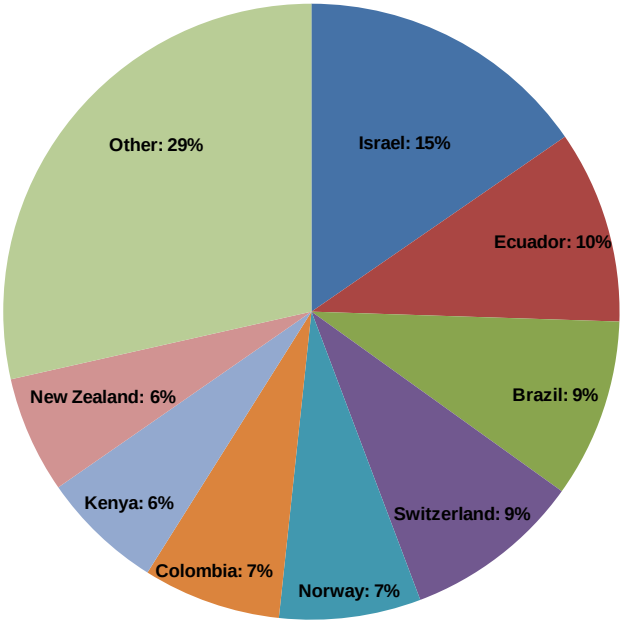
Source: CPVO data, January 1995 - July 2010

Figure A7.14 Protection duration in Vegetable crops



Source: CPVO data, January 1995 - July 2010

Figure A7.15 Israel accounts for the highest number of technical reports sold by the CPVO in the 1998-2009 period, with other countries such as Ecuador, Brazil and Kenya also accounting for significant numbers of sales in more recent years



Source: Community Plant Variety Office, 2009. Annual Report

Table A7.3 CPVR grants across EU MS by crop varietal category (1996-2010)

MS (main applicant)	Agricultural	Fruit	Ornamentals	Vegetable	Total	% of grand total
NL	518	70	7,172	1,656	**9,416**	32.1
DE	1,562	111	2,828	118	**4,619**	15.8
FR	2,630	394	775	332	**4,131**	14.1
DK	247	0	1,235	18	**1,500**	5.1
UK	417	57	856	57	**1,387**	4.7
IT	107	156	368	27	**658**	2.3
BE	51	19	557	3	**630**	2.2
ES	102	123	170	24	**419**	1.4
SE	92	7	45	1	**145**	0.5
AT	76	5	6	2	**89**	0.3
CZ	40	28	3	0	**71**	0.2
PL	50	9	4	1	**64**	0.2
HU	14	8	11	11	**44**	0.1
IE	25	0	18	0	**43**	0.1
CY	11	1	21	0	**33**	0.1
EL	11	2	2	0	**15**	0.05
SI	6	0	0	0	**6**	0.02
LU	2	0	3	0	**5**	0.02
RO	0	4	0	0	**4**	0.01
PT	0	2	1	0	**3**	0.01
EE	0	0	2	0	**2**	0.01
FI	1	0	1	0	**2**	0.01
MT	0	0	2	0	**2**	0.01
SK	0	1	0	0	**1**	0.01
BG	0	1	0	0	**1**	0.01
LT	0	0	0	0	**0**	0.00
LV	0	0	0	0	**0**	0.00
EU 27 Total	**5,962**	**998**	**14,080**	**2,250**	**23,290**	**79.50**
Grand Total	**7,472**	**1,321**	**17,527**	**2,974**	**29,294**	

Source: GHK analysis of CPVO data (1996-2010, data available up to July 2010)

Annex 8 PVR as Adaptation of Patent Principles

The key criteria for protection under patent law are (1) Inventive step (or non-obviousness) (2) Utility (3) Novelty and (4) Disclosure. The criterion of 'identifiability' requires that an innovation must be capable of precise description so that it can be distinguished from what already exists. 'Novelty' requires that an innovation refers to subject matter (products or processes) not already known to the public at the date of the patent application. 'Utility' requires that the use of an innovation must be identified, though economic viability of use is not necessary. 'Disclosure' requires that the description of the innovation should enable 'a person skilled in the art' to reproduce the innovation. We briefly discuss below how these concepts have been adapted to the special characteristics of plant variety innovations to facilitate the application of IPRs.

Inventive Step

Under patent law an invention must encompass more than an obvious extension of what was previously known. In the case of plant varieties, the conventional method of developing a new plant variety–crossing followed by selection—is a well-formulated one, with ingenuity applied in identifying further crosses for development. Though astute selection is the key to success, conceptually, this process is in many ways similar to the one used for the development of traditional varieties on farmers' fields (Eyzaguirre and Iwanaga: 1996). Therefore, the non-obviousness standard that can be applied to plant varieties has to be lower than that applied to, say, path-breaking industrial inventions. The inventive step requirement in PVP has been specified by requiring that the variety offered for protection is unique--distinct from known varieties. Distinctness is sufficient for genera and species for which reference varieties are already known. But in the case of a previously unknown wild relative or other discovery, it may be difficult to establish distinctness. In such cases, evidence of human effort and intervention has to be shown. The right under PVP, therefore, accrues to the breeder who has bred or discovered and developed a variety.

The criterion of distinctness implies that a variety must be distinguishable from other known varieties in terms of 'important' characteristics (UPOV: 1994a). Systematic botany that identifies varieties in terms of well-defined morphological characteristics has made it possible to apply the distinctness criterion in a practical way. The distinctness criterion leads to two other criteria for protection of plant varieties - uniformity and stability. Uniformity implies that a group of plants of a given variety must exhibit only a limited amount of variation in its distinguishing characteristics. Stability requires that these distinguishing characteristics remain unchanged after repeated cycles of propagation. Uniformity and stability are important aspects of distinguishing characteristics, because without them a variety is not distinguishable over time, making a protection system inoperative.

Utility

Industrial application/utility at a minimum requires some use for the invention to be identified in the application, but the use need not be efficient in the sense of being commercially viable compared to competing products. In the case of plant varieties, utility may have to be judged along several dimensions, such as yield, resistance to biotic and abiotic stresses and adaptation to specific locations (or aesthetic value) and it may not always be easy to specify the incremental utility accruing from a variety. But it must be noted that in countries where mandatory variety registration systems are in force, evaluation of varieties for 'value in cultivation and use' (VCU) is routinely done. Therefore, the incorporation of a utility criterion in PVP should not be considered to be infeasible. But plant breeders have generally resisted this idea (UPOV: 1987). It has been argued that, for plant varieties capable of being used in agriculture and horticulture, or even indirectly used as lines for subsequent breeding, utility should be deemed to be self-evident. Even materials discovered in the wild may contain useful resistance or other beneficial traits. The utility criterion has, therefore, been dispensed with in the case of plant varieties in PVP law - a variety can be protected as long as it is distinct, uniform and stable and does not need to demonstrate utility.

Novelty

The 'novelty' requirement of patent law means that an invention must be new so that society is not granting privileges for materials already in the public domain. Some systems specify absolute novelty (no prior disclosure, for example, under the European Patent Convention) whereas other systems allow a period after initial announcement within which protection can be granted. Detailed stipulations specify the exact terms and conditions under which a patent is judged to be new for novelty purposes.

In the case of plant varieties (especially when new varieties are the result of selection) absolute novelty may be difficult to establish. Moreover, unlike inventions, which can be accessed by a written description, plant varieties exist physically and become available only when physical material is accessed. Accordingly, novelty is deemed to be lost only when physical material of a variety is freely available. This will usually occur when a variety is commercialised. Therefore, in the case of plant varieties, it is the concept of 'commercial novelty' which is applied, that is, the variety should not have been offered for sale for more than a prescribed period.

Disclosure

A fundamental principle of patent law is that patent rights are granted against full 'disclosure' of the invention. Patent disclosures serve multiple functions, such as revealing the invention, providing information, which allows the patent to be duplicated on expiration of the patent, and contributing to the 'storehouse' of technical information. The criterion for disclosure is that it must be 'enabling', i.e. it must enable a person skilled in the art to recreate the invention. Disclosure poses problems in the context of plant varieties because new varieties may be the result of spontaneous mutations occurring in nature or simply because the information on the derivative history of a variety may be lacking. A written description of the variety does not enable it to be replicated. The disclosure requirement in PVP law has been handled by requiring a deposit of a sample of seeds or propagating material of the protected variety and also by requiring the breeder to maintain the protected variety (so that the PVP Authority can verify that the variety still exists). The deposited sample also serves as a reference sample.

Annex 9 Farm Saved Seed – European Case Studies

Farm Saved Seed in the European Union

Under European law, royalties must be paid by growers (farmers) that plant crops using harvested seeds of protected varieties and those derived from them (but not hybrids of varieties) (FERA, 2005). These royalties compensate the breeders of protected plant varieties.

The system for collecting farm saved seed (FSS) royalties differs across European Member States (MS). The most common method of collecting FSS royalties relies on self declaration by the grower; the grower declares how much FSS from protected varieties has been used, and then pays the appropriate charge.

There are significant problems with the system for collecting payment for the use of FSS from protected varieties. In general, these problems are related to the interpretation and application of the legislation, and the false (or non-) declaration of FSS of protected variety.

The case studies below illustrate the FSS royalty collation policies of four MS, describing what works well and what could be done to improve the collection processes.

The farm saved seed system in the United Kingdom

In the United Kingdom (UK) FSS royalties apply to and are collected on agricultural and horticultural crops. Crops include cereals, oilseeds, potatoes, peas and beans as well as fruit and herbage. The UK FSS system is based on voluntary declaration, underpinned by legal regulation. A number of farmers qualify for exemption from the FSS payment requirements if they are either classed as small farmers, or have saved seed of a nominated variety before the regulations came into force.

Logistics of Collection

The FSS system within the UK relies on a system of voluntary declaration. Growers must submit information regarding their FSS use to the British Society of Plant Breeders (BSPB). The BSPB are funded by a percentage of all royalty payments they collect (roughly 10%) including certified seed sales as well as saved seed declarations. Approximately 20% of all FSS royalty payments in the UK originate from self declaration by growers (Maplestone, 2011). Mobile seed processers provide services such as seed cleaning and pesticide dressing to growers. Seed processors receive a fee from the BSPB to declare levels of FSS use; they are responsible for the majority (80%) of FSS declarations (Maplestone, 2011).

FSS payment rates are based on two systems. One relates to combinable crops, for which a standard royalty is generated per crop per species each year. The other relates to potatoes only; seed payment rates are set by the owners of each eligible variety.

The remuneration level for combinable crops is generated through an agreement between BSPB and the farming unions. A percentage of the full licensed product charge is agreed upon each year for each protected variety. For example, current remuneration levels for wheat and peas are 52.5% and 47% of full licensed product charges, respectively (Maplestone, 2011). The fee for potatoes is set by breeders. It is currently set at 50% of the licence fee, the minimum fee under European Commission Regulation 2605/98 (Maplestone, 2011).

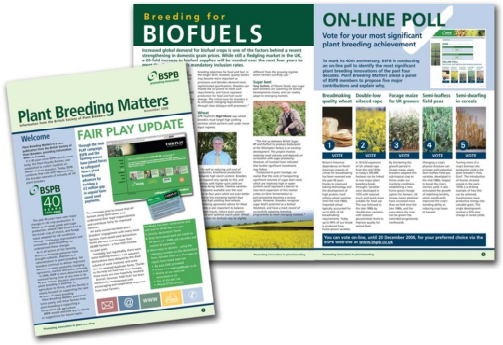
Information and Enforcement

Declaration of FSS use is mandatory and non return of declaration forms is classified as a criminal offence under UK law. The BSPB has developed a comprehensive farmer database (19,000+ farmers) which displays discrepancies in returns and provides a basis for establishing non returns and persistent offenders (Maplestone, 2009).

Due to previous rulings of the European Court of Justice it has proved difficult for the BSPB to enforce action on farmers that do not return declaration forms. The BSPB can request information from growers, but the grower is not obliged to provide this information. For example, it is extremely difficult for the BSPB to pursue a grower that returns a declaration form stating that no FSS of protected varieties has been used, even if the BSPB has indications of use (Maplestone, 2011). BSPB attempt to avoid criminal proceedings wherever possible due to the complexity and difficulty involved in the cases.

The BSPB has recognised that effective communication is central to conveying the importance of the plant breeding industry, and that royalty payments maintain its viability. The BPSB has, in partnership with farming unions, sought to reinforce the message regarding farm saved seed through a campaign called Fair Play on Farm Saved Seed. This campaign is intended to inform farmers of their legal responsibilities with regard to FSS (BSPB, 2005). Information is conveyed through a dedicated website, and advertised through farming unions and other organisations (0). The BSPB also arranges visits by farmers to plant breeders.

Examples of promotional material developed by BSPB to inform farmers of their responsibilities to pay FSS royalties (top) and of the importance of plant breeding to the industry (bottom)



Source: BSPB (2010)

Effectiveness of the UK system

The UK approach to FSS royalty collection has been more successful than approaches in other MS. Much of this success relates to the effective communication between breeders and growers through publications and campaigns. The BSPB is supported by major farming unions and industry bodies, which reinforces the importance of paying FSS royalties.

Compliance is high in the UK; many farmers return their declaration forms indicating FSS use. The simplicity of the declaration process, which is a strength of the UK system, reduces the burden of self declaration by growers (Maplestone, 2011). However, enforcement is difficult for the few who knowingly do not declare their use of FSS. Legal action is rare and is viewed by the BSPB as a last resort.

The alternative UK system

The Royalty Area Collection (RAC) scheme for FSS fee collection has been established on a small scale in the UK. It is administered by the Breeders Intellectual Property Office (BIPO), a private collection agency. Currently the scheme only covers a limited number of varieties of oats, peas and beans protected by a few breeders, though the scope of the scheme may increase (BIPO, 2010).

The BIPO scheme is based on contractual agreements between farmers and breeders. It is not covered by European PVR laws. The key difference between the BSPB-led scheme and the BIPO scheme is its charging structure; royalties are charged and valued separately from the seed itself. This charging structure is levied not just on FSS but on all certified varieties sold. It is assumed that if a specific variety has agronomic benefit to the grower, then that grower will be willing to pay for the benefit he has gained from the breeding of that seed. Effectively if a grower wants that particular variety, s/he must enter a contractual arrangement to pay a royalty for the agronomic benefit of the genetic improvement.

The rationale behind the BIPO scheme is that when genetic improvement is charged separately, breeders will gain a better price for their varieties and growers attach greater value to the genetic benefits of their chosen crops, creating a better relationship with the breeder (BIPO, 2011). Effectively the new scheme means that all seeds of a particular variety planted are eligible for a standard price that values the intellectual property of the seed genetics. This effectively means the end of FSS for these varieties, as charging is a blanket process regardless of how the seed was obtained.

It is too early to evaluate whether the BIPO scheme is working due to its small scale and limited varieties currently using the method.

The farm saved seed system in Germany

The German system aims to promote a balance between growers and breeders. Growers are obliged to provide information to breeders and pay remuneration for any seed used (Schmitz, 2009), and the rights of plant breeders to royalty payments are supported.

Logistics of Collection

The plant breeding community within Germany is working together to safeguard plant protection rights through the Saatguttreuhandverwaltungs-GmbH (STV) which acts on behalf of approximately 50 plant breeding companies. STV is responsible for royalty and license fee collections from growers, with the aim of eradicating the 'black market' seed trade (i.e. the purchase and subsequent sales of cereal grains for sowing) (BDP, 2011).

Under German law farmers do not require permission to use FSS, and there are no restrictions on its use or processing. In return, they are obliged to provide information on the use of FSS and pay equitable remuneration to the breeders (Schmitz, 2009). The balance between breeder and farmer envisaged by the regulations does not appear to work in practice. The German system is experiencing a rising number of non disclosures of FSS use. Farmers classified as 'small' do not have to make FSS payments. In 47% of cases, farmers have incorrectly classified themselves as 'small'. There are similar inconsistencies in the data provided by seed processers; approximately 60% of declarations have been found to include discrepancies, and 67% include the incorrect FSS rate (Schmitz, 2009). False declarations make it extremely difficult for an accurate remuneration payment to be issued to farmers. The total amount of FSS payment received is much lower than it should be. It is estimated that approximately 50% of all seed cultivated in Germany arises from FSS varieties, culminating in a potential €12M per year FSS remuneration of which only €6M is currently collected (Schmitz, 2009).

Information and Enforcement

The STV has a database of around 271,000 farmer addresses of which it is estimated that 95,000 are effectively eligible for FSS payments (Schmitz, 2009).

Whilst breeders and the STV may be aware that FSS is being used on certain holdings, it is difficult in practice to obtain robust information from farmers and seed processers regarding the varieties used and their volume. Farmers are legally obligated to declare their volume of farm saved seed and pay the breeder although in practice this is difficult to enforce and easy to fabricate. Subsequently the efficacy of the system for collection of FSS payments from farmers in Germany largely relies on the information disclosed by farmers and seed processors (ISF, 2005). However, there are no specific legal requirements for seed processers to gain information from farmers on the precise varieties used. The lack of information regarding the varieties used means that seed companies cannot determine the correct royalty fee.

Effectiveness of the German system

The German system of collecting royalty payments from FSS consists of a voluntary declaration underpinned by a legal obligation, which is monitored and enforced by a breeder operated organisation. It is estimated that the German system fails to collect annual royalty payments of approximately €6M (Schmitz, 2009). The number of non disclosures of FSS has markedly increased in Germany over the last decade, from 6000 farmers in 1996-1997 to 23,000 in 2006-2007 (Schmitz, 2009).

There are several weaknesses in the German system. The STV does not have established agreements with seed processers (as in the UK) and therefore receives no collection from a potentially valuable source (80% of all collections in the UK). Individual breeders and STV have little power when it comes to

requesting information from farmers over their use of FSS. In addition, the level of communication between STV and growers may not be sufficient to enforce the message that plant breeding matters (as in the British system). Survey responses from German farmers for this evaluation indicate a high level of distrust amongst farmers of the STV.

The farm saved seed system in the Czech Republic

Legal Basis

The Czech system of collecting FSS royalties is underpinned by national legislation[53] (Czech Republic, 2000). Under the legislation a farmer may use his/her own FSS from a protected variety without consent of the breeder. This is subject to an obligation that the farmer has to convey to the breeder at any requested time the amount of FSS used. The breeder is also entitled to request information from the seed processer at any time which relates to the seed processed by them. In turn the processer is also obliged to inform the breeder of the amount of FSS handled by them[54]. Following the requests for information, farmers have 6 months to pay remuneration for the protected variety at 50% of the usual licensing fee. Breaking the law with regard to declaring FSS use is considered an administrative wrongdoing and can be investigated and fined up to CZK 500,000 (approximately €20,500) (Dukat, 2008).

Since the ECJ court rulings, the Czech system must operate in the same way as any other Member State. Subsequently, although the legislation supports breeders' rights to royalties, in practice it carries little weight in relation to the obligations of farmers and processers to provide information.

Logistics of Collection

Druvod CZ, a cooperative, has been established by the major plant breeders to administer the collection of FSS royalties (Druvod CZ, 2011). Alongside the condition that breeders may freely request information on the use of FSS, farmers must complete self declaration forms dispatched twice yearly by the cooperative (for winter and spring crops). The questionnaire is also sent to seed processers once every two years to validate the authenticity of the data provided by the farmers. The cooperative carries out random inspections of the data disclosed in the questionnaires.

There are details for 5,915 farmers held on the cooperative's database who are each sent questionnaires on FSS usage. The Druvod CZ is not a government organisation and as such has no legal ties. It acts on behalf of the breeders and conducts legal enforcement only when reasonable evidence indicates false or no declarations. The questionnaires sent to seed processers are used primarily to validate and cross check farmer's declarations. This is supported by a random inspection system.

Effectiveness of the Czech system

There is little indication as to the efficacy of the Czech scheme. The system is designed to establish a good relationship between growers and breeders, and there is a clear understanding of the need for plant breeding royalties (Dukat, 2008). As demonstrated in the UK context, this communication can be a valuable asset and may significantly increase the response rate by growers and their willingness to pay royalties.

Collecting royalties is expensive, which may be due to the large cost associated with sending questionnaires to farmers on the database (Dukat, 2008). However, the cooperative has an incomplete database of farmers for which to send declaration forms, ensuring less FSS royalties are collected. For example, there were approximately 39,400 agricultural holdings in the Czech Republic in 2007 (Eurostat, 2011). At least 41% (16,154) of these farms are known to exclusively farm specialised crops or general field crops, with many cropping alongside livestock (13.3%) (Eurostat, 2011). But the FSS database contains only 5,915 farmers. In this respect the database used to collect royalties is incomplete, missing a significant number of holdings.

[53] Act 408/2000 on the protection of plant variety rights

[54] Article 19; Czech Republic, 2000

The farm saved seed system in France

FSS royalty collection in France differs markedly from the self declaration schemes of Britain and Germany outlined above. The scheme applies to soft wheat only; it does not apply to other plant varieties as with the systems of other MS.

FSS payment is mandatory in France and is charged in the form of a tax on all 'soft' wheat[55] delivered to grain processers (GRAIN, 2007). This charge is levied irrespective of what the seed was used for. Those who have bought their seed from a certified breeder are reimbursed at a later date, since they have already paid the royalty through purchase of certified seed. In this way, only those who use FSS pay an appropriate royalty tax on its use.

From this tax, 85% is paid back to the breeders, proportionate to their seed sales, with the remainder funding research into crop improvement (Kastler, 2010). This compulsory contribution is currently set at €0.5 / tonne of wheat sold for a total €7M a year (Bouvet, 2009). Compared to the total royalties collected in Germany for FSS (approximately €6M for all protected varieties), the French system of a compulsory tax collects a substantial sum of royalties for just one species. False declarations occur, but are thought to be limited (Kastler, 2010).

The French system of royalty payments functions particularly well for soft wheat as the entire crop must be sent to accredited storage agencies which are tasked with deducting the payments. While this system is effective, it only covers one species and collection of the tax relies on very specific conditions: the tax must be paid at the point of processing. There is no information to indicate whether the French system is likely to be rolled out to other protected varieties. Applying the same collection mechanism for other species that do not require processing and are sold on the open market could be more difficult to achieve.

[55] Wheat with a high starch content used in the production of food, such as bread.

Annex 10 Enforcement Directive & CPVR *acquis* Interactions

The Enforcement Directive: Aims and Scope

Aims:

The overarching aim of the Directive is to create a certain level of homogeneity in the judicial enforcement mechanisms for intellectual property rights across Member States; it seeks 'minimum harmonization'. There are differences in court practices and procedures between Member States with regard to issues of injunction, preservation of evidence, ascertaining damages and other civil corrective measures. This in effect leads to differences in the actual level of judicial protection offered to intellectual property rights.

Whilst the substantive legal regimes are similar since they are in compliance with TRIPS and other international conventions the very nature of intellectual property rights makes it expedient that enforcement mechanisms be harmonized to ensure uniform and adequate redress across Member States. The Directive thus seeks to reconcile 'major disparities' between Member States in the enforcement of intellectual property rights.

The Enforcement Directive explicitly does not aim to harmonise rules for judicial cooperation, jurisdiction, and enforcement of civil/commercial matters. It follows that this directive in general and in its particular provisions cannot be inferred to supersede EU legislation on such matters. Furthermore, the Directive does not aim to deal with substantive intellectual property law and its applicability extends only so far as it prescribes the enforcement of existing national laws. Its main aim is to provide effective mechanisms to prevent and punish intellectual property rights infringements across the EU.

Scope:

The scope of the Enforcement Directive is limited to any intellectual property law infringements as defined by the national law of Member States or EU law. The Directive does not affect any substantive EU intellectual property law, international obligations of Member States or intellectual property rights-related national criminal procedures. It covers in its prescriptive ambit all intellectual property rights covered by national and EU laws.

The scope of the Directive does not include all infringements but only those carried out for commercial purposes or which cause significant harm to the rights holder. The Directive itself does not define 'commercial scale' or 'significant harm' and in doing so leaves it open to national legislative or judicial forums. Proving the commercial dimension of intellectual property infringements can be a particularly onerous task and as evidenced from the judicial innovations in different Member States there is a need for the courts to proactively assert their jurisdiction in accessing and preserving evidence and take expedient interlocutory action such as removing the offending object from the commercial space. The Directive provides for mechanisms on all these aspects.

The Directive grants the locus for invoking the measures to the rights holder, licensees, collective rights management bodies and professional defence bodies. It goes beyond TRIPS in granting petitioner status to the last two categories.

Status of Implementation by Member States

As per a 2010 European Commission report on the application of the Enforcement Directive, the transposition of the Directive by Member States has been highly delayed and the filing of the application under the Directive also remains incomplete. Although Member States have gone beyond the prescriptions of the Directive on certain aspects such as ascertaining damages, several provisions remain un- implemented by the Member States. Article 7(1) of the Directive, which relates to preserving evidence as a pre-trial process has not been implemented by many Member States (e.g. Czech Republic, Greece, Hungary, Malta, and Poland.). Similarly Member States have not transposed Article 12 providing for alternative measures. Some voluntary measures, however, such as sampling have been duly incorporated by the Member States.

Transposition operates at different levels and needs to be distinguished accordingly. Some provisions of the Directive such as Article 6(2) and Article (7) are inspired by national laws or jurisprudence of different Member States and have been transposed by other Member States through specific legislative

instruments. In some Member States these provisions are part of the general procedural laws and therefore have not been specifically transposed for intellectual property infringement proceedings. Since these provisions of evidence discovery and gathering are usually used in criminal proceedings, in the absence of specific transposition or established judicial precedence of usage some national courts may not be able to employ these provisions in intellectual property infringement cases. Lack of harmonisation on this issue has made cross border collection of evidence very difficult.

Even measures that have been duly transposed have differing effect because of the interpretive differences between different courts. Article 6(1) enables the complainant to ask the judicial authority to order the opposing party to produce evidence under its control. But some Member States by placing a heavy burden on the complainant of describing the exact location/nature of the evidence sought significantly weaken the intent of the Article. As per Para 14 of the preamble of the Directive, Articles 6(2), 8(1) and 9(2) need to be applied only in respect of acts carried out on a commercial scale. However the directive provides no definition of commercial scale.

Article 8 of the Directive deals with the Right to Information and has found wide recognition and usage amongst MS. Applicability is limited to varying degrees in MS because of the Right to Privacy and Protection of Personal Data laws. This is severely restricted in countries such as Spain and Austria where data disclosure can be made only in very specific cases. The European Court of Justice has emphasised the need to balance the various rights but this 'balancing' would be the preserve of the national courts, and national courts may not be prepared to create exceptions in established procedural laws on issues as central as the right to privacy. Evidence legally procured in one country might be inadmissible in another country; such substantive reconciliation is admittedly outside the scope of the Directive.

Interlocutory injunctions including injunction against intermediaries are being widely used by Member States although the latter has a restrictive application in some Member States and overall the scope of injunctions and evidence required varies across national courts. A key area here is the issue of cross border injunctions which is most complicated in the realm of patents as courts would be exceeding their jurisdiction in assuming jurisdiction over a foreign patent. It is difficult to locate a legally appropriate basis of assuming jurisdiction over foreign patents and for this reason rulings of the European Court of Justice have limited the practice of cross border injunctions.

The jurisprudential development of recall of goods as per Article 10 is nascent in most Member States. Issues of variance arise around the stage at which recall and removal can be used and the real effect of each. In some countries, recall and definitive removal are used without any distinction (e.g. Greece, Spain, and Romania) whilst in the majority of the Member States recall is used as a temporary measure preceding removal and destruction.

The Directive in most parts is implemented by the Member States. But since much of the Directive deals with matters of civil procedure, differing court practices and judicial ethos is liable to limit the extent of harmonisation in effect. For example ordinary civil courts will apply their established standards of evidence in granting injunctive relief which whilst technically in conformity with the Directive can have very different results across Member States.

The Enforcement Directive and the Regulation on CPVR

The CPVR is an independent regulation and to that extent it has an inbuilt enforcement regime. The Enforcement Directive includes plant variety rights and thus also includes in its purview rights created under CPVR. The Enforcement Directive is a general directive for enforcement of all intellectual property rights whereas the CPVR Regulation creates a specific right. Both of these instruments have concurrent application but some enforcement provisions in the CPVR Basic Regulation do not compliment the Enforcement Directive, resulting in potential contradictions.

Both instruments are intended to be read together and need to be interpreted harmoniously for enforcement purposes. But since the CPVR did not envisage a separate Enforcement Directive, some of its enforcement provisions conflict with or do not adequately compliment the Enforcement Directive. Each of the differences described in Table 4.2 can be remedied through specific amendments to the CPVR *acquis* or by adding an overarching clause to the effect that the CPVR recognizes the Enforcement Directive as a method for enforcing rights created under it and all enforcement clauses should be deemed to give effect to the Directive. The former has the slight advantage of tailoring the convergence more precisely.

Annex 11 CPVR *acquis* and S&PM Directives - Synergies

Both the CPVR *acquis* and S&PM Directives have DUS testing requirements in common, although the legal basis for the two differs. The legal base for the Common Catalogues Directives is article 37 of the Treaty establishing the EU, whereas the one for Council Regulation (EC) 2100/94 defining the Community PVR rules is article 235 of the same Treaty.

Currently DUS testing relies on morphological features only and is usually carried out over two growing seasons (years) with candidate varieties being compared to varieties 'known in the Community'. In essence if a variety is not known it is new, and a prerequisite of granting protective rights is showing the 'newness' is distinct from known varieties and this distinctiveness is stable over the years with the crop remaining uniform and true to type. Judging these differences requires that collections of known varieties are maintained, against which new varieties can be assessed. This can be costly, particularly where regional growing conditions create variation in the phenotype. Differences in wage rates between MS can add further to costs in high wage countries if uniform DUS trials are applied across the Community. These factors can be a disincentive to uniform EU-wide DUS testing.

The review of the EU *acquis* on the marketing of seed and propagating material (2010) indicated the absence of a common DUS requirement for the registration of new varieties on the marketing of fruit crops, ornamentals and vegetatively propagated vegetables, yet DUS testing of these crops exists in certain MS. Differences also exist between MS in other aspects of DUS testing. Clearly if the EU is to have a legally viable common market in seeds and propagating materials, DUS requirements should extend to all MS, but to do so in the absence of a single agreed standard across the EU may introduce more confusion. The CPVO, in consultation with National Competent Authorities (NCA) and breeders, is in a good position to produce a set of agreed Standard Operating Procedures (SOPs) for use across the Community. The auditing of these SOPs would be the responsibility of the CPVO or delegated to the NCAs and breeders. The DUS test data could then be available for use to support both EU- wide PVRs and the S&PM Directives.

Consultations with plant breeding organisations in several MS shows them to use both Directive 2004/48/EC[56], and Regulation (EC) No 1383/2003 concerning customs action against goods suspected of infringing certain intellectual property rights[57] , although knowledge of the regulations is patchy. A uniform DUS strategy with appropriate testing regimes will provide better more accessible information to support this 'enforcing' legislation. In so doing it will improve the value of obtaining PVR protection and assist with the better control of markets.

The full synergy between the CPVR, S&PM and other legislative frameworks will not be achieved without adapting DUS testing and standards to incorporate new breeding technologies using molecular tools and in particular DNA markers. The S&PM *acquis* review pointed out that DNA analysis carried out by one MS showed nine popular clones approved in another MS were in fact only two varieties with different names in the national register.

This suggest that DUS testing done uniformly across the EU and using molecular as well as field based assessments will support a degree of synergy across at least four pieces of legislation. The adoption of molecular techniques can reduce costs whilst increasing the rigour of the assessments. This combination should make it a more attractive tool for legislators and breeders. An updated DUS regime could provide a cost effective 'one key, several doors' approach that should benefit all MS.

[56] Directive 2004/48/EC on the enforcement of intellectual property rights

[57] Regulation (EC) No 1383/2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights

Annex 12 Patent Protection in the EU

The TRIPS Agreement is the multilateral mechanism for ensuring effective IPR systems under the WTO. The EU and its Member States are WTO members and party to the TRIPS Agreement. Article 27(1) of the TRIPS Agreement requires all WTO Members to provide patent protection for inventions across all fields of technology, subject to the provisions of paragraphs 2 and 3 (the so-called 'optional exclusions').[58] Article 27(3)(b) allows Members to exclude plants and animals but requires that plant varieties are protected either by patents or by an effective *sui generis* system (including CPVR) or any combination thereof.

The rules on the patentability of biotechnological inventions are governed by the EU Directive 98/44/EC on the legal protection of biotechnological inventions. This Directive is aligned with requirements as set out in the TRIPS Agreement and as a consequence, distinguishes between inventions relating to plant and animal material which *are* patentable and those which *are not*. This differentiation concerns the means of achieving the product concerned. That is, a plant or animal variety is generally obtained by essentially biological processes, which are not patentable. In effect, therefore, a biotechnological invention may be patented so long as it does not pertain only to a single plant variety. As a result, patents on plants can include a plant variety, without applying directly to that plant variety.

Directive 98/44/EC has been implemented into the national patent laws of the Member States. Although the EU is not a party to the European Patent Convention (EPC), its MS are, and as a consequence, the Directive is implemented into the legal framework of the EPC.

In determining whether a biotechnological invention is patentable, the exception stated in Article 53(b) must be considered:

> *European Patents shall not be granted in respect of: (b) Plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes and to the products thereof*

The ultimate decision on whether to grant a patent depends on whether this exclusion is relevant. The terms 'plant varieties', 'animal varieties', 'biological processes for the production of plants or animals' and 'microbiological processes' mentioned in this Article are not defined in greater detail by the EPC.

The Boards of Appeal of the European Patent Office (EPO) have issued decisions to interpret these terms, which impact on what can and cannot be considered patentable. The European Parliament and the Council adopted Directive 98/44/EC on 6 July 1998 (the 'Biotechnology Directive') to further specify the terms laid out in Article 53(b).

The EU legislative framework does not, however, eliminate or reduce the possibility of dual protection for plant varieties. This is because inventions concerning plants are patentable if the technical feasibility of the invention is not confined to a particular plant variety. That is, plant groupings of a higher or a lower taxonomic level than a variety can be protected by a patent, if they have incorporated the patented genetic element. This view was confirmed by the Enlarged EPO Board of Appeal in the *Novartis* case (OJ EPO 111) which held that when the claim to a process for the production of a plant variety is examined, the exclusion of plant varieties from patenting would not apply.

In effect, therefore, a biotechnological invention may be patented so long as it does not pertain only to a single plant variety. The restriction on patenting pertaining to plant varieties is defined very narrowly. As a result, patents on plants can include a plant variety, without applying directly to that plant variety.

[58] Article 27(2): 'Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such an exclusion is not made merely because the exploitation is prohibited by their law'.

Article 27(3): 'Members may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, *Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof*...' [Emphasis added].

Annex 13 List of Stakeholders Consulted

Stakeholders involved in the consultation are listed in the following tables.

Key

✓	Request sent/response received and/or interview conducted
×	Request sent/no response
Declined	Request sent/participation declined
Deferred	Request sent/participant deferred participation to another stakeholder
Expected	Request sent/response expected but not yet received
NA	Not applicable — no request was sent and no response is expected

Breeders	**Survey response received**	**Interview conducted**
CEP Innovation	×	✓
Ciopora	✓	✓
European Seed Association (ESA)	✓	✓
International Seed Federation (ISF)	Deferred[59]	Deferred
British Society of Plant Breeders (BSPB)	✓	NA
Plantum NL	✓	×
CRA-W (Centre for Agricultural Research - Wallonia), Belgium	✓	NA
Breeders' Intellectual Property Office (BIPO)	✓	NA
Cereal Research Non-Profit Ltd., Hungary	✓	NA
Société Coopérative d'Intérêt Agricole des Sélectionneurs Obtenteurs de Variétés Végétales (SICASOV) Group	✓	✓
Growers	**Survey response received**	**Interview conducted**
Copa-Cogeca	✓	✓
International Association of Horticultural Producers (AIPH) Committee for Environment & Plant Health	✓	✓
The Global Partnership for Safe and Sustainable Agriculture (GLOBALGAP, formerly EurepGap)	×	×
National Farmers Union of England and Wales	✓	NA
Confédération Paysanne	✓	NA
Fédération Nationale des Agriculteurs Multiplicateurs de Semences (FNAMS) (FR)	✓	NA
Austrian Chamber of Agriculture	✓	NA

[59] ISF deferred its response to the stakeholder consultation to ESA.

Deutscher Bauernverband e.V. (DE)	✓	NA
Dutch Arable Farmers Union (NAV)	✓	NA
Federation of Swedish Farmers	✓	NA
Coordinadora de Organizaciones de Agricultores y Ganaderos (COAG-IR) (ES)	✓	NA
UNITERRE (CH)	✓	NA
Agrisupply	**Survey response received**	**Interview conducted**
European Mobile Seeds Association (EMSA)	✓	✓
Agricultural Industries Confederation	×	×
National Association of Agricultural Contractors	✓	✓
Traders	**Survey response received**	**Interview conducted**
Comité du Commerce des cereals, aliments du bétail, oléagineux, huile d'olive, huiles et graisses et agrofournitures (COCERAL)	×	×
EUROPATAT	✓	✓
FRESHFEL Europe	×	×
Union Fleurs	×	×
Forest Industry	**Survey response received**	**Interview conducted**
European Landowners' Organization (ELO)	×	×
Confederation of European Forest Owners (CEPF)	Declined	NA
European State Forest Association (EUSTAFOR)	×	×
CEI-Bois	×	×
European Forest Nursery Association (EFNA)	Declined	NA
Non Governmental Organisations (NGOs)	**Survey response received**	**Interview conducted**
Bureau Européen des Unions de Consommateurs / The European Consumers' Organisation (BEUC)	×	×
European Initiative for Sustainable Development in Agriculture (EISA)	×	×
IFOAM EU Group	×	×
Forests and the European Union Resource Network (Fern)	×	×
European Environmental Bureau (EEB)	Declined	NA
World Wildlife Fund (WWF)	×	×
Coordination Nationale de Défense des Semences de Ferme (CNDSF)	✓	×
Friends of the Earth Europe	✓	✓
Greenpeace	×	×
European Coordination via Campesina	✓	×

Initiative for GE-free Seeds and Breeding (IG Saatgut)	✓	✓
The Knowledge Centre for Agriculture (VFL) (Denmark)	✓	NA

Member State representatives

NL	Survey response received	Interview conducted
Standing Committee on Community Plant Variety Rights	✓	✓
Standing Committee on Seeds	✓	✓
Standing Committee on Fruit Genera and Species	✓	✓
Standing Committee on Ornamental Plants	✓	✓
Standing Committee on Seeds -- Forestry	✓	✓
DE	**Survey response received**	**Interview conducted**
Standing Committee on Community Plant Variety Rights	✓	✓
Standing Committee on Seeds	✓	✓
Standing Committee on Fruit Genera and Species & Ornamental Plants	×	×
Standing Committee on Ornamental Plants	×	×
Standing Committee on Seeds -- Forestry	×	×
FR	**Survey response received**	**Interview conducted**
Standing Committee on Community Plant Variety Rights	✓	✓
Standing Committee on Seeds	✓	✓
Standing Committee on Fruit Genera and Species	×	×
Standing Committee on Ornamental Plants	×	×
Standing Committee on Seeds -- Forestry	✓	✓
UK	**Survey response received**	**Interview conducted**
Standing Committee on Community Plant Variety Rights	✓	✓
Standing Committee on Seeds	✓	✓
Standing Committee on Fruit Genera and Species	✓	✓
Standing Committee on Ornamental Plants	✓	✓
Standing Committee on Seeds -- Forestry	✓	×

DK	Survey response received	Interview conducted
Standing Committee on Community Plant Variety Rights	✓	✓
Standing Committee on Seeds	×	×
Standing Committee on Fruit Genera and Species	×	×
Standing Committee on Ornamental Plants	×	×
Standing Committee on Seeds -- Forestry	×	×
ES	**Survey response received**	**Interview conducted**
Standing Committee on Community Plant Variety Rights	✓	✓
Standing Committee on Seeds	×	×
Standing Committee on Fruit Genera and Species	×	✓
Standing Committee on Ornamental Plants	×	✓
Standing Committee on Seeds -- Forestry	×	✓
CZ	**Survey response received**	**Interview conducted**
Standing Committee on Community Plant Variety Rights	✓	✓
Standing Committee on Seeds	✓	×
Standing Committee on Fruit Genera and Species	✓	×
Standing Committee on Ornamental Plants	✓	×
Standing Committee on Seeds -- Forestry	×	×
PL	**Survey response received**	**Interview conducted**
Standing Committee on Community Plant Variety Rights	✓	✓
Standing Committee on Seeds	✓	✓
Standing Committee on Fruit Genera and Species	×	×
Standing Committee on Ornamental Plants	×	×
Standing Committee on Seeds -- Forestry	×	×
RO	**Survey response received**	**Interview conducted[60]**
Standing Committee on Community Plant Variety Rights	✓	✓
Standing Committee on Seeds	✓	✓
Standing Committee on Fruit Genera and Species	✓	✓
Standing Committee on Ornamental Plants	✓	✓

[60] Committee representatives have deferred their response to Elena Checiu, Technical Liaison Officer. Interview conducted with Ms Checiu on 27 October 2010.

Standing Committee on Seeds -- Forestry	✓	✓
Technical Liaison Offices in the EU Member States with the CPVO	**Survey response received**	**Interview conducted**
Executive Agency of Variety Testing, Bulgaria	×	×
Department of Variety Testing, UKSUP, Slovakia	✓	×
Research Centre for Cultivar Testing, COBORU, Poland	✓	✓
Seeds and Other Propagation Material Unit, Plant Health Department, Malta	✓	×
Ministry for Food, Agriculture and Fisheries, Plant Directorate, Denmark	✓	✓
Agricultural Research Institute, Ministry of Agriculture, natural resources and environment, Cyprus	×	×
Direcção-Geral de Agricultura e Desenvolvimento Rural, Portugal	✓	×
Raad Voor Plantenrassen, Netherlands	✓	✓
Bundesamt für ernährungssicherheit, Austria	✓	×
Central Agricultural Office, Hungary	×	×
Ministry of Agriculture, Forestry and Food, Phytosanitary Administration of the Republic of Slovenia	×	×
GEVES, Services Accords de Coopération Internationale, France	✓	✓
Lithuanian State Plant Varieties Testing Centre, Lithuania	✓	×
Ministry of Agriculture of the Republic of Latvia, Seed Control Department, Latvia	✓	×
Swedish Board of Agriculture, Sweden	×	×
European Commission, SANCO Health and Consumer Protection DG, Belgium	✓	×
Department of Agriculture and Food, Office of the Controller of Plant Breeders Rights, Ireland	×	×
Food and Environment Research Agency (FERA), United Kingdom	✓	✓
KTTK-Plant Production Inspection Centre, Seed Testing Department, Finland	×	×
State Office for Inventions and Trademarks, Romania	✓	✓
Plant Production Inspectorate, Variety Control Department, Estonia	×	×
Bundessortenamt, Germany	✓	✓
UKZUZ, Central Institute for Supervising and Testing in Agriculture, Czech Republic	✓	×
Oficina Española de Variedades Vegetales, Spain	✓	✓
Ministry of Rural Development, Variety Research Institute of Cultivated Plants, Greece	×	×
Ministero delle Politiche Agricole e Forestali, Italy	✓	✓
Office de la Propriete Intellectuelle, Belgium	×	×
Administration des Services Techniques de l'Agriculture, Service de la Production Végétale, Luxembourg	✓	×
European and International Organisations	**Survey response received**	**Interview conducted**

Community Plant Variety Office (CPVO/OCVV)	NA	✓
European Food Safety Authority (EFSA)	NA	×
European Patent Office (EPO)	NA	✓
World Trade Organisation (WTO)	NA	×
International Union for the Protection of New Varieties of Plants (UPOV)	Declined	NA
Organisation for Economic Cooperation and Development (OECD/OCDE)	NA	×
FAO Secretary of the International Treaty on Plant Genetic Resources for Food and Agriculture	NA	×
International Seed Testing Association (ISTA)	NA	×
Commission Services Concerned with Intellectual Property and CPVR	**Survey response received**	**Interview conducted**
DG Agriculture	NA	×
DG Development	NA	✓
DG Environment	NA	×
DG Enterprise	NA	Declined
DG External Relations	NA	×
DG Health and Consumer Protection	NA	×
DG Internal Market	NA	×
DG Research	NA	×
DG Trade	NA	×
General Secretariat of the Commission	NA	✓

Questionnaires received and stakeholders covered – MS representatives[61]

MS	Priority MS	Questionnaires received	Interviews conducted	Stakeholders covered	Total stakeholders
AT	×	1	0	3	6
BE	×	2	1	3	6
BG	×	1	0	4	3
CY	×	2	0	2	4
CZ	✓	4	2	5	6
DE	✓	3	2	5	6
DK	✓	1	1	2	3
EE	×	1	0	2	6
EL	×	1	0	4	3
ES	✓	1	1	3	6
FI	×	2	0	3	6
FR	✓	4	2	7	8
HU	×	2	0	4	7
IE	×	1	0	5	5
IT	×	2	1	3	6
LT	×	1	0	4	6
LU	×	1	0	2	3
LV	×	2	0	4	5
MT	×	0*	0	1	1
NL	✓	3	2	3	3
PL	✓	2	2	4	6
PT	×	1	0	2	4
RO	✓	1	1	5	5
SE	×	2	0	5	5
SI	×	1	0	3	3
SK	×	1	0	3	4
UK	✓	1	1	4	5
Total		**44**	**16**	**95****	**133****

[61] *Email response received **Excluding MT, 94 stakeholders were covered out of a total of 132.

The list of organisations representative of plant breeders/ plant growers from which survey responses were received (excluding privately owned companies)

International organisations
International Community of Breeders of Asexually Reproduced Ornamental and Fruit Plants (CIOPORA)
International Association of Horticultural Producers (AIPH)
Association Internationale des Sélectionneurs pour la Protection de Obtentions Végétales (ASSINSEL)/ International Association of Plant Breeders for the Protection of Plant Varieties
EU-level organisations
European Seed Association (ESA)
Société Coopérative d'Intérêt Agricole des Sélectionneurs Obtenteurs de Variétés Végétales (SICASOV Group)
Copa-Cogeca
Euralis Semences
Breeders' Intellectual Property Office (BIPO)
European Mobile Seed Association (EMSA)
European Potato Trade Association (Europatat)
National-level organisations
Plantum NL
British Society of Plant Breeders (BSPB) Ltd. (UK)
National Farmers Union of England and Wales (NFU)
Union Francaise des Semenciers (FR)
Confédération Paysanne
Fédération Nationale des Agriculteurs Multiplicateurs de Semences (FNAMS) (FR)
Austrian Chamber of Agriculture
Deutscher Bauernverband e.V. (DE)
Bundesverband Deutscher Pflanzenzuchter e.V. (BDP)/ German Plant Breeders' Association (DE)
Sammenslutningen af Danske Sortsejere (APVD) (DK)
Swedish Seed Trade Association (SE)
Association of Hungarian Plant Breeders (HU)
Associazione Italiana Sementi (ASSOSEMENTI) (IT)
Jõgeva Plant Breeding Institute (EE)
Cereal Research Non-Profit Ltd. (HU)
Danko Plant Breeders Ltd. (PL)
National Association of Agricultural Contractors (NAAC) (UK)
Danish Seed Council (DK)
Hungarian Seed Association (HU)
Romanian Association of Breeders, Producers and Traders of Seeds and Propagating Material (AMSEM) (RO)
UNITERRE (CH)
Dutch Arable Farmers Union (NAV)

Federation of Swedish Farmers
Coordinadora de Organizaciones de Agricultores y Ganaderos (COAG-IR) (ES)

Other organisations from which survey responses were received

Organisation name	Organisation type
Walloon Agricultural Research Centre (CRA-W)	Research institute (Walloon region, Belgium)
Friends of the Earth Europe (FoEE)	NGO (International)
Arbeitsgemeinschaft bäuerliche Landwirtschaft e.V. (AbL)	NGO (DE)
The Knowledge Centre for Agriculture (VFL)	NGO (DK)

List of private breeder enterprises from which survey responses were received

Large enterprises *(more than 250 employees)*
Groupe Limagrain and subsidiaries (Vilmorin, Clause, Nickerson Zwaan B.V.)
Pioneer Hi-Bred Inc.
Syngenta Seeds
KWS SAAT AG
RAGT Semences
Rijk Zwaan Zaadteelt en Zaadhandel B.V.
Monsanto
Maison Florimond Desprez S.A.S.
Royal Van Zanten
Floricultura B.V.
SESVanderHave
Krishidhan Seeds Europe B.V.
Bejo Zaden B.V.
Deutsche Saatveredelung AG
Medium-sized enterprises *(50-250 employees)*
HZPC Holland B.V.
Norddeutsche Pflanzenzucht H.G. Lembke KG
AGRICO Cooperative
Schaap Holland
KP Holland
Plantenkwekerij Van der Lugt VOF
CZAV
Plantenkwekerij Jongerius Houten B.V.
Takii Europe B.V.
Wayland Holding B.V.
Pothos Plant
Könst Breeding B.V.
Hilverda Kooij B.V.
Florist de Kwakel
Deliflor Chrysanten B.V.
Combinations S&V B.V.
Sion
Schreurs Holland B.V.
Schoneveld Breeding
Klugt Bleiswijk B.V.
Leo Ammerlaan B.V.
Germicopa S.A.S.
Sande B.V.

Plantenkwekerij Brabant Plant B.V.
Small enterprises *(10-50 employees)*
Aardam
Mak Breeding B.V.
Moerheim New Plant B.V.
Aardbeiculturen van der Werf VOF
Penning Freesia B.V.
Songrow B.V.
Bartelsstek B.V.
Danespo A/S
Kwekerij 'De Stadsweiden'
Westlandse Plantenkwekerij (WPK)
Horteve Breeding
Royalty Administration International C.V.
Plantenkwekerij Grootscholten B.V.
M. van Veen B.V.
Holland-Select Research B.V.
Hem Genetics B.V.
Van Rijn - KWS B.V.
De Groot en Slot Allium B.V.
C. Meijer B.V.
Sejet Plant Breeding
Pop Vriend Seeds B.V.
Senova Limited
Bingenheimer Saatgut AG
Micro-sized enterprises *(fewer than 10 employees)*
Aardappelveredelingsbedrijf Jalving B.V.
Evers Europa B.V.
Fobek B.V.
Green Works International BV
Könst Research BV
Lantmannen SW Seed BV
Mansholt's Veredelingsbedrijf B.V.
ABZ Aardbeien uit Zaad Holding B.V.
De Jong Research B.V.
EconSeeds B.V.
Kweekbedrijf Smeenge
Wulfinghoff Alstroemeria B.V.
Nordic Maize breeding
Inova Fruit B.V.

Green Works International B.V.
Fa. Gebr. Plas
Topcolor Breeding VOF
CEP INNOVATION SARL
NOVADI SARL
Vitro Westland B.V.

Breakdown of respondents to growers' survey by location

Location	Number of representative associations of plant growers/ farmers which responded to survey	Number of individual plant grower/ farmer respondents
FR	4	12
DE	2	10
UK	2	5
NL	1	0
SE	1	0
ES	1	0

Annex 14 Policy Options Screening

The screening exercise considered all policy options, including those arising directly from the evaluation results and those proposed through ongoing European Commission initiatives, inputs from the stakeholder consultation, industry position papers and discussion, and third party research. For all measures considered, there is also the alternative of doing nothing (i.e. the *status quo* scenario). That forms the baseline against which all measures are assessed.

Policy option screening

Issue	Option	Screened out?	Justification
Interaction w/ S&PM Directives	Implement 'one key, several doors' approach	N	This option is carried forward as Primary Issue Option A
Interaction w/ patent system	Extend breeders' exemption to all patents	Y	Requires changes to patent legislation; this is outside the scope of the CPVR *acquis*
	Extend research exemption to all patents	Y	Requires changes to patent legislation; this is outside the scope of the CPVR *acquis*
	Improve info provision for protected varieties	N	This option is carried forward as Primary Issue Option B
Interaction w/ access to information regulation	Clarify procedures regarding access to information	N	This option is carried forward as Secondary Issue Option K
Interaction w/ international instruments	Relax uniformity requirements	Y	Requires changes that are unrelated to the functioning of the CPVR system
	Require disclosure of origin	Y	Requires changes to UPOV; this is outside the scope of the CPVR *acquis*
EFTA extension	Extend CPVR *acquis* to EFTA countries	N	This option is carried forward as Primary Issue Option D
EDVs	CPVO-led support for protocol & threshold development	N	This option is carried forward as Primary Issue Option E
Protection duration	Extend for all species	Y	Data on CPVR 'lifespans' do not support such an extension
	Extend for all varieties (except trees, vines, potatoes)	Y	Data on CPVR 'lifespans' do not support such an extension
	Extend on a case-by-case basis	N	This option is carried forward as Primary Issue Option F
Agriculture exemption: Reporting obligation	Amend the BR to obligate growers to report 'yes' or 'no' whether they have used FSS	N	This option is carried forward as Primary Issue Option H1
Agriculture exemption 'Small farmer exemption'	Redefine 'small farmer'	N	This option is carried forward as Primary Issue Option H3
	Remove the 'small farmer' exemption from the legislation	N	This option is carried forward as Primary Issue Option H4
Agriculture exemption 'Own holding' definition	Redefine 'own holding'	N	This option is carried forward as Primary Issue Option H5
Agriculture exemption	Redefine 'equitable	N	This option is carried forward as

Issue	Option	Screened out?	Justification
'Equitable remuneration' definition	remuneration'		Primary Issue Option H6
Applications & examinations	Implement 'one key, several doors' approach	N	This option is carried forward as Primary Issue Option A
	Adjust testing protocols for additional characteristics	N	This option is carried forward as Secondary Issue Option L1
	Reduce info requirements	N	This option is carried forward as Secondary Issue Option L2
	Facilitate communication	N	This option is carried forward as Secondary Issue Option L3
	Assess fee payment lag for testing centres	N	This option is carried forward as Secondary Issue Option L4
	Regionalised testing	Y	Scientifically problematic – some species require specific climatic conditions
	Official licensing for testing	N	This option is carried forward as Secondary Issue Option L5
Interaction with Enforcement Directive	Amend BR to include Enforcement Directive	N	This option is carried forward as Primary Issue Option C
Specialised courts	National courts	N	This option is carried forward as Secondary Issue Option I1
	EU-level court	N	This option is carried forward as Secondary Issue Option I2
Harvested materials	Amend BR to unqualified protection for harvested materials	N	This option is carried forward as Secondary Issue Option J1
	Extend scope of protection to products of harvested materials	N	This option is carried forward as Secondary Issue Option J2
	Extend scope of protection to transit of harvested materials	N	This option is carried forward as Secondary Issue Option J3
Capacity building	CPVO-led support for molecular markers	N	This option is carried forward as Secondary Issue Option M1
	CPVO-led support for sample banking of genetic materials	N	This option is carried forward as Secondary Issue Option M2
	CPVO-led outreach to third countries	N	This option is carried forward as Secondary Issue Option M3
Hiring senior management in CPVO	Amend BR to align with current hiring practices within the Commission	N	This option is carried forward as Secondary Issue Option N
Errors in the Basic Regulation	Amend BR to correct errors	N	This option is carried forward as Secondary Issue Option O

Annex 15Overview of Potential Policy Options

The retained options (Annex 14) have been grouped into two categories - primary issues (i.e. high priority) and secondary issues (i.e. low priority) and then further grouped into a set of main options and sub-options. The following tables present each issue and the corresponding (potential) response.

Category I Policy Options – Primary Issues

		Issue	Option
A		Interaction with the S&PM Directives results in multiple DUS testing and variety denomination requirements for plant varieties	Implement the 'one key, several doors' approach to DUS testing and variety denominations
B		Interaction with the patent system results in overlapping protection for some plant varieties and patents. This creates uncertainty for plant breeders and potential conflicts where the provisions of the CPVR *acquis* (particularly the breeders' exemption) are not available under patent legislation	Improve information provision for protected varieties (led by CPVO)
C		Interaction with the Enforcement Directive	Amend Basic Regulation (BR) to accommodate Enforcement Directive
D		Consider whether to extend the CPVR *aquis* to EFTA countries	Extend the CPVR *acquis* to EFTA countries
E		There are no official protocols or standards for determining whether a plant variety is 'essentially derived', resulting in uncertainty for breeders in conducting their research programmes and court cases using similar evidence but resulting in different judgments.	CPVO plays a greater role in supporting protocol and EDV threshold development, in collaboration with the plant breeding industry
F		The duration of protection may not be adequate to ensure that plant breeders can obtain a return on investment where breeding programmes and variety development are particularly long	Extend the duration of protection on a case-by-case basis
G	G1	Legal interpretation of FSS users' obligation to report creates practical difficulties with royalty collection	Amend the CPVR BR to obligate growers to report 'yes' or 'no' upon request whether they have used farm saved seed
	G2	The appropriate definition of a 'small farmer' is contentious and the current definition is no longer in use	Amend Regulation (EC) No 1768/95to redefine a 'small farmer'
	G3	The 'small farmer' exemption is contentious and could be removed from Regulation(EC) No 1768/95	Change Regulation (EC) No 1768/95 to remove the 'small farmer' exemption
	G4	The 'own holding' exemption could be clarified to better reflect farming practices	Amend Regulation (EC) No 1768/95 to redefine the 'own holding' definition
	G5	There is scope to clarify the definition of 'equitable remuneration'	Amend Regulation (EC) No 1768/95 to redefine the 'equitable remuneration' definition

Category II Policy Options – Secondary Issues

		Issue	Option
H	H1	Courts in many MS do not have enough knowledge of CPVR-related issues to make informed judgements; similar court cases have different results	Develop a system of specialised national courts with knowledge of issues related to PVR
	H2	Courts in many MS do not have enough knowledge of CPVR-related issues to make informed judgements; similar court cases have different results	Develop a specialised EU-level court with knowledge of issues related to PVR
I	I1	There are differences between the UPOV 1991 definition of 'harvested materials' and that provided in the CPVR BR, which creates loopholes that prevent CPVR rights' holders from enforcing their rights in some cases	Amend the Basic Regulation to provide unqualified protection for harvested materials
	I2	There is scope to expand the protection for harvested materials to the products made from harvested materials	Extend scope of protection to products of harvested materials
	I3	There is scope to expand the protection for harvested materials to the transit of harvested materials	Extend scope of protection to the transit of harvested materials
J		There are interactions between access to information legislation and the CPVR BR which require clarification for the CPVO	Clarify procedures regarding access to information in cases of *lex specialis* with regarding to Article 88 pertaining to CPVR applications.
K	K1	DUS testing protocols do not include some important additional characteristics, which prevent varieties which are obviously distinct from obtaining CPVR protection	Adjust the testing protocols to account for additional characteristics
	K2	The information requirements where CPVO takes over a DUS report from a national PVR system are considered to be too burdensome	Reduce the information requirements where a DUS test report is taken over by CPVO from a national system
	K3	Communication between breeders, CPVO and testing centres could be improved to reduce the time lag between application and receipt of the grant (or rejection) and to improve the overall test results (e.g. reducing errors)	CPVO facilitates better communication between applicants/rights' holders and the CPVO, as well as the national testing centres
	K4	A fee payment lag has been identified for at least some testing centres, which creates a financial burden for testing centres	Assess the fee payment lag for national testing centres
	K5	Official licensing could be used to improve DUS testing results and reduce the costs	Consider official licensing for private companies to participate in DUS testing
L	L1	CPVO could further support the use of molecular markers for infringement cases	CPVO-led support for molecular marker use in infringement cases
	L2	CPVO could further support sample banking of genetic materials	CPVO-led support for sample banking of genetic materials
	L3	CPVO could further support outreach efforts to third countries	CPVO-led outreach to third countries
M		There are difficulties with the procedures to hire senior management in the CPVO	Amend the Basic Regulation to align hiring procedures with current Commission practices
N		There are some editorial errors in the Basic Regulation	Amend the Basic Regulation to correct any errors

Annex 16 Assessment of Potential Policy Options

Option A Assessment – Interaction with the S&PM Directive

There are links between the Seed Marketing Directives and the CPVR *acquis* where DUS testing and variety denomination are required for listing and certification (under the Seed Marketing Directives) and for plant variety protection (under the CPVR *acquis*). In some cases, two sets of DUS tests and variety denomination procedures are required where they may be protected by CPVR and nationally listed. Additional tests may be required where a CPVR has also received national plant variety protection. The 'one key, several doors' approach would remedy this duplication through DUS testing and variety denomination coordination via CPVO so that only one procedure is used for national listing, CPVR and national plant variety rights.

Option A: Adopt the 'One Key, Several Doors' Approach to DUS Testing and Variety Denomination

Parameter	Score	Comment
Contribution	+++	Efficiency gains and reduce administrative burdens could be achieved by removing duplicate requirements for common processes between the Seed Marketing Directives and CPVR *aquis.* The 'one key, several doors' approach would allow one DUS test and variety denomination procedure to satisfy the requirements for CPVR, national PVR and national certification purposes.
Feasibility	+	This option requires changes to the Basic Regulation. The S&PM Evaluation provides a preliminary assessment of this option's feasibility and basic requirements. DUS testing requirements would have to be harmonised across CPVR and seed marketing systems. Reference collections would require reassessment, which could prove a considerable challenge for MS with large collections and/or scarce funding. CPVO would require extra capacity and expertise to manage the system, as the number of certified plants is large, and does not perfectly overlap with CPVR or national PVR. The variety denomination database system would need to be complete and a system implemented to ensure adequate denomination checks against possible uses (CPVR, PVR, and certification).
Stakeholder support	++	Some plant breeders and MS representatives indicated a preference for the 'one key, several doors' approach to DUS testing and variety denomination. Tests would be conducted by audited and entrusted testing centres to reduce testing quality concerns across all three systems (CPVR, national PVR and certification).
Admin burdens and costs	(+)/(-)	The option proposed could significantly streamline procedures and reduce costs for plant breeders. As noted previously, however, the costs at CPVO and national testing centre costs may increase. These costs may need to be offset by increased application and testing fees. CPVO and national testing centres may lose income in some cases, because fewer tests will be performed. But where CPVO becomes responsible for all national listing tests, income may significantly increase due to a much larger number of required tests for national listing.
Coherence	++	This option would bring the Seed Marketing Directives and CPVR *acquis* into closer alignment. A working variety denomination checking system would also bring the CPVR *acquis* into closer alignment with geographical indications and thus the TRIPS Agreement.
Wider impacts	++	This option should facilitate the more efficient functioning of the EU market. Overall cost to plant breeders to obtain PVP and seed marketing ought to fall. Improvements made to reference collections could also facilitate the collection and conservation of EU biodiversity. Geographical indications have benefits for preserving traditional cultures, geographical biodiversity and regional markets, and the CPVR system contributes to those benefits through closer alignment with this IPR system.

Option B Assessment – Interaction with the patent system

The EU legislative framework for patents allows for overlap between patents and plant variety rights. EffectivelyThis is a major concern, particularly as patents become more prevalent in agricultural research. This option provides for CPVO to assemble and publish more information regarding plant-related patents and their implications for particular plant varieties. This could comprise a database of relevant patents, with commentary and discussion from CPVO regarding the potential impacts on plant varieties. Additional information (e.g. outside studies or CPVO-prepared analysis) could also be provided.

Option B: Improve Information Provision for Protected Varieties

Parameter	Score	Comment
Contribution	+	CPVO could be instrumental in reducing concerns regarding the overlap between patents and plant variety rights by facilitating breeders' knowledge about protected plant technologies that might overlap with protected plant varieties.
Feasibility	++	CPVO will need to keep track of plant-related patents and produce materials that help explain the implications of these patents to plant breeders. Expertise within CPVO will be required to prepare the database and prepare explanatory materials.
Stakeholder support	++	Some plant breeders indicated that better access to information about plant-related patents would enable them to make more informed decisions regarding their own research on plant varieties. Member State representatives also support initiatives that help to resolve problems between plant variety rights and patents.
Admin burdens and costs	-	Administrative burdens will be incurred to implement this system. A budget and funding mechanism would need to be identified.
Coherence	+	This option will help to improve coherence between the patent system and CPVR by informing plant breeders of potential overlap between the varieties for which they hold CPVR and for research to develop new varieties. In this way, breeders can be informed of the options and potential barriers they may encounter in their breeding programmes.
Wider impacts	++	Greater transparency and access to information on potential overlap between PVR and patents can facilitate EU breeding programmes, which may have positive impacts on agricultural development and the seed and propagating materials industry.

Option C Assessment – Interaction with the Enforcement Directive

There is a tension between the CPVR Basic Regulation on infringement procedures and the EU Enforcement Directive (2004/48/EC). There are a number of potential points of conflict which should be considered for revision, which are outlined in Table 4.2 of the main report. In particular, Articles 94 and 97 of the Basic Regulation have a high degree of conflict with the Enforcement Directive and should be amended.

Option C: Amending the Basic Regulation to make explicit rights holders' access to the Enforcement Directive in cases of infringement

Parameter	Score	Comment
Contribution	+	This option provides an additional opportunity for rights holders to enforce their CPVR and could provide additional confidence that there are mechanisms available to resolve their enforcement problems. The advantage of this option is that amendments to the Basic Regulation will provide rights holders with access to the strongest possible mechanism to enforce their right. Its impact, however, would be affected by the way the Directive itself has been implemented. Some Member States have not fully implemented the Directive or have done so unevenly. The Directive is of limited use until implementation is complete and uniform.
Feasibility	+++	Amending the Basic Regulation requires some changes to the text in the Basic Regulation provisions related to infringement procedures to align with the provisions in the Enforcement Directive.
Stakeholder support	+++	The majority of plant breeders and MS representatives indicated that enforcement is their primary concern regarding the CPVR system. Changes that may improve the overall issue of enforcement have high stakeholder support.
Admin burdens and costs	0	No additional administrative burdens or costs are expected to result from the recommended changes.
Coherence	+++	The Basic Regulation predates the Enforcement Directive by approximately ten years and therefore did not consider the Directive in its drafting. The intent of the Enforcement Directive is to provide legal tools and remedies for all matters related to intellectual property, including plant variety rights. Amending the Basic Regulation to align these two pieces of legislation would be a positive development in this regard.
Wider impacts	+	Where the Enforcement Directive operates as intended it should reduce enforcement problems for infringement cases and therefore facilitate better functioning of the EU market. Enforcement is also important for effective protection and exploitation of a plant variety right. Effective enforcement is essential to incentivising innovation in agriculture for the EU.

Option D Assessment – Extension to EFTA Countries

The European Free Trade Association (EFTA) promotes free trade and economic integration for these countries and is linked to the EU through trade agreements. This evaluation has considered the possibility of extending the CPVR *acquis* to EFTA countries in order to harmonise their plant variety rights systems with that of the EU.

Option D: Extend the CPVR *acquis* to EFTA countries

Parameter	Score	Comment
Contribution	+	This option does not address a recognised deficiency in the CPVR system, but rather attempts to bring policy and therefore trade relationships between the EU and EFTA countries into closer alignment.
Feasibility	++	If EFTA countries adopt the CPVR system they must also adopt EU legislation on variety listing and on intellectual property enforcement. This may pose a challenge for EFTA countries, where similar systems are not already in place, but should be straightforward where a similar system is already used.
Stakeholder support	++	All plant breeders, MS representatives and stakeholders contacted in Switzerland regarding this option consider this to be a positive development for the CPVR *acquis*.
Admin burdens and costs	+	Plant breeders can use one application process to obtain rights in the EU and EFTA countries, reducing administrative burdens. It may also increase EU plant breeders' competitiveness in EFTA countries. No additional burdens are expected for CPVO, as the CPVR application and testing procedures remain the same.
Coherence	+++	EFTA promotes free trade and economic integration for these countries and is linked to the European Union. Extending the CPVR system to EFTA countries would harmonise plant variety rights between the EU and EFTA countries, therefore bringing their trade polices closer into alignment.
Wider impacts	++	This option would significantly improve the level of protection afforded to breeders in EFTA countries. The current PVR protection in these countries is currently less comprehensive than it is under the CPVR system. It could also improve enforcement of plant variety rights. Additionally, many breeders operating at EU level already have close economic contacts with EFTA countries, and the extension offers additional opportunities to strengthen EU economic ties with EFTA countries.

Option E Assessment – EDV thresholds and protocols

There are no standardised protocols or thresholds developed by CPVO or Member States to determine EDVS, thought these instruments have been developed for a limited number of species by plant breeders' associations. Disagreements over EDV determinations can be difficult to resolve where there are no established procedures or thresholds, and industry would benefit from these, particularly in court procedures. CPVO could play a greater role in assisting industry develop standardised approaches to determining EDVS for the most economically important species.

Option E: CPVO-led support for protocol development to determine EDVs and support dispute resolution

Parameter	Score	Comment
Contribution	++	The International Seed Federation and CIOPORA have each, with assistance from industry, developed several crop specific protocols and thresholds that can reverse the burden of proof in favour of the initial variety right's holder in EDV disputes. The involvement of the CPVO in this process can lend credibility and legitimacy to the process, and its expertise can add to the robustness of each protocol. The potential for such protocols to assist with assessing EDVs is significant and can help resolve enforcement concerns in this area.
Feasibility	++	Industry has supported thresholds and protocols for those plant varieties that are most economically important and most subject to infringement (e.g. roses). These can provide models for the further development of species-specific protocols. Each species must have its own protocol developed, however, as the criteria to determine EDVs can differ widely among species. This could be a laborious and time-consuming process, and may be unwarranted for species where EDVs are less prevalent or their infringement does not pose a significant economic concern to breeders.
Stakeholder support	++	Breeders favour establishing protocols and thresholds that are set through engagement between the CPVO and industry. Breeders stressed the need for a uniform protocol, because currently the variance in technical determination methods often yields different results.
Admin burdens and costs	--	As indicated above, the costs of producing protocols can be high, as a protocol is in theory required for each species. Development of a species-specific protocol may be unwarranted in cases where EDVs are less prevalent or their infringement is not economically important to breeders. Protocol development will be facilitated by the models already in existence, but each species will have to be judged on the particular merits of developing a specific protocol based on the costs involved and returns expected. This process must occur on a case-by-case process and would require assessment by industry and CPVO, accordingly. Where industry wishes to develop protocols, additional funding from the benefitting parties may be required to ensure that CPVO can continue to operate on a cost recovery basis.
Coherence	++	Protocols can be used both for CPVR and for plant variety rights at the national level. There are thus implications for the assessment and enforcement of national-level PVR under this option. This would be a positive development for national PVR for the same reasons as described for CPVR and would pose no foreseen conflicts.
Wider impacts	+	As with other enforcement-related issues, improving enforcement should facilitate better functioning of the EU market. It would also help ensure more fair and transparent global trading practices. Enforcement is essential to a rights holder's ability to effectively protect and exploit their invention. Effective enforcement is essential to incentivising innovation in agriculture for the EU.

Option F Assessment – Extend the duration of protection on a case-by-case basis

On average, a CPVR 'lifespan' is much shorter than the duration of protection offered through the *acquis*. Nevertheless, varieties require longer periods to obtain a return on investment than others, and may extend beyond the available protection duration. For these varieties, the duration may be extended on a case-by-case basis, with an application for extension made by the rights' holder as the CPVR approaches the end of its protection period (e.g. 20 years, for varieties offered 25 years of protection). The decision to grant the extension would only be made at this point, rather than during the original application process.

Option F: Extend the duration of protection on a case-by-case basis

Parameter	Score	Comment
Contribution	+	The time required for costs to be recovered varies greatly by plant species, and depends on breeding programme costs over a 5 to 12 year period, as well as the popularity of the new cultivar and the duration of that popularity. Some plant varieties, particularly varieties of species of tree, vine, potato, and a few types of fruits and vegetables may warrant longer protection durations than currently provided in the legislation.
Feasibility	+	The Basic Regulation would require amendment. Additionally, this option would require the development of a new assessment process to determine which plant varieties would receive extended protection. Protocols must be developed to assess each extension request. The number of expected cases, based on observed trends in CPVR, is likely to be small, however.
Stakeholder support	+++ -- 0	The plant breeding industry strongly supports extensions for some plant varieties. Other stakeholders presented a mixed view, suggesting that there are species and cases deserving of extended protection, and others indicating the duration is already sufficient. Grower responses indicate that the duration of protection is currently sufficient; a few growers indicated that the durations are currently excessive. The majority of Member State representatives indicated that the current durations of protection are sufficient.
Admin burdens and costs	-	The case-by-case approach would require ongoing assessment procedures by CPVO. Additional administrative costs to CPVO are a potential drawback to this option, but could be offset through setting an appropriate fee for processing the extension. The estimated number of varieties where an extension may be granted is expected to be fairly small, based on current trends in CPVR protection.
Coherence	--	Trademarks may be extended on a case-by-case basis, which aligns with one of the sub-options presented here. Patents and trademarks receive shorter durations of protection, however, so extending the duration is a move away from the durations set in other areas of IPR (with the exception of copyright, which has a longer duration of protection). National PVR systems currently have similar or less lengthy durations of protection as the CPVR system, with the exception of the Netherlands.
Wider impacts	(+)/(-)	Breeding programmes may expand for some species where current durations prevent adequate returns on investment, thus improving the availability of new varieties for agricultural production. Extensions would need to be made for short periods of time (e.g. five years) to ensure that the system remains balanced in terms of ensuring that plant materials are also available for further research and development.

Option G1 Assessment –Amend the provision of information requirements in the agriculture exemption

CPVR holders currently find it difficult to obtain royalties for FSS use due to ECJ rulings that limit their ability to request information from farmers. Amending the Basic Regulation to obligate growers to declare whether they have used farm saved seed ('yes' or 'no') relieves the burden on breeders to discover its use. This option leaves the terms of license and payment collection obligations unchanged. A designated authority would be required to make the request on behalf of the breeders—either an organisation chosen by breeders or a Member State authority where an organisation is not designated.

Option G1: Amend the provision of information requirements

Parameter	Score	Comment
Contribution	++	Amending the Basic Regulation to require growers to indicate whether they have used FSS could greatly facilitate the ability of rights' holders to enforce CPVR and provide them with additional confidence that there are mechanisms available that will adequately resolve their enforcement problems. The advantage of this option is that it will provide rights holders with a procedure for collecting information about farm saved seed use that is still in keeping with the judgment in *Schulin v STV*. It also creates a more level playing field for growers in different Member States. Its impact, however, would be affected its implementation. Different MS have implemented farm saved seed provisions differently and in many cases, not at all. This option is of limited use until all MS implement FSS royalty collection systems. This option will not prevent wilful evasion where farmers choose to indicate they are not using farm saved seed in cases where they are in fact using FSS.
Feasibility	+	This option requires changes to the Basic Regulation, and the FSS Working Group has already outlined a preliminary set of procedures and responsibilities. Implementation may be quite difficult, however, particularly where MS representatives and authorities are reluctant to be involved in what they view (and the legislation has previously indicated) to be a private matter. Additionally, in MS with many small farmers, information collection may still prove time consuming and costly.
Stakeholder support	++	The majority of plant breeders and MS representatives indicated that enforcement is their primary concern regarding the CPVR system. Changes that may improve the overall issue of enforcement have high stakeholder support. In particular, the ability to successfully collect information regarding farm saved seed use was one of the most often cited potential resolutions to enforcement issues faced by breeders. Growers in many cases are eager to arrive at a resolution that is flexible, does not add administrative burdens and ensures the system is fair for all growers—for those who plant only certified seed and do not use FSS, those who use FSS legally, and those who evade FSS royalty collection.
Admin burdens and costs	-	Member State and Commission resources would be required for the amendment of the Basic Regulation to accommodate this change. Where the system is implemented, the administrative burdens may initially be high where a MS does not already designate an authority or other organisation to make the FSS request. Additional costs will fall to a designated organisation where one is chosen to collect information, but additional royalty collection opportunities should help to offset system operating costs. Where an authority collects information, the form establishing the request should represent a minimal administrative burden. This option should not present significant additional burdens on growers, particularly where the request is made through the Single Farm Payment Form, with which growers are already familiar.
Coherence	++	This option allows breeders to collect information on FSS use (per provisions in the Basic Regulation), but is within the meaning of the ECJ decision in *Schulin v STV.* This proposal also coheres with the opportunities for farm saved seed systems set out in UPOV.
Wider impacts	+	Where MS implement this option and associated measures fully, it should reduce enforcement problems related to farm saved seed use and therefore facilitate better functioning of the EU market. Effective enforcement is essential to incentivising innovation in agriculture for the EU.

Option G2 Assessment – Redefine the 'small farmer' exemption in Regulation (EC) No 1768/95

The 'small farmer' definition in Regulation (EC) No 1768/95 is no longer in use for the purposes of determining exemptions from royalty payments for FSS. Member States no longer record nor calculate the size of small farmers. Thresholds currently differ across MS, creating confusion and inconsistency across the EU. Redefining the exemption using common guidelines and enforcement procedures could help to resolve these issues.

Option G2: Redefine the 'small farmer' exemption in Regulation (EC) No 1768/95

Parameter	Score	Comment
Contribution	++	The 'small farmer' definition in Regulation (EC) No 1768/95 is no longer in use for the purposes of determining exemptions from royalty payments for FSS. Member States no longer record nor calculate the size of small farmers. Thresholds currently differ across MS, creating confusion and inconsistency across the EU. Redefining the exemption using common guidelines and enforcement procedures could help to resolve these issues.
Feasibility	-	Common guidelines for defining 'small farmers' may be hard to agree due to variance in agricultural practices across the EU. For example, farm size criteria negatively affect farmers where a larger farm size obscures low yields.
Stakeholder support	+	Both the breeding industry and farming groups cite lack of cooperation from public authorities in establishing appropriate guidelines for determining who qualifies as a 'small farmer' and establishing effective enforcement procedures. Most breeders believe the exemption should be amended. Growers and MS representatives also support amendments.
Admin burdens and costs	-	Administrative burdens will be incurred to agree and develop guidelines and procedures for defining 'small farmers' in different EU MS. Implementing the guidelines for royalty collection purposes may be costly to all parties
Coherence	++	UPOV recognises exceptions to plant breeders' rights including a 'small farmer' exemption. Furthermore, a new definition of small farmer will likely be adopted within the CAP reform that will take place before the end of 2013. At that time, there may be an opportunity for the CPVR to adopt the new definition within the CAP framework, thus simultaneously harmonising the definition across these pieces of EU legislation.
Wider impacts	+	The exemption helps to support the rural economy (e.g. family farms) and disadvantaged groups (e.g. semi-subsistence farms) but does not work in practice. Establishing new guidelines for who qualifies as a 'small farmer' can improve the viability of this exemption for breeders and growers while keep with these wider objectives.

Option G3 Assessment – Remove the 'small farmer' exemption from Regulation (EC) No 1768/95

The 'small farmer' definition in Regulation (EC) No 1768/95 is no longer in use for the purposes of determining exemptions from royalty payments for FSS. Member States no longer record nor calculate the size of small farmers. Thresholds currently differ across MS, creating confusion and inconsistency across the EU. Breeders would like to see the 'small farmer' exemption removed from Regulation (EC) No 1768/95.

Option G3: Remove the 'small farmer' exemption in Regulation (EC) No 1768/95

Parameter	Score	Comment
Contribution	+	The 'small farmer' definition in Regulation (EC) No 1768/95 is no longer in use for the purposes of determining exemptions from royalty payments for FSS. Removing the exemption would allow rights' holders to decide whether or not to pursue royalty payments based on a cost-benefit basis, which could improve uptake of the CPVR system in MS with a large number of small farmers. Equally, removing the exemption may not substantially alter the number of farmers for which royalty payments are sought.
Feasibility	--	This option requires a change to Regulation (EC) No 1768/95. It is likely to receive substantial opposition from farmers and stakeholder groups that support rural development and agriculture across the EU. It may be politically infeasible.
Stakeholder support	++ --	Breeders strongly support removing the 'small farmer' exemption. Growers and Member State representatives strongly oppose this option.
Admin burdens and costs	(+)/(-)	This option will require modest administrative burdens with respect to implementing the change. Rights' holders incur some costs to pursue these growers, but rights' holders are free to choose whether or not to pursue royalties from these growers based on their own cost-benefit analysis. Growers will incur costs for royalty payments where they were previously exempted.
Coherence	+	UPOV recognises exceptions to plant breeders' rights including a 'small farmer' exemption. Nonetheless, removing the exemption is an option available to signatories to UPOV 1991.
Wider impacts	--	The exemption helps to support the rural economy (e.g. family farms) and disadvantaged groups (e.g. semi-subsistence farms). Removing it will remove the support that it provides to farmers in line with these objectives.

Option G4 Assessment – Redefine 'own holding' in Regulation (EC) No 1768/95

UPOV 1991 allows farmers to sow farm saved seed for particular varieties on their 'own holding' if they pay 'equitable remuneration' to the rights' holder each year. Both growers and breeders cite dissatisfaction with the 'own holding' definition. The 'own holding' definition could be redefined and harmonised across EU Member States to reflect modern farming practices and reduce uncertainties regarding what qualifies as an 'own holding'.

Option G4: Redefine 'own holding' in Regulation (EC) No 1768/95

Parameter	Score	Comment
Contribution	+	The current definition of 'own holding' may not adequately reflect modern farming practices. This creates additional problems for farmers where the 'own holding' definition does not correspond with how farm businesses are structured. Moreover, the variation in the definition of 'own holding' across MS may create market distortions and confusion for farmers with multiple holdings in different EU MS. Clarifying the 'own holding' definition and harmonising it across the EU could help to correct these problems.
Feasibility	-	This option requires changes to the list of exempted species in Regulation (EC) No 1768/95. MS will also need to change their definitions in line with any new guidelines. In practice, it may be difficult to agree a new definition of 'own holding', where different farming practices across the EU complicate both widening and narrowing the definition.
Stakeholder support	+	Breeders prefer a stricter definition that confines 'own holding' to a single, contiguous property. Growers prefer a broader definition that accommodates changing farming practices, including businesses with multiple properties in a single Member State or with multiple properties in more than one Member State. Both groups would like to see the definition amended.
Admin burdens and costs	+	Some Member State and Commission resources would be required for the amendment of Regulation (EC) No 1768/95 to accommodate this and other proposed changes.
Coherence	+	One option is to adopt the definition of a 'holding' per the Single Farm Payment scheme (i.e. the farm covered by the SFP registration number), so that a farm 'holding' under the SFP definition is the same as the 'own holding' definition under the CPVR system. Changing the 'own holding' definition to correspond with the CAP definition of a farm for the Single Farm Payment would help align Common Agricultural Policy with the CPVR system and eliminate discrepancies in the 'own holding' definition among Member States. Where Member States decide to use the Single Farm Payment form as a way to collect information on farm saved seed use, aligning the definitions would also reduce potential confusion from farmers as to what farm saved seed applies in a given case.
Wider impacts	(+)/(-)	This option needs to be carefully investigated to ensure that it does not define 'own holding' too narrowly considering modern farming practices.

Option G5 Assessment – Assess and redefine 'equitable remuneration' in Regulation (EC) No 1768/95

Regulation (EC) No 1768/95 provides for two situations: one in which the rights holder and the grower agree to a remuneration level and one in which the parties cannot agree (whereby the remuneration level is fixed at 50% of the cost for licenses propagating material. 'Equitable remuneration' could be adjusted to provide for additional remuneration levels to accommodate a variety of species and/or circumstances.

Option G5: Assess and redefine 'equitable remuneration' in Regulation (EC) No 1768/95

Parameter	Score	Comment
Contribution	+	The '50% rule' may represent a market distortion because other pricing levels are theoretically available (market-led pricing) that could be agreed between rights' holders and growers that are higher or lower than this level.
Feasibility	+	This option requires assessing the definition's coherence with UPOV and potentially amending Regulation (EC) No 1768/95.
Stakeholder support	+	Breeders are dissatisfied with the current definition of 'equitable remuneration', indicating that it interferes with a functioning market-led resolution to 'equitable' remuneration levels. Grower responses were very limited, but the few who responded to the survey indicated that the concept is important but should not create market distortions.
Admin burdens and costs	-	Some administrative burdens for the Commission will result from reviewing the 'equitable remuneration' definition and proposing alternatives.
Coherence	+	The definition in Regulation (EC) No 1768/95 indicates that equitable remuneration must be 'sensibly lower' than the cost of licensed seed for that variety. The 'sensibly lower' wording is not present in the UPOV Convention and therefore may not be in alignment with UPOV as a result. This wording requires review before any additional remuneration levels are considered in order to ensure that the UPOV and CPVR definitions are compatible.
Wider impacts	+	This option could help to resolve unfair competition across EU markets where 'equitable remuneration' levels vary on products traded between Member States.

Option H1 Assessment – Introduce specialised national courts for PVR cases

CPVR enforcement is one of the most important issues to stakeholders consulted for this evaluation. In particular, rights' holders are not able to effectively resolve infringement disputes because the costs of courts cases far outweigh their perceived benefit where courts do not have appropriate or adequate specialised knowledge regarding intellectual property rights-related issues and for CPVR in particular. Specialised national courts, which already operate in some MS, could help to alleviate this problem.

Option H1: Specialised national courts (i.e. one or more PVP-designated court per Member State)

Parameter	Score	Comment
Contribution	+	Specialised national courts could reassure rights' holders that robust mechanisms are available to them for enforcing their rights. Such courts have the added benefit of understanding issues particular to a MS. In MS where a significant number of CPVRs are held, specialised courts could make an important contribution to reducing contradictory judgments on similar cases within the same MS. In MS where few CPVR are held, specialised courts would have far less impact because they would not have the opportunity to accumulate sufficient specialised knowledge. CPVR are an EU-wide right, however, and it is possible that the same infringement case is heard before national courts in several MS. Variation among national systems may still result in different results on the same issue, for the same CPVR.
Feasibility	++	A similar system already exists in other areas of intellectual property rights, specifically for the Community Trademark Regulation and Design Regulations. Where competent courts are already authorised for trademark and design cases, CPVR cases could also be heard. Currently, three Member States already have specialised courts for CPVR cases, three have designated courts (i.e. for IPR cases, including patents and trademarks), and the remainder have no such specialised courts. Developing new designated courts where they did not previously exist could be accomplished by modelling them on those that operate in other Member States. It is likely that in practice such a court would not only hear cases related to CPVR, as the costs of such a system are likely to far outweigh the number of cases supporting such a system. Rather, a designated court might specialise in IPR-related issues more broadly alongside those cases it hears in other areas of law.
Stakeholder support	++	Breeders support the option of specialised or designated courts in each MS. They believe such as system will significantly improve their ability to enforce CPVR. Designated national courts would also increase the probability that stakeholders could utilise their native/preferred language in the proceedings and that proceedings would be more familiar (than for regional courts or an EU-wide court).
Admin burdens and costs	(+)/(-)	No additional administrative burdens or costs are expected for MS where such courts already exist, except where expertise in their design may be needed to assist in setting up similar courts in other MS. In MS where no such courts currently exist, the initial design and implementation burdens and costs may be high, though as specialised knowledge is acquired, the costs should be lower than in the *status quo* scenario as cases are processed more efficiently and effectively. Costs to the parties may be higher than the *status quo* scenario, where travel times are increased to the competent court, but costs may be lower than for an EU-wide court. More detailed examination of the viability of the option would be required as a separate exercise if it was decided to take this option forward. Issues include demand, establishment and operational costs, as well as the likelihood that travel times and other administrative costs may increase or decrease.
Coherence	++	A similar system already exists for the Community Trademark Regulation and for the Design Regulations. Competent national courts are also already operating to hear patent cases. Specialised or designated courts cohere with similar enforcement opportunities available under different intellectual property rights systems in the EU.
Wider impacts	++	Improving enforcement should facilitate better functioning of the EU market. Enforcement is essential to a rights holder's ability to effectively protect and exploit their invention. Effective enforcement is essential to incentivising innovation in agriculture for the EU.

Option H2 Assessment – Introduce a specialised EU-level court for PVR cases

CPVR enforcement is one of the most important issues to stakeholders consulted for this evaluation. In particular, rights' holders are not able to effectively resolve infringement disputes because the costs of courts cases far outweigh their perceived benefit where courts do not have appropriate or adequate specialised knowledge regarding intellectual property rights-related issues and for CPVR in particular. An EU-level court dedicated to IPR issues, with specialised knowledge of CPVR-related issues could help to alleviate this problem.

Option H2: Specialised EU court (i.e. one EU-level court)

Parameter	Score	Comment
Contribution	++	A single court would have the greatest focus on CPVR cases and therefore offer the greatest assurance of consistent outcomes. An EU-wide court would have the added benefit of concentrating CPVR-related knowledge to the greatest degree among the two proposed scenarios. Experience and expertise could be aggregated among all MS. This option reduces the likelihood of different outcomes for similar cases due to national or regional interpretation of CPVR rules. A drawback is the lack of the understanding of issues particular to a MS that MS-level courts could provide.
Feasibility	+	The patent court proposal[62] includes a EU wide central court at the appellate level as part of the two tier mechanism. No similar system yet exists in other areas of intellectual property rights, but proposals have been drawn up that weigh the merits and demerits of such a system for patents. Developing a new EU court system where one does not previously exist could prove to be a challenge, though the patent proposals could be taken as a comparative preliminary assessment and may offer potential models. The ECJ recently rejected the patent court proposal in its current form, which reduces the likelihood of its establishment.
Stakeholder support	++	The majority of breeders and MS representatives support the option of specialised or designated courts. They believe such a system will significantly improve their ability to enforce CPVRs. Language barriers could pose a challenge for the parties, as a limited set of EU languages would like be used in an EU-wide court. Due consideration must be given to the ability of claimants to travel to such a court.
Admin burdens and costs	(+)/(-)	The burdens and costs in the design and implementation of an EU court system could be high. Over time, however, as specialised knowledge is acquired, the costs should be lower than in the alternative scenarios presented above, as cases are processed more efficiently and effectively. More detailed examination of the viability of the option would be required as a separate exercise if it was decided to take this option forward. Costs to the parties may be higher than the alternative scenarios, where travel times are increased to the specialised court. Further investigation is required to determine whether travel times and other administrative costs are likely to increase or decrease as a result of a specialised EU court.
Coherence	+	No similar systems exist in other areas of intellectual property, though there are models in other areas of law, e.g. the European Court of Human Rights.
Wider impacts	++	As with other enforcement-related issues, improving enforcement should facilitate better functioning of the EU market. Enforcement is essential to a rights holder's ability to effectively protect and exploit their invention. Effective enforcement is essential to incentivising innovation in agriculture for the EU.

[62] Commission of the European Communities (2007) *Communication from the Commission to the European Parliament and the Council—Enhancing the patent system in Europe,* Brussels, 3.4.2007, COM (2007) 165 final.

Option I1 Assessment – Expand the scope of protection for harvested materials by amending the definition of protection

UPOV 1991 extends the breeder's ability to enforce rights against unauthorised multiplication of the protected variety. The scope of protection is extended in the same way in the CPVR Basic Regulation. The protection of harvested material is not sufficiently well-defined in the Basic Regulation, however, resulting in uncertainties and loopholes in the protection that a breeder can expect from a CPVR. This could be corrected by ensuring the language for harvested materials is identical in the Basic Regulation to that provided by UPOV.

Option I1: Amend the definition of protection for harvested materials

Parameter	Score	Comment
Contribution	++	The scope of protection for harvested materials provided by UPOV 1991 should in principle be extended in the same way in the CPVR Basic Regulation. Some stakeholders have argued that the protection of harvested material is not sufficiently well-defined in the CPVR legislation, resulting in uncertainties and loopholes in the protection that a breeder can expect from a CPVR. This is a particular problem for varieties protected in the EU but grown illegally in third countries and then imported back into the EU. The Basic Regulation does not grant unqualified protection to the harvested material of CPVR-protected varieties. Amending Article 13(3) so as to provide for the unqualified protection of harvested material may enable plant breeders to better enforce their right when 'illegally grown' plants from a third country are imported into the EU.
Feasibility	+++	This option would require an amendment to the text of the legislation. The new language would have to conform to UPOV's rules.
Stakeholder support	++ -	Plant breeders strongly support better aligning the scope of protection for harvested materials in the Basic Regulation with UPOV. Growers are concerned about the impact this may have on infringement claims for harvested material produced in the EU. Where plant material is grown legally, however, the provisions related to harvested material should not apply in any case.
Admin burdens and costs	(+)/(-)	Changes to the text of the Basic Regulation should present low or no additional administrative burdens or other costs on stakeholders. The effects of these changes, however, may be costly to growers if they result in a substantial increase in unwarranted infringement claims on harvested materials.
Coherence	+++	These changes will bring the CPVR legislation and UPOV into closer alignment. This will improve coherence between the CPVR system and the international instrument on which it is based.
Wider impacts	++	As with other enforcement-related issues, improving enforcement should facilitate better functioning of the EU market. It would also help ensure more fair and transparent global trading practices. Enforcement is essential to a rights holder's ability to effectively protect and exploit their invention, and to incentivise innovation in agriculture for the EU.

Option I2 Assessment – Expand the scope of protection for harvested materials by extending protection to products made from protected varieties

UPOV 1991 provides the option to extend the scope of protection for harvested materials to the products made from protected varieties. Some plant breeders strongly support this possibility, and particularly where products return to the EU from third countries, which were produced from illegally propagated protected varieties.

Option I2: Extend the scope of protection to products made from protected varieties

Parameter	Score	Comment
Contribution	+	Extending the title holder's rights to products made from protected varieties (where the rights holder is unable to exercise his right in relation to the use of propagating material or harvested material cf. Art. 14(3) UPOV 1991) could help reduce the enforcement problems related to illegally propagated materials returning to the EU as processed materials such as apple juice or perfume.
Feasibility	--	UPOV provides the option for its members to extend the scope of protection in this way. But while the problem lies in particular sectors (e.g. ornamentals and fruits), changes would extend to all agricultural sectors and would apply equally to cases within the EU as to those between a CPVR holder and a third country grower/producer. The scope of protection would be widened significantly, bringing with it the potential for rights holders to exert control across most of the food supply chain. There are likely to be significant challenges for enforcement. It is likely to bring parties into infringement cases who should not otherwise be involved (e.g. food manufacturers and retailers). Finally, it is difficult to prove the use of protected varieties in such products.
Stakeholder support	+ ---	This option is strongly supported by some plant breeders This option is widely unpopular with growers.
Admin burdens and costs	(+)/(-)	Implementing the change is likely to result in few costs. Excessively high costs may result from infringement cases, however.
Coherence	+	This option coheres with UPOV provisions.
Wider impacts	--	This option, while providing a degree of additional support to breeders in the range of available options for enforcing their rights, is not proportionate to the expected impacts of such a change across the food supply chain.

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Option I3 Assessment – Expand the scope of protection for harvested materials by extending protection to transit of harvested materials

UPOV 1991 provides the option to extend the scope of protection for harvested materials to the transit of protected varieties. Some plant breeders strongly support this possibility, and particularly where products are transiting through the EU upon entry from third countries, where the harvested materials were produced through illegally propagated protected varieties.

Option I3: Extend the scope of protection to the transit of protected harvested materials

Parameter	Score	Comment
Contribution	+	Extending the title holder's rights to the transit of harvested material from protected varieties (where the rights holder is unable to exercise his right in relation to the use of propagating material or harvested material cf. Art. 14(3) UPOV 1991) could help reduce the enforcement problems related to illegally propagated materials returning to the EU.
Feasibility	--	UPOV provides the option for its members to extend the scope of protection in this way. But while the problem lies in particular sectors (e.g. ornamentals and fruits), changes would extend to all agricultural sectors and would apply equally to cases within the EU as to those between a CPVR holder and a third country grower/producer. This significantly extends the scope of protection. There are likely to be significant challenges for enforcement, as the case law of the ECJ on transit of trademarked goods is not very favourable for trademark holders who wish to act against transit of e.g. counterfeiting goods.
Stakeholder support	+ ---	This option is strongly supported by some plant breeders This option is widely unpopular with growers.
Admin burdens and costs	(+)/(-)	Implementing the change is likely to result in few costs. Excessively high costs may result from infringement cases, however.
Coherence	+	This option coheres with UPOV provisions.
Wider impacts	-	This option, while providing a degree of additional support to breeders in the range of available options for enforcing their rights, is not proportionate to the expected impacts of such a change across the EU market.

Option J Assessment – Clarify access to information legislation for CPVO

The CPVO would like to have greater clarity on the rules regarding public access to documents and which of the available appeal procedures should be applied in a given case. Complexity arises as a result of the interplay between information access provisions in the CPVR Basic Regulation and the more recent Public Access Regulation (1049/2001/EC).

Option J: Clarify access to information requirements for CPVO

Parameter	Score	Comment
Contribution	+	Amending the Basic Regulation to align the BR with access to information legislation would assist the CPVO in carrying out its duties with respect to providing access to information.
Feasibility	++	This option requires an amendment to the Basic Regulation.
Stakeholder support	+	The CPVO favours clarification in the legislation regarding the exceptions which apply to the rules on access to documents and which appeal procedure should be applied. No other stakeholders raised this issue.
Admin burdens and costs	++	This option will reduce the administrative burdens on CPVO where 'access to information' issues arise. No additional costs or burdens are anticipated.
Coherence	++	This option will bring the CPVR Basic Regulation and Council Regulation (EC) No 1049/2001 into closer alignment.
Wider impacts		N/A

Option K1 Assessment – Improve application and testing procedures by adjusting testing protocols to accommodate additional characteristics

The CPVO Administrative Council adopts protocols specifying testing protocols and reporting requirements, which are based on the relevant UPOV guidelines, where a species is covered by such guidelines. Some Member State representatives indicated, however, that the guidelines are not flexible enough to be adapted, for example, to additional characteristics of interest in a particular MS or for a particular species (e.g. disease resistance). CPVO should consider whether additional characteristics can be added to accommodate important traits that are not readily identifiable through the current protocols.

Option K1: Adjust testing protocols to accommodate additional characteristics

Parameter	Score	Comment
Contribution	+	There are some characteristics that are not adequately covered by the current testing protocols. For example, lettuce varieties are increasingly differentiated largely on the basis of their disease resistance, which is also their most important economic benefit. This would allow varieties which are clearly different to be considered for CPVR protection.
Feasibility	--	The President of the CPVO is empowered to add characteristics to the current guidelines; the President will only act on this issue when it has been thoroughly examined at UPOV level. Changes are unlikely without an initiative by UPOV in this matter.
Stakeholder support	+	Some breeders and Member State representatives have indicated support for this option, but it is not a high priority.
Admin burdens and costs	(+)/(-)	Some administrative burdens will be incurred for each additional characteristic under consideration. The associated costs are unknown. This issue requires further investigation.
Coherence	(+)/(-)	This option would need to be considered in light of the possibilities afforded by UPOV 1991 rules
Wider impacts	++	Additional characteristics may include traits that are important for achieving environmental objectives (e.g. disease resistance or drought tolerance) and responding to consumer preferences (e.g. taste and smell of foods).

Option K2 Assessment – Improve application and testing procedures by reducing information requirements where a DUS report is taken over by CPVO from a national system

Where CPVO takes over DUS test reports from national authorities in support of a CPVR, stakeholders suggest that it is unnecessary to request all correspondence between the applicant and the examination office that conducted the test. CPVO could review its documentation requests and consider reducing these requirements.

Option K2: Reduce information requirements where a DUS report is taken over by CPVO from a national system

Parameter	Score	Comment
Contribution	(+)/(-)	This option would reduce the burdens on plant breeders where a DUS report is taken over by CPVO from a national PVR system. A lack of all necessary information could be problematic in view of (later) appeal proceedings before the Board of Appeal and other courts.
Feasibility	++	This option would be easy to implement
Stakeholder support	+	Some plant breeders support this option.
Admin burdens and costs	+	Currently, the requirements are seen to create an unnecessary administrative burden for plant breeders; this option would reduce or eliminate that burden
Coherence		N/A
Wider impacts		N/A

Option K3 Assessment – Improve application and testing procedures by facilitating communication amongst applicants, testing centres and CPVO

The stakeholder consultation indicated that some breeders are dissatisfied with the level of communication between CPVO and applicants, as well as applicants' ability to contact the testing centre for their plant variety. This could be improved through increased and more efficient communication, led by CPVO. Breeders could be in closer and more direct contact with testing centres, as well, in order to avoid delays where additional information is required.

Option K3: CPVO facilitates better communication amongst applicants, testing centres and CPVO

Parameter	Score	Comment
Contribution	+	Better communication between CPVO and applicants could improve testing results (e.g. reducing testing mistakes) and reduce the time required to conduct tests
Feasibility	+	Improved communication can be facilitated by mechanisms to allow applicants to directly contact CPVO and to have direct access to the national testing centres
Stakeholder support	+	Some plant breeders observed that closer interaction between breeders and CPVO staff would be an improvement in the application process.
Admin burdens and costs	-	Administrative costs to facilitate communication are expected to be minimal
Coherence		N/A
Wider impacts		N/A

Option K4 Assessment – Improve application and testing procedures by assessing the fee payment lag for national testing centres

There may be a time lag between conducting a DUS examination and receipt of the fee from CPVO to cover the costs of the tests. In these cases, testing centres must subsidise the cost of testing until payment is received. Additionally, the rules regarding fee payment by CPVO indicate that 100% of the fee should be provided on commencement of the test, rather than on or after completion.

Investigate reported delays between testing and receipt of payment by testing centres.

Option K4: Assess the fee payment lag for national testing centres

Parameter	Score	Comment
Contribution	+	Some MS representatives indicated that the fees are not actually paid until significant time has passed following test completion, which is a significant burden on testing centres. Prompt reimbursement (according to the rules set out by CPVO, i.e. upon test commencement, or according to standard payment delivery practices, e.g. within 60 days of test completion) would help to resolve the problem.
Feasibility	(+)/(-)	Further investigation is required as to the cause of the payment delay in order to better understand whether it can be improved.
Stakeholder support	+	Some Member State representatives support this option, but it was not an issue raised by most representatives.
Admin burdens and costs	+	One Member State representative indicated that the lag between DUS testing and payment by CPVO is two years, creating an unnecessary burden on the examination offices as they must therefore pre-finance testing. Correcting this problem could be a significant benefit to testing centres.
Coherence		N/A
Wider impacts		N/A

Option K5 Assessment – Improve application and testing procedures by licensing private companies to conduct DUS tests

The application and testing procedures could be improved both in their quality and efficiency in conducting the tests and processing the applications. In particular, some breeders are concerned that some testing centres lack the appropriate infrastructure to conduct high quality DUS tests. To resolve these issues, breeders' organisations could be licensed to conduct administration, DUS tests and data analysis (but would not be involved in decision making).

Option K5: Consider licensing of private companies to conduct DUS tests

Parameter	Score	Comment
Contribution	+	This option could improve testing quality where the industry reference collections are more comprehensive than public collections. This could also alleviate issues related to inefficiencies arising from expanding reference collections at Member State level.
Feasibility	-	Industry participation in DUS testing already occurs in some MS; its viability on a wider scale would require further exploration. Some conflicts may arise with respect to the existing official testing infrastructure and the respective powers of those testing centres. The future relationship between those offices and licensed breeder's organisations may be negatively impacted. There is also potential for conflict amongst breeders where neutrality in testing cannot be verified.
Stakeholder support	+	Some breeders support the possibility of wider industry participation in DUS testing.
Admin burdens and costs	-	Cost efficiencies could result where the industry reference collections are more comprehensive than public collections and where tests could be conducted with less expense.
Coherence		N/A
Wider impacts		N/A

Option L1 Assessment – Implement capacity-building measures within CPVO through promotion of molecular marker use in infringement cases

Enforcement is a primary concern for CPVR holders. Molecular markers could be used to a greater extent in infringement cases to assess plagiarism and fraud in CPVRs. CPVO could facilitate the development of protocols and standards, as well as help to determine the freedom to operate in using different proprietary tools.

Option L1: CPVO-led for molecular marker use in infringement cases

Parameter	Score	Comment
Contribution	+	The benefits of molecular marker testing include speed, replicability and increasing affordability.
Feasibility	--	Barriers include difficulty in determining appropriate methods, protocols, standards and freedom to operate for using molecular marker tools. These barriers are significant and require further investigation to assess whether they can be sufficiently overcome.
Stakeholder support	+	Breeders and some Member State representatives support the use of molecular markers to assist in determining infringement claims, but were careful to note that this method should be used in conjunction with, but not instead of, morphological and other assessments.
Admin burdens and costs	(+)/(-)	The administrative burdens and associated costs could be high to support decisions on the use of particular tests, the tests themselves and ongoing research regarding innovations in the methods and techniques. But costs may also be reduced for testing and verifying infringement claims. The balance of costs is unclear and requires further investigation.
Coherence		N/A
Wider impacts	+	As with other enforcement-related issues, improving enforcement should facilitate better functioning of the EU market. It would also help ensure more fair and transparent global trading practices. Enforcement is essential to a rights holder's ability to effectively protect and exploit their invention, and to incentivise innovation in agriculture for the EU.

Option L2 Assessment – Implement capacity-building measures within CPVO through support for sample banking of genetic materials

Genetic materials are currently banked at testing centres on a small scale, at the breeder's request, to provide a sample for use in enforcement claims. This could be encouraged on a wider scale or standardised for all plant variety rights granted.

Option L2: CPVO-led support for sample banking of genetic materials

Parameter	Score	Comment
Contribution	++	Samples of genetic materials from protected varieties can be used in infringement cases and to facilitate identification of new varieties for CPVR protection. They may also support conservation and preservation of genetic materials.
Feasibility	-	CPVO has already piloted two sample banking projects—one for rose and one for potato. Procedures and methods are thus in place to extend this option to other species. Expanding the banking of genetic material, however, does poses the problem of increasing the size of collections at testing centres, requiring more capacity in facilities and staff to maintain them.
Stakeholder support	(+)/(-)	Support by breeders is generally positive, but overall support is unknown.
Admin burdens and costs	(+)/(-)	Administrative and cost burdens could be high, but these are currently unknown and would need to be assessed. One option would be to extend the cost of banking a sample and subsequent testing to requests made by plant breeders. That way, only those who stood to benefit from such a system would have to pay, and this payment could help offset the costs of storage and testing for the centres.
Coherence	++	This option may help to support efforts to conserve and preserve genetic resources, in line with wider EU policy and international treaty objectives
Wider impacts	+	As with other enforcement-related issues, improving enforcement should facilitate better functioning of the EU market. It would also help ensure more fair and transparent global trading practices. Enforcement is essential to a rights holder's ability to effectively protect and exploit their invention, and to incentivise innovation in agriculture for the EU.

5.3.1.3

Option L3 Assessment – Implement capacity-building measures within CPVO through outreach to third countries

CPVO could provide greater outreach to third countries in the development of their PVR systems.

Option L3: CPVO-led outreach to third countries

Parameter	Score	Comment
Contribution	+	CPVO support to third countries can assist in the development of relevant and appropriate PVR systems in other parts of the world that conform to TRIPS and WTO obligations.
Feasibility	+	The CPVO can and should continue and expand its outreach to help third countries develop UPOV compliant plant variety rights systems modelled on the CPVR *acquis*.
Stakeholder support	(+)/(-)	The industry view favours the CPVO initiating measures to establish the foundation of a system in line with the CPVR in third countries, where feasible. The extent of third countries' interest in such help would depend, among other factors, on the degree to which they adopt systems incorporating TRIPS and UPOV 1991 provisions.
Admin burdens and costs	-	CPVO will incur modest administrative burdens and associated costs to pursue third country outreach.
Coherence	++	This option coheres with wider EU policy objectives and international instruments to bring trading partners into closer alignment on IPR issues under WTO.
Wider impacts	++	Plant breeding research and development is increasing in emerging markets such as China and India, followed by a rise in the number of applicants for CPVR based in these countries. The potential for patents to assume greater importance is also expected in developing countries, highlighting the significance of the breeder's exemption (or similar provisions) if countries adopt patents for plant varieties in lieu of a system based on the CPVR structure. Adopting a sui generis system of PVR protection based on UPOV 1991 can reduce potential conflicts arising from patent protection.

Option M Assessment – Amend the Basic Regulation to align with current hiring practices in the European Commission for hiring senior management

There are procedural issues related to hiring senior management in CPVO where the rules laid down in the Basic Regulation no longer align with current Commission practices. The Basic Regulation could be amended to resolve these difficulties.

Option M: Amend the Basic Regulation rules on hiring procedures for senior management

Parameter	Score	Comment
Contribution	+	Amending the Basic Regulation to align with current Commission practices will reduce problems encountered where the rules currently differ. This will reduce the time and effort involved in hiring procedures and bring CPVR procedures in line with those practiced in other EU agencies.
Feasibility	+++	This option requires amendments to the Basic Regulation. They can be modelled on the rules set out for other EU agencies.
Stakeholder support	+	CPVO and the Commission support this option. Breeders organisations have also indicated that they support this option in order to facilitate the smooth and continuous functioning of the CPVO.
Admin burdens and costs	0	No administrative burdens or costs are anticipated.
Coherence	+++	This option coheres with hiring practices for other EU agencies.
Wider impacts		N/A

Option N Assessment– Correct errors in the Basic Regulation

There are some editorial errors in the Basic Regulation; any revision to the Regulation should consider correcting them. This could be done alongside any other potential revisions to the Basic Regulation.

Option N: Correct errors in the Basic Regulation

Parameter	Score	Comment
Contribution	++	Correcting editorial errors will improve the interpretation of the CPVR Basic Regulation and make it a more robust instrument. There are no foreseen drawbacks.
Feasibility	+++	CPVO has maintained a list of errors which can be made available on request.
Stakeholder support	+	CPVO and some plant breeders' representative associations have indicated errors in the Basic Regulation that require amendment
Admin burdens and costs	0	No administrative burdens or costs are anticipated.
Coherence		N/A
Wider impacts		N/A

Annex 17 Option Assessment Scorecard

Each issue and its associated option are presented in the table below with their ratings for each criterion and a total rating for each option considered. In order to compare the options, the ratings are each assigned equal weighting. Thus, the options with a net positive rating are recommended for further consideration and those with a net negative rating are not.

Those options with a net positive rating are then categorised according to their initial priority ranking (primary or secondary).

- The remaining options of primary importance to the evaluation and where the expected impact is significantly positive (i.e. with a net ranking of '++') are the recommended options to take forward.
- The remaining options of secondary importance to the evaluation, and where the expected impact is significantly positive (i.e. with a net ranking of '++') are recommended for further consideration.

CPVR acquis - option assessment scorecard

	Issue	Option	Parameter/Score								Net rating	Recommend? (Y/N)
			Contribution	Feasibility	Stakeholder support			Admin burdens/ costs	Coherence with other policies	Wider impacts		
					Breeders	Growers	MS Reps					
A	Interaction w/ S&PM Directives	Implement 'one key, several doors' approach	+++	+	++	++	++	(+)/(-)	++	++	++	Y
B	Interaction w/ patent system	Improve information provision for protected varieties	+	++	++	0	++	-	+	++	++	Y
C	Interaction with the Enforcement Directive	Amend BR to accommodate Enforcement Directive	+	+++	+++	++	+++	0	+++	+	++	Y
D	EFTA extension	Extend CPVR *acquis* to EFTA countries	+	++	++	++	++	+	+++	++	++	Y

		Issue	Option	Parameter/Score								Net rating	Recommend? (Y/N)
				Contribution	Feasibility	Stakeholder support			Admin burdens/ costs	Coherence with other policies	Wider impacts		
						Breeders	Growers	MS Reps					
E		EDV determinations	CPVO-led support for protocol & threshold development	++	++	++	0	0	--	++	+	**++**	**Y**
F		Protection duration	Case-by-case extensions	+	+	+++	--	0	-	--	(+)/(-)	(+)/(-)	**N**
G	G1	Reporting obligation	Amend CPVR BR to obligate growers to report 'yes' or 'no' whether they have used FSS	++	+	++	++	++	-	++	+	**++**	**Y**
	G2	'Small farmer exemption'	Amend Regulation (EC) No 1768/95 to redefine a 'small farmer'	++	-	+	+	+	-	++	+	**+**	**N**
	G3	'Small farmer exemption'	Change Regulation (EC) No 1768/95 to eliminate the 'small farmer' exemption	+	--	++	--	--	(+)/(-)	+	--	**--**	**N**
	G4	'Own holding definition'	Amend Regulation (EC) No 1768/95 to redefine the 'own holding' definition	+	-	+	+	0	+	+	(+)/(-)	**+**	**N**
	G5	'Equitable remuneration' definition	Amend Regulation (EC) No 1768/95 to redefine the 'equitable remuneration' definition	+	+	+	+	0	-	+	+	**+**	**N**
H	H1	Specialised courts	National specialised courts	+	++	++	0	0	(+)/(-)	++	++	**++**	**Y**

	Issue	Option	Parameter/Score								Net rating	Recommend? (Y/N)
			Contribution	Feasibility	Stakeholder support			Admin burdens/ costs	Coherence with other policies	Wider impacts		
					Breeders	Growers	MS Reps					
	H2	EU-level specialised court	++	+	++	0	0	(+)/(-)	+	++	**++**	**Y**
I	I1	Harvested materials	Amend CPVR BR to provide unqualified protection for harvested materials	++	+++	++	-	0	(+)/(-)	+++	++	**++**	**Y**
	I2		Extend scope of protection to products of harvested materials	+	--	+	---	0	(+)/(-)	+	--	**-**	**N**
	I3		Extend scope of protection to transited harvested materials	+	--	+	---	0	(+)/(-)	+	-	**-**	**N**
J		Interaction with access to information legislation	Clarify procedures with CPVO	+	++	+	0	0	++	++	0	**++**	**Y**
K	K1	Applications & examinations	Adjust testing protocols for additional characteristics	+	--	+	0	+	(+)/(-)	(+)/(-)	++	**+**	**N**
	K2		Reduce info requirements	(+)/(-)	++	+	0	0	+	N/A	N/A	**+**	**N**
	K3		Facilitate communication	+	+	+	0	0	-	N/A	N/A	**+**	**N**
	K4		Assess fee payment lag for testing centres	+	(+)/(-)	0	0	+	+	N/A	N/A	**+**	**N**

	Issue	Option	Parameter/Score								Net rating	Recommend? (Y/N)
			Contribution	Feasibility	Stakeholder support			Admin burdens/ costs	Coherence with other policies	Wider impacts		
					Breeders	Growers	MS Reps					
	K5	Official licensing for testing	+	-	+	0	0	-	N/A	N/A	**(+)/(-)**	**N**
L	L1	CPVO-led support for molecular markers	+	--	+	0	+	(+)/(-)	N/A	+	**+**	**N**
	L2	CPVO-led support for sample banking of genetic materials	++	-	(+)/(-)	0	0	(+)/(-)	++	+	**++**	**Y**
	L3	CPVO-led outreach to third countries	+	+	(+)/(-)	0	0	-	++	++	**++**	**Y**
M		Hiring senior management in CPVO	Amend BR to align practices with Commission policies	+	+++	+	0	0	+	+++	N/A	**++**	**Y**
N		Errors in the Basic Regulation	Amend BR to correct errors	+++	++	+	N/A	N/A	0	N/A	N/A	**++**	**Y**

Annex 18 Glossary of Key Terms

Agriculture exemption	Acknowledges the farmers' right to use farm saved seed. The breeders' right extends only to seed produced for commercial marketing. Consequently, farm saved seed use is outside the purview of the breeders' right.
Breeders' exemption	Provides that use of a protected variety as the initial source of variation for creating further new varieties and marketing them does not require the breeder's authorisation.
Certification regulations	Controlled seed quality (physical and genetic purity) through field inspections at different seed production stages.
Common Agricultural Policy	A system of EU agricultural subsidies and programmes that includes production quotas and ceilings with the aim of providing farmers with a reasonable standard of living and consumers with quality food at fair prices within the EU.
Common catalogue	A catalogue of varieties of agricultural plant species, these catalogues are established on the basis of information received from EU Member States. They list those varieties whose seed is subject to no marketing restrictions within the EU as regards variety. Varieties must meet standards, notably pertaining to distinctness, uniformity, stability and, in the case of agriculture, value for cultivation and use (VCU) in order to be listed.
Distinctness, uniformity, stability (DUS)	The criteria, in addition to variety denomination, on which a plant variety right is determined. DUS testing and variety denominations are required for plant variety protection and for listing and certification.
Equitable remuneration	Remuneration which is 'sensibly lower' than the charge for equivalent certified seed. Regulation (EC) 1768/95 provides for two situations: one in which the rights holder and the grower agree to a remuneration level and one in which the parties cannot agree (whereby the remuneration level is fixed at 50% of the cost for licensing propagating material).
Essentially derived varieties (EDV)	A variety predominantly derived from an initially protected variety. The provision is an attempt to reduce the problems with imitation that can result from the breeders' exemption. An EDV is distinct from the initial variety in accordance with the provisions for distinctness set out in the CPVR Basic Regulation. In the case of an EDV, the initial rights' holder is also considered to be the rights' holder of the EDV.
Farm saved seed (FSS)	Seeds kept from the previous year's harvest and replanted on the same farm without the farmer having to pay the breeder royalties.
Genetic erosion	The reduction of a gene pool for plants or animals where an already endangered species has difficulty reproducing
Molecular markers	Molecular markers are found at specific locations of the genome and are used to 'flag' the position of a particular gene or the inheritance of a particular characteristic.
National Listing	Only plant varieties on a National List or in the common catalogue may be marketed. National listing requires that a plant variety conform to DUS and VCU criteria.
Own holding	Considered to include only the contiguous area designated as a 'holding' by CAP legislation and therefore would not cover any other holdings owned by the same farmer. There is no set definition of 'own holding' in the CPVR regulation, and its interpretation for this purpose varies by Member State.
Patent	An exclusive right to the benefits of an invention or improvement granted by a national Patent Office, for a specific period of time, on the basis that it is novel, non-obvious, and useful.

Phytosanitary	Literally, plant health. Can require the restricting or prohibiting of the importation and marketing of certain plant species, or products of these plants, so as to prevent the introduction or spread of plant pests or pathogens that these plants may carry.
Plant genetic resources	The reproductive or vegetative propagating material of cultivated varieties in current use and newly developed varieties, obsolete cultivars, primitive cultivars , wild and weedy species, near relatives of cultivated varieties and special genetic stocks (including elite and current breeder's lines and mutants).
Plant propagating material	Seeds, parts of plants and all plant material, including rootstocks, intended for the production and reproduction of plants.
Plant variety rights	The recognition of the intellectual property rights of plant breeders in their varieties. Plant variety rights offer legal protection of a new plant variety granted to the breeder or his successor in title. The effect is that prior authorization is required before the material can be used for commercial purposes.
Small farmer exemption	Under the CPVR Regulation, the agriculture exemption provides for a small farmer exemption. A 'small farmer' is defined as a producer with fewer than 92 tonnes of annual cereal production or less than 185 tonnes of potatoes. Small farmers are not required to pay remuneration to CPVR holders for the use of farm saved seed.
Sui generis	Literally, something that is unique. The TRIPs Agreement requires WTO Members to protect new plant varieties using either a patent system or a *sui generis* system, tailored to the needs of plant breeding, or some combination thereof.
Trademark	A distinctive design, picture, emblem, logo or wording (or combination) affixed to goods for sale to identify the manufacturer as the source of the product and to distinguish them from goods sold or made by others. Trademarks are one form of intellectual property right available in the EU.
Value for cultivation and use (VCU)	A test of merit for a plant variety to determine differences of productivity, quality, pest and disease resistance and/or other commercially important qualities to qualify for marketing.
Variety denomination	The name of a new variety. Seeds and propagating materials are to be sold under the proper variety name, and labelled by variety and producer. The breeder owns the registered variety name.

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