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Evaluation of the Community *acquis* on the marketing of seed and plant propagating material (S&PM)

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Final Report

Submitted by:

Food Chain Evaluation Consortium (FCEC)

Civic Consulting - Van Dijk MC -

Arcadia International - Agra CEAS

Project Leader: Arcadia International E.E.I.G.

European Commission

DG SANCO

Rue de la Loi 200

1049 Brussels

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Contact for this assignment:
Mr. Daniel Traon, Managing Partner
Arcadia International E.E.I.G.
Avenue des Princes Brabançons, 35
B-1170 Brussels
Belgium
Telephone: +32 (0)56 48 50 18
Fax: +32 (0)2 675 87 32
Email: daniel.traon@arcadia-international.net

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Prepared by the Food Chain Evaluation Consortium (FCEC)
Civic Consulting – Van Dijk MC
Arcadia International – Agra CEAS

Project Leader: Arcadia International E.E.I.G.

Food Chain Evaluation Consortium
C/o Civic Consulting
Potsdamer Strasse 150
D-10783 Berlin-Germany
Telephone: +49-30-2196-2297
Fax: +49-30-2196-2298
E-mail: alleweldt@civic-consulting.de

Expert Team

Arcadia International:
Mr D. Traon
Mr. P. Caramangiu
Dr Ph. Guest
Dr. R. de Borchgrave

Van Dijk Management Consultants:
Mr D. Spaey
Ms L. van Nieuwenhuyse
Mr A. Sofias
Ms S. Gonzalo

Civic Consulting:
Dr F. Alleweldt
Dr S. Kara
Dr S. Williams
Ms K. Schubert

Agra CEAS:
Mr C. Caspari
Dr D. Bradley
Dr E. Oliver
Dr M. Christodoulou

fcec

Food Chain Evaluation Consortium
Civic Consulting – Van Dijk MC
Arcadia International – Agra CEAS

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Acronyms

ABDP: Association of Bio-Dynamic Plant Breeders
AGPB: Association Générale des Producteurs de Blés et autres céréales
AIPH: International Association for Horticultural Producers
AOA: Area Of Adaptation
B: Beet
BDP: Bundesverband Deutscher Pflanzenzüchter e.V.
BSA: Bundessortenamt
BSPB: British Society of Plant Breeders
C: Cereals
CAC: Conformitas Agraria Communitatis
CC: Common Catalogue
CFIA: Canadian Food Inspection Agency
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
CPE: Coordination Paysanne Européenne (newly renamed European Coordination Via Campesina)
COREPER: The Permanent Representatives Committee
CPVO: Community Plant Variety Office
DEFRA: Department for Environment, Food and Rural Affairs
DNA: Deoxyribonucleic acid
DUS: Distinctness, Uniformity, Stability
ECPA: European Crop Protection Association
EFNA: European Forest Nursery Association
ESA: European Seed Association
ESCAA: European Seed Certification Agencies Association
ESGG: European Seed Grower Groups
EPPO: European and Mediterranean Plant Protection Organisation
EU: European Union
FCEC: Food Chain Evaluation Consortium
FIBL: Research Institute of Organic Agriculture
FO: Forest
FP: Fodder Plants
FR: Fruits
FRM: Group 'Forestry Material'
FSS: Farm Saved Seed
FTE: Full Time Equivalent
GxExL: Genotype by Environment by Legislation
GEVES: Groupe d'Etude et de contrôle des Variétés et des Semences
GM: Genetically Modified
GMO: Genetically Modified Organism
GNIS: Groupement National Interprofessionnel des Semences et plants
GURTS: Genetic Use Restriction Technologies
IA: Impact Assessment
ICRA: International Cultivar Registration Authorities
IP: Intellectual Properties
IPGRI (today Biodiversity International): International Plant Genetic Resources Institute
ISF: International Seed Federation
ISTIS: State Institute for Variety Testing and Registration (in RO)
MS: Member States
MT: Metric tonnes
NGO: Non-Governmental Organisation
NIAB: National Institute of Agricultural Botany
NMS: New Member State
NFU: National Farmers' Union
PNT: Plant with Novel Trait
OECD: Organisation for Economic Co-operation and Development

OF: Oil & Fibre plants
OJEC: Official Journal of the European Communities
P: Potatoes
PBR: Plant Breeders' Rights
PH: Plant Health
PM: Group 'Propagating Material'
PPM: Propagating Plant Material
PVR: Plant Variety Rights
PPP: Plant Protection Products
Q: Evaluation Question
RNQP: Regulated Non-Quarantine Pests
S: Group 'Seed'
SCPS: Standing Committee on Seeds and Propagating Material for Agriculture, Horticulture and Forestry
SCFP: Standing Committee on Propagating Material and Plants of Fruits genera and Species
SCPH: Standing Committee on Plant Health
SCPOP: Standing Committee on Propagating Material of Ornamental Plants
SCPVR: Standing Committee on Community Plant Variety Rights
SLIM Initiative: (Simpler Legislation for the Internal Market), launched by the Commission in May 1996
SME: Small and Medium-sized Enterprise
SPS: Sanitary and Phytosanitary measures
S&PM: Seed & Plant Propagating Material
STREP: Specific Targeted Research Project
SOC: Service Officiel de Contrôle et de Certification
TBT: Technical Barriers to Trade
TCs: Third Countries
ToR: Terms of Reference
UN-ECE: United Nations – Economic Commission for Europe
UPOV: International Union for the Protection of New Varieties of Plants
USD: US dollar
USDA: United States Department of Agriculture
VI: Vine
VG: Vegetable other than seed
VS: Vegetable Seed
VCU: Value for Cultivation and Use
WG: Working Group
WOSR: Winter Oil Seed Rape

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EXECUTIVE SUMMARY

BACKGROUND AND METHODOLOGY

The aim of the evaluation of the Community *acquis* on the marketing of seed and plant propagating material (S&PM), is to establish objectively how effectively and efficiently the legislation has met its original objectives, and to identify its strengths and areas for improvement and its robustness with regard to potential new challenges affecting this field. It also aims to analyse the coherence of the intervention with other related interventions, and with the OECD and other international standards as well as to assess the relevance and the utility of the intervention.

As the evaluation is placed in the general context of the Better Regulation initiative of the Community, it should endeavour to identify the current and possible future problems and needs. It should suggest possible objectives that the Community should pursue in order to respond to the identified problems and needs, as well as realistic options to achieve the proposed objectives.

In doing so, it has considered the social, environmental and economic impacts of each of those options, as well as their feasibility, stakeholders´ level of support and their strengths and weaknesses. The concepts of simplification and reduction of administrative burden on the public authorities and the private sector stakeholders should be behind the analysis of the relevant options.

This evaluation has been prepared between December 2007 and August 2008 by a team from the Food Chain Evaluation Consortium (FCEC) headed by Arcadia International. It has been conducted under the direction of a DG SANCO Steering Group consisting of representatives from various Commission services and Member States (MS).

To address the wide range of issues set out in the Terms of References (ToR), the FCEC team has conducted a substantial stakeholders' consultation including a large qualitative survey (280 return questionnaires), a cost survey (38 return questionnaires) and a series of 55 interviews. One of the key challenges of the evaluation has been for the evaluation team to understand the immense range of complex technical, administrative and policy issues which are subsumed under the Community legislation heading.

From the start of the process, the motivation of the actors has been extremely high in participating to this evaluation as illustrated by the very high return rate for the two questionnaires.

KEY FINDINGS FROM THE ANALYSIS OF PAST/CURRENT PERFORMANCE OF THE S&PM COMMUNITY LEGISLATION

Original needs and achievements

The Community legislation on S&PM, that dates back to the 60s, is based on two main pillars, i.e. the variety/material registration and the certification of S&PM lots. It consists of 12 basic Council Directives and is structured into one horizontal Directive on the Common Catalogue of varieties of agricultural plant species and 11 vertical Marketing Directives, among which 6 Seed Directives (for fodder plant seed, cereal seed, beet seed, seed potatoes, seed of oil and fibre plants and vegetable seed), 4 Plant Propagating Material Directives (vine propagating material, fruit propagating material, vegetable other than seed and ornamental plants) and 1 Forest Reproductive Material Directive.

Among the 12 original Directives, 9 have been updated and amended frequently but not substantially. The core principles have not changed and the intervention logic has not been amended. In the framework of the SLIM exercice, two Directives (ornamental plants in 1998 and forest reproductive material in 1999) have been totally redrafted. The Directive on vine has been recasted for improved clarity and transparency in 2001.

The objectives at the time when the S&PM Community legislation was first developed was to improve the productivity of agriculture to secure food security in the EU, to improve the competitiveness of the related sectors and to contribute to the harmonisation of the legislation at Community level leading to more open markets.

Most of the stakeholders consider that the S&PM Community legislation has been effective in achieving these objectives and that free-marketing of S&PM is observed in the EU. For them, this Community legislation is remaining useful.

Implementation of the Community legislation has a quite unique profile in the agro-business and even wider, in the life science area. Whereas for the registration of plant protection products, pharmaceutical products, fertilisers, machinery, it is up to the applicant to present the data package for evaluation by the authorities, in the S&PM sector, the data are being produced by the official authorities. Stakeholders that have been interviewed are attached to that approach and consider that the role of the official authorities (at EU or national level) is crucial in guaranteeing the equal access to all EU players (including SMEs) on the S&PM internal market.

As regards the Community provisions for registration, both VCU (Value for Cultivation and Use) and DUS (Distinctness, Uniformity, Stability) are largely considered as essential and robust tools for conventional agriculture. VCU trials permit to evaluate the agronomic performances of the varieties and to prohibit marketing of non sufficiently performing ones while DUS establishes the identity of the products to allow seed certification and seed trade control.

Community VCU provisions exist only for agricultural crops species, though some VCU requirements for cultivation (adaptation to some conditions, behaviour against particular diseases, etc.) and use (characterisics providing information for processing, etc.) are included in DUS protocols for vegetables. Also, vegetable sectors have established their own efficient systems, where new varieties are assessed in close cooperation with users. Moreover, a reference to the evaluation of the pomological value appears in the new fruit plants Directive. The qualitative survey has shown that, overall, stakeholders do not wish to see a change to these successful and well-established systems.

The Common Catalogues on agricultural and vegetable seed species are perceived as a powerful tool by the private operators (and the SMEs in particular) to facilitate the marketing of S&PM; i.e. once a variety is listed on a national catalogue, it is listed on the Common Catalogue and becomes marketable in the entire Community. However, for crop sectors without a Common Catalogue, no significant internal market issues have been reported.

As regards the Community provisions for certification, it is generally agreed that they have established rules and operating practices that have helped the conventional European seed industry to become a world market leader, producing S&PM of high quality and health. Statutory certification leads to an increased confidence of farmers/buyers in the quality when buying S&PM.

Users have also highlighted the important role of the certification provisions as a possible policy lever for the EU, that could be used to enforce other legislation (e.g. GMOs).

A large majority of survey respondents considers that the standards used for certification are fully relevant, with the exception of the fruit plants standards. The newly adopted fruit plants Directive aims to overcome the identified deficiencies.

Overall, EU rules are aligned with international standards and guidelines (OECD), with the exception of the EU rules for seed potatoes which have less stringent tolerances for certification than the UN-ECE standards.

The survey results indicate that majority of stakeholders consider the comparative trials as fully appropriate for ensuring the harmonisation of inspection practices. Currently, such comparative tests and trials are no more carried out by DG SANCO for administrative reasons.

Overall, the costs linked to the implementation of the Community legislation are generally considered as reasonable and proportionate, in particular as regards the certification costs.

As the S&PM currently produced in the EU are of high quality, reduction of the cost of certification is gaining in importance. Indeed, as far as the Community legislation permits it, some MS have taken initiatives to make the process more efficient and reduce accordingly the costs and administrative burden. For instance, several MS like FR and the UK have set up certification 'under official supervision'. The Netherlands and DK have merged the certification and phytosanitary inspection bodies on a crop by crop approach.

A Working Group, limited to a few MS' experts and Commission representatives, was created in 2006 to analyse the possible extension of the role and activities of the Community Plant Variety Office (CPVO), which today, according to the current EU legislation, has an unique responsibility on Plant Variety Rights. Up to now, the discussion of the WG have resulted in 1) a proposal for a centralised checking of variety denomination using the current CPVO database for the purposes of National listing, Community listing, National PVR and Community PVR as well as 2) five options for a possible role of CPVO in managing the Common Catalogues and in National listings. Among those 5 options, the WG was clearly in favour of the approach *'one key – several doors'*, i.e. the adoption and the auditing by the CPVO of quality requirements for DUS testing not only as concerns the Community PVR system but also or possibly in respect of national PVR and listing systems. However, no common position was reached within the members of the WG as concerns a managing or organisational role of the CPVO in respect of DUS testing to be performed for national listing and national PVR granting purposes. They consider that such roles might be a long term effect after the implementation of the *'one key – several doors'* approach.

Remaining problems or inconsistencies and emergence of new needs

The environment in which the Community legislation operates has completely changed in less than 30 years. The S&PM sector acts in an ever-increasing international context in constant evolution, where globalisation, the development of plant biotechnology and new consumer demands e.g. organic food play an important role. A competitive S&PM sector with many players, mainly medium and small companies, has established in most of crop sectors that are in constant evolution and that have created large segmentations between the crops and their actors leading to complexity.

Despite the very good achievements of the S&PM Community legislation, the examination of the 12 Directives, as well as the interviews have pointed out the complexity of such legislation, which is a mix of legislative and technical provisions, as well as its lack of flexibility to quickly adapt to a changing market environment.

The current governance of the Community legislation, mainly using the instrument of Directives that need to be transposed into national legislation, a number of technical elements that can be amended only at Council level and the discussion of both technical and legal issues during the meetings of the three Standing Committees on S&PM, are an adding factor that makes any decision difficult to be approved and time consuming.

Overall, the current complexity of the Community legislation reflects the complexity of the S&PM sectors, which will remain in the future or even intensify.

Furthermore, the non-harmonised implementation of some Community provisions, the existence of additional national implementing measures, the non-harmonised framework for costs and responsibility sharing as well as the lack of organised circuits for the exchange of information between the MS have led to the absence of a level-playing field.

For example, as VCU provisions are not defined in detail in the Community legislation, there are as many official systems as MS as regards the assessment of VCU of a variety. The provision that any variety may be freely marketed in the entire Community if it is registered in a national catalogue and consequently transferred into a Common Catalogue creates a system of *'27 VCU keys – one door'*. As such, a breeder may register his variety on the national catalogue of a MS 'X' to get the right, through the Common Catalogue, to access the market of a MS 'Y'. This situation asks the question about the relevance of the EU VCU provisions in particular as a prerequisite for the admission of a variety to the

Common Catalogue. It has also put the national registration systems in competition to maintain their activity.

Additionally, the relevance of the indicators of effectiveness of VCU may be questioned as several crop sectors where VCU is not compulsory and as several 3rd countries with no regulatory tests are considered as competitive as the regulated VCU crop sectors.

The implementation of the DUS provisions has also led to differences between the MS as regards the size of the reference collection, the testing protocols or the data analysis, as illustrated by the different characteristics of the national schemes for the DUS testing of Winter Oil Seed Rape reaching the extent that it is influencing the choice of a MS for registration of varieties.

Stakeholders active in crops of minor importance, niche and emerging markets consider that the current variety registration and certification costs for the testing of seeds of niche varieties, e.g. landraces, populations or organic varieties, are too expensive and not proportionate to their market size.

Associations of users and suppliers insist on the need to improve the contents, the accessibility, the use and the management of the Common Catalogues on agricultural and vegetable species; by adding information on origins or defined parameters of interest to the users; organising the data better in e.g. a database format allowing for search facilities or making it accessible to all authorised parties via the internet. Furthermore, removing the obligation to publish any national newly registered variety in the Official Journal of the European Communities would reduce the laps of time for its inclusion in the Common Calatogues and make it marketable EU-wide as soon as the MS notifies it.

Survey results indicate that productivity is still an important driver but that other drivers have emerged and in particular the sufficient quality of S&PM, the plant health, sustainability aspects of agricultural production, the information to the users (in particular as regards forest reproductive material which has a long-term return on investment), the food safety and the diversity of the varieties.

As regards 'food safety', the example in the EU legislation on contaminants in food (Commission Regulation EC No 401/2006) where maximum levels of mycotoxins in food are being regulated demonstrates the value to consider plant breeding as one tool of the public health strategy and the potential for integrating such kind of criteria for the registration of varieties. More largely, the FCEC considers that it would be valuable to extend such consideration to the analysis of the need to use seed legislation (plant breeding) as a component of food safety, public health strategy and environmental protection.

Illegal imports and usages of S&PM, although not quantified, are perceived as an actual threat to the S&PM sectors which could be due at least in part to a non sufficiently precise and clear definition of 'marketing'.

The majority of stakeholders consulted ask for the establishment of a minimum threshold for the adventitious presence of genetically modified organisms in non GM seed to solve the problem of the zero tolerance that is set by the current legislation.

The establishment of a true internal market for treated seed has also been presented as a key requirement. A new proposal for a regulation on plant protection products to be adopted in 2009 is addressing this issue and should guarantee the free circulation of treated seed.

Finally, agriculture has to adapt to new consumer demands e.g. organic food and to the integration of agriculture in the food chain. The Community legislation should consider and respond to these evolutions in a flexible or pro-active manner in order to secure the development of these emerging markets.

SCENARIOS FOR THE FUTURE

Three scenarios have been examined: Scenario 1: 'Status quo' scenario, Scenario 2: 'Suppress' scenario and Scenario 3: 'Modify' scenario.

In the 'Status quo' scenario, the structure and provisions of the Community legislation will be maintained as they currently stand. The 'Status quo' scenario assumes the continuation without change of the current arrangements. The difficulties summarised above persist.

Despite the fact that the S&PM Community legislation has achieved good performances, the 'Status quo' scenario is not advisable because it is not in line with the Better Regulation initiative and because the majority of stakeholders have expressed their wish to see the S&PM legislation maintained at Community level but to adapt it, as illustrated by a series of initiatives already taken to that end at EU or MS level (the Commission Working Group on the possible extension of the role of the CPVO, the DEFRA consultation (UK) on possibilities for Better Regulation, the promotion of the certification 'under official supervision' in several MS, the integration of plant health and seed inspection services in some MS, etc.).

In the 'Suppress' scenario, the current Community provisions for the registration and marketing of S&PM are suppressed. It is then up to the MS to decide if they maintain the implementing regulations developed at national level for national listing and certification or if this is left to self-regulation by the markets. Survey results have clearly indicated that the large majority of stakeholders does not support the 'Suppress' scenario. The removal of the Community legislation would lead to different regulatory approaches at MS level with the possibility to threaten the principle of the internal market and leading to a lack of transparency of EU market. Under self-regulation, industry would further compete in term of product quality, price and consumer choice with a risk of reduction of product quality inducing a reduction of users acceptance and confidence in S&PM products.

The results from the stakeholders' consultation support the 'Modify' scenario. In terms of strategic focus, the evaluation has highlighted the need to move forward a policy which is more focused on crop sectors specificities and by taking into account the segmentation of food and other markets. This can be achieved via a simplification of the current Community legislation with the additional objectives of introducing adaptability within the regulatory framework in order to address the specific needs of the different sectors in a fast changing environment and to adjust costs to the size of the targeted markets.

For the reasons as outlined above, the 'Modify' scenario is the preferred one.

POSSIBLE OBJECTIVES OF THE 'MODIFY' SCENARIO AND OPTIONS TO ACHIEVE THEM

Objective: simplify the current Community legislation

Two options are examined to review and simplify the Community legislation:

- The first option consists in revising the legislative text of each Directive in order to remove the inconsistencies, discrepancies and gaps, and to clarify key definition meaning (e.g. marketing, industrial use, etc.) and by this, to increase its readability, consistency and understandability. The FCEC considers that this option is mainly short-term and easy to implement. It would be applied in priority to old Directives. It will facilitate the operational management and the implementation of the Community legislation without changing its intervention logic and without inducing lot of flexibility. FCEC team considers that this approach is of value short-term but will not facilitate long term flexibility of the legislation.
- The second option, which includes the main tasks of previous option replaces the current structure of the Community legislation with a structure distinguishing between the pillars 'Registration' and 'Marketing' and splitting the technical aspects from the more horizontal legal provisions.

  According to such structure, a first piece of horizontal framework legislation (called 'Registration') would set the general standards for registration of seed varieties and plant propagating material

based on adapted VCU requirements, identification of varieties based on DUS as well as on variety denomination and on the Common Catalogue. Its provisions should be consistent with the Community system on Plant variety protection. The FCEC believes that it is important that harmonised rules are defined and therefore is recommending a regulation as legal instrument.

The second part would present the legal requirements for 'Marketing' S&PM and should comprise the general provisions with regard to certification. Its provisions should be consistent with internationally recognised certification schemes. To this horizontal legislation will be attached individual technical annexes per species or groups of species and its usage e.g. in the case of beet species one for sugar beet and another one for fodder beet where minimum standards for marketing should be defined. This segmentation per usage for a given species should be implemented, only, when the segmentation is non-disputable and when one variety cannot move from one usage to another, or when a variety cannot be marketed for 2 different usages.

Such proposal consists in a revision of the intervention logic of the S&PM Community legislation. FCEC considers that it is partly easy and a long-term option, which requires further consultation and discussion.

Whenever possible, the separation between the legal and the technical provisions would be further supported with a separation between the legal and the technical discussions. The FCEC considers that this option is short term and partly easy to implement.

In both approaches, special attention should be paid to reviewing some key basic elements of the Community legislation such as definitions, usage criteria, list of species/crops to be covered by the legislation or not, principles of 'industrial use' and 'not for forestry purposes'.

Objective: introduce flexibility within the regulatory framework

To introduce more flexibility in the regulatory framework, possible options are:

- To make the official rules for uniformity of a variety more flexible, in order to allow the registration of non uniform varieties e.g. conservation varieties at costs proportionate to the niche markets they target. In such a case, it would be important to also develop a traceability system with indication of the origin of the marketed variety, of the varieties used for its breeding as well as the specific breeding methods used and to inform the user accordingly;
- To make VCU rules evolve to adapt to any type of agriculture (i.e. varieties developed for specific uses) and to test varieties created by new technologies. The stakeholders'consultation has highlighted their fear of modifying the current European VCU provisions. The FCEC considers that an impact assessment on the effects at national level of any change in the European VCU provisions would be appropriate. Cautious analysis could also be made of the case of Canada, where authorities and breeders have considered reviewing their VCU system with a more fexible system on a crop by crop basis;
- To adapt the requirements for the marketing of seeds to defined categories i.e. several categories per species as done for the forest reproductive material and the propagating material. The FCEC considers this option as difficult to implement and long-term, especially in a context where it is important to stay in line with international standards.

Objective: Reduce the differences between MS as regards the implementation of the Community legislation and contribute thereby to the creation of a level-playing field.

Possible options to support this objective are:

- To promote the coordination of VCU testing, the extension of bilateral or the establishment of multilateral agreements for DUS testing. In the opinion of the FCEC, this option is not easy to implement and mid-term;

- To restart the comparative tests and trials and make them more relevant by ensuring that more formal follow-up through the decision making process and monitoring is applied;
- To audit the implementation of the Community legislation on a regular basis, in particular as regards the provisions for certification and DUS. The FCEC considers that this option is mid-term and is not an easy task as technical dedicated expertise is required;
- As regards seed potatoes, to further align the EU rules with the international standard of the UN-ECE.

Objective: Promote costs reduction approaches and introduce flexibility in the operating system.

Possible approaches for cost reduction and increased flexibility are:

- To promote the integration of plant health and certification inspection schemes by possibly integrating plant health and S&PM Community legislation. The FCEC considers that this option is partly easy to implement and short-term;
- To promote the implementation of the certification 'under official supervision'. In the opinion of the FCEC, this option is easy to implement and mid-term;
- To extend the certification 'under official supervision' to pre-basic and basic crops and to explore other areas where it could be extended. For the FCEC, this option is partly easy and short term;
- To support the morphological analysis of the variety with molecular tools, that could be used independently from the growing season, and in particular DNA markers. This option is partly easy and mid term. As indicated by some stakeholders, the use of such new technologies could lead to very stringent contraints and be potentially more discriminating than 'morphology' so that the FCEC considers that additional analysis (in depth feasibility and cost/benefit analysis according to crops) is required for appropriate decision-making. Molecular tools are already used to discriminate between GM events and are already broadly used by most of breeders (e.g. Marker Assisted Selection).

Objective: Secure long-term consistency with the other EU policies, and especially on GMOs, Plant Protection Products, Plant Health, Human Health/Food Safety

Possible options to implement this recommendation are:

- To integrate the plant health and seed certification legislation. In the opinion of the FCEC, this option is not easy to implement and mid-term;
- To explicity mention in the certification provisions the control of GM varieties and the adventitious GM presence in non-GM seed. The FCEC considers that this option is quite easy to implement and short-term;
- To implement in the S&PM Community legislation provisions leading to risk reduction of contaminant in food. The FCEC considers that this option is partly easy to implement and mid term;
- To identify additional links between the S&PM Community legislation and the Food law. For the FCEC, this option is difficult to implement and long-term;
- In addition to these, attention should be paid to consistency with the Common Agricultural Policy including its Rural Development policy, and the Environmental Policy (e.g. biodiversity, climate change). In the opinion of the FCEC, this option is easy to implement and short term.

Objective: Finalise the current discussion on the extension of the role of the CPVO and further identify additional synergies with the CPVO expertise leading to significant benefits to the S&PM sectors.

As explained above, the main options currently discussed within the framework of the CPVO Working Group concern the checking of the variety denomination by the CPVO based on their centralised database as well as the adoption and auditing of quality requirements for DUS testing by the CPVO. Any modification of the role of the CPVO will need legislative change to implement. Whereas the first one seems relatively easy to implement in the short-term, the second one still need to be further discussed and examined.

Extension of discussions to other possibilities could add more value to the approach, like the principle *'one key – several doors'* by which the same and unique DUS testing would be implemented for listing and for Plant Variety Right.

Objective: Reinforce provisions dedicated to inform users

Such objective could be achieved by reviewing the Community provisions related to:

- Suppliers' documents in the forestry area, which currently suffer from a lack of harmonisation;
- Small packages, which are perceived as not enough defined;
- Information contained in the common catalogues.

1. INTRODUCTION

In the framework of the Commission's Better Regulation initiative, and following the initiative of the British EU Presidency, DG SANCO assessed that it was appropriate to undertake an external evaluation of the Community legislation on the marketing of seed and plant propagating material (S&PM).

The Food Chain Evaluation Consortium (FCEC) was designated for this evaluation, in the context of the framework contract for evaluation and evaluation related services – Lot 3: Food Chain.

The evaluation is based on DG SANCO Terms of Reference (ToR) of the 7th of July 2007, which are provided in Annex 1.

It took place from December 2007 to August 2008 and has consisted in three phases: the inception phase aiming at refining the evaluation methodology, the interim phase aiming at collecting data and discussing the progress of work and preliminary results with DG SANCO and the steering group and the final phase aiming at analysing the data, developing the options for the future, and reporting to the Commission.

The FCEC consortium has worked in co-operation with a steering group designated by DG SANCO and made of representatives from the Member States (i.e. DK, FR, HU, NL, and the UK) and Commission DGs (i.e. DG AGRI, DG ENTR, DG ENV, DG TRADE and DG SANCO). The main role of this steering group has been to facilitate and support the evaluation process in order to ensure that the final report is a high quality document providing usable input to the decision making process. Individual members of the steering group contributed their skills and knowledge of the area under evaluation or of the evaluation process itself.

2. OBJECTIVES OF THE EVALUATION

The Commission's Better Regulation initiative of June 2002 aims at ensuring that Better Regulation is pursued in the daily legislative work of the Community but also calls for attention to the stock of Community legislation, which sometimes dates back several decades. Since the foundation of the European Communities, this body of existing legislation has never been subject to a comprehensive review of its organisation, presentation and proportionality. This initiative includes among other things the simplification of legislation and the reduction of the administrative burden on the public authorities and the private sector.

The evaluation of the S&PM legislation and its implementation in the Community is expected to:

- Establish objectively how effectively and efficiently the legislation has met its original objectives;
- Identify its strengths and areas for improvement and its robustness with regard to new and potential future challenges affecting this field;
- Analyse the coherence of the intervention with other related interventions, and with the OECD and other international standards;
- Assess the relevance and the utility of the intervention.

In doing so, this evaluation has both a technical and a strategic component.

The results will be used as input for drafting an Impact Assessment with the view to possibly review the S&PM legislation.

The evaluation's primary aim is to:

- Identify the current problems and needs;
- Suggest possible objectives that the Community should pursue in order to respond to the identified problems and current and expected future needs;
- Identify different realistic options to achieve the proposed objectives;
- Analyse the main social, environmental and economic impacts of each of those options, as well as their feasibility, stakeholders' level of support and their strengths and weaknesses.

3. SCOPE OF THE EVALUATION

According to the ToR, the evaluation addresses the 12 basic Council Directives of the S&PM legislation (operational scope), as transposed and implemented by the MS since the origin of the various Community texts (temporal scope). It covers the EU market (geographical scope). The evaluation has a forward looking component (temporal scope), in the sense that it examines options to ensure that the legislation supports a harmonious further development of agriculture, horticulture and forestry, and its supply sector, and make recommendations accordingly.

The 12 Directives are as follows:

- Council Directive 66/401/EEC of 14 June 1966 on the marketing of fodder plant seed;
- Council Directive 66/402/EEC of 14 June 1966 on the marketing of cereal seed;
- Council Directive 2002/53/EC of 13 June 2002 on the Common Catalogue of varieties of agricultural plant species;
- Council Directive 2002/54/EC of 13 June 2002 on the marketing of beet seed;
- Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed;
- Council Directive 2002/56/EC of 13 June 2002 on the marketing of seed potatoes;
- Council Directive 2002/57/EC of 13 June 2002 on the marketing of seed of oil and fibre plants;
- Council Directive 68/193/EEC of 9 April 1968 on the marketing of material for the vegetative propagation of the vine;
- Council Directive 92/33/EEC of 28 April 1992 on the marketing of vegetable propagating and planting material, other than seed;
- Council Directive 92/34/EEC of 28 April 1992 on the marketing of fruit plant propagating material and fruit plants intended for fruit production;
- Council Directive 1998/56/EC of 20 July 1998 on the marketing of propagating material of ornamental plants;
- Council Directive 1999/105/EC of 22 December 1999 on the marketing of forest reproductive material.

For the purpose of data collection and analysis and as suggested by DG SANCO officials, the FCEC team has grouped those 12 basic Council Directives into 3 groups as follows:

- The group 'Seed' (S) gathers the crops/species regulated under Council Directives 66/401/EEC (FP-fodder plant seed), 66/402/EEC (C-cereal seed), 2002/53/EC (Common Catalogue of varieties of agricultural plant species), 2002/54/EC (B-beet seed), 2002/55/EC (VG-vegetable seed), 2002/56/EC (P-seed potatoes), 2002/57/EC (OF-seed of oil and fibre plants);
- The group 'Propagating Material' (PM) includes the crops/species regulated under Council Directives 68/193/EEC (VI-material for vegetative propagation of the vine), 92/33/EEC (vegetable propagating and planting material other than seed), 92/34/EEC (fruit plant propagating material and fruit plants intended for fruit production) 98/56/EC (ornamental plants);
- The group 'Forestry Material' (FRM) which refers to Council Directive 1999/105/EC on the marketing of forest reproductive material.

The evaluation also addresses the specific needs of the marketing of conservation varieties, the issue of the coherence between the seed marketing legislation and the other interventions of DG SANCO, such as the phytosanitary aspects, and look into the impact of the cultivation of GM seed crops.

It does not cover the scope of Community Plant variety Rights (Council Regulation (EC) No 2100/94) but it takes into account the links that exist between the S&PM legislation and the Plant Variety Rights.

Clear statements of several stakeholders have been made during the evaluation questioning the relevance of the evaluation due to the fact the PVR's legislation is only indirectly covered in the exercise.

4. METHODOLOGY

4.1. OVERALL METHODOLOGICAL APPROACH

Our overall approach has combined a range of evaluation tools including: documentary review, preliminary survey, qualitative survey, costs survey, interviews, and in-depth studies.

The preliminary survey has aimed at identifying the key national stakeholders in the area of marketing of S&PM.

The primary objective of the qualitative and costs surveys has been to get an overall picture of the past /current performances or costs of the EU S&PM legislation and of the preferred options for the future.

During the interviews, the objective has been to collect and challenge the points of view of national institutions and stakeholders on the advantages/disadvantages, feasibility as well as positive and negative effects of the options for the future. The interviews have also been the opportunity to further discuss the '*lessons from the past'* stemming from the analysis of the results of the qualitative survey.

The in-depth studies have focused on specific or complex issues requiring dedicated evaluation resources.

4.2. SURVEYS OF STAKEHOLDERS

4.2.1. Preliminary survey

A preliminary questionnaire was sent on December 20, 2007 to all delegates (EU 27) of the Standing Committees (SCPS, SCFP, and SCFOP) with the objective to identify the key national stakeholders in the area of the marketing of seed, plant propagating material and forestry material, i.e. the key representatives of the policy making authorities; variety/material registration authorities; certification authorities; professional associations of users of S&PM (including organic farming); professional associations of suppliers of S&PM (breeders and multipliers) and other stakeholders (for example NGO's, Institutes, etc.).

Breeders, multipliers and users of S&PM have not been targeted individually but through their professional associations at national and European levels (ESA, CIOPORA, EFNA and COPA-COGECA).

4.2.2. Qualitative survey

A qualitative questionnaire has been sent electronically to all stakeholders that have been identified by the Member States in the preliminary questionnaire as well as to additional stakeholders identified by FCEC.

All stakeholders have received the same and unique questionnaire. One filled in questionnaire might concern one group of crops only, i.e. seed, propagating material or forestry material. Stakeholders wishing to answer for several groups were specifically asked to use as many questionnaires as required. A copy of the qualitative questionnaire is provided in Annex 2.

That questionnaire was available in Word format and online on the DG SANCO website with the objective to have an open and transparent debate, involving all potentially interested stakeholders.

The survey questionnaire was disseminated on the 18th and 19th of February 2008 via targeted emailing to 629 addresses. The deadline for sending back questionnaires was the 11th of April 2008. Some stakeholders specifically asked for extra-time so that the ultimate deadline had been fixed at the 30th of April 2008.

280 return questionnaires had been received. Only 14 questionnaires were filled in online whereas most of responses (266) have been provided using the questionnaire in Word format.

Among them, 244 responses have been retained for data analysis. They represent all the received questionnaires minus the 36 bias questionnaires as follows:

- 21 questionnaires filled in by individual companies. As mentioned above, individual companies have only been considered through the associations representing them at national and or European level. Those questionnaires have not been considered for the statistical analysis;
- 15 similar questionnaires, which are copies at regional level of one questionnaire filled in at national level. The questionnaire filled in at national level has been retained. The 15 other ones have not been considered for the statistical analysis.

The profile of retained respondents is as follows:

Table 1 - Profile of respondents retained for the analysis of the replies to the qualitative survey

Country	Nb of return questionnaires					Nb of people	Nb of organisations	Type of organisation					
	Total	% total	Seed	PM	Forestry			Policy making	Variety registration	Certification	Association of users of S&PM	Association of suppliers of S&PM	Others
AT	9	3,7%	6	2	1	8	6	3	3	4	1		1
BE	18	7,4%	12	3	3	15	10	5	9	7	2	3	1
BG	3	1,2%	1	1	1	2	2	1	2	3			
CY	4	1,6%	3		1	4	4	1	1	1	1	2	1
CZ	8	3,3%	5	2	1	5	5	3	3	4	1	3	
DE	12	4,9%	8	3	1	8	8	1	1	1	3	7	
DK	8	3,3%	6	1	1	8	6	4		4	2	4	
EE	3	1,2%	2		1	3	3	2		2			
ES	8	3,3%	5	3		4	4	2	2	2	4	6	
FI	5	2,0%	4	1		5	5	1	2	1	1		1
FR	42	17,2%	32	7	3	39	35	8	9	5	10	18	5
GR	5	2,0%	3	1	1	4	2	3		3		2	
HU	10	4,1%	6	3	1	7	4	3	2	4	1	2	
IE	2	0,8%	1	1		2	1	2	1	2			
IT	7	2,9%	7			6	6			1	2	4	
LT	3	1,2%	2		1	3	3			2		1	
LU	1	0,4%	1			1	1	1	1	1			
LV	3	1,2%	2		1	3	3	1	1	1		1	
MT	2	0,8%	1	1		1	1	2	2	2			
NL	22	9,0%	10	10	2	17	11	2	6	5	2	10	1
NW	1	0,4%	1			1	1			1			
PL	9	3,7%	5	4		5	5	2	2	2		3	
PT	4	1,6%	2	1	1	4	3	3	2	3		1	
RO	3	1,2%	2	1		3	2	1	2	1			
SE	13	5,3%	7	3	3	10	10	3	2	3	2	4	2
SI	5	2,0%	2	2	1	5	3	2	3	3			
SK	5	2,0%	3	2		3	2	2	1	2			
UK	12	4,9%	8	3	1	12	9	4	1	4	4	5	
EU	11	4,5%	9	1	1	9	8		1		4	7	
International	6	2,5%	3	3		6	5		2	1	1	1	3
Total	**244**	**100%**	**159**	**59**	**26**	**203**	**168**	**62**	**61**	**75**	**41**	**84**	**15**

Those responses come from 203 people (i.e. 41 people have answered for more than one group of crops) belonging to 168 organisations (i.e. representatives of different departments/units of a same organisation have responded to the survey). Only 18 respondents had not been contacted via targeted email.

Those 244 responses cover all MS as well as 8 European and 5 international organisations.

The MS most represented are FR (17,2%) NL (9%), BE (7, 4%) followed by SE, DE, and the UK (around 5% each).

The proportions of seed, PM and forestry questionnaires are respectively 65%, 24% and 11%.

Among all respondents, 62 (25%) are active in policy-making, 61 (25%) are active in variety registration, 75 (31%) are active in certification, 41 (17%) represent the users, 84 (34%) represent the

suppliers and 15 (6%) represent other stakeholders. A same respondent could be active in more than one area, e.g. policy-making and registration, users and suppliers.

The initial objective of the FCEC team was to develop a methodology to weight the respondents to the qualitative survey according to two indicators: 1) the individual economic importance of the MS and 2) the economic importance of each group of crops within each MS.

To that end, it consulted several databases i.e. FAO, Eurostat, USDA, ISF, etc. and discussed with the industry (ESA and EFNA).

A methodology was submitted for comments to DG SANCO and the Steering Group and was discussed during the interim meeting on the 8th of April 2008.

All parties agreed that defining a reliable weighting methodology was not possible because:

- The 2 selected indicators were not reliable enough, due to lack of complete and homogeneous data;
- Public market data are hardly available at EU level for the propagating material and forestry sectors;
- Basing the weighting methodology on economic considerations would lead to the opinions of 11 MS representing less than 1% of the market (according to ISF 2006 data) not being considered.

In addition, the overall profile of respondents (table 1 above) shows an acceptable representativeness of both the MS and the sectors, thus reducing the need to define adjustment measures.

Moreover, the replies to the qualitative survey are only one element of the stakeholders' consultation, which also includes the costs survey, the stakeholders' interviews and the in-depth studies. The steering group concluded that applying a weighting methodology could distort the significance of the qualitative questionnaire and decided to pursue a '*question by question'* approach as follows:

- Where the results to a question of the qualitative questionnaire are clear (e.g. 80% of respondents held the same opinion), further analysis of MS, group of crops or group of stakeholders does not add any value;
- In cases where the results to a question are less clear, the FCEC team segments the responses according to MS, group of crops or group of stakeholders;
- Statistical results to each question are completed with a qualitative treatment of the respondents' comments.

4.2.3. Costs survey

The objectives of the data collection on costs, limited to the area of the marketing of seeds, have been threefold:

- To get a picture as reliable as possible of the costs associated with the implementation of the legislation for some crops in some EU MS;
- To analyse the effects on costs of the preferred options (as suggested in the qualitative survey) for a revision of the legislation;
- To identify as much as possible the part of the costs related to administrative tasks.

The first objective has been targeted during the costs survey and during the in-depth studies.

The second and the third objectives have been subject to discussion with interviewees during the in-depth study on costs.

The costs survey has targeted:

- At national level, the authorities responsible for variety/material registration and/or certification activities (through the delegates to Standing Committee on Seeds) and the professional

associations of breeders and seed producers. The companies have not been targeted individually but through the associations representing them at national and or European level;

- At European level, the ESA (European Seed Association).

All stakeholders have received the same and unique questionnaire in Excel format. Respondents had the possibility to provide costs data for a group of seed crops or per seed crop. A copy of the costs questionnaire is provided in Annex 3.

The costs questionnaire was disseminated on the 10th and 11th of March 2008 via targeted emailing to 116 addresses. It was also posted on the DG SANCO website to invite a wider public response. The deadline for responses was the 3rd of May 2008. Some stakeholders specifically asked for extra time so that the ultimate deadline had been fixed at the 15th of May 2008.

38 questionnaires have been returned (questionnaires completed by 31 respondents from 28 organisations). The profile of respondents is presented in the table below.

Table 2 - Profile of respondents to the cost survey

MS	Nb	Data on registration costs	Data on certification costs	Type of organisations						Crops
				Policy making	Variety registration	Certification	Association of users of S&PM	Association of suppliers of S&PM	Others	
AT	1	1	1		1	1				All seed crops
BE	1	1	1		1	1				All seed crops
CY	1	1						1		Registration: FP, C
CY	1		1						1	Registration: C
CY	1	1	1	1	1	1				Registration: FP, C,VG, OF Certification: C
CZ	1	1	1	1	1	1				C
DE	1	1	1							All seed crops
DK	1	1	1					1		C
DK	1	1			1					Registration: C
DK	1	1			1					Registration: FP
DK	1	1			1					Registration:B
DK	1	1			1					Registration: VG
DK	1	1			1					Registration:P
DK	1	1			1					Registration: OF
DK	1		1	1	1	1				F
DK	1		1	1	1	1				Certification: P
EE	1		1			1				Certif: FP, C, VG, OF
EE	1	1			1	1				Registr:All seed crops
FI	1			1	1					FP,C,P,OF
FR	1	1						1		VG
FR	1	1	1		1	1				Registration: all seed crops Certification: FP, C, B, P, OF
FR	1	1	1					1		OF
FR	1	1	1					1		Registration:C
IE	1	1	1	1	1	1				FP,C,P,OF
IT	1	1	1					1		All seed crops
IT	1	1	1		1	1				All seed crops
LT	1	1	1			1				All seed crops
MT	1			1	1	1				-
NL	1				1					Registr:All seed crops
PL	1							1		All seed crops
RO	1	1			1					Registr:All seed crops
SE	1	1						1		Registr:FP,C,OF
SE	1			1	1	1				All seed crops
SK	1		1			1				Certif:All seed crops
SK	1	1			1					Registr:VG
SK	1	1			1					Registr:VG
UK	1		1	1		1				P
UK	1	1	1	1	1	1				Registration: all seed crops Certification: FP, C, B, OF
Total	38	27	20	10	24	17	0	8	1	

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

The in-depth study has focused on the analysis of the registration and certification costs in two MS, i.e. France and Denmark.

In practice, it has consisted in 4 face-to-face interviews with variety registration and certification authorities of those two MS. FCEC had planned to get the point of view of the seed industry during a face-to-face interview with the European Seed Association (ESA), on the basis of their reply to the cost survey. However, the ESA mentioned in a letter to the FCEC that such estimation was hardly possible and should require a deeper guidance document and more time to try to collect reliable quantitative data.

4.3. INTERVIEWS OF STAKEHOLDERS

A wide spectrum of EC officials and stakeholders, covering the range of interests in the marketing of S&PM, has been selected for interview (see table 3). Those interviews aimed mainly at knowing about the key issues of the S&PM sector (exploratory interviews), discussing the options/scenarios for the future as well as specific issues not covered or insufficiently covered during the surveys (in-depth interviews).

A total of 55 interviews were conducted, but in reality, the actual number of interviews is higher due to repeated interviews in several cases and a significant number of group interviews that encompassed a large number of participants. It should be noticed that additional interviews took place in the framework of the in-depth/case studies. These interviews are not listed in the following table but in the in-depth study summaries.

Table 3 - Interview programme

Organisation		Number of interviews
EU institutions		
DG SANCO		4
DG AGRI		2
DG TRADE		1
DG ENTR		1
DG SANCO + DG AGRI + DG ENV		1
CPVO		1
European Parliament		1
Economic and Social Committee		1
National authorities		
EU MS		
Group Forestry (group interview with representatives from BE, DE and SE)		1
Group Seed (group interview with representatives from IT, HU, SE, DE)		1
Group Propagating Material (group interview with representatives of SP, PL, BE and GR)		1
GNIS/SOC (FR)	Certification	2
GEVES (FR)	Registration	2
BSA (DE)	Registration & Certification	1
MAAF-DP (DK)	Registration & Certification	2
DEFRA (UK)	Registration & Certification	1
Ministry of LNV (NL)	Registration & Certification	1
MAPA (ES)	Registration & Certification	1
Ministry of Agriculture (LU)	Registration & Certification	1
ENSE (IT)	Registration & Certification	1
Ministry of Agriculture (RO)	Registration & Certification	1
COBORU (PL)	Registration & Certification	1
ISTIS (RO)	Registration	1
Third countries		
Canadian Food Inspection Agency (CA)		1
USDA United States Department of Agriculture (USDA) (US)		1
Post-registration		
ARVALIS (FR)		1
NIAB (UK)		1

Association of users	
National level	
AGPB (FR)	1
NFU (UK)	1
NAAC (UK)	1
DANISH AGRICULTURAL COUNCIL (DK)	1
EU level	
COPA-COGECA	2
Association of suppliers	
National level	
BDP (DE)	1
PLANTUM (NL)	1
BSPB (UK)	1
AIC (UK)	1
ANSEM (RO)	1
EU level	
ESA	3
CIOPORA	1
International level	
ABDP (Association of Bio-Dynamic Plant Breeders)	1
Other	
OECD	1
International Seed Federation (ISF)	1
European Crop Protection Association (ECPA)	1
FIBL (Institut de recherche de l'agriculture biologique)	1
EUROPABIO	1
Total	**55**

4.4. IN-DEPTH STUDIES

The FCEC team, DG SANCO and the steering group have agreed on 9 cases for in-depth study, as follows:

In-depth study 1: Effects of the implementation of the EU S&PM legislation in one New Member State (NMS)

Selected MS: Romania

Methodology: Three face-to-face interviews with registration & certification authorities and suppliers.

Themes for questions during the interviews:

- Degree of adequacy between the national legislation and EU legislation before accession;
- Time and resources required to implement the legislation;
- Support received from EU;
- Consequences for authorities in terms of management of activities (advantages, disadvantages, specific issues linked to this implementation, etc…);
- Actual status of implementation.

In-depth study 2: Analysis of the effects on costs of the implementation of the preferred options for better regulation

Selected MS: France and Denmark

Methodology: Four face-to-face interviews with registration and certification authorities in selected MS.

In-depth study 3: Conservation varieties

Methodology:

- Literature review;
- Three face-to-face interviews with partners to the STREP[1] project "Farm Seed Opportunities" and DG SANCO.

Themes for questions during the interviews:

- Background;
- Overall objectives;
- Limits of S&PM legislation with regards to the diversity of varieties derived from the on farm conservation / management / breeding;
- Quality of relations with authorities;
- Evaluation of the first Commission Directive on conservation varieties;
- Preferred approach for further development.

In-depth study 4: Analysis for one crop on the effects of suppressing VCU testing (winter wheat)

Selected MS: Denmark, France, Germany, Hungary, UK; based on the average number of applications per MS as mentioned in the "*Comparative study of National Listing Systems for some agriculture crops in the main European countries*" carried out by the GEVES in January 2003.

Methodology:

Step 1: Short questionnaire sent to the authorities in charge of VCU testing in the selected MS, to the ESA and to COPA-COGECA.

Step 2: Follow-up by phone interviews or face-to-face meeting when a visit was planned to discuss other aspects of the evaluation such as a discussion on the options/scenarios for the future.

Themes for questions in the VCU questionnaire:

Description of the VCU testing network (closed questions to the authorities in DK, DE, FR, HU and UK):

- Average number of applications /year;
- Duration of the testing;
- Total number of trials;
- Distribution of field trials (authorities vs. industry);
- Average VCU acceptance rate;
- Fees per application;
- Average approximate costs to run the VCU network;
- Approximate number of FTEs dedicated to the management of the VCU network.

Effects of suppressing VCU testing on (semi-open questions to the authorities in DK, FR, DE, HU, UK, ESA and COPA-COGECA):

- Time to market (number of years before a variety can enter the market);
- Performance of the varieties;
- Suitability of varieties to market needs;
- Information to the users;

[1] STREP project contract no. 044345, under the 6th Framework Programme, priority 8.1, "Specific Support to Policies."

- Consequences for breeders' Post-registration schemes;
- Level of costs borne by:
  - Authorities
  - Suppliers
  - Users;
- Other direct and/or indirect effects to be expected.

In-depth study 5: Analysis for one crop of the feasibility of having DUS testing at European level rather than at national level (winter oilseed rape)

Selected MS: CZ, DK, FR, DE, IT, PL, UK; based on actual implementation of major DUS sites.

Methodology:

Step 1: Short questionnaire sent to the official authorities in charge of DUS testing in the selected countries, to the ESA, COPA-COGECA and the CPVO.

Step 2: Follow-up by phone interviews or face-to-face meeting when a visit was planned to discuss other aspects of the evaluation such as a discussion on the options/scenarios for the future.

Themes for questions in the DUS questionnaire:

Description of the MS DUS testing networks (closed questions to the authorities in CZ, DK, FR, DE, IT, PL and UK):

- Average number of applications /year;
- Duration of the testing;
- Fees per application;
- Size of the reference collection;
- Average approximate cost to run the DUS testing;
- Approximate number of FTEs dedicated to the management of the DUS testing.

Effects of setting-up DUS testing at European level on (semi-open questions to authorities in CZ, DK, FR, DE, IT, PL, UK, ESA, COPA-COGECA and CPVO):

- Time to market (number of years before a variety can enter the market);
- Consequences for breeders;
- Reasons why it has not been done yet;
- Flexibility of the system;
- Selection of DUS centres;
- Level of costs borne by:
  - Authorities;
  - Suppliers;
  - Users;
- Other direct and/or indirect effects to be expected.

In-depth study 6: Clarification of the definition of the terms 'marketing', 'seed', and 'seed marketing'

Methodology:

- Literature review;
- Three face-to-face interviews with stakeholders.

Themes for questions during the interviews:

- Identification and listing of actual issues;
- The impact of the legislation on modern farming practices;
- Illegal EU imports of S&PM (background, issues, possible solutions);
- S&PM produced in EU and exported to third countries;
- Perimeter of marketing to be covered by Community legislation.

In-depth study 7: Analysis for one crop of the extension of the certification activities carried out under official supervision; **in-depth study 8:** Analysis of the possible advantages of a 3rd private party body set-up for supervision

Selected MS: France.

Methodology:

- Literature review;
- Linked with the in-depth study on the analysis of the effects on costs (in depth study 2):
  - Face-to-face interviews with the certification authorities identified in the framework of the in depth study 2;
  - One face-to-face interview with the ESA.

Themes for questions during the interviews:

- Consequences for breeders;
- Reasons why the extension of the certification activities has not yet been done;
- Feasibility, e.g. flexibility of the system to adapt to a new operational structure;
- Effects on the quality of seeds;
- Effects on the level of costs borne by:
  - Authorities;
  - Suppliers;
  - Users;
- Other direct and/or indirect effects.

In-depth study 9: Analysis of the interest to connect and to bring together the seed phytosanitary requirements with the certification legislation of plant health.

Selected MS: Germany, Italy, the Netherlands, Poland, UK; based on the national S&PM market size for seed potatoes, vegetables and ornamentals plants in which phytosanitary aspects are of relevance.

Methodology:

- Phone and face to face interviews with MS authorities and suppliers (e.g. NL which merged both authorities in 2007);
- One face to face interview with DG SANCO - plant health service;
- Additional possible interview with EPPO, if relevant.

Themes for questions during the interviews:

- Identified issues at EU and MS levels;
- Opportunities to group plant health and S&PM legislation at community level;
- Consequences (operational, costs, etc…) for the MS;
- Expected improvements.

4.5. METHODOLOGY FOR THE PRESENTATION OF RESULTS

The results of the evaluation are presented by distinguishing between the analysis of the past/current performance of the S&PM legislation, the presentation of the scenarios for the future and the preliminary analysis of the impact of those scenarios.

For the analysis of the past/current performance, the FCEC team distinguishes between the variety/material registration activity and the certification activity. For each activity, it draws conclusions and recommendations on a complete analysis including the current implementation of the activity, its costs, utility, effectiveness, efficiency as well as the results of any specific in-depth study related to it.

This analysis of the past/current performance is completed with the one of some over-arching issues (i.e. horizontal issues such as the structure of the S&PM legislation, the legal instrument, the role of the CPVO, the perimeter of the terms 'marketing', 'seed', 'seed marketing' and the quality of the information to the users) as well as other issues (i.e. the impact of the S&PM legislation on the marketing of conservation varieties).

When relevant, the FCEC team distinguishes between the groups of crops (Seed, Propagating Material and Forestry Material), the type of stakeholders (policy-making authorities, registration authorities, certification authorities, associations of S&PM suppliers and associations of S&PM users) and/or the MS (EU12 MS or EU15 MS).

In case reference is made to the results of the qualitative survey, the text specifies the concerned question of the questionnaire as well as the number of respondents (identified by 'n=') having answered to the specific question. Not all sections and questions of the questionnaire were relevant to all stakeholders targeted by the survey. A copy of the results of the qualitative survey is provided in Annex 4.

The different sections on conclusions and recommendations focus on the overall possible recommendations for the EU S&PM legislation in the future, as suggested in the qualitative questionnaire or as formulated by the stakeholders on their own initiative. In case one or several stakeholders or the FCEC make suggestions to improve a specific issue in the future, it is identifiable with a line in the margin as shown on this paragraph. A list of those specific suggestions is provided in Annex 5.

The link between the structure of the final report and the evaluation questions as listed in the ToR is provided in Annex 6.

Reliability of the data on costs (Group Seed only)

The costs for the public authorities and the private operators vary in each MS according to the structure of the public administration (i.e. centralised or decentralised structure), the level of requirements imposed by the national legislation for certification, the way the certification activity is organised (i.e. certification under official examination or certification under official supervision), the importance of each individual crop, etc.

All data provided by the national authorities result of real annual expenditures. Typically, data are extracted from the authorities' accounts and the level of details is based on the structure of the accounting system.

Of course such accounting system does not exist at the level of the associations of suppliers, which have estimated costs on the basis of data provided by their members.

The FCEC team has made a detailed quality control of the cost estimates provided by respondents, on the basis of the comments they provided in their questionnaire, by contacting them by email or phone to get additional explanations when required as well as by comparing figures between MS. Overall, the FCEC considers that the costs provided are sufficiently reliable to support the overall objectives of the evaluation.

Furthermore, the costs identified by the public authorities and the private operators reflect the implementation of the legislation at national level, in which additional provisions, to the EU ones, have been implemented. Therefore, the figures presented in this report do not segregate costs related to implementation of the EU legislation from costs generated by the national additional provisions. This remark mainly concerns most of the EU 15 MS, such as France and Germany.

5. BACKGROUND INFORMATION

5.1. INTERVENTION LOGIC (PAST)

The intervention logic presents the conceptual link from an intervention's input to the support of operational, specific and general objectives.

The general objectives are the overall goals of the intervention.

The specific objectives are the immediate objectives of the intervention, i.e. the targets that first need to be reached in order for the general objectives to be achieved.

And, the operational objectives are normally expressed in terms of outputs that the intervention should produce. The achievement of these objectives is usually under the direct control of those managing the intervention.

The figure below summarises the past/current intervention logic of the Community legislation on the marketing of S&PM:

Figure 1 – Intervention logic of the Community legislation on the marketing of S&PM (past/current)

General objectives

- To improve productivity in agriculture
- To improve the competitiveness of S&PM sector
- To contribute to the good functioning of the internal market

Specific objectives

- To ensure that no new variety can be marketed unless it is genuinely new and an improvement on varieties already being sold
- To ensure S&PM lots of high quality
- To harmonise the marketing standards at Community level

- To set up the legal framework for VARIETY/MATERIAL REGISTRATION
  - To test the new varieties in view of official listing: DUS test (for vegetable and agricultural crops), VCU test (for agricultural crops);
  - To register the varieties in official catalogues.
- To set up the legal framework for CERTIFICATION, in order to produce high quality seed/material by:
  - Controlling the correct varietal identity on the basis of DUS results;
  - Examining the respect of standards for e.g. varietal purity, freedom from disease, analytical purity, germination capacity, weed and other crop seeds content ;
  - Supervising the sealing, labelling and sampling of seeds.

Inputs

S&PM Community legislation

Common Catalogue (requirements for registration of varieties of agricultural plant species)
2002/53/EC (common catalogue)

Marketing of agricultural and vegetable seeds (requirements for certification)
66/401/EEC (fodder plant seed)
66/402/EEC (cereal seed)
2002/54/EC (beet seed)
2002/55/EC (vegetable seed – including the requirements for registration of varieties of vegetable species)
2002/56/EC (seed potatoes)
2002/57/EC (seed of oil and fibre plants)

Marketing of propagating material (requirements for certification)
68/193/EEC (material for vegetative propagation of the vine)
92/33/EEC (vegetable propagating and planting material other than seed)
92/34/EEC (fruit plant propagating material and fruit plants intended for fruit production)
98/56/EC (ornamental plants)

Marketing of forestry material (requirements for certification)
1999/105/EC (forest reproductive material)

S&PM Marketing Directives have existed since the mid 1960s. The main need felt at the time when these Directives were first adopted was to improve the productivity of agriculture by providing the farmers with S&PM lots of high quality (certification) belonging to new and improved varieties (registration of varieties in official catalogues and testing in view of official listing). The production and marketing of S&PM of high quality would contribute to improve the competitiveness of the related sectors within the EU and on the world markets. At the same time, it was expected that the industry (breeders and producers) would benefit from the harmonisation of the legislation at Community level leading to more open markets.

To support those objectives, the EU has developed a legal framework of 12 Directives based on two main pillars/activities as follows:

- Variety/material registration, which refers mainly to Directives 2002/53/EC and 2002/55/EC. Those Directives impose to all MS to compile one or more national catalogues of the varieties accepted for certification and marketing on their territory. To be accepted, a variety must be Distinct, Stable and sufficiently Uniform (DUS) and, in the case of agricultural crops, it must be of satisfactory Value for Cultivation and Use (VCU). The Directives also foresee the compilation of a Common Catalogue of varieties, based on national catalogues only. Once a new variety is listed in the national catalogue, it is registered for the entire EU and listed in the Common Catalogue of varieties of agricultural plant species or the Common Catalogue of varieties of vegetable species. It becomes *de facto* freely marketable within the Community;
- Certification, which refers to Directives 66/401/EEC, 66/402/EEC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 68/193/EEC, 92/33/EEC, 92/34/EEC, 98/56/EC and 1999/105/EC. Certification imposes to all MS to apply production schemes, which are intended by official control to ensure identity, varietal purity, germination capacity, freedom from diseases, etc. In order to ensure the identity of the S&PM, those Directives establish rules on packaging, sampling, sealing and marking.

Not all species have the same obligations. The link between the 12 Directives of the legislation and the main obligations for VCU, DUS, Denomination, National Listing, Maintenance, Certification, is presented at section 7, which analyses the past/current performance of the S&PM legislation.

It has to be noticed that implementation of the Community legislation has a quite unique profile in the agro-business area and even wider, in the life science area. Whereas for plant protection products, pharmaceutical products and machinery products, it is up to the applicant to present the data package for evaluation for registration by the authorities; in the S&PM sector, the official authorities are producing the data. This situation is the heritage of individual regulatory framework developments.

5.2. HISTORY OF THE DEVELOPMENT OF THE S&PM LEGISLATION

5.2.1. Origin

The Directives of the S&PM legislation find their legal basis in the Article 37 of the Treaty establishing the European Community, according to which the activities of the Community are to include measures implementing the Common Agricultural Policy. The development of the S&PM legislation dates back to the 60s, as presented in the following table.

Table 4 – Initial versions of the current Community S&PM Directives

Current Community S&PM Directives	Initial Community S&PM Directives
66/401/EEC (fodder plant seed)	Idem
66/402/EEC (cereal seed)	Idem
68/193/EEC (material for vegetative propagation of the vine)	Idem - Heavily amended by 2002/11/EC (SLIM exercise)

92/33/EEC (vegetable propagating and planting material other than seed)	Idem
92/34/EEC (fruit plant propagating material and fruit plants intended for fruit production)	Idem
98/56/EC (ornamental plants)	Council Directive 91/682/EEC of 19 December 1991
1999/105/EC (forest reproductive material)	Council Directive 66/404/EEC of 14 June 1966 Council Directive 71/161/EEC of 30 March 1971
2002/53/EC (Common Catalogue)	Council Directive 70/457/EEC of 29 September 1970
2002/54/EC (beet seed)	Council Directive 66/400/EEC
2002/55/EC (vegetable seed)	Council Directive 70/458/EEC of 29 September 1970
2002/56/EC (seed potatoes)	Council Directive 66/403/EEC of 14 June 1966
2002/57/EC (seed of oil and fibre plants)	Council Directive 69/208EEC of 30 June 1969

The majority of Council Directives for the marketing of S&PM has first been issued between 1966 and 1971, i.e. Council Directives for the marketing of fodder plant seed, cereal seed, beet seed, vegetable seed, seed potatoes, seed of oil and fibre plants, material for vegetative propagation of the vine, forest reproductive material as well the Council Directive on the Common Catalogue. Some Directives are more recent as the Council Directive for the marketing of vegetable propagating and planting material other than seed and the one for the marketing of ornamental plants.

These original Directives have been updated both frequently and substantially, creating the need for clarity and transparency. In some cases, this has been pursued in the current versions. For example, subsequent updates of the Common Catalogue over a period of 30 years since its introduction in 1970[2] have led to the current codified Directive adopted in 2002.

In other cases, for example, the marketing Directives on fodder plant seed, cereal seed, and propagating material (particularly of vine PM) the original Directives are still in force although these have been subject to a large number of amendments.

The SLIM initiative (Simpler Legislation for the Internal Market) launched by the Commission in May 1996 has lead to the recasting of the Council Directive on the marketing of ornamental plants in 1998 as well as to the '2002' Directives (2002/53/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC). Directives 66/401/EEC and 66/402/EEC were not included in this SLIM initiative as some amendments were ongoing at the time when the Directives were recast.

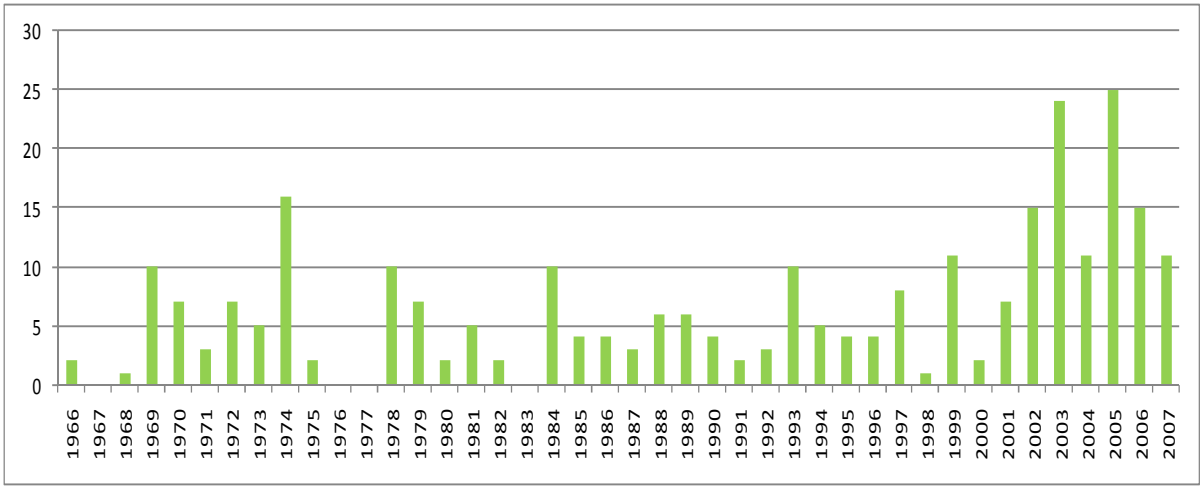
As a follow-up to the OECD revision of its trade scheme for forest reproductive material in the mid 1990s, the EU undertook to renew its old directive so that there would be only one set of definitions and rules for marketing of forest reproductive material. The new Directive (1999/105/EC) has standards that reflect the 1999 membership of 15 member states as compared with the original six. Compared to the Directive of 1966, the number of species concerned has increased dramatically.

At the time when the evaluation was carried out, a Commission proposal for a recast of the fruit Directive was discussed at Council level. Council Directive 2008/90/EC, based on this proposal, was adopted on 29 September 2008 and was published in the OJ L 267 on 8 October 2008.

[2] Council Directive 70/457/EEC of 29 September 1970 on the common catalogue of varieties of agricultural plant species.

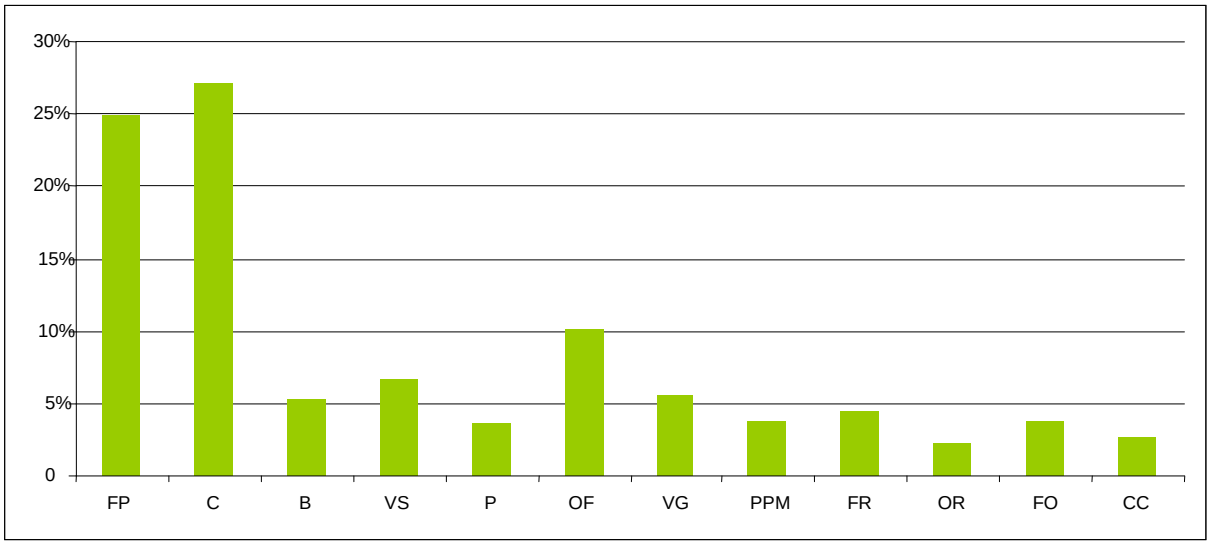
5.2.2. Number and evolution of legislative texts

Graph 1 - Number of Community regulatory texts (still in force) related to the marketing of S&PM per year



Source: compiled by Arcadia International based on the list of Community legislation applicable on 1st March 2006 – updated for texts published before 1st January 2008.

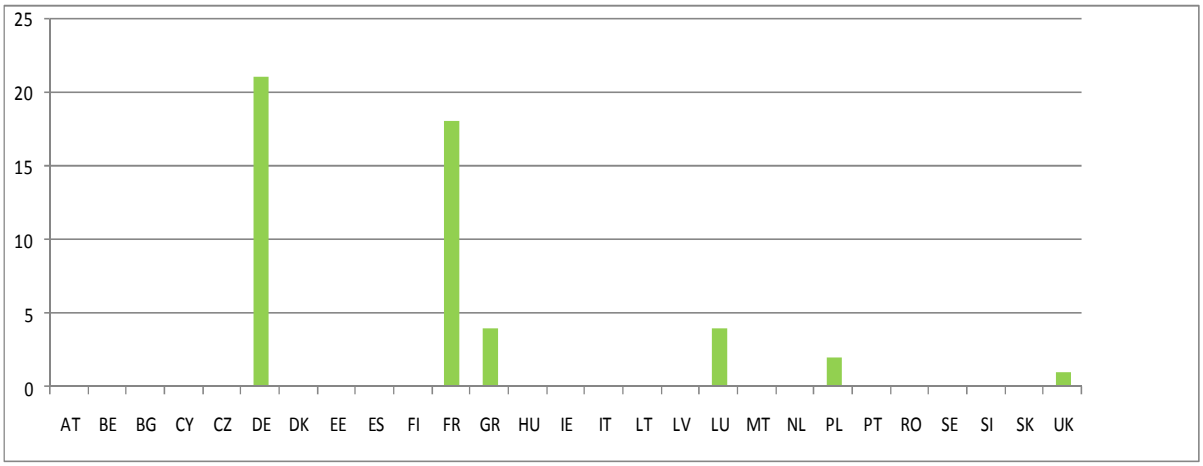
Graph 2 – Proportion (in %) of Community regulatory texts (still in force) related to the marketing of S&PM per year (per crop and group of crops)



Source: compiled by Arcadia International based on the list of Community legislation applicable on 1st March 2006 – updated for texts published before 1st January 2008.

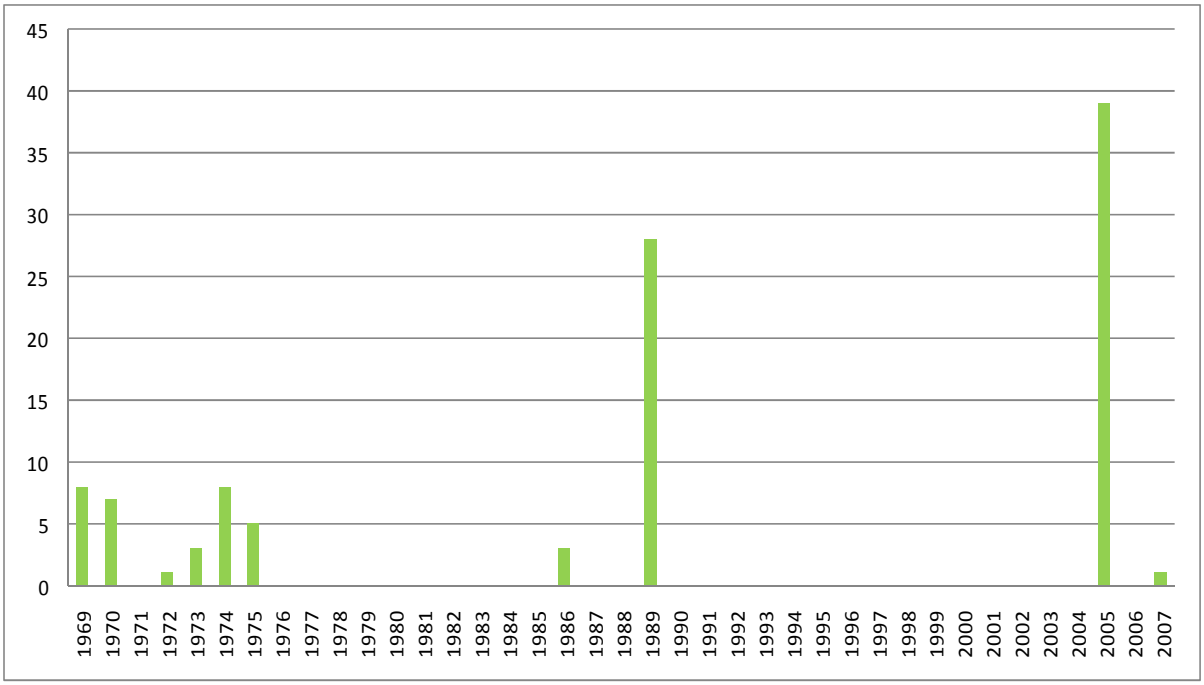
5.2.3. Exemptions of application in the MS & authorisations for more strict provisions

Graph 3 – Number of Commission Decisions (still in force) authorising Member States to restrict the marketing of S&PM or authorizing them to make more strict provisions (per MS)



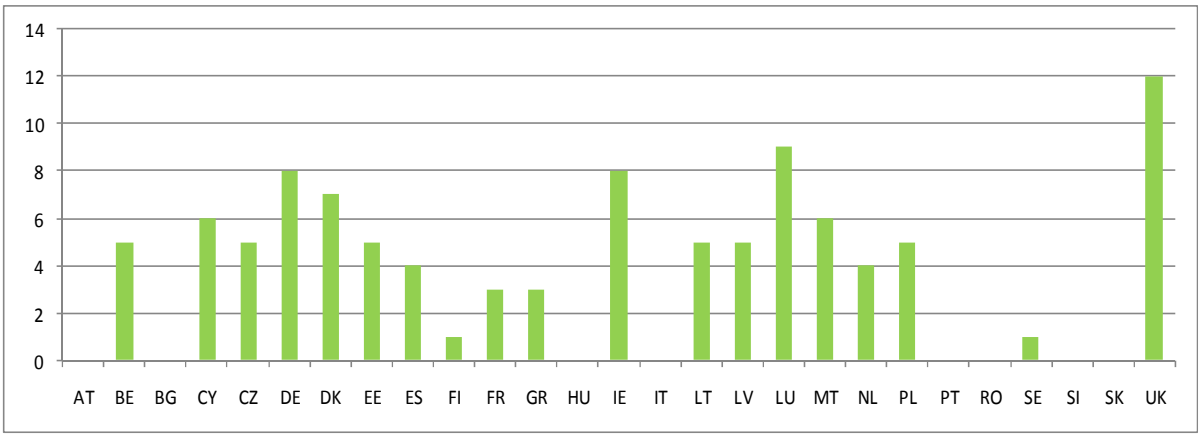
Source: compiled by Arcadia International based on the list of Community legislation applicable on 1st March 2006 – updated for texts published before 1st January 2008.

Graph 4 – Number of Commission Decisions (still in force) authorising Member States to restrict the marketing of S&PM or authorizing them to make more strict provisions (per year)



Source: compiled by Arcadia International based on the list of Community legislation applicable on 1st March 2006 – updated for texts published before 1st January 2008.

Graph 5 – Number of Commission Decisions per country granting exemptions to the application of some Directives on the marketing of S&PM

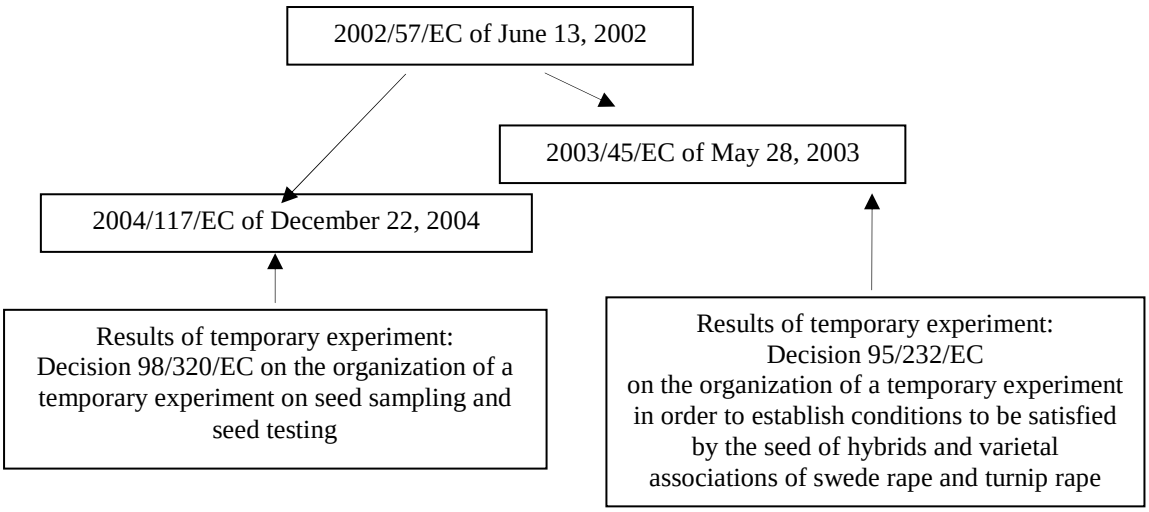


Source: compiled by Arcadia International based on the list of Community legislation applicable on 1st March 2006 – updated for texts published before 1st January 2008.

In the context of the 2004 enlargement, derogations were granted for FRM to Poland, for barley (analytical purity) to Cyprus and for variety registration to CY, MT, LV, SI (5 years transition). In 2004, a same type of derogation has been granted to a number of additional NMS, but only for 3 years (based on Art 42 of the Act of accession). These 2 elements explained the high figures for 2005 on the graph 4.

Having explained that point, the above statistics do not highlight significant trends. It can be mentioned that the Graph 1 indicates that the number of Community regulatory texts (still in force) is slightly inflating from 2001-02 and mainly due to EU enlargement and consequences of recasting some Directives in early 2000. This may be explained by the necessity to update certain old Directives based on other ongoing activities such as temporary experiments. The oil & fibre plants Directive gives a concrete example in that respect, where 3 major texts have been published is less than 30 months time as presented on the next figure.

Figure 2 – Major evolution of regulatory requirements for oil & fibre plants from 2002 to 2004



5.3. CONTEXT INTO WHICH THE S&PM LEGISLATION OPERATES

5.3.1. Description of the seed sector in the EU

This analysis summarises the situation of the seed sector in the EU and the context in which it operates. More data and statistics are presented in annex 12. It is limited to seed only, because of the difficulty to get reliable market data for some plant propagating materials as well as for forestry material (seed or plants). Even more, it appears that stakeholders have a different view on the trend of the competitiveness in the forestry sectors leading to a possible non-reliable analysis.

The following table is a simple example on maize highlighting the difficulties of summarizing statistics in the seed sector as different data sources show differences and as data, structure is not consistent across documents.

Table 5 – Seed production statistics variability in Maize

Maize (2006 data)		
	Source of information	
	GAIN report	**ESCAA Database**
Volumes of certified seed (in Tons)		
France	100 000	155 322
Hungary	68 500	84 846
Germany	52 650	
Italy	28 350	24 752
	Source of information	
	ESA	**ESCAA Database**
Multiplication area (in Ha)		
France	54 000	39 159
Hungary	25 000	19 352
Romania	15 000	8 965
Austria	5 300	5 007
Italy	4 500	2 925

Source: compiled by Arcadia International

Although the seed industry is crucial for modern agriculture, worldwide total sales and profits are not as large as for other agricultural inputs, such as pesticides, machinery and fertilizers.

The global commercial seed market place, which continues to experience a robust growth, approached a value of 24 billion USD in 2006[3]. The Context Network estimates that the 2006 proprietary part of the global commercial seed market value has reached 19,6 billion USD, an increase of nearly 40% over 2001 estimates.

Maize and soybean, representing nearly 50% of the global seed market, are by far the two largest seed crop markets.

Traditionally, the seed markets were national markets with quite a low volume of international exchanges. This has changed during the last 20 years. The seed trade is estimated to have more than tripled between 1970 and 1994, and quadrupled between 1985 and 2005.

The European Seed Association (ESA) estimates that the EU commercial seed (true seeds only) market value has reached approximately between 6,5 and 7,1 billion Euros and represents more than

[3] Source : International Seed Federation (ISF)

20% of the total worldwide market for commercial seed. USDA estimates the EU market size for planting seeds at 6,1 USD million[4].

The EU is the largest exporter with an estimated export value of 2,7 billion Euros representing more than 60% of the total worldwide export value of 4,9 billion Euros.

This evolution is quite unique in the agri-business sector especially when we compare the European seed market evolution with the pesticides market (PPP), which are today quite equivalent in market value at about 6,5 billion Euros (PPP market value estimation at 6 769 million Euros in 2004 by ECPA).

The EU market for agrochemicals has been relatively flat during the last 15 years. In 2004, the global PPP market was valued at 24 734 million Euros, the European area market share amounted to 6 769 million Euros, or 27,4 % of the total[5]. The EU market for agrochemicals is in a transition phase because of legislative and structural changes due to the reform of the Common Agricultural Policy (CAP), and because of individual government legislative measures to cut usage.

In comparison, there is still an important potential on the international market for improved seed.

Several sources indicate an annual growth rate of about 5% for field crops at global level, based on the following major drivers:

- It is widely believed that only one-third of global seed consumption is commercially traded;
- Crops consumption is expected to grow. In the OECD-FAO agricultural outlook 2007-2016, worldwide wheat consumption is estimated to increase by nearly 10% by 2016 due to key economic factors such as population growth, rising income in developing countries inducing meat consumption increase, increased demand for higher value foods;
- Emerging economies of China, India, Brazil and Russia;
- Assumptions related to evolving biofuel production.

In 2006/2007, EU grain seed production was anticipated to increase due to the reasons mentioned above. Because of the increased acreage for grain seed production, EU grass seed production was expected to decline in 2007. Currently the market for grass seeds is in an oversupply situation.

The EU became a net exporter of seeds for sowing in 2002/2003, and its trade surplus has gradually increased since then to 300 million USD in 2005/2006. Both EU imports and EU exports evolutions are related to a strong increase of exchanges in vegetable seeds.

For several decades after plant breeding emerged as a recognized field of science in the late 19th century, almost all plant breeding activities took place in public institutes with a gradual shift of breeding activities to the private sector during the 20th century. This may explain why plant breeders (public first and then public & private) have been largely involved in the development of national regulatory frameworks.

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

The emergence of biotechnology in agriculture in the 1980s has led to a complete reorganization of the sector. Today, leading seed groups are largely owned or allied with the world leading chemical/plant

[4] USDA Foreign Agriculture Service. GAIN report E47011-2007

[5] ECPA, Annual Report 2004-2005

protection companies. Consolidation through mergers and acquisitions took place in major field crops, and is currently ongoing in the vegetable sectors. Chemicals companies' interests in investing in biotech are linked to the fact that many pesticides used in agriculture may be replaced by transgenic crops, which have a biologically inbuilt resistance.

In 1996, the world top 10 seed companies were representing about 37% of the worldwide market; in 2004, the top 10 accounted for nearly 50% of the worldwide-certified seed market[6]. Monsanto, the actual market leader was not present in the top 10 in 1996.

The European seed sector is characterized by a large segmentation (from national SMEs involved in cereals or ornamentals only to international companies with a multi-crops approach).

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

In 2005, ESA statistics indicated that 21 companies, out of 41 ESA individual members, have an annual turnover of less than 50 million Euros while the 3 largest companies have a turnover of more than 250 million Euros each. These statistics show that the EU seed sector is still made of a majority of small and medium size companies (SME's).

As mentioned above, industry consolidation that started about 15 years ago happened in field crops areas. Genetic material, biotechnologies and their associated Intellectual Property Rights (IPRs) have been in fact leading to a new restructuring of the relations between agrochemical, biotech, food processing, and seed companies. Plant breeding, considered in the past as a "*secret*" and "*non-scientific*" activity, is moving to a high-tech industry involving more and more trans-national companies. This consolidation has created a visible break between biotech-in and biotech-out companies.

In the EU15 MS, the number of employees in the private seed sector amounts to around 30 000. The personnel involved in private R&D (plant breeding) are around 5 000 and these are working in around 600 major research stations according to ESA figures.

The existence of a plant breeding capacity is a precondition for the release of well-adapted plant varieties suited to the growing conditions, resistant to pests and diseases, with the quality requirements that the food and feed industry requires.

We observe 2 major groups of breeders as follows:

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

5.3.2. Challenges for the future

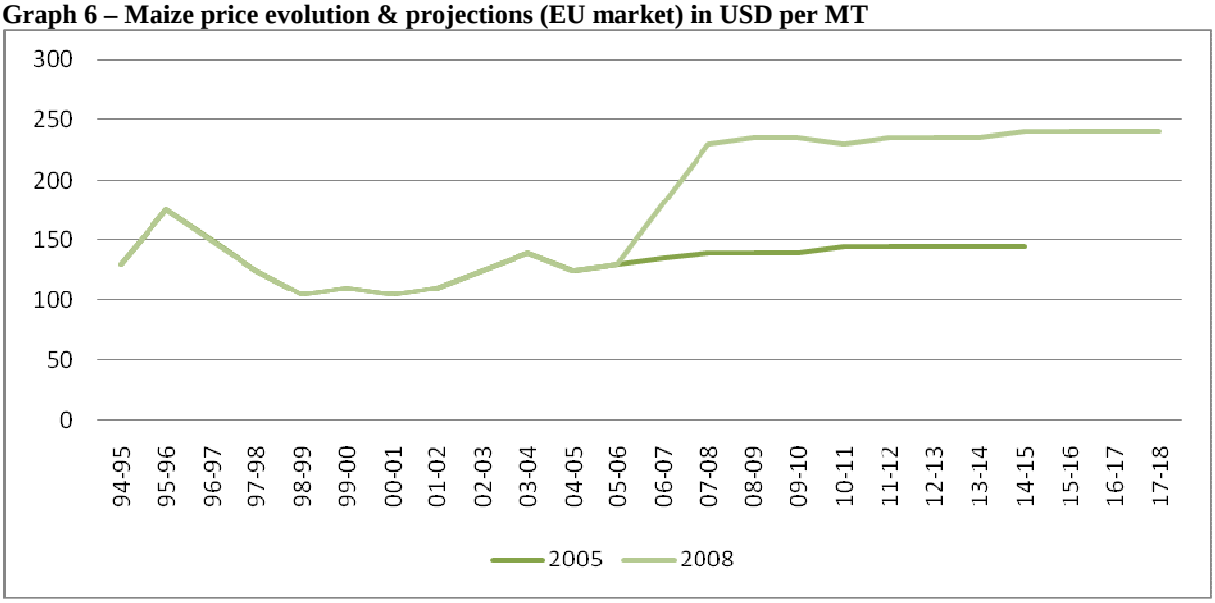
The seed sector is facing several key challenges, as listed by the Steering Group in the ToR of the evaluation (see Annex 1). An additional "*surprising*" one appeared in the last 18 months, which is the price increase of commodity grain.

The economic factors that contribute to higher commodity prices have been widely discussed and are not presented in this document.

[6] Source : ETC 2006 report

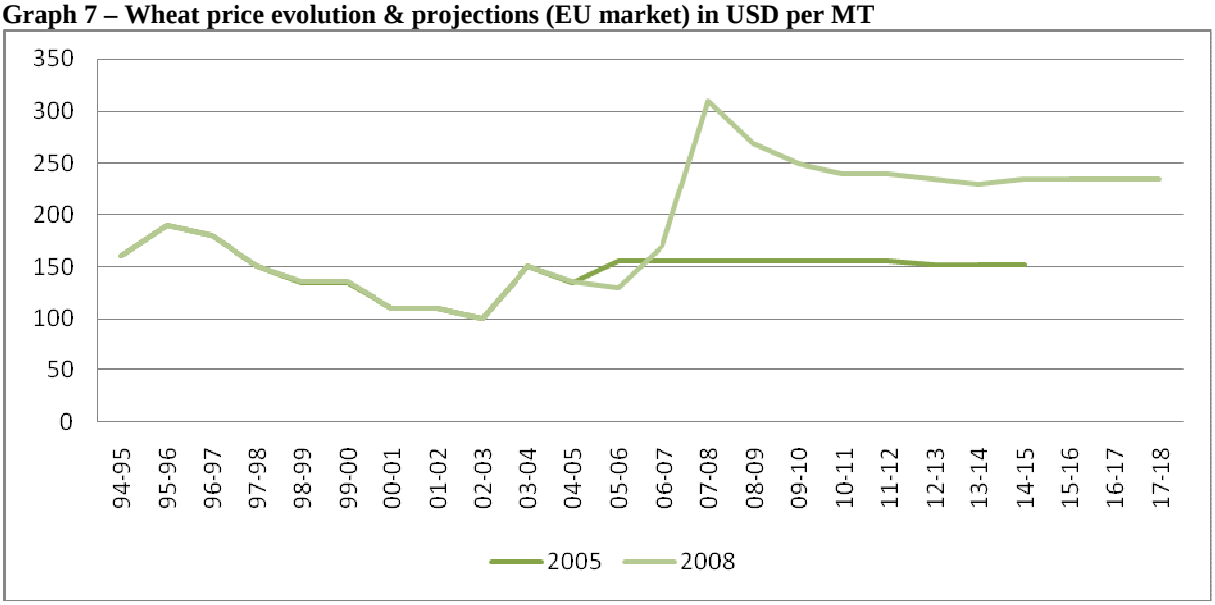
Commodity Price Increases

Graph 6 – Maize price evolution & projections (EU market) in USD per MT



Source: Food and Agricultural Policy Research Institute, agricultural outlook 2005 and 2008

Graph 7 – Wheat price evolution & projections (EU market) in USD per MT



Source: Food and Agricultural Policy Research Institute, agricultural outlook 2005 and 2008

Economists predict that grain prices will remain high over the next decade even if they may fall from current records as demonstrated by the 2008 first semester statistics.

Possible impacts on seed sector

This situation affects the complete agro-food value chain as often demonstrated during the last 12 months and results in food prices increases and volatility.

The seed sector, especially seed multiplication, may be affected by this recent evolution. Economic incentive to produce seed instead of commodity grain is not as high as in the past and could lead to a possible lack of financial motivation in producing seeds and move of the place for seed production impacting the volume of farm saved seed.

According to GNIS, France is facing difficulties to find seed multipliers acreages in maize. In 2008, offer of seed multiplication area by seed companies is higher than the seed multipliers (farmers) demand.

This situation could lead to a movement of seed production acreages to NMS (Romania for maize) where labour and production costs are lower. In that respect, it has been noticed maize seed production in Romania have significantly increased during the last 3 years (+ 15% in 2 years time).

As a positive impact to the industry, R&D and technology will again become profitable, due the high prices.

Higher grain prices impacts on the seed sector have to be monitored and taken into consideration in any impact assessment to be developed prior to any regulation change to the Community legislation.

5.3.3. Farmers' approach to varietal choice in agricultural crops

Professional users (farmers) of seed consider varietal choice as a key economic factor for the cost-effectiveness of the crops. It is being perceived as an investment that will lead to the annual revenue of the farm. Spraying a crop to control a plant disease can be repeated if the first treatment is inefficient. For seed, only one selection of a product (variety) is possible. This element is even more important in multi-year crops (e.g. fruits, forestry) when quality of the S&PM product may be seen only a couple of years after planting.

Farmers, therefore, pay much more attention to the selection of the new varieties they will integrate on their farm, than on other agricultural inputs (PPPs, fertilisers) as there is a complex interaction between the selection of a variety on the one hand and climatic conditions, soil preparation, plant protection, fertilisation, harvesting and crop rotation on the other hand (genotype-environment-interaction (GxE). As product-life cycle of varieties is rather short, best varieties stay about 4 to 6 years on top; farmers are, before each seeding period, looking at available information related to the quality and performances of the varieties and are even visiting field trials to have a look on new promising varieties. Their interest is to get access to independent data from trials that have been carried out as close as possible to their own farms by using the agronomical practice applied to their farm. Additionally, as variety selection is a key decision, farmers are used to test the new varieties on small acreages the first year to secure that it fits to the local cropping conditions. Finally, farmer's choice is based on the selection of new better (socio-) economic & environmental performances in local environment under dedicated farmer practices.

Sources of information vary from country to country and even from region to region, depending the local retailing structure. Information comes from different sources (cooperatives, retailers, official authorities, public and private technical institutes, seed companies). Major crop sectors of the agricultural industry have organised their own information on variety performances through recommended list trials and post registration networks. In some areas, it is reported that too many data are being produced leading to some level of confusions; in others, farmers do not have any data, at all, to take a decision.

5.4. OVERALL CONCLUSIONS

The Directives of the S&PM legislation find their legal basis in the Article 37 of the Treaty establishing the European Community and have existed since the mid 1960s. The objectives at the time when it was first developed was to improve the productivity of agriculture, to improve the competitiveness of the related sectors and to contribute to the harmonisation of the legislation at Community level leading to more open markets.

The Community legislation is based on two main pillars, i.e. the variety/material registration and the certification of S&PM lots, and covers the agricultural seeds (fodder plant, cereal, beet, potatoes, oil and fibre plants), the vegetable seeds, the propagating material (vegetable, vine, fruit and ornamental) as well as the forestry reproductive material.

Implementation of the Community legislation has a quite unique profile in the agro-business and even wider, in the life science area. Whereas for plant protection products, pharmaceutical products and machinery, it is up to the applicant to present the data package for evaluation by the authorities for registration purpose; in the S&PM sector, the data are being produced under official controls by the competent authorities themselves for DUS and VCU. Part of VCU tests is being sub-contracting to technical organisms or/and the plant breeders.

The 12 original Directives have been updated and amended frequently but not substantially. The core principles have not changed and the intervention logic has not been amended. Some of them have been recast for improved clarity in early 2000.

Requests for exemptions stay quite limited with no significant increase in time. Additionally, evolution of number of regulatory texts over years does not highlight any particular major issue due the legislation provisions.

For several decades after plant breeding emerged as a recognized field of science in the late 19th century, almost all plant breeding activities took place in public institutes with a gradual shift of breeding activities to the private sector during the 20th century. Today, The S&PM sector operates in an ever-increasing international context in constant evolution, where globalisation and the development of plant biotechnology play an important role. On global terms, EU competitiveness of S&PM sector seems satisfactory but hides significant variability when analysing competitiveness crop by crop. The lack of consolidated market statistics in certain areas such as ornamentals and forestry does not permit correct competitiveness assessments.

S&PM is not any longer one sector and should be considered as a set of several sectors, which are becoming more and more specific in terms of type of products, type and number of actors, competitiveness, product life cycle, R&D efforts, added value and return on investment. S&PM supply systems come in a variety of forms, and operate at a range of levels (international, national, regional and local) and with different S&PM materials used for different purposes. Players are multiple, and mainly medium and small size companies (SME's). Only a couple of them have a multinational dimension. Several interviewees are seeing the seed sector as a "*small secret specialised business*".

Additionally, the environment in which the S&PM users operate has, also, completely changed in less than 30 years. Today, major sectors of the agricultural industry have organised the production of their own information on variety performances to provide viable product information to farmers, which pay more and more attention to the selection of varieties to be grown on their farm. This is especially true in EU15 MS, less in NMS where the agricultural sector is still under development.

Finally, agriculture is going through a new development phase due the food prices increases, and probably future prices volatility, in which the seed sector needs to be flexible enough to adapt to these evolutions. Regulatory framework should, also be flexible to adapt to market and citizens' demands in order to secure S&PM sectors competitiveness.

6. THE 12 BASIC DIRECTIVES OF THE S&PM LEGISLATION

6.1. DESCRIPTION OF THE DIRECTIVES

Sections 6.1.1. to 6.1.4. describe the Community legislation as regards its organisational structure, its scope, its perimeter as well as the consistency between the provisions of the Directives (internal consistency of the legislation).

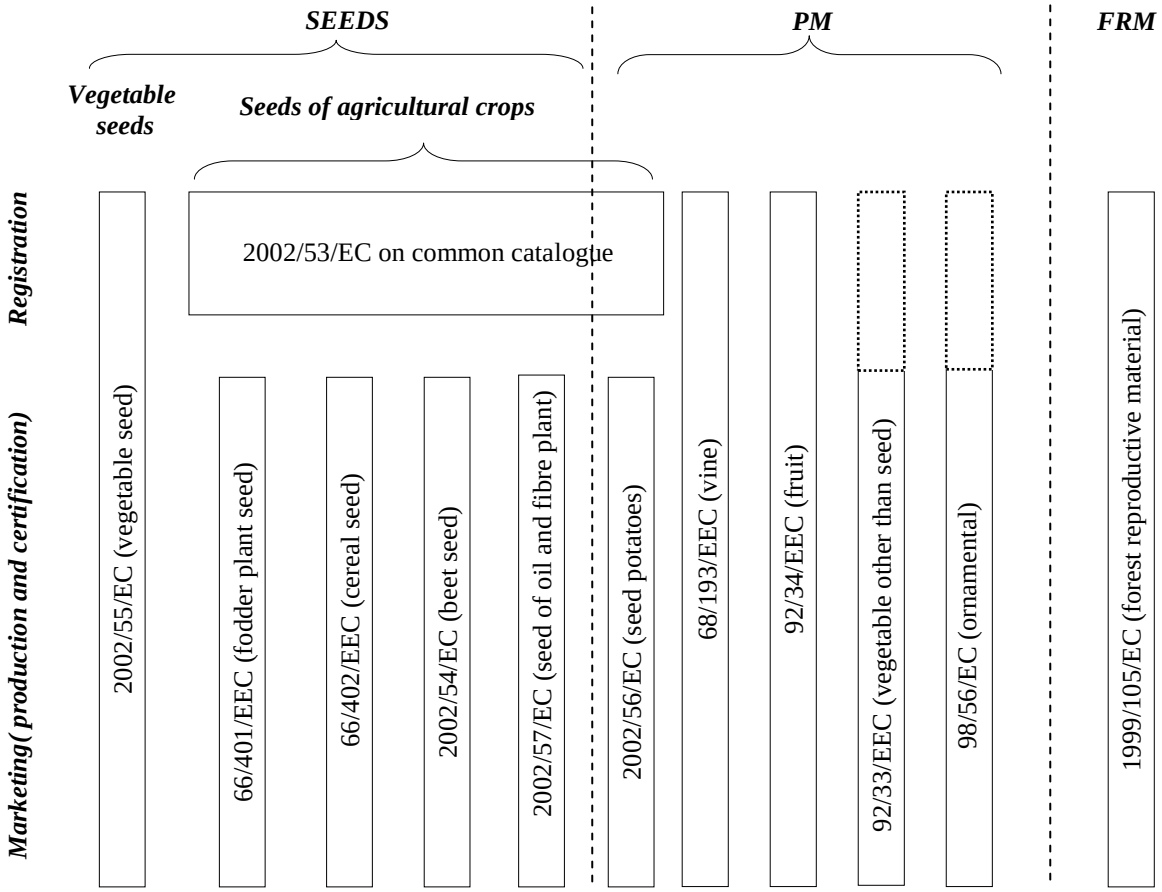
6.1.1. Organisational structure

Of the 12 basic Directives, one Directive concerns the establishment of a Common Catalogue of the varieties of agricultural plant species, six Directives relate to the marketing of agricultural and vegetable seed, four Directives to the marketing of propagating material and one Directive to the marketing of forestry material.

The Directive on the Common Catalogue for agricultural crops (Council Directive 2002/53/EC) has a horizontal structure and defines requirements for the registration of the various agricultural crops seed varieties with the exception of vegetable species varieties, for which the registration requirements are laid down in the marketing Directive (Council Directive 2002/55/EC). It is applicable to beet seed, fodder plant seed, cereal seed, seed potatoes and seed of oil and fibre plants.

The marketing Directives have a vertical structure (per crop or group of crops) and define requirements for S&PM marketing. They, also, contain some provisions related to registration of material and/or varieties via national listing or even via Common Catalogue in the case of vine. The ornamentals Directive do not contain such provisions and does not establish any obligation of implementing national catalogues.

Figure 3 – Structure of the 12 basic Directives of the legislation



It has to be noticed that although seed potatoes are in fact propagating material, the Directive on the marketing of seed potatoes is considered mostly together with the Directives for "*true seed for agriculture*" and is covered by CC Directive 2002/53/EC.

Additionally, it must be noted that two Directives exist for vegetables: Directive 2002/55/EC for vegetable seed and Directive 92/33/EEC for vegetable PM other than seed. This could lead to unclear legal situation (e.g. plants of listed vegetable varieties, which are grafted on unlisted rootstocks).

When looking at the content of the Community S&PM Directives, the evaluation team makes the following observations:

- The updated Directives, for example those dating from 2002 (i.e. including the Common Catalogue and some of the seed marketing Directives) and their amendments, are generally found to be sufficiently logically structured, clear and relatively easier to read;
- The old Directives, especially those dating from the mid 1960s, present more problems especially as these have undergone a significant number of substantial amendments. In these cases, the consolidated versions are particularly complex and confusing, with multiple and often erroneous or outdated cross-referencing, making them difficult to read.

6.1.2. Scope of the S&PM legislation

The Community legislation applies to the production with a view to marketing and to the marketing of S&PM within the Community. It does not apply to:

- The supply of S&PM to official testing and inspection bodies;
- The supply of S&PM to providers of services for processing or packaging;
- The supply of seed under certain conditions to providers of services for the production of certain agricultural raw materials, intended for industrial purposes, or seed propagation for that purpose;
- S&PM shown to be intended for export to 3rd countries. Not all S&PM produced in the EU and exported outside the EU are subjected to the provisions of the legislation. As mentioned during the interviews, this has led to situations where a variety rejected in the EU has been marketed in 3rd countries with less stringent rules.

Interviewees expressed several concerns regarding the definition of 'industrial use' and the correct implementation of this exemption as it's seems that MS have interpreted that exception differently, in particular as regards its application to 'holdings'. A specific case on marketing special wheat varieties for baking purposes is exempted from EU provisions in France and not in Hungary.

Additionally, when looking at canned & frozen vegetable and sugar beet organisations which show a high integration of actors from seed suppliers to product processors, via farmers; we may consider that these crops are being managed for 'industrial use'. However, exemption is not applying to these crop sectors.

Examples of exemptions based on this provision are very limited. On the top of the wheat example already mentioned, interviewees listed a second example on potatoes being produced for starch extraction in the NL and Germany.

Current development of biodiesel in Europe may lead to further discussion on this provision. All these productions will be managed for processing use only and being implemented via contractual approach between farmers and processors. Shall these productions be excluded from applications of marketing provisions or not?

FCEC team considers that it is necessary to review the terms and scope of the exemption regarding 'industrial use' to bring more clarity on the implementation of such provision, if still relevant for the future.

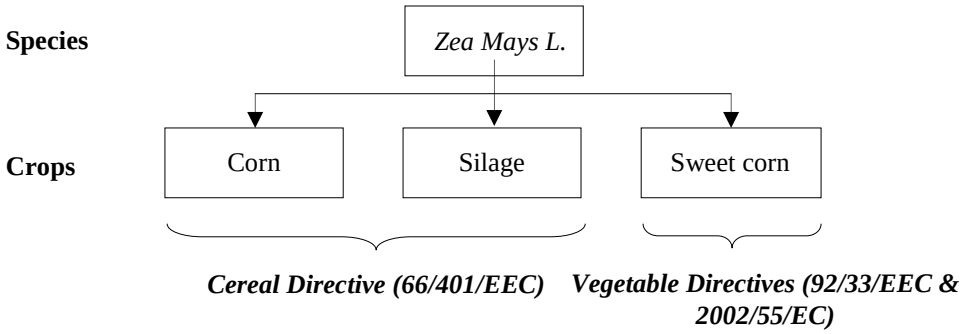
Community legislation does not apply to S&PM being produced for exporting to 3rd countries. This exemption has led to the situation where several breeding companies have exported seed of reduced

quality to neighbouring 3rd countries. Several interviewees, especially the ones at international's level, are considering that this situation is creating an ethical issue ("*not good enough for internal EU market, but good for 3rd countries*"). Actually, seed marketing with 3rd countries is based on OECD schemes (58 countries) or free marketing (e.g. India, China, South East Asia excepted Australia and New-Zealand). These practices seem to reduce as most of neighbouring countries to EU have adopted seed legislative frameworks.

Several marketing Directives can cover only one species e.g. the beet (2002/54/EC), potatoes (2002/56/EC) and vine (68/193/EEC). A couple of others cover a group of species e.g. cereal (66/402/EEC), fodder plant (66/401/EEC), and oil and fibre plants (2002/57/EC). Other Directives are based on the final usage of the material and/or varieties e.g. vegetable propagating and planting material other than seed (92/33/EEC), fruits (92/34/EEC), and forest reproductive material (199/105/EC). Finally, it has to be mentioned that no species are listed in the Annexes of the ornamental Directive (98/56/EC) as any ornamental plant (i.e. all species) are covered by the legislation.

A given species may be included in several Directives, mainly based on the final usage of the species. As an example, *Zea mays L.* covers maize when speaking about corn or silage as agricultural crops and therefore included in cereal seed Directive (66/401/EEC). When talking about sweet corn, *Zea mays L.* is listed in the vegetable Directive (92/33/EEC) and in Directive 2002/55/EC (see figure 4). This situation exists for several other species such as *Beta vulgaris L.* (sugar and fodder beets vs. chards).

Figure 4 – Case of one species (Zea Mays L.) covered by several Directives



The basic principle is that the S&PM legislation applies to crops/species of major economic importance in the EU.

Nevertheless, there are cases where a same Directive covers crops with different economic importance; e.g. the seed and oil fibre Directive covers winter rapeseed (major economic importance) and spring rapeseed (minor economic importance). The beet Directive covers the sugar beet (major economic importance) and the fodder beet (minor economic importance).

Imposing the same set of obligations for all crops under a same species could be explained by the need to avoid, in the case where different obligations would apply, the production of crops of major economic importance under the less stringent obligations defined for crops of minor economic importance. Such risk exists for some species (e.g. production of vine clones under the obligations of an ornamental and then cultivated for grape or vine production) but is not systematic. Keeping listed crops of minor economic importance is a disincentive for SME's that would like to exploit these niche markets, as they may have to support registration and certification costs, which are not adequate to the size of market.

Finally, the Community S&PM legislation, e.g. tobacco, do not cover some crops of high current economic value. Similarly, some crops not covered by the legislation could get an important economic value in the future with the development of the biofuels, e.g. *miscanthus*, sweet sorghum.

6.1.3. Perimeter of the S&PM legislation

The extent to which the perimeter of each directive is clearly defined (i.e. the species covered versus the species not covered) varies between Directives.

Overall, the seed Directives provide in their Article 2 details of the species currently regulated. Because a minor crop in one Member State may be a major one in another Member State, the Directives cater for such anomalies by allowing Member States to derogate from applying the provisions of the seed marketing Directives to any species which are not normally reproduced or marketed in their territory. For example, the UK has derogations against cotton and rice.

Since there has been considerable change in the relative economic importance of crop species over time, most of stakeholders and interviewees consider it is appropriate to review the lists of species covered by the Directives.

Directive 1999/105/EC defines in its article 2 forest reproductive material as *'reproductive material of those tree species and artificial hybrids thereof which are important for forestry purposes in all or part of the Community and in particular those which are listed in Annex I'*.

As discussed during the interview of forestry experts, there are some practical problems linked with the expression 'non-forestry purposes'. Such problems have been summarised in the Report of the Working Party on Forest Reproductive Material hold in Hoeven (NL) in September 2007, as follows:

- *'Some species which are listed in Directive 1999/105/EC of the Council can be used for purposes other than for forestry: conifers can be sown and raised with the aim to be marketed as Christmas trees, Fagus sylvatica and Carpinus betula as hedge plants, Prunus avium as rootstocks for the production of fruit or ornamental trees;*
- *When it is clear from the start that harvest of the reproductive material and the production of the plants is not intended for (multipurpose) forestry some member states prefer to exclude entirely the reproductive material of these genera or species from the obligations of registration and inspection such as they are prescribed by the FRM Regulations;*
- *Other MS however understand from Directive 1999/105/EC that at least the seeds of all the species listed in annex 1 of the Directive should be marketed according to the principles of the Directive, whatever the ultimate aim of the plants which will be raised from these seeds. This implies that the origin of each harvested and marketed seed lot should be traceable by means of the reference to an officially issued master certificate;*
- *This procedure is however not evident for growers or for inspection services which have no affinity with the FRM Regulations. The EC Directives dealing with propagating material of fruits or ornamentals do not specify official approval of seed producing units or the certification of reproductive material at harvest;*
- *There is therefore more than one possibility for marketing plants of the above mentioned species: either accompanied by a suppliers document such as specified by Directive 1999/105/EC (regulating marketing of forest reproductive material) with the mention "not for forestry purposes" or as ornamental plants accompanied by a suppliers document such as specified under Directive 1998/56/EC (regulating marketing of propagating material of ornamentals);*
- *When P. avium is considered as a fruit plant the propagating material and the plants should be accompanied by a supplier's document or a certificate such as specified under Directive 1992/34/EC (regulating marketing of propagating material and plants of fruits);*
- *In some member states the question has arisen whether the reproductive material of Populus and Robinia, as short or medium term harvestable units for biomass (and therefore considered as "not for forestry purposes"), should be certified and inspected under Directive 1999/105/EC. Unlike the above-mentioned species, it is not evident to consider them as ornamental plants with the result that they could be produced in the absence of any supervision from the authority;*

- *Many suppliers, especially in the Netherlands and in Belgium, find that the negative expression "not for forestry purposes" should not be part of vocabulary to be used in Regulations dealing with "forest reproductive material" and are therefore reluctant to include it on further suppliers documents based on Directive 1999/105/EC. In their view, the expression is in conflict with the essence of the Directive and they consider that the customer is informed enough based on the category.*

As concluded at the working party, there is a need for regulatory clarification in the future concerning marketing of FRM which is clearly considered not to be for 'forestry purposes' or is clearly not intended to be marketed or planted for long term forestry purposes.

6.1.4. Consistency between the provisions of the Directives

The large body of frequently updated legislation over the last 40 years may have created issues of lack of clarity and coherence.

As regards the internal consistency, the examination of the various Directives has shown the following type of gaps, discrepancies or inconsistencies:

- Cross-referencing to outdated legislation. For example, in the case of Directive 66/401/EEC on fodder plant seed[7], this makes various references to the repealed Common Catalogue (Directive 70/457/EEC)[8] rather than the current one (Directive 2002/53/EC). Similar inconsistencies were found in Directive 66/402/EEC on cereal seed[9].

Differences also exist in the specific way in which 'seed' and 'marketing' are being described and presented in each Directive:

- The Common Catalogue (Directive 2002/53/EC) does not contain any specific definitions for the terms 'seed' and 'marketing';
- By contrast, all of the marketing Directives contain a detailed definition for both terms. An overview of these definitions for each Directive of the seed legislation is provided in Annex 7;
- The definition of 'marketing' is consistently followed in detail in all Directives (see Annex 7);
- Similarly, the seed definitions are detailed in the same way in all Directives, depending on the type of seed as applicable in each case.

Additional inconsistencies in the definition of certain terms exist in the different texts. The term 'clone' is being defined in 2 existing Directives:

- In the vine Directive (68/193/EEC), clone is being defined as "*a clone is the vegetative progeny of a variety which is true to a vine stock on account of varietal identity, its phenotypic characters and its state of health"*;
- In the forestry Directive (1999/105/EC), clone definition is "*Groups of individuals (ramets) derived originally from a single individual (ortet) by vegetative propagation, for example by cuttings, micropropagation, grafts, layers or divisions"*.

According to experts interviewed, these 2 definitions are not fully consistent; and these experts indicated that during the recast of the fruit Directive, a 3rd definition was discussed and accepted.

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7 Latest consolidated version of 3 January 2008.

8 For example the authorisation provisions for GM material, Article 4a.1 (Directive 66/401/EEC): *"In the case of genetically modified material, such authorisation may be granted only if all appropriate measures have been taken to avoid adverse effects on human health and the environment. For the environment risk assessment to be carried out in this respect, the provisions of Article 7(4) of Directive 70/457/EEC shall apply accordingly."* Similar cross-references to Directive 70/457/EEC were found in Articles 13.1, 15.1, 22a.1(b) and in the Annexes of Directive 66/401/EEC.

9 Latest consolidated version of 20 June 2006.

These kinds of perceived inconsistencies are key elements to be considered when thinking about simplification of regulatory texts by reducing their number. In the section 5.4, FCEC concludes that the S&PM sector is more and more fragmented to the point that S&PM should be considered as a set of individual crop sectors.
This element points out the necessity/non-necessity and the benefits to solve these internal inconsistencies. There are no clear benefits to having a unique approved definition for 'Clone' as this will take lot of energy to try to get a consensus. Benefits of harmonizing definitions do not seem important enough knowing the difficulties of the exercise.

FCEC team consider that harmonization should be sought for legal provisions across regulatory texts, but when talking about technical elements e.g. term and definitions, harmonization is not fully required and should be considered on a case-by-case basis and on a crop sector-by-crop sector basis.

6.2. CONSISTENCY OF THE S&PM LEGISLATION WITH OTHER EC POLICY INTERVENTIONS

Obvious links exist between the Community legislation and the European legislative framework pertaining to the Community Plant Variety Rights, Plant Health, Plant Protection Products, Genetically Modified Organisms, and Trade; and these relations are being presented hereafter.

An additional analysis has been done in relation to EU legislation on Contaminants in food. Apparently, there is no link between the S&PM legislation and this legislation. However, as presented at section 6.2.2, relations exist when considering the S&PM sector in the context of the complete food chain.

6.2.1. Plant Variety Rights

Council Regulation (EC) 2100/94 defines the Community rules on Plant Variety Rights. It has to be highlighted that legal basis for this Regulation is article 235 of the Treaty establishing the European Community when the Seed Marketing Directives are based on article 37. This point is further developed in section related to extension of the role of CPVO (section 7.3.4).

The 2 main links between that Council Regulation and the Community S&PM legislation concern the DUS and variety denomination provisions, which are both required for the purpose of protection and the one of registration of a variety on a national listing.

As indicated in the implementing Directive 2003/90/EC[10], the DUS examination for the purpose of registration refers to the conditions laid down either in the protocols of the Administrative Council of the Community Plant Variety Office (CPVO) or in the test guidelines of the International Union for the Protection of New Varieties of Plants (UPOV).

The DUS examination for the purpose of protection is carried out by taking into consideration the test guidelines of the UPOV. Those guidelines provide detailed practical guidance on certain aspects of the examination of DUS and identify appropriate characteristics for variety description.

As regards examination for the acceptance of a variety, it is observed that, in certain cases, MS have decided to adapt the criteria list, e.g. to remove a criteria for better efficiency of the testing process or to add a national criteria.

[10] Commission Directive 2003/90/EC setting out implementing measures for the purposes of Council Directive 2002/53/EC

The main identified issues are:

- "*Variety*"[11] is being defined in Council Regulation (EC) 2100/94, similarly as it defined at UPOV, but there is no definition of variety in the seed marketing Directives[12];
- Lack of harmonisation of the texts regarding the description of varieties that should be included in the reference collection. The one in the 2100/94 is in line with the UPOV convention (a new variety must be compared with all varieties of common knowledge); the one of the Directives is not (a new variety must be compared with all existing varieties in the EU). However, application of Art. 9.3[13] of CC Directives leads to the same listings of references.

Such elements supports the current discussion within the CPVO on the possible extension of its role from the granting of protection of variety rights to the DUS testing for variety listing (see section 7.3.4.) inducing the concept of "*one key, several doors*".

The second link between the Community legislation and the CPVR Regulation is the variety denomination. In particular in regard to the enforcement of Community Plant Variety Rights it is of major importance that the varieties which are protected, can be easily identified.
The variety denomination is the only identifier for a variety. Thus, the variety denomination for a variety must be the same in all Member States. This is also required by Article 20 (5) of the UPOV 1991 Act, to which the European Community and most of its member states are member.
Several stakeholders, mainly from the industry, consider that neither in Directive 98/56/EC nor in Directive 92/34/EEC the obligation to use the proper variety denomination is included in a stringent and sufficient manner.

The CPVR Regulation determines in its Article 17 (Use of variety denominations):

- Any person who, within the territory of the Community, offers or disposes of to others for commercial purposes variety constituents of a protected variety, or a variety covered by the provisions of Article 13 (5), must use the variety denomination designated pursuant to Article 63;
- Any person effecting such acts in respect of any other material of the variety, must inform of that denomination in accordance with other provisions in law or if a request is made by an authority, by the purchaser or by any other person having a legitimate interest.

These two paragraphs shall apply even after the termination of the Community Plant Variety Right. Thus, the propagation of a protected variety must not be offered or disposed of to others without the proper variety denomination.

[11] *'variety'* shall be taken to mean a plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a plant variety right are fully met, can be:
- defined by the expression of the characteristics that results from a given genotype or combination of genotypes,
- distinguished from any other plant grouping by the expression of at least one of the said characteristics, and
- considered as a unit with regard to its suitability for being propagated unchanged.

[12] *'Variety'* definition is under discussion at OECD level.

[13] In taking into account the information available, Member States shall also ensure that a variety which is not clearly distinguishable:

- from a variety previously accepted in the Member State in question or in another Member State, or

- from another variety which has been assessed with regard to distinctness, stability and uniformity in accordance with rules corresponding to those of this Directive, without, however, being a variety known in the Community within the meaning of Article 5(1),

bears the name of that variety. This provision shall not apply if this name is likely to mislead or cause confusion concerning the variety in question, or if, pursuant to all the provisions of the Member State concerned governing the names of varieties, other facts prevent its utilisation, or if the rights of third parties impede the free use of that name in connection with the variety in question.

Article 1 (2) first hyphen of Directive 98/56/EC and Article 2 of Directive 92/34/EEC rule that these Directives shall not apply to material shown to be intended for the export to third countries. This is in contradiction to Article 17 of the CPVR Regulation.

It also conflicts with paragraph (11) of the introduction of Directive 98/56/EC, according to which it is in the interest of the purchasers of propagating material that the names of varieties or of groups be known and that their identity be safeguarded. This applies for purchasers in 3rd countries, too.

Article 1 (2) second hyphen of Directive 98/56/EC is also in contradiction to Article 17 of the CPVR Regulation, which does not include any exemption for the use of the variety denomination for propagating material.

Article 8 of Directive 98/56/EC does not sufficiently stipulate that propagating material may be offered and sold only with the proper variety denomination. The exemptions in Article 8 (3) and (4) of Directive 98/56/EC are also in contradiction to Article 17 of the CPVR Regulation.

In Article 9 (1) of Directive 92/34/EEC it shall be made clear that the variety denomination must be used. The term "*with reference to the variety*" is not sufficiently clear.

The use of one and the same variety denomination in all Member States must be obligatory. However, in Articles 9 (2) of Directives 98/56/EC and 92/34/EEC the use of the variety denomination is put under a reservation only ("*as far as possible*").

6.2.2. Human Health (i.e. EU legislation on contaminants in food)

S&PM are rarely associated to possible risks to human health even if several historical examples demonstrate that adverse effects to human health have been caused by S&PM i.e. ergot alkaloids in rye varieties.

In order to show the possible interest of considering S&PM regulatory framework as a tool to contribute to human health, we are focusing in this analysis on contaminants in food, as an example.

Apparently, no link exists between the Community S&PM legislation and the EU one on contaminants in food, represented by the following legislative texts:

- Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs;
- Commission Regulation (EC) No 1882/2006 of 19 December 2006 laying down methods of sampling and analysis for the official control of the levels of nitrates in certain foodstuffs;
- Commission Recommendation 2006/583/EC of 17 August 2006 on the prevention and reduction of *Fusarium* toxins in cereals and cereal products;
- Draft Commission Recommendation on the monitoring of the presence of ergot alkaloids in feed and food.

Nevertheless, our analysis of the interest in linking the S&PM legislation with the EU legislation on Contaminants in food focuses on the two following case examples: 1) the control of the levels of mycotoxins in cereals and 2) the control of the levels of nitrates in vegetables.

Case 1: control of the levels of mycotoxins in cereals

EU legislation on contaminants in food regulates 4 different mycotoxins by setting-up maximum levels in foodstuffs. Regulations in mycotoxins have been established in many MS to protect the consumer from the harmful effects on mycotoxins.

The term 'mycotoxin' is used for the toxic chemical products formed by a few fungal species (e.g. *Fusarium spp, alternaria spp., Claviceps purpurea, etc.*) that readily colonise crops in the field or after

harvest and thus pose a potential threat to human and animal health through the ingestion of food products prepared from these commodities.

Each mycotoxin is produced by one or more very specific fungal species. In some cases one species can form more than one mycotoxin. For example the aflatoxins can be formed by *Aspergillus flavus*, *Aspergillus parasiticus* and a limited number of other *Aspergilli*. Only part of these fungal species is plant pathogen, other toxigenic species, present in the plants, have no effect on the plant health.

The Community S&PM legislation mentions the need to examine the resistance of varieties to plant pathogen diseases. Such examination is carried out from an agronomical point of view in VCU networks and not with the objective of avoiding the appearance of mycotoxins in the foodstuffs processed from those grains. Actually, no provision of the Community S&PM legislation targets non-plant pathogen diseases at the source of appearance of mycotoxins, such as *fusarium* infecting the grains of developing cereals such as wheat and maize.

As highlighted during the interviews, increasing the consistency between the Community S&PM legislation and the legislation for the reduction of mycotoxins would imply to attack the problem at the source and to examine the variety resistance to non-pathogen diseases contributing to the production of mycotoxins. This would require defining examination criteria, minimum resistance levels as well as testing methods, what seems nevertheless quite difficult to do from a scientific point of view.

Case 2: control of the level of nitrates in vegetables.

Currently, the examination of any new variety of vegetable plant doesn't look at its capacity of absorbing nitrates from soil leading to possible human health & environmental impacts. Better consistency between the Community S&PM legislation and the legislation for the reduction of nitrates in foodstuffs could be achieved by examining the absorption capacity of varieties used for the production of vegetable, as several interviewees indicated that genetic variability exists for this characteristic.

Today there is no legislative obstacle for breeders to work on such characteristics interesting for human health and environmental protection, but on the other hand the current legislative framework is not an incentive to guide the breeders in these directions knowing that, today, breeders can hardly value this characteristics on the market place.

In conclusion, these two simple examples may demonstrate the value to consider plant breeding as one component of public health strategy and the potential for integrating such kind of criteria during the examination of varieties for acceptance as marketable S&PM. To answer to the question if there is a need to use seed legislation for driving plant-breeding efforts as a tool in food safety, public health strategies and environmental protection, a deeper analysis is required.
Plant breeding future is oriented toward qualitative demand of the consumers for better food and improved nutritional composition of food products that could benefit from plant breeding.

6.2.3. Plant Health

The emphasis on plant health varies considerably amongst the various Directives. An overview of the key relevant provisions of the S&PM legislation is provided in Annex 9.

The provisions on plant health are most prominent in the Directives dealing with the marketing of PM, in particular those on seed potatoes (Directive 2002/56/EC), vegetable and fruit PM (Directives 92/33/EEC and 92/34/EEC) and the PM of ornamental plants (Directive 98/56/EC). In these Directives, reference to both quality and plant health is consistently made throughout the legislation (see Annex 9). These make provisions for harmonised conditions on plant health, to be established based on Community comparative tests and trials, the notification of plant health problems to the Standing Committee on Plant Health (SCPH), and the equivalence of imports from 3rd countries if these plant health conditions are satisfied.

The most thorough of the seed marketing Directives with regards to plant health appears to be the one on seed potatoes (Directive 2002/56/EC). This includes rules on Community comparative tests and trials to be used to develop harmonised methods for checking conditions of compliance, including on

plant health. Even in this case, no specific reference is made to the relevant horizontal plant health legislation, except under the conditions of equivalence for imports from 3rd countries where reference is made to compliance with the conditions of Directive 2000/29/EC.

Plant health Regulation (Council Directive 2000/29/EC) targets quarantine diseases when plant diseases distinguish between 'quarantine pests' and 'quality diseases & pests' (see figure 5).

According to the definition of the International Plant Protection Convention (IPPC), quarantine pests are pests of potential economic or environmental importance to an area, which are not present there or which, if present, are not widespread, and are being officially controlled.

Council Directive 2000/29/EC addresses protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community. Based on this Directive, national plant protection services are charged to conduct regular surveys on the presence of certain harmful organisms in the respective Member States and to take the appropriate measures to prevent further spreading of these organisms within the Community.

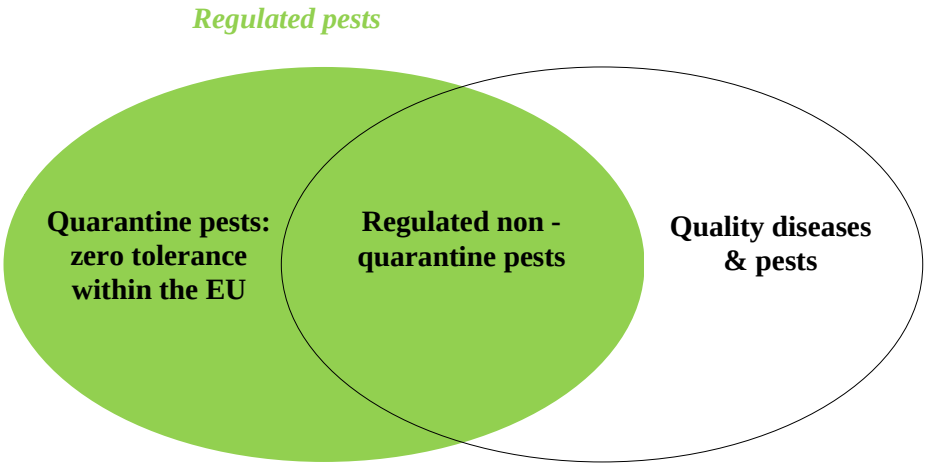
Action to exclude, contain or eradicate them is co-ordinated across the European Community through Council Directive 2000/29/EC which regulates the movement within the EU of certain plants or plant products and other objects which are potential carriers of quarantine harmful organisms of relevance for the entire Community.

Other specific EU regulations are crops specific such as in potatoes where 4 main Directives regulated potatoes diseases control[14]. The quarantine pests have a zero tolerance within the EU.

Plants, plant products and other objects are subject to specific conditions governing the control of their production that include inspections at the place of production to secure zero presence of the pathogens. They are also to be accompanied by a plant passport when moved. This document gives evidence that the material has successfully undergone the Community checking system.

Quality diseases & pests are pests that affect yield and quality of the production but that do not qualify as quarantine pests and are not covered by the plant health legislation, mainly because they are already widely distributed and are hardly dependent on human intervention for their spread. Within this category, a small group of pests, i.e. the regulated non-quarantine pests, are nevertheless prohibited or only permitted within a certain tolerance on planting material such as certified seed potatoes, seeds and certain ornamental, vegetable and fruit plants. For seeds, it is specified that all harmful organisms must be at the lowest possible level.

Figure 5 – Regulated pests within the EU



[14] Council Directive 69/464/EEC on control of Potato Warth Disease, Council Directive 2007/33/EC on the control of potato cyst nematodes, Council Directive 93/85/EEC on the control of potato ring rot, and Council Directive 98/57/EC on the control of *Rastonia solanacearum.*

DG SANCO has established a working group in 2004 to exchange information on the issue of Regulated Non-Quarantine Pests[15]. Most likely the harmful organisms listed in the Community legislation, in particular those which are transmitted on plants for planting, may qualify for RNQPs.

Council Directives on the marketing of S&PM lay down general plant health requirements such as *"harmful organisms which reduce the usefulness of the seed/propagating material shall be at the lowest possible level"* and some specific ones including requirements for weeds. In particular, a clear link exists between Directive 2002/56/EC on the marketing of seed potatoes and two Directives on control of Potato Diseases, i.e. Directive 69/464/EEC on control of potato wart disease and Directive 2007/33/EC on the control of potato cyst nematodes.

The responses from the qualitative survey indicate that 81% of respondents to this question (n=201) consider that the Community legislation on plant health has had a positive impact on the free marketing of S&PM (Q 1.1.4., n=201). In their comments, a few respondents specifically mentioned that, despite the overall positive effects, some unrealistic or unreasonable requirements in the Community legislation on plant health do have a negative impact.

The analysis of stakeholders' comments to the survey question on the consistency between the provisions of the Community S&PM legislation and those of other regulations (Q 1.1.6.) shows some inconsistencies between Directives on the marketing of S&PM and the plant health as follows:

Inconsistencies in the legislation

- There is some duplication between the PM Directives and the plant health Directive, with some organisms listed in both;
- Concerning flower bulbs, the requirements of Directives 98/56/EC and 2000/29/EC differ on some points for the same crops;
- Inconsistencies within the S&PM regulations have also been notified during the interviews, especially for vegetable when considering PM produced from seed. A plant producer has to guarantee that the plants he is selling are pathogen free, when the seed he is buying to produce its plants are not pathogen free guaranteed as the lists of pathogens between the 2 Directives are not identical;
- The above marketing Directives refer to the relevant EU horizontal plant health legislation, although in most cases this is in reference to Directive 77/93/EEC[16] which has been repealed in 2000 (Directive 2000/29/EC[17]). The reference to the current Directive 2000/29/EC has therefore not been consistently updated in these Directives;
- The seed Directives, with the exception of the vegetable seeds and the seed potatoes ones, make no reference at all to plant health. This is in contradiction to the Common Catalogue (Directive 2002/53/EC) which includes provisions for prohibition of use if plant health risk is established, although without making any specific reference to the relevant horizontal plant health legislation (i.e. to Directive 2000/29/EC or the repealed Directive 77/93/EEC).

Inconsistencies linked to the implementation of the legislation

- Under the Directive on the marketing of seed potatoes (2002/56/EC) transport of Farm Saved Seed (potatoes intended for planting for own use) from one production site to another is allowed without the obligation to certify them. However according to the plant health Directive 2000/29

[15] 'Regulated Non-Quarantine Pest' is defined as a non-quarantine pest whose presence in plants for planting affects the intended use of those plants with an economically unacceptable impact and which is therefore regulated within the territory of the importing contracting party.

[16] Council Directive 77/93/EEC of 21 December 1976 on protective measures against the introduction into the Member States of harmful organisms of plants or plant products

[17] Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community

transport of (uncertified) potatoes intended for planting (including Farm Saved Seed) from one production site to another should be accompanied by an European plant passport, and this should be controlled by the authorities;

- The fact that responsibilities for marketing Directives and plant health Directives are split over different authorities in most of MS, leads to inefficiencies in inspections and sometimes contradictory approaches. For example the marketing Directives allow for delegation of inspections 'under official supervision' whereas plant health Directive allows delegation provided that the organisation that gets the mandate is working exclusively for public authorities;
- Seed potatoes officially certified on the basis of Directive 2002/56/EC should satisfy minimum conditions as specified in Annex I and II of the Directive. A number of these conditions are related to certain plant diseases. Seed potatoes used as FSS are in general not officially inspected, even if in some MS there is an obligation for official inspection. Directive on brown rot control lays down a specific timing for notification of results of plant health controls on farm saved seed, but does not say that it is a MS obligation to incorporate FSS in their surveys. It is the opinion of several interviewees, that, to ensure the quality and plant health in the future, control and registration should be applied to FSS as well.

In conclusion, these inconsistencies should be considered as a much better consistency could be achieved quite easily on topics such as registration, definitions, and documents. One MS authority proposes to transfer quarantine disease from seed marketing Directives to plant health Directive to avoid duplication.

As the plant health regulatory framework is planned to be evaluated in early 2009, it is recommended to share this analysis with the SANCO officers in charge of that sector.

From an organisational point of view, it seems that there is room for better integration of the phytosanitary inspection with the inspection for the purpose of certification. This point is further evaluated at section 7.2.11.

6.2.4. Plant Protection Products (PPP)

Council Directive 91/414/EC concerns the authorization, placing on the market, use and control within the Community of plant protection products in commercial form and the placing on the market and control within the Community of active substances.

According to the Council Directive, Member States shall prescribe that plant protection products may not be placed on the market and used in their territory unless they have authorized the product. Member States shall also ensure that a plant protection product is not authorized unless its active substances are listed in Annex I of the Directive. In other words, whereas the authorisation of active substances takes place at Community level with registration on a Community list, the one of plant protection products takes place at the level of each MS.

The responses from the qualitative survey indicate that 60% of respondents to this question consider that the Community legislation on PPP has had a negative impact on the free marketing of S&PM (Q 1.1.4., n=162). This proportion increases to 89% if we consider the responses of the group Suppliers (n=70).

In their comments, several industrial stakeholders from the group Seed specify that the lack of a EU wide authorisation for PPP for use as seed treatments and the related lack of a common provision for the marketing of such treated seed in line with the general seed marketing Directives constitute a major obstacle for the S&PM industry.

As an example, PM treated with PPPs could cause problems after delivering the PM or the produce in other MS because the PM contains a PPP which has not been authorized in that specific MS.

A new proposal for a Regulation on pesticides (Regulation of the European Parliament and of the Council concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC) is already very advanced in the pipeline and should be

adopted by the European Parliament and the Council in 2009. This proposal deals with the seed treatment as it foresees that a seed treatment product approved in one Member State will be accepted in all the other Member State. This will guarantee the free circulation of treated seed.

Some stakeholders from the group PM mention that the availability of plant protection products in Member States has decreased due to the re-evaluation of active ingredients on Community level, what gives less possibility to control plant diseases inclusive the diseases regulated in the plant health Directive.

In conclusion, inconsistency exists between the Community S&PM legislation and the PPP Directive in what concerns the marketing of treated S&PM, as seeds accepted for marketing within the entire Community must be registered in each MS to which it is intended in what concerns the products used for seed treatment. Further consistency would be searched for in the future.

The new proposal for a Regulation on pesticides that should be adopted by the European Parliament and the Council in 2009 is considering this issue and includes provisions to guarantee the free circulation of treated seed.

The European Commission has proposed a strategy (Thematic Strategy on Sustainable Use of Pesticides) to address the threats posed by the use of pesticides to human health and the environment. A proposal for a Framework Directive sets out common objectives and requirements in order to ensure coherence throughout the EU between the Member States which have already adopted measures addressing these threats and those who have not. The strategy will also contain two additional law proposals: one on the requirements to be met by new pesticide application equipment and the other one on the collection of statistics on plant protection products. Together with the strategy, the Commission has put forward a proposal for a Regulation revising Council Directive 91/414/EC on the placing of PPP on the market.

These proposals on the Thematic Strategy on Sustainable Use of Pesticides are under discussion, but a clear monitoring of the outcome of this proposal to identify possible inconsistencies with S&PM legislation (e.g. requirement to establish a pesticide-free buffer zone around water points may lead to difficulties to farmers for seeding within these buffer zones when using treated seed).

6.2.5. GMO's

The policy on GMO's relates to three main aspects: the release of GMO's in the environment, the food and feed safety and the coexistence.

Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms ensures that the MS take all appropriate measures to avoid adverse effects on human health and the environment, which might arise from the deliberate release or the placing on the market of GMOs.

Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed lays down Community procedures for the authorisation and supervision of genetically modified food and feed as well as provisions for their labelling.

Regulation (EC) No 1830/2003 of the European Parliament and of the Council provides a framework for the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms.

No compelling Community legislation exists on the approach of co-existence. Since only authorised genetically modified organisms (GMOs) can be cultivated in the EU and the environmental and health aspects are already covered by Community legislation, the issues to be addressed in the context of coexistence concern the economic aspects of the mixture of GM and non-GM crops and the appropriate measures to prevent such mixture.

Article 26a of Directive 2001/18/EC allows Member States to take appropriate national measures on coexistence in order to avoid the unintended presence of GMOs in other products, without, however, establishing an obligation for Member States to take action.

On 23 July 2003, the Commission adopted Recommendation 2003/556/EC on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming, which is intended to help Member States develop national legislative or other strategies for coexistence. It contains a list of general principles to be taken into account when developing national approaches and a list of technical measures.

Coexistence measures of the MS have to be notified in application of Directive 98/34/EC. DG Enterprise together with other DGs, including DG SANCO, assesses the measures for their proportionality and their compliance with the principle of free marketing laid down in Article 22 of Directive 2001/18/EC.

Overall, the logical structure and cross-referencing of the Directives in terms of the provisions relating to S&PM of GM varieties merits further alignment to the European legislative framework on GM material.

An overview of the key relevant provisions of the S&PM legislation is provided in Annex 8. In most cases, these provide for an environmental impact assessment, in accordance with Directive 90/220/EEC on GMOs, as a pre-requisite to the approval of GM varieties for entry into the national and Common Catalogues and for the authorisation of GM varieties for marketing purposes. This reference is outdated as Directive 90/220/EEC[18] has been repealed by Directive 2001/18/EC[19] which lays down the methods and procedures for such an assessment. Only Directive 68/193/EEC makes the correct reference to the current GMO legislation (i.e. Directive 2001/18/EC).

A further number of gaps, discrepancies or inconsistencies can be noted, as follows:

- Under the authorisation for marketing provisions, the link to the measures taken to avoid adverse effects on human health is not pursued to the same extent as the link to the environmental effects. The environmental impact assessment required in accordance with the provisions of Directive 90/220/EEC is laid down in the various relevant Articles of the Common Catalogue Directive and in the marketing Directives (see Annex 8);
- On the other hand, reference to the approval conditions in connection with the human health objectives, in the context of the GM food and feed, is made only briefly in the Common Catalogue Directive (preamble 17 and Article 4.5) and is not at all found in the majority of the marketing Directives[20];
- In the case of the old marketing Directives (fodder plant seeds and cereal seeds, Directives 66/401/EEC and 66/402/EEC respectively), the environmental impact assessment for the authorisation of the marketing of GM varieties refers to the provisions of Article 7(4) of the repealed Common Catalogue Directive 70/457/EEC, rather than the actual Directive 2002/53/EC.

The responses from the qualitative survey (Q 1.1.4. n=156) indicate that 65% of respondents consider that the Community legislation on authorisation of GMO's has had a negative impact on the free marketing of S&PM, mainly because of the lack of thresholds for the adventitious

[18] Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms

[19] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC.

[20] With the exception of:

- The legislation on vegetable seeds (Directive 2002/55/EC). This Directive has a special '*self-standing*' structure, with a combination of provisions for registration to a common catalogue (such as those made in Directive 2002/53/EC) and for authorization of marketing. Under its registration provisions (which are similar to those of Directive 2002/53), Directive 2002/55/EC makes reference (in preamble 17 and Article 4.3) to the novel foods Regulation 258/97 and to the GM food and feed Regulation 1829/2003/EC;
- Directive 98/193/EEC. This includes extensive reference both to environmental impact assessments according to the GM legislation as it currently stands (Directive 2001/18/EC), and to human health effects according to the provisions of the GM food and feed Regulation 1829/2003/EC.

presence of GMOs in non-GM seed lots. When considering the group 'Suppliers active in the seed sector', this proportion increases to 91% (n=66).

The lack of provision in the seed Directives on the threshold for adventitious presence of GMO's, meaning that the current situation is unclear. Member States follow different approaches concerning the threshold of adventitious presence of GMO seed. Several interviewees mentioned that some MS established 'more or less official' thresholds with an important variability. With the GM Food and Feed Regulation, the EU set such a labelling threshold at a level of 0,9% for the adventitious presence of GMOs and derived materials in non-GM food and feed products, but there is still no threshold for the presence of GM seed in non-GM seed.

The seed Directives define minimum isolation distances that can be different to the ones defined in the MS regulations on coexistence. For instance, annex I of Directive 66/402/EEC requires that the crop of *Zea mays L.* is at a minimum distance of 200 meters from neighbouring source of pollen which may result in undesirable foreign pollination, whereas the national regulations on co-existence for GM maize impose minimum distances of 25 meters in The Netherlands, 200 meters in Luxemburg, 400 meters in HU. These elements are perceived as inconsistencies by several stakeholders, but these different distances address different issues: seed purity on the one side and labelling rules on the other side.

In any case, it could be said that for seed production, the isolation distances that would be required to ensure the current extremely low levels would be much longer than the ones established by the national coexistence laws. The reason is that in the absence of seeds thresholds, MS have not yet defined isolation distances for seed production in maize to prevent from GM contamination (such distances could not be specified anyway), but some MS have specified such distances for other crops. The current situation leaves producers of maize seeds with the difficulty that they cannot rely on the obligation for GM producers to implement the distances required. Thus the burden of responsibility for coexistence lies on the GM crop growers vis-à-vis non-GM crop growers, but it lies on the seed producers in the case of seed production.

However, it has to be mentioned that due to the fact that GM crops production has not occurred much in seed production areas, the application of coexistence rules regarding seed production has not become a practical issue in most regions.

A couple of other aspects require harmonisation, especially when defining a threshold for adventitious presence:

- Sharing of responsibilities for seed producers (GM *vs*. non-GM);
- Purity measurements (PCR *vs*. visual inspection).

Several interviewees mentioned that high quality certified seed is one of the measures for the management of coexistence. In seed production, some legal obligations like e.g. minimum distances and regulations on crop rotation are applied to meet general criteria. Other measures traditionally used like special field inspections and elimination of off-types, barrier crops and many others are voluntary requirements set up for the special purpose of producing seeds for very specific market demands may help in managing coexistence.

In conclusion, whereas no Community legislation exists on the issue of coexistence, the MS have developed their own regulation on this matter, what has lead to differences between MS and potential problems of definition of responsibility in case of GM contamination. Majority of stakeholders consulted during the survey asks for the definition of a minimum threshold for adventitious presence.

6.2.6. Trade policy

The responses from the qualitative survey (Q 1.1.4., n=154) indicate that 66% of respondents consider that the Trade policy (e.g. Policy of DG Trade, SPS agreement, TBT agreement) has had a positive impact on the free marketing of S&PM. 14% of respondents consider that it has had a negative impact.

When specifying the reasons therefore, they mention that:

- Trade agreements obstruct the limitation of marketing authorisation for transgenic seeds and the geographic protection of local varieties (5 respondents);
- The non-compliance of EU with international rules on GMOs put EU farmers at a disadvantage compared to their competitors worldwide (3 respondents).

The analysis of stakeholders' comments to the survey question on the consistency between the provisions of the Community S&PM legislation and those of other regulations (Q 1.1.6.) indicate that there is a good consistency between the EU S&PM legislation and the trade policy, because of the overall compatibility of EU provisions with international standards, agreements and procedures (see section 7.2.4. below on Coherence with OECD and UN-ECE standards).

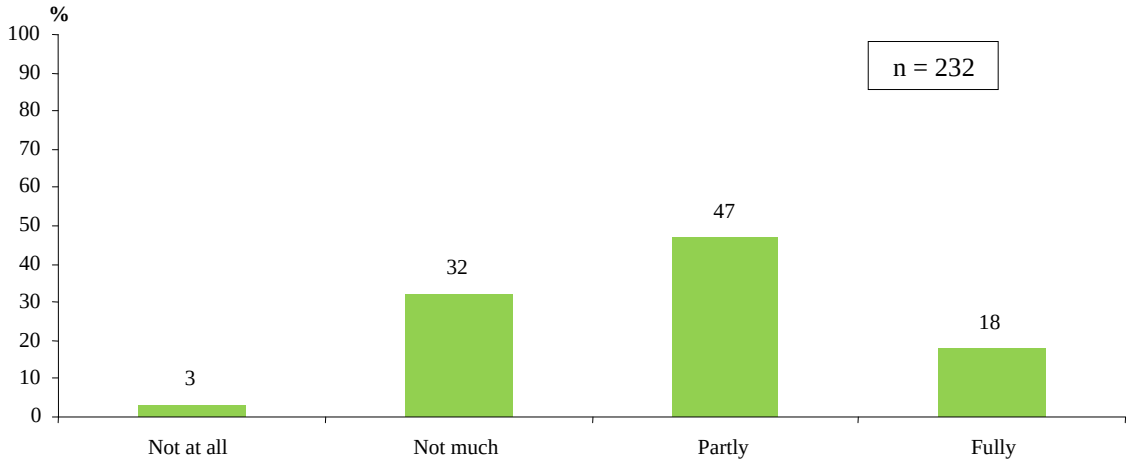
6.3. IMPLEMENTATION OF THE S&PM LEGISLATION IN THE MEMBER STATES

Sections 6.3.1 to 6.3.6 below examine the implementation of the S&PM Directives, in particular their simplicity, ease of implementation, utility, effectiveness, efficiency as well as the conclusions from the recent experience of such implementation in the new MS.

6.3.1. Simplicity of the S&PM Directives

The responses from the qualitative survey indicate that 35% of the respondents to this question (Q 1.1.6, n=232) believe that the provisions of the S&PM legislation are not at all or not much easy to understand.

Graph 8 - Provision of the EU S&PM – Extent to which the legislation is easy to understand



When considering the responding authorities only, such proportion decreases to 24% for respondents active in policy-making (n=62), to 19% for respondents active in registration (n=58) and to 12% for respondents active in certification (n=74).

The proportion of respondents indicating that the provisions are not at all or not much easy to understand is larger for the group 'Seed' (43% of respondents, n=152) than for the group 'Propagating material' (20%, n=56) and the group 'Forestry Material' (21%, n=24).

When looking at the comments provided by the respondents to this question, it seems that such difficulty is mainly attributable to the complexity of the subject matter, the legal character of those texts (legal language is not always easy to read for e.g. users of S&PM), the importance of the technical component in those texts (not all readers are technical experts), the existence of a main part referring to annexes and *vice versa*.

Nevertheless, majority of respondents acknowledge that such characteristics are unlikely to change in the future and believe that the existing Directives must remain separate. They are too many complex and unique issues for certain individual species, for example potatoes, so that a composite document compiling several Directives would be confusing.

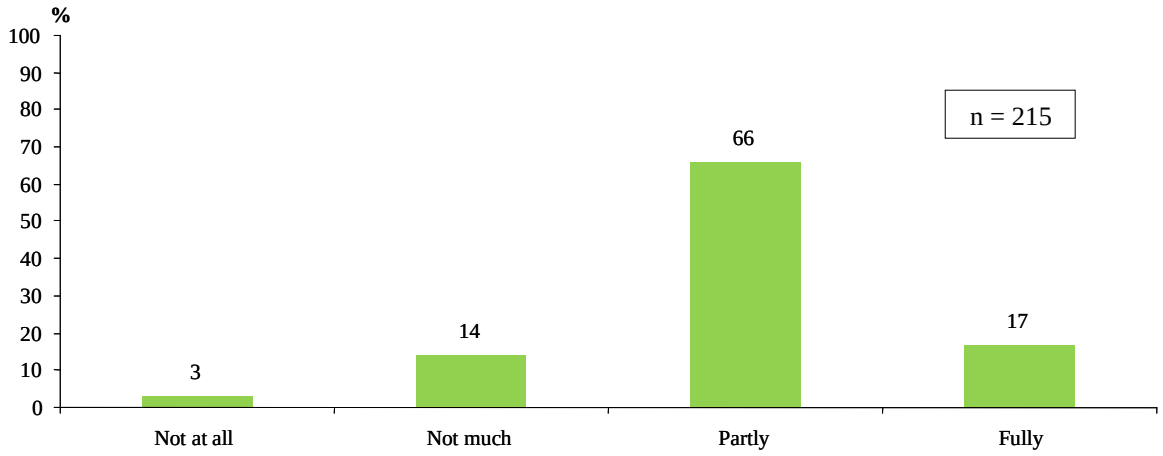
The update of several Directives in 2002 (Common Catalogue Directive and some seed marketing Directives) is expected to have brought more clarity and rationality. Contrarily, the old Directives appear as more complex and confusing as they have never been recast (see section 6.1.4.)

Most of respondents also consider that the Directives could also be improved as regards their consistency with the Community legislation on plant health, plant protection product and GMO (see sections 6.2.3. to 6.2.5) and the clarity of some technical provisions (e.g. technical provisions for fodder plant species).

6.3.2. Ease of implementation of the S&PM Directives

17% of stakeholders responded to the question (Q 1.1.6., n=215) of ease of implementation of the S&PM Directives with "not at all" or "not much".

Graph 9 - Provision of the EU S&PM – Extent to which the legislation is easy to implement



The reasons they specify for explaining such difficulty relate to the complexity of the subject matter, the lack of clarity of some provisions or definitions and cases of inconsistency with e.g. the plant health requirements.

As mentioned by some stakeholders, the easiness of implementation also depends on the level of development of the political and administrative structures.

The type of legal instrument can also act on the easiness of implementation. With a Directive, national authorities know the result to be achieved and choice the form and methods for transposing it into their national legal framework. Compared to a Directive, a Regulation is of general application and is directly applicable in all Member States.

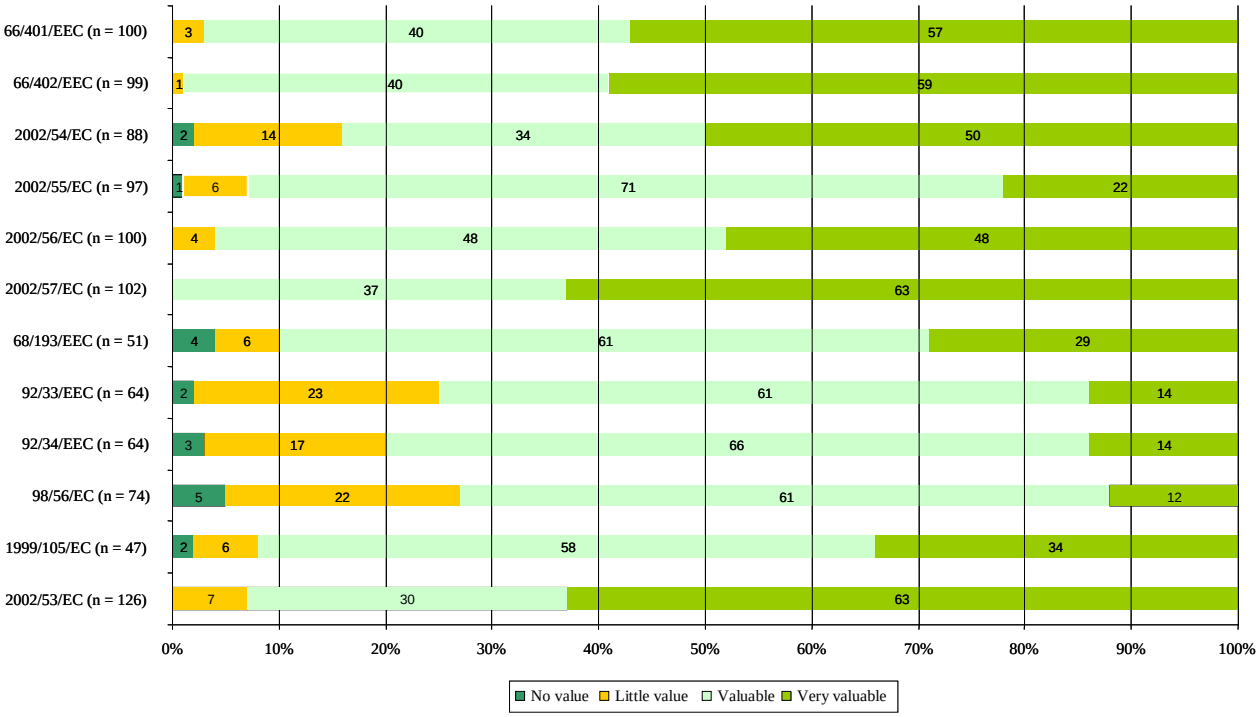
When asked about their willingness to maintain Directives or to replace them with Regulations (Q 1.2.3.), majority of respondents to the qualitative survey are in favour of maintaining Directives. This point is further discussed at section 7.3.2.

6.3.3. Utility of the S&PM Directives

The possible difficulties to understand and/or implement the legislation (see sections 6.3.1 and 6.3.2) seem not to impact on the opinion of stakeholders on the overall utility of the Community S&PM legislation. **The responses from the qualitative survey show that 59% of respondents find it partly useful and 39% of them find it fully useful (Q 1.1.6., n=231).**

When looking at the value of the Directives of the legislation (Q 1.1.7.), the large majority of respondents find them valuable or very valuable, as summarised in the table below:

Graph 10 – Utility of the 12 Directives of the legislation



Compared to the other Directives, Directive 2002/54/EC (beet seed), as well as Directives on the marketing of vegetable, ornamental and fruit propagating and planting material are considered as a little bit less valuable.

As regards the legislation on propagating material, the reason mainly mentioned by stakeholders is that it contains general provisions only (with exemption of Directive 68/193/EEC) and does not define precise norms for quality. In their opinion, the definition of such norms would however be a difficult challenge considering the very large diversity of the species concerned.

Some stakeholders of the beet sector consider that the requirements for beet seeds are mainly created by the sugar industry.

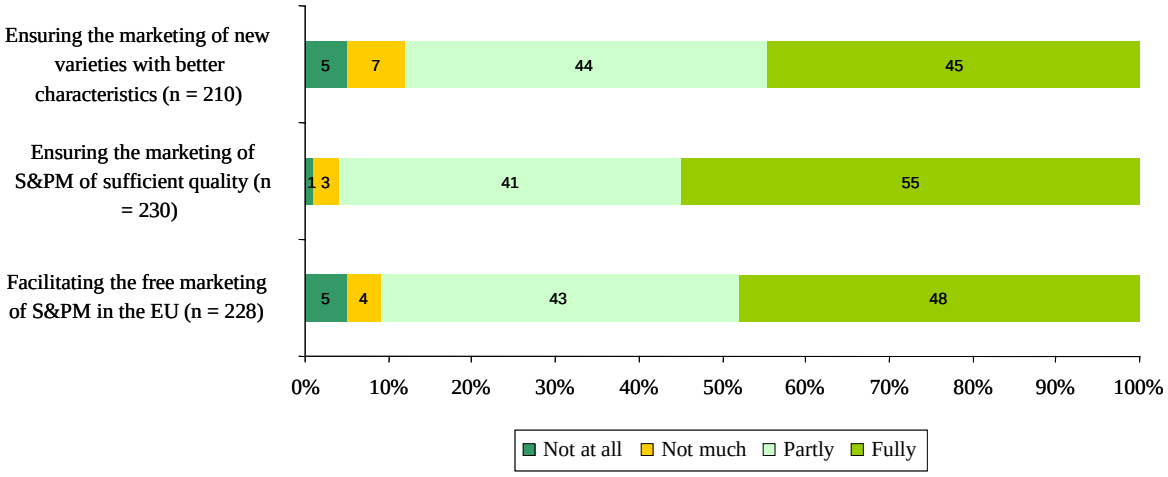
Stakeholders' criticism on the fruit Directive refers to the fact that national certification schemes seem to prevail in this area. A Commission proposal for a recast of the fruit Directive is currently being discussed at Council level[21]. One objective of the new Directive is the harmonisation of the conditions of plant health and quality applicable to the fruit plant propagating material and fruit plants intended for fruit production.

6.3.4. Effectiveness in achieving the free marketing of S&PM in the EU

Questions 1.1.1. to 1.1.3. of the qualitative survey asked about the effectiveness of the EU S&PM legislation in 1) ensuring the marketing of new varieties with better characteristics, 2) ensuring the marketing of S&PM of good quality and 3) facilitating the free marketing of S&PM in the EU.

[21] At the time when the evaluation was carried out, a Commission proposal for a recast of the fruit Directive was discussed at Council level. Council Directive 2008/90/EC, based on this proposal, was adopted on 29 September 2008 and was published in the OJ L 267 on 8 October

Graph 11 - Effectiveness of the EU S&PM legislation



Most of respondents consider that such effectiveness has been at least partly achieved, i.e. 89% of respondents (n= 210) have answered 'partly' or 'fully' for point 1), 96% of them (n=230) have answered 'partly' or 'fully' for point 2) and 91% of them (n=228) have answered 'partly' or 'fully' for point 3).

As summarised by one respondent, generally, the legislation has been effective in ensuring the marketing of ever better varieties to European growers. It has established rules and operating practices that have helped the European seed industry to become a world market leader in terms of turnover as well as in terms of volumes, producing the highest quality of seeds for use inside as well as outside the EU. Section 7.1.4.2. provides figures on the yield increase and the genetic progress of varieties.

48% of respondents (n=228) consider that the EU S&PM legislation has been fully effective in facilitating the free marketing of S&PM in the EU. Such proportion increases to 73% when focusing on the respondents from the forestry area (n=22). Representatives from national authorities have a more positive opinion on this aspect than associations of users and suppliers, i.e. answer 'fully' mentioned respectively by 68% of respondents active in policy making (n=59), 68% of respondents active in registration (n=56), 66% of respondents active in certification (n=71), 39% of associations of users (n=36) and 25% of association of suppliers (n=81). This however does not mean that users and suppliers were not satisfied, as only 28% and 10% respectively have mentioned that the legislation was 'not al all' or 'not much' effective to the aim of free marketing.

To explain the possible lack of effectiveness of the S&PM legislation, several respondents have commented as follows:

Effectiveness in ensuring the marketing of new varieties with better characteristics

- In the view of several stakeholders, the introduction of new varieties depends on the possibilities to get a good return on the investment in breeding. The current legislation does not ensure the effective official support for the enforcement of breeders' rights resulting in a lack of return of investment for breeders. This leads to a diminishing economic interest in certain crops, in particular in small and fragmented vegetable markets. This shortcoming is threatening a sustainable positive development in these crops in the future;
- The acceptance of varieties with better characteristics has been differently interpreted according to the country;
- Whilst the legislation has been generally effective there is an inherent lack of flexibility which can be to the detriment of varieties with specific characteristics.

Effectiveness in ensuring the marketing of S&PM of good quality

- Quality doesn't (only) depend on the S&PM legislation. The quality standards, which companies take into account, are often higher than the standards in the Directives. The higher standards are used in order to get a strong market position;
- In vegetable crops, quality has been driven primarily by the market and by advances in breeding technology which have encouraged the development of hybrid varieties, rather than by the legislation. Several stakeholders also consider that neither seed certification nor VCU requirements contribute to improving vegetable seed quality. Certified seed are not marketed by the vegetable seed industry and are not demanded by its customers. Seed companies consistently produce standard seed at quality levels that are considerably higher than the ones established by the seed marketing Directive for vegetable seed;
- In the past the fruit Directive (92/34/EEC) has been effective for strawberries and apples but nowadays their quality is more regulated by the market. It remains of more importance for soft fruit like burrs, berries and raspberries. For CAC material, the sufficient quality has not been met because requirements are too general;
- For ornamentals, the introduction of the EC Plant Passport (Directive 2000/59/EC) has been more effective on the quality (quality aspects concerning pests and diseases) than the legislation;
- With regard to seed potatoes, the market requirements have changed dramatically over the years but changes to the legislation take too long to keep pace with these changes in quality requirements;
- With regard to plant health, the tolerances are too high for several diseases and some of the diseases are not regulated.

Effectiveness in facilitating the free marketing of S&PM in the EU

- The invoking of national safeguards, the lack of harmonization of registration protocols (DUS, VCU), even if for DUS Directives 2003/90/EC and 2003/91/EC impose the use of CPVO or UPOV protocols for nearly all species covered by the marketing directives, the lack of harmonization as regards to the implementation of phytosanitary requirements and the lack of common rules for the marketing of treated seed, the lack of legislation of grass seed mixtures (has been solved but with delay), are problems that are limiting the free marketing of the S&PM between the Member States in the EU. They constitute a risk of a *de-facto* re-nationalisation of the legislation covering the seed sector;
- There is a lack of transparency about certification scheme requirements within MS, which restricts the movement of certified material between schemes;
- Acceptance of pre-basic and basic propagating material of fruit species still depends on bilateral arrangements between MS. Free marketing is only true for CAC materials;
- The legislation was not effective in facilitating the free marketing of seed of conservation varieties;
- The lack of thresholds for adventitious presence of GMO has made free marketing of seed of species with currently known GM events very difficult.

Finally, the very large majority of respondents to the survey (EQ 1.1.5.) consider that the legislation has positively contributed to the competitiveness of the S&PM within the EU (84% of 208 respondents), the competitiveness on the world markets of S&PM produced in the EU (78% of 185 respondents), the income of plant breeders (80% of 170 respondents), the income of S&PM producers (83% of 173 respondents), the income of farmers (79% of 169 respondents) and the funding of plant breeding improvement efforts (74% of 155 respondents).

6.3.5. Efficiency in achieving the free marketing of S&PM in the EU

The overall opinion of the FCEC team is that the S&PM sector has always looked at an efficient process (including variety registration and certification), mainly because the profits are not as large in this sector as for other agricultural inputs, such as pesticides, as well as due to the short life cycle of the S&PM products.

Nevertheless, as commented by several respondents to the qualitative survey, some elements have contributed to reduce such efficiency, in particular 1) the lack of harmonisation between the national provisions; 2) the creation of impediments by national official or semi-official bodies.

Lack of harmonisation between the national provisions

- Insufficient equivalence between the national registration and/or certification schemes; e.g. some MS impose VCU test for turf grass whereas some other do not, different rules for field inspection, no rules for re-labelling, etc.;
- Lack of Common Catalogue for fruit and vine;
- Lack of harmonised interpretation of seed health requirements; e.g. different threshold value for seedborne diseases in different MS;
- Lack of harmonisation for DUS test which drives CPVO and MS to analyse DUS results based on different basis;
- As regards ornamentals, insufficient harmonisation of regulation for variety denomination (i.e. cultivar naming);
- As regards forestry reproductive material, lack of harmonisation of the supplier's documents elaborated in different languages.

Impediments created by national official or semi-official bodies

Seed:

- Establishment of national recommended lists based on the VCU recommended trials carried out for the varieties listed on the national catalogue;
- Additional control in a MS of seed potatoes certified in another MS to preserve the national seed potato production from the introduction of parasite that are absent on their territory such as potato virusYntn, Powdery scab, Rattle virus, etc.

FRM:

- Establishment of list of recommended provenances, often associated with premiums for the users, which favour the locally produced materials;
- Demand for additional information over and above the *items* specified in the Directive.

PM:

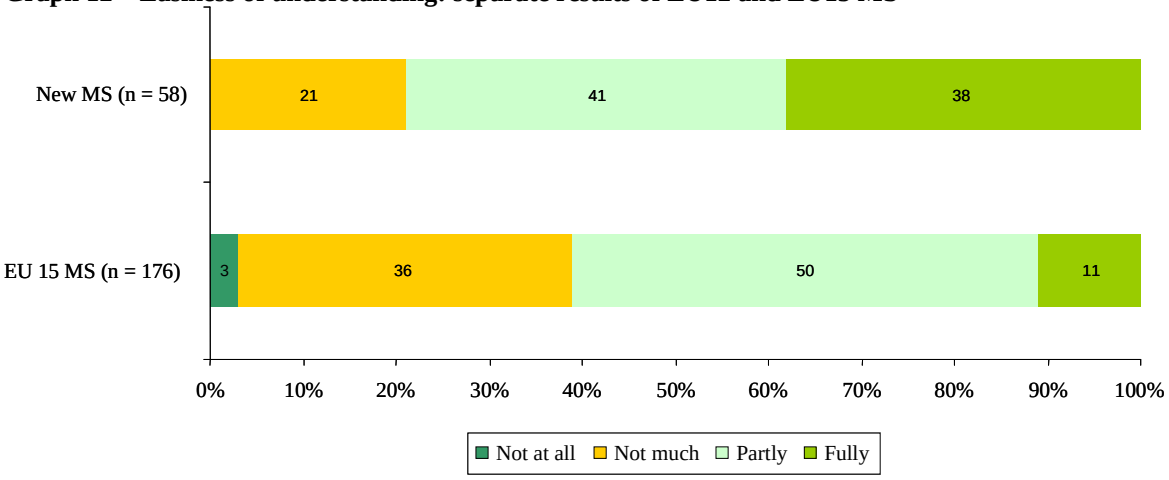
- Specific requirements for suppliers of vegetable plants to treat the seeds they use against PepMV;
- Instructions in a MS not to sell young plants in another MS.

More generally, several stakeholders highlighted that there is currently not a level playing field in costs applied for variety/material registration and S&PM lots certification from one MS to another as well as in the distribution of costs between the public and the private bodies throughout the EU, what could have distorted the market in some cases.

6.3.6. Results of the in-depth study in new Member State(s)

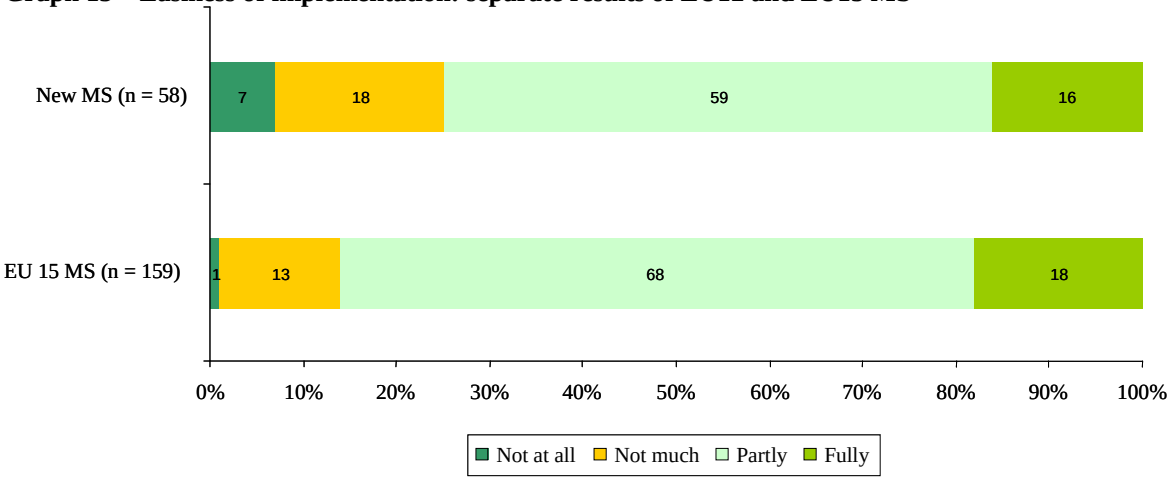
The comparison of the responses provided by new MS to the ones provided by the EU15 MS to the questions of easiness of understanding and easiness of implementation of the Directives (Q 1.1.6.) is as follows:

Graph 12 – Easiness of understanding: separate results of EU12 and EU15 MS



A larger proportion of respondents from the NMS consider that the Directives are fully easy to understand (38% compared to 11%).

Graph 13 – Easiness of implementation: separate results of EU12 and EU15 MS



Contrarily, a larger proportion of respondents from the NMS consider that the Directives are not at all or not much easy to implement (25% compared to 14%).

From these general results covering all NMS, a deeper analysis has been carried out in Romania by face-to-face meetings in Bucarest with national authorities (Ministry of Agriculture: National Inspection for Quality of Seeds and ISTIS[22]) and representatives of the suppliers (ANSEM).

[22] ISTIS is the state institute for variety testing and registration in Romania

Inputs and comments from the AMSEM were quite limited. As all EU provisions have been implemented in national laws during a large period of time, about 10 years, as explained below, the exercise has been quite transparent for the suppliers.

Ministry of Agriculture representatives for both registration and certification indicates that the Directives were quite easy to understand and that the translation and implementation in the Romanian regulatory framework has not created major issues.

Harmonisation with EU texts started in 1997 with a recast of the national regulatory framework as well as with complete reorganisation of the structures. Based on Law n° 57/1997, the State Commission for Variety Testing and Homologation was reorganised and so, the State Institute for Variety Testing and Registration (ISTIS) was established, with the same attributions and organisational structure. It functions on the basis of the Law N° 266/2002, as a public institute subordinated to the Ministry of Agriculture and Rural Development. ISTIS performs technical examination of the Romanian and foreign varieties which apply for the registration in the national catalogue of varieties of agricultural and vegetable species. After these two rounds of legislative and organisational adjustments (1997 and 2002), a third one happened in 2005.

Romanian authorities have been supported during this transition period through 2 major projects. First support came from the NL, based on a 2 year project financed by NL government, and was mainly a legal support for addressing harmonisation issues. The second project was a PHARE[23] project, financed by both EU and RO, which took place in 2005-06. Several experts coming from NL and FR concentrated their support on implementation of certification schemes. It has to be highlighted, also, that RO was present at OECD for a large number of years, so was very aware of EU standards and provisions before starting the harmonisation. That aspect facilitated the integration, especially for certification.

As the first harmonisation activities started in 1997, no extra local resources were required and the harmonisation was achieved smoothly.

The first national laws with EU provisions were established in 2003 and all EU provisions on the 12 basic texts have been integrated into national laws by mid 2006.

Operational implementation of the legislation created more issues, especially in the area of Variety Registration. Historically, NMS were focusing registration mainly on VCU, and much less on DUS criteria. RO was not use to exporter seed, it was for their own national use, so not lot of emphasis was put on DUS, and DUS was not conducted properly when comparing to UPOV standards. This is especially true for the set-up and management of the reference collection. Traditionally, DUS tests were carried out by comparing applications to national varieties only.

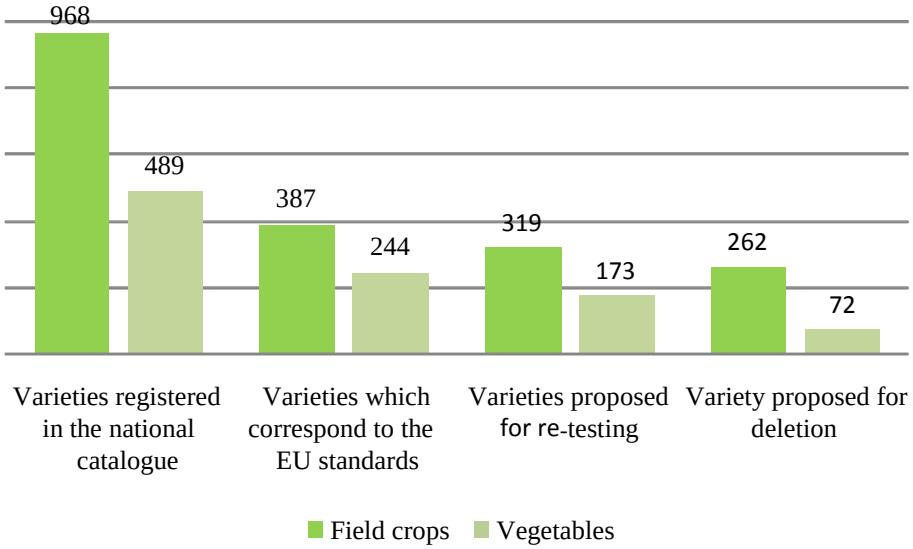
After adhesion, ISTIS has had to implement a correct reference collection in line with the legislation leading to several high investments in equipments (e.g. cold storage, adequate seed material). In total, 7 different DUS sites have been equipped to fulfil EU regulations.

Additionally, a 3 years derogation (2007 to 2009) has been granted to re-test listed varieties for DUS according to new principles. A couple of remarks from the qualitative questionnaire indicate that the derogation period should had been longer than 3 years, and that many useful old varieties are being lost as this period of 3 years is too short.

Not all these varieties will match EU standards and the following consequences on the national catalogue are expected as the following:

[23] The Programme of Community aid to the countries of Central and Eastern Europe (PHARE) is the main financial instrument of the pre-accession strategy for the Central and Eastern European countries (CEECs) which have applied for membership of the European Union. Since 1994, PHARE's tasks have been adapted to the priorities and needs of each CEEC.

Graph 14 – Situation of the varieties registered in the RO catalogue, re-testing and proposed for deletion



Two other major impacts affected the seed sector:

- Lot of imported new varieties not adapted for the local growing conditions were sold to small farmers leading to low yielding crops affecting farmers' income;
- Staff in the Ministry has had lot of difficulties to understand that e.g. derogations' requests should be submitted to EU creating a staff strong emotional effect.

Possible other consequence of these adjustments is the evolution of prices to conduct the registration tests, mainly DUS, leading to increases in fees to be paid by the applicants.

New member states consider that the Community legislation easy to understand and that the translation into national languages and implementation in the national regulatory frameworks didn't create any key issues. Problems occur for the practical implementation of the legislation and especially regarding harmonisation of DUS leading to significant investments in order to set-up DUS testing facilities in line with EU requirements.

6.4. GOVERNANCE OF THE S&PM LEGISLATION

This section of the final report is in addition to the evaluation questions as formulated in the ToR. Because most of interviewees made comments on the issue of governance, the FCEC team considers that it is worthwhile summarizing them into a separate section of the report. Comments of interviewees concern the relevance of the allocation of the management of the S&PM legislation to DG SANCO as well as the role and functioning of the standing committees.

Relevance of the allocation of the management of the S&PM legislation *to DG SANCO*

Only few interviewees consider that DG SANCO is the appropriate DG for governing the legislation. S&PM is core segment of crop production, and therefore Community legislation should be managed by DG AGRI, as it was in the past.

FCEC considers that grouping all elements of the Food Chain under the same DG (SANCO) allows to get an integrated, complete and much more structured approach as S&PM are the first element of the food chain.

Role and Functioning of the standing committees

Three Regulatory Committees[24] and their working groups assist the European Commission in the development of Community measures.

The Standing Committees have delegated powers from the European Council of Ministers to give opinions with regard to changes to the Annexes of the Directives, for instance to standards or to lists of species covered by the Directives. Changes to the body of the Directives, with the exception of the list of species, may only be made by the European Council of Ministers.

In certain exceptional circumstances, the Commission's Standing Committee may authorise provisional changes by way of a formal temporary experiment. Such experiments are designed to trial and evaluate improved alternatives to Directive provisions and may not extend beyond 7 years. Any permanent changes would require adoption by the European Council of Ministers.

The Standing Committees meet several times a year. The purpose of those meetings is to exchange views, discuss key issues and vote draft Commission decisions. Both technical and legal issues are discussed during the meetings of the standing committees, what has driven MS to come to meetings with the double expertise (i.e. one technical expert and one legal expert).

Several interviewees have mentioned that, in the enlarged EU, it would be more appropriate to discuss the technical issues during separate technical working group, as already done in the forestry area in 2007[25]. During the exploratory interview of national representatives of forestry authorities, people have highlighted the positive points of this approach, i.e. the lightening of the technical discussions during the meetings of the SCPS, an improved communication between technical experts on their experience of implementing the EU forestry provisions, etc.

When asked on the efficiency of the process to adopt new legislation, interviewees consider that decision-making in the area of S&PM is/has been a very slow process in several cases, for instance the adoption of Directives on conservation varieties. The past management of the Standing Committees was largely based on consensus, which seems not an adapted approach any longer with 27 MS. EU12 MS S&PM sectors are much more traditional than in the EU 15 MS leading to much more difficulties to reach consensus. An adapted approach should be sought and implemented in order to facilitate discussions, decision-making and rebuilt confidence.

The FCEC team believes that the wider use of technical working groups could possibly contribute to the better understanding of the matter subject to vote as well as to more exchanges between MS prior to voting.

Such technical platform for exchange between parties could become even more relevant, in case where the procedure of co-decision[26] is enlarged to the area of S&PM in the future. The co-decision procedure is based on the principle of parity and means that neither the European Parliament nor the Council may adopt legislation without the other's assent. This platform could, also, define EU guidelines for testing new traits. In certain cases, responsibility should remain within the national authority, and case-by-case approach should be preferred.

[24]SCPS: Standing Committee on Seeds and Propagating Material for Agriculture, Horticulture and Forestry
SCFP: Standing Committee on Propagating Material and Plants of Fruits Genera and Species
SCPOP: Standing Committee on Propagating Material of Ornamental Plants

[25] Working Partly on Forest Reproductive Material organised jointly by NL and BE on the 11th and 12th of September 2007 in Hoeven (NL)

[26] It has been established by the Maastricht Treaty, and extended and adapted by the Treaty of Amsterdam to make it more effective. It currently covers 43 areas. The S&PM Directives are based on the Article 37 of the Treaty of Rome which does not foresee the procedure of co-decision. However, the Treaty of Lisbon, officially signed by the Heads of the Member States on 13 December 2007, foresees to enlarge the co-decision procedure to the agricultural area. It still has to be ratified by each Member State in order for it to come into force.

6.5. OVERALL CONCLUSIONS

Of the 12 basic Directives of the legislation, one Directive has a horizontal structure and defines the obligations for the registration of varieties of agricultural plant species (Directive 2002/53/EC on the Common Catalogue). The remaining Directives are marketing Directives defining principally the obligations for the production and certification of S&PM, but which also contains requirements for registration when relevant.

Only crops/species of EU economic importance shall be included in the Community legislation. The list of species seems, today, outdated and should be reviewed and this approach do not answer to issues related to species which vary in economic importance across MS. FCEC approach would be to consider that the usage should be linked to the species for listing to allow to have enough flexibility for different usages of a specific usages e.g. sugar beet vs. fodder beet. This approach is feasible for usages that are highly specific and for which one variety cannot move for one "*species x usage* " to another.

The S&PM legislation does not apply to the supply of seed for 'industrial use'. Industrial use is not clearly enough defined and it is appropriate to review its terms and scope of the exemption to bring more clarity on the implementation of such provision, if still relevant.

Differences exist between the 12 Directives of the legislation in what concerns:

- Clarity: the updated Directives are clearer than the old ones, which have undergone a significant number of substantial amendments. Discrepancies or inconsistencies exist within the Directives (for instances cross-referencing to outdated legislation) as well as with the specific areas of Genetically Modified (GM) varieties and of plant health, what may well create confusion and misinterpretation of the rules;
- Scope: Some Directives refer to a species, other ones to a group of species or to the use of the plant. There are cases where 1) several Directives cover a same species; 2) crops of major and minor economic importance are subject to the same obligations under one Directive; 3) some crops of high current economic value are not covered by the legislation;
- Perimeters: most of Directives provide details of the species they regulate. However, no list of species is provided in Ornamental Directive (98/56/EC), as all species are included. Also, as regards the marketing of forestry reproductive material, there are some practical problems linked to the expression 'not for forestry purpose'.

For the future, there seems to be a valid case for:

- Specifying the perimeter of the Directive on the marketing of PM of ornamental plants;
- Clarifying the rules concerning the marketing of FRM which is clearly considered not to be fit for forestry purposes or is clearly not intended to be marketed or planted for long term forestry purposes;
- Further aligning the various provisions of the EU S&PM legislation both internally (between the S&PM Directives) for the legal provisions only; when talking about technical elements e.g. terms, and definitions harmonisation is not adding any added value and would require large efforts; and externally with the overall EU GMOs regulatory framework as well as the current relevant horizontal plant health legislation (Directive 2002/29/EC).

Clear links exist between the EU S&PM legislation and the legislation pertaining to the Community Plant Variety Rights (PVR), Plant Health, Plant Protection Products (PPP), Genetically Modified Organisms (GMO) and Trade. There seems to be room for improved consistency with the legislation on PVR (reference collections), PPP (i.e. for the marketing of treated seeds) and GMOs (e.g. adventitious presence). The legislation seems consistent with the legislation on plant health but better integration could be searched for in the future between the phytosanitary inspection and the inspection for certification purpose. This point is further examined at section 7.2.11.

The analysis, searching for interactions between the legislation and the EU legislation on Contaminants in food, demonstrates that when considering seed as part of the food chain, interesting perspectives may be identified e.g. mycotoxins. Therefore, there is a valid case for considering plant breeding as one component of the human health strategy.

Overall, the results from the survey and the interviews indicate that the large majority of stakeholders consider that the 12 Directives of the legislation are valuable or very valuable.

The internal market for the marketing of S&PM is perceived as being well established but several elements lead to the absence of a level-playing field; i.e. the non-harmonised implementation of some Community provision, the existence of additional national implementing measures; a lack of organised circuit for the exchange of information between the MS and the non-harmonised framework for costs and responsibility sharing.

7. ANALYSIS OF THE PAST/CURRENT PERFORMANCE OF THE S&PM LEGISLATION

7.1. VARIETY/MATERIAL REGISTRATION

7.1.1. Introduction

7.1.1.1. Concerned Council Directives of the S&PM legislation

Table 6 – Provisions of the EU S&PM legislation related to variety/material registration[

Area	Directive	EU S&PM provisions					
		DUS	VCU	Variety Denomination	National Listing	Variety Maintenance	Common Catalogue
Seed (beet, fodder plant, cereal, potato and oil and fibre plant)	2002/53/EC	Art. 4 (1), 5 (1, 2, 3), 7 (1, 2(a), 2(b)), 9 (3), 10(2), 12 (1), 13(2)	Art. 4 (1), 5 (4), 7 (2 (c)), 12 (1), 16(2b)	Art. 9 (2, 6), 13(3)	Art. 3 (1), 9(1)	Art. 9(1), 11	Art. 1 (2), 3 (3), 17
Vegetable Seed	2002/55/EC	Art. 4 (1), 5 (1,2,3), 7 (1, 2, 3), 9(3), 12 (2)	Art. 4 (1)*	Art. 9 (2, 3, 6), 13(3)	Art. 3 (2), 9(1)	Art. 11	Art. 3 (3, 4), 17
PM	68/193/EEC (Vine)	Art. 5a, 5b	No	No	Art. 5 (1)	Art. 5g	Art 5e(2)
	92/33/EEC (Vegetable PM)	Art 9	No	No	Art. 9 (2)	Art 9(2)	No
	92/34/EEC (Fruit)	Art 9 (5 (a))	No	Art. 9 (2)	No	Art.3(c, d, g, h)	Art. 9 (6) (not implemented in practice)
	98/56/EC (Ornamental)	No	No	Art. 9 (2)	Art. 9 (1)	No	No
Forestry	1999/105/EC	No	Art.2c(ii) Uniformity	No	Art. 10	No	Art. 11 (1)

** Only for industrial chicory*

Considering the group Seed, Directives 2002/53/EC and 2002/55/EC impose to all MS to compile one or more national catalogues of the accepted varieties. It also foresees the creation of a Common Catalogue, which is compiled based on the national catalogues only. The principle is that once a new variety is listed in the national catalogue, it is registered for the entire EU, listed in the Common Catalogue, and becomes freely marketable within the Community. The Commission updating procedure of the Common Catalogue may induce some delays to make eligible the new variety for the free marketing.

Any MS that wants to restrict or to prohibit the marketing on its territory of a variety accepted in another MS must be authorised to do so by the Commission.

Directive 68/193/EEC stipulates that each MS shall establish a catalogue of the vine varieties and clones officially accepted and that these lists are communicated to other MS.

Concerning vegetable propagating and planting material, *genera* and species listed in annex II of Council Directive 92/33/EEC shall not be marketed unless they belong to a variety officially accepted in at least one MS.

The overall principle for fruit and ornamental propagating material is that it may be marketed with a reference to a variety, only if the variety concerned is legally protected by a plant variety right or officially registered or commonly known or entered on a list kept by a supplier with its entailed description and denomination.

Council Directive 1999/105/EEC stipulates that forest reproductive material may not be marketed unless it is one of the four categories specified by the Directive (source-identified, selected, qualified, and tested). Basic material must be approved by reference to a unit known as the unit of approval. The Directive foresees that all information on units of approval of basic material approved on a MS territory is held in a national register, including information about the area(s) in which the material is found or the exact geographical location (depending upon the category). A Community list may be drawn up based on the national lists.

7.1.1.2. Implementation in the MS

Organisation of the variety/material registration in the MS

The way the provisions on DUS, VCU, variety denomination, maintenance and Common Catalogue are implemented in the MS is presented in sections 7.1.3. to 7.1.6.

Overall, the main obligations linked to the registration of seed varieties are the development of DUS and VCU testing networks.

The aim of the VCU tests (applicable to agricultural plant species) is to predict the agronomical value of a new variety in comparison with existing marketed varieties. Therefore, a number of trials (locations/years) are necessary which results in experimental costs. Furthermore, because of the specific characteristics of each MS (climate, soil, etc.) and specific traits like disease resistance or technological value (e.g. baking value for wheat varieties), the VCU tests are carried out differently in each MS. Annex 10 gives an overall picture of the VCU networks in the EU 27 MS.

The aim of the DUS (applicable to agricultural plant species and vegetable species) is to permit the identification and description of varieties, as a core prerequisite for seed certification at the seed trade control.

DUS testing is more harmonised than the VCU one. Usually, the DUS tests are conducted over 2 years and the duration of the VCU tests varies between 2 and 3 years.

The comparative study of national listing systems conducted by the GEVES[27] in 2003 provides a description of the VCU testing practical conditions in several countries.

[27] Comparative Study of National Listing Systems for some Agricultural Crops in the Main European Countries, GEVES, January 2003

Table 7 – Comparison of the VCU practical conditions for the testing of winter oilseed rape in Germany and Italy

	Germany	Italy
Experimental protocol		
Duration of the testing	3 years	2 years
Trial series	2 (1 in Year 1, 1 in Y2 et Y3)	1
Number of yield trials / trial series	Y1 : 15 Y2/A3 : 15	4
Varieties evaluation - Characteristics		
Yield	- Grain	- Grain
Resistance to diseases	- *Phoma* - *Sclerotinia* - *Alternaria*	
Behaviour with respect to factors in the physical environment	- Lodging - Winter hardiness - Earliness	
Quality	- Oil content - Glucosinolates content	- Oil content - Glucosinolates content - Erucic acid content
Checks varieties	- Varieties on the National List with the same genetic structure	- Control varieties from the same precocity group
Average VCU acceptance rate	- 15 %	- 75 %

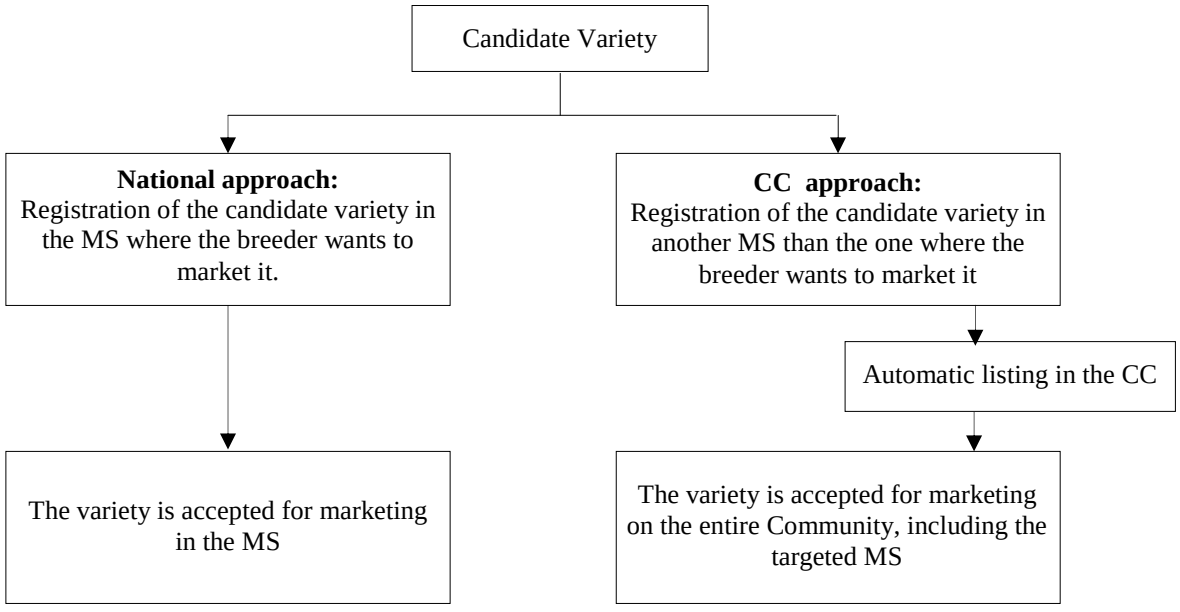
Source: compiled on the basis of the Comparative study of GEVES (2003)

Important differences exist in the way VCU tests are conducted in MS as demonstrated in the previous table comparing VCU networks for winter oilseed rape in Germany and Italy.

Taking into account that once a seed variety is listed on a national catalogue it becomes marketable in the entire Community, such differences may influence the breeder when deciding on the best way to get its variety registered.

As illustrated below, two alternatives exist to market a seed variety on the territory of a given MS: the first one is to get it listed on the national catalogue of the MS concerned (preferred approach for the breeder); the second one is to get it listed on the national catalogue of another MS (e.g. with less stringent provisions) and get it marketable on the targeted MS via the Common Catalogue.

Figure 6 – Approaches to get a variety marketable on the territory of a given MS



Coming back to the comparison between Italy and Germany, getting one new variety of winter oilseed rape registered in Italy takes 3 years (2 years of tests + around 1 year to get the official approvals) if the breeder uses the Common Catalogue approach (i.e. he registers its variety in Italy and gets it marketable in Germany through the Common Catalogue) compared to 4 years if it uses the national one. Conducting the VCU for winter oilseed rape in Italy seems also less costly than doing it in Germany (because of less numerous trials and less numerous evaluated characteristics) and seems to have a higher chance of acceptance.

However, the Common Catalogue approach does not provide any information on the agronomical value of the variety when cultivated in Germany, as the VCU tests have been carried out in Italy so that the German user will need additional information before buying it.

In order to guarantee the agronomical value of the varieties marketed on their territory, the majority of the EU 15 MS have implemented post-registration networks. Hungary is currently re-implementing such network, as they realized after their accession to the EU that any supplier might market a new variety on their territory without any obligation to guarantee an agronomical value to the user.

Existence of bilateral agreements

Several MS have concluded bilateral agreements for the conducting of DUS tests; i.e. they agree with another MS that the DUS tests for a given species take place on the territory of the other MS while the variety, if accepted, remains listed on their national catalogue.

Such agreements do not exist for VCU tests, whereas not prohibited by the Community legislation. Germany had implemented that provision in its seed law but is not using. Without any agreement, Luxembourg has been using this option to complete local data sets for their decision-making.

It should be highlighted that this last provision of the legislation, allowing the possibility to exchange VCU data across MS, is not well known. Several key actors have been quite surprised when indicating that no provision prevents from this data exchange.

Tasks of the official authorities versus the private bodies

In all MS, the DUS and the VCU obligations are under the responsibility of the official authorities. Some MS sub-contract the conducting of some VCU trials (in particular the first year of trials) to breeders or/and post-registration bodies but they remain responsible for the analysis of the results and the decision-making. The different experiences including breeder companies for DUS and VCU and professional organisations for VCU for several years, is the demonstration of the feasibility of a monitoring system along the same lines as the certification under official supervision.

Comparison with other regulatory frameworks in key markets outside the EU (see Annex 11)

In Australia, there are no mandatory requirements for official VCU testing but varieties must be registered by the Australian Seeds Authority Limited (ASA) and added to the ASA National list before they can be certified.

In Canada, depending upon the crop kind, registration for some varieties may include a merit requirement to establish that new varieties are as good as, or better than existing varieties. “Merit” generally refers to the varietal characteristics that enhance the variety’s value for a particular use in a region of Canada. Performance testing refers to variety trials, historically conducted by provincial or university extension services, to determine a variety’s relative quality and yield over time. Normally, three years of data are required for most crop kinds subject to registration. It has to be noticed that trialling systems are crop specific and that efforts are shared between official authorities and industry. For instance, in Canola, a 2 years system is in place. Breeders have to provide data coming from Private co-op trials (first year of testing), and public co-ops trials are conducted for 1 year (second year of testing).

DUS assessment exists in Canada. It is carried out based on data provided by the breeder, without conducting any official field trials.

Canada's example is being considered in several other parts of this report as Canada has conducted a consultation to review their variety registration scheme, in particular the VCU. "*The current Canadian variety registration system lacks sufficient flexibility to address the specific needs of different crop sectors in a rapidly changing agricultural environment. In some cases, the system imposes a disproportionate regulatory burden on developers of new crop varieties and creates impediments to innovation and to the timely availability of new varieties*."

The revision of the Canadian registration system is under discussion from almost 10 years and has lead to a recent proposal (June 18, 2008) to create a flexible variety registration scheme. This proposal can be consulted at http://www.inspection.gc.ca/english/plaveg/variet/vartoce.shtml

In the United States, there is no variety registration system and no national review system, so no statutory performance testing to approve varieties before they can be sold. Breeders at universities mainly, carry out the testing of variety performance. The assessment protocols integrate a range of the standard parameters that exist in the VCU tests but there is no performance threshold. This system allows a greater flexibility in the release of varieties for specific purposes and niche markets but it should be stressed that in the USA, the legislation governing the relations between buyer and seller are quite different from the EU legislation.

7.1.2. Variety registration costs (seed sector only)

7.1.2.1. General context

The current distribution of seed registration costs between the public and the private bodies in the MS is summarised in the following table.

Table 8 – Current distribution of seed registration costs between public and private bodies in the MS

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

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

7.1.2.2. Structure of the variety registration costs

The ToR of the evaluation distinguish between three types of costs, i.e. the administrative costs, the compliance costs and the enforcement costs, which they define as follows:

- Administrative costs i.e. those costs incurred by companies and public authorities in meeting legal obligations to provide information on their action or production to public authorities or private parties;
- Compliance costs i.e. those costs linked to changes in the method of production linked to legal obligations;
- Enforcement costs i.e. costs for public authorities and the Commission resulting from implementation.

During the interviews of stakeholders, it appeared that the public authorities and the private operators (suppliers of S&PM) do not distinguish between such categories of costs. Overall, they distinguish between costs per activity, grouped into costs centres.

The major costs centres identified for the variety registration are as follows:

- Pre-registration costs: costs related to the production of preliminary data (VCU); production of data for application submission (DUS) and administrative costs for applications preparation and submission;
- Registration costs:
  - *DUS management costs*
  - *VCU management costs*

For each of these 2 activities, FCEC identified sub-costs centres as following:

- For DUS:
  - Technical and administrative management of demands
  - Planning of experimentation
  - Reception and disposal of materials
  - Conducting of experimentation
  - Networks management and co-ordination
  - Trials approval including field visits
  - Validation and treatment of data
  - Maintenance of reference collections
- For VCU:
  - Technical and administrative management of demands
  - Planning of experimentation
  - Reception and disposal of materials
  - Conducting of experimentation
  - Networks management and co-ordination
  - Trials approval including field visits
  - Validation and treatment of data

However after discussions with several experts and competent authorities, it has been decided not to collect any data on these sub-costs centres during the cost survey as it was clearly mentioned that authorities are not segmenting costs at that level of details. Some detailed figures from France have been collected during the in-depth studies and are presented in the confidential final report on costs.

- Post-registration costs:
  - Costs related to the administrative management of approved varieties, i.e. denomination and publications
  - Costs for the maintenance of varieties.

7.1.2.3. Overall estimation of the annual variety registration costs in the MS

FCEC conducted a simulation to estimate overall costs of the implementation of the Community legislation. The total variety registration costs and certification costs for the group Seed for competent authorities can reasonably be estimated at around 120 million EUR per year[28].

The total registration costs are estimated at around 36 million EUR for all crops of the group Seed for the 8 MS that have submitted complete datasets. Based on ISF statistics, it is recognised that these 8 MS represents about 70% of the EU market values for seed.

Based on the data compiled by FCEC during the cost study, variety registration costs represents 43% of the total costs linked to the implementation of the Community legislation by the national authorities. This percentage varies considerably from one MS to another from 13,8% to 78,5%. These figures are, globally, in line with the national structure of the seed business and the national approach of variety registration by competent authorities.

The differences in the registration costs possibly depend on:

- The difference in the number of applications received each year by the different MS;
- The variability of the labour costs of each MS;
- The variability of the VCU network sizes according to crops. The VCU network size (number of individual testing sites) depends of the size of the country in which the network is implemented. That leads to situations where for the same crop, the VCU network size can be limited to 3-4 sites in a small MS, where in a large neighbouring country the VCU network is based on more than 20 sites;
- The variability of the DUS network sizes according to crops. The most costly part of DUS tests is the management of the reference collection that can vary in number by 4-5 from one MS to another;
- The extent to which the MS has imposed obligations in addition to the Community ones.

Pre-registration costs that cover production of data needed for application filling, and the preparation and management of application files are being reported. These costs are mainly borne by the private sector, and associations of suppliers that responded to the cost survey reported cases where significant costs were engaged e.g. up to 1 million EUR per year for all applications of all companies of the given association.

DUS and VCU costs represent the most important part of the total variety registration costs. Overall, the DUS and VCU costs for competent authorities represent more than 5 million EUR for all seed crops in the major markets. For the majority of the responding national authorities, the proportion of the VCU costs is larger than the one of the DUS costs, but with large a variability between MS. It has to be noticed that for DUS, the costs have been underestimated for the MS that are using bilateral agreements to perform the tests in a foreign MS.

Post-registration costs, for competent authorities, are in the average range of +/- 5-7 % of the total registration costs.

Data presented by the industry are structured differently from the ones presented by the competent authorities and do not permit large comparison between official costs and breeders costs.

Due to a lack of data provided by respondents, the two additional analyses on the costs/applications and the adjustments of costs to labour costs to assess the efficiency of the registration system could not be carried out.

[28] Simulation details are presented in the confidential final report on costs submitted to the Commission services

7.1.2.4. Tentative estimation of the part of the administrative costs – French example – and identification of opportunities for cost reduction

The administrative costs are defined in the ToR of the evaluation as the costs incurred by companies and public authorities in meeting legal obligations to provide information on their action or production to public authorities or private bodies.

The annexes of the Impact Assessment Guidelines defined by the Commission identifies 12 types of information obligations, as follows:

1. Notification of (specific) activities
2. Submission of (recurring) reports
3. Information labelling for third parties
4. Non labelling information for third parties
5. Application for individual authorisation or exemption
6. Application for general authorisation or exemption
7. Registration
8. Certification of products or processes
9. Inspection
10. Cooperation with audits
11. Application for subsidy or grant
12. Other

This list shows the potential complexity of elaborating a clear definition of the administrative costs that is understandable and usable by stakeholders.

In order to get an indication of how important could be the administrative costs in the registration costs, the FCEC focuses on the French example.

For confidentiality reasons, the results are presented in the final report on costs.

Overall, the FCEC team believes there are no real opportunities in trying to further reduce the registration costs (including the administrative ones) in each MS, because:

- The registration costs represent 1,3% of the size of the EU markets for seed and other planting material[29];
- The administrative costs represent a minor part of the total registration costs, for which there has been a constant effort made by the MS in trying to reduce them (without modifying the registration obligations implemented in each MS).

In its opinion, the problem is not the level of costs linked to the implementation of the Community S&PM legislation in each MS but more that each MS has implemented its own VCU and DUS testing networks without looking for economy of scale through collaboration.

Consequently, the FCEC team considers that there are opportunities for reduction of the registration costs by promoting a different organisation of the DUS and VCU tests carried out in the EU, as presented in sections 7.1.3.5., 7.1.3.6. and 7.1.4.4. below. The main options considered there are:

- Extend the bilateral agreements in order to rationalize the number of DUS testing sites in the EU;
- Have a same and unique DUS testing for marketing and for Community Plant Variety Rights system (‘*one key-several doors’* approach);
- Allow recognition of other MS’ VCU data for national listing (bilateral agreement);
- Allow coordination between MS of official observations and national decisions possibly under bilateral agreements.

[29] Calculated as the sum of sizes of the internal market of 19 selected EU MS

7.1.3. DUS

Table 9 below summarises the Community DUS provisions.

Table 9–- Provisions of the EU S&PM legislation related to DUS

Crops	Council Directives	Community DUS provisions	
		Ref Art.	**Description of the obligation**
Beet seed	2002/53/EC	Art. 4 (1)	MS shall ensure that a variety is accepted only if it is distinct, sufficiently uniform and stable.
Fodder plant seed Cereal seed Seed potatoes Seed of oil and fibre plants		Art. 5 (1, 2, 3)	A variety shall be regarded as distinct if, whatever the origin, artificial or natural, of the initial variation from which it has resulted; it is clearly distinguishable in one or more important characteristics from any other variety known in the Community. The characteristics of a variety must be capable of precise recognition and precise definition. A variety known in the Community shall be any variety which, at the time when the application for the acceptance of the variety to be assessed is duly made, is: - either listed in the Common Catalogue of varieties of agricultural plant species or the catalogue of varieties of vegetable species; - or, without being listed in one of those catalogues, has been accepted or submitted for acceptance in the Member State in question or in another Member State, either for certification and marketing, or for certification for other countries; - unless the conditions are no longer fulfilled in all the Member States concerned before the decision on the application for acceptance of the variety to be assessed is taken. A variety shall be regarded as sufficiently uniform if, apart from a very few aberrations, the plants of which it is composed are, account being taken of the distinctive features of the reproductive systems of the plants, similar or genetically identical as regards the characteristics, taken as a whole, which are considered for this purpose. A variety shall be regarded as stable if, after successive propagation or multiplications or at the end of each cycle (where the breeder has defined a particular cycle of propagation or multiplications), it remains true to the description of its essential characteristics.

		Art 7 (1, 2(a), 2(b))	MS shall provide that the acceptance of varieties be based on the results of official examinations, particularly growing trials, covering a sufficient number of characteristics for the variety to be described. The methods used for determining characteristics must be exact and reliable. In order to establish distinctness, the growing trials shall include at least the available comparable varieties which are varieties known in the Community. The following shall be fixed in accordance with the Committee procedure, account being taken of current scientific and technical knowledge: - the characteristics to be covered as a minimum by the examinations of the various species; - the minimum requirements for carrying out the examination.
		Art 9(3)	In taking into account the information available, Member States shall also ensure that a variety which is not clearly distinguishable: - from a variety previously accepted in the Member State in question or in another Member State, or - from another variety which has been assessed with regard to distinctness, stability and uniformity in accordance with rules corresponding to those of this Directive, without, however, being a variety known in the Community within the meaning of Article 5(1), bears the name of that variety. This provision shall not apply if this name is likely to mislead or cause confusion concerning the variety in question, or if, pursuant to all the provisions of the Member State concerned governing the names of varieties, other facts prevent its utilisation, or if the rights of third parties impede the free use of that name in connection with the variety in question.
		Art 12 (1)	The acceptance shall be valid until the end of the tenth calendar year following acceptance.
Vegetable Seed	2002/55/EC	Art 4 (1), 5 (1, 2, 3), 7 (1, 2), 9 (3), 12 (1)	As Art. 4 (1), 5 (1, 2, 3), 7 (1, 2(a), 2(b)) and 12 (1) of Council Directive 2002/53/EC

Material for vegetative propagation of the vine	68/193/EEC	Art 5a	As Art 4 (1) of Council Directive 2002/53/EC
		Art 5b	A variety shall be deemed distinct if it is clearly distinguishable, by reference to the expression of the characteristics resulting from a particular genotype or combination of genotypes, from any other variety whose existence is a matter of common knowledge in the Community. A variety shall be deemed to be a matter of common knowledge in the Community if, on the date on which application is duly made for its acceptance, it either is entered in the catalogue of the Member State in question or of another Member State or is the subject of an application for acceptance in the Member State in question or in another Member State, unless the conditions referred to in the first sentence of this paragraph are no longer met in all the Member States concerned before a decision is made regarding the application for acceptance of the new variety being assessed. A variety shall be deemed stable if the expression of the characters, which are included in the examination for distinctness, as well as any others used for the variety description, remains unchanged after repeated propagation. A variety shall be deemed uniform if, subject to the variation that may be expected from the particular features of its propagation, it is uniform in the expression of those characters, which are included in the examination for distinctness, as well as any others used for describing the variety.
Vegetable propagating and planting material other than seed	92/33/EEC	Art 9.1. Without prejudice to Article 2, vegetable propagating and planting material which belongs to genera or species listed in Annex II and is also covered by Directive 70/458/EEC shall not be marketed within the Community unless it belongs to a variety accepted in accordance with Directive 70/458/EEC.>>>Directive 70/458/EEC:Art 4. The Member bStates shall ensure that a variety is accepted only if it is distinct, stable and sufficiently uniform>>>Directive 2002/55/EC is the codified version of Directive 70/458/EEC and contains the same provision in its Art 4.1	
Fruit plant propagating material and fruit plants	92/34/EEC	Art 9 (5 (a)	Requirements for the official registration shall be established in accordance with the Committee procedure, taking into account current scientific and technical knowledge and covering the conditions of official acceptance, which may include, in particular distinctness, stability and sufficient uniformity
Ornamental plants	98/56/EC	No	
Forest reproductive material	1999/105/EC	No	

Community DUS provisions exist for the seed and vine areas. Currently, the DUS testing relies on morphological features only and is usually being carried out on 2 years. In certain cases, a 3rd year is added to validate 2 first-year results.

There is currently no common DUS requirement for the registration of new varieties on the market of fruit crops, ornamental crops and vegetatively propagated vegetables. Nevertheless, DUS testing of those crops exists in certain MS.

For the purpose of examining the distinctness of the candidate variety, MS have set up their reference collections based on very precise EU provisions.

Article 5 (1) of Council Directives 2002/53/EC and 2002/55/EC as well as Article 5b of Council Directive 68/193/EEC (see table 9) define the varieties to include in such reference collections, by referring to the varieties '*known in the Community'* (seeds) or '*whose existence is a matter of common knowledge in the Community*' (vine).

Article 9 (3) of Council Directives 2002/53/EC and 2002/55/EC requirements (see table 9) imply that any other variety previously accepted in any MS and not listed any longer (old varieties) shall be included in the reference collection.

It is the opinion of the FCEC team that, on the basis of those articles, it is easy to clearly understand which varieties do the reference collections have to contain, but that correct implementation of these provisions is nearly impossible. As example, the reference collections should contain all varieties that are already registered in all MS, and collecting these varieties are not creating deep issues; but when talking about varieties in DUS tests and not listed yet, the gathering of these varieties is very difficult for practical logistic reasons.

7.1.3.1. Links with UPOV and Plant Variety Rights (PVR)

Links with UPOV

Article 7 of Directives 2002/53/EC and 2002/55/EC stipulates that MS shall provide that the acceptance of varieties be based on the results of official examinations, particularly growing trials, covering a sufficient number of characteristics for the variety to be described.

Directives 2003/90/EC[30] and 2003/91/EC[31] set up the implementing measures for the official examination of certain varieties. For this purpose, they refer to the test guidelines developed by the CPVO and the UPOV and provide in their annexes I and II separate lists of the species, which shall comply with the CPVO test guidelines, and those, which shall comply with the UPOV one. National law applies for the species not listed in their annexes.

Links with Plant Variety Rights

Council Regulation (EC) 2100/94 defines the Community rules on Plant Variety Rights (PVR). To be granted PVR, a variety must:

- Be distinct, sufficiently uniform and stable;
- Be new;
- The applicant must be entitled to the grant of rights;
- Have a suitable name.

[30] Commission Directive 2003/90/EC of 6 October 2003 setting out implementing measures for the purposes of Article 7 of Council Directive 2002/53/EC as regards the characteristics to be covered as a minimum by the examination and the minimum conditions for examining certain varieties of agricultural plant species

[31] Commission Directive 2003/91/EC of 6 October 2003 setting out implementing measures for the purposes of Article 7 of Council Directive 2002/55/EC as regards the characteristics to be covered as a minimum by the examination and the minimum conditions for examining certain varieties of vegetable species

The DUS tests are common both to the Community S&PM legislation and the legislation on PVR[32]. Nevertheless, while the seed legislation defines the reference collection as '*any other variety known in the Community*', the PVR one refers to the '*any other variety whose existence is a matter of common knowledge*'.

It stipulates that the existence of another variety shall in particular be deemed to be a matter of common knowledge if:

- It was the object of a plant variety right or entered in an official register of plant varieties, in the Community or any State, or in any intergovernmental organization with relevant competence;
- An application for the granting of a plant variety right in its respect or for its entering in such an official register was filed, provided the application has led to the granting or entering in the meantime.

It must be noted that, contrarily to the current Community S&PM legislation[33] where variety is not being defined, the PVR legislation defines what is a 'variety' (Article 5 (2) of Council Regulation (EC) 2100/94), as follows:

For the purpose of this Regulation, 'variety' shall be taken to mean a plant grouping within a single botanical tax on of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a plant variety right are fully met, can be:

- Defined by the expression of the characteristics that results from a given genotype or combination of genotypes;
- Distinguished from any other plant grouping by the expression of at least one of the said characteristics and;
- Considered as a unit with regard to its suitability for being propagated unchanged.

7.1.3.2. Utility

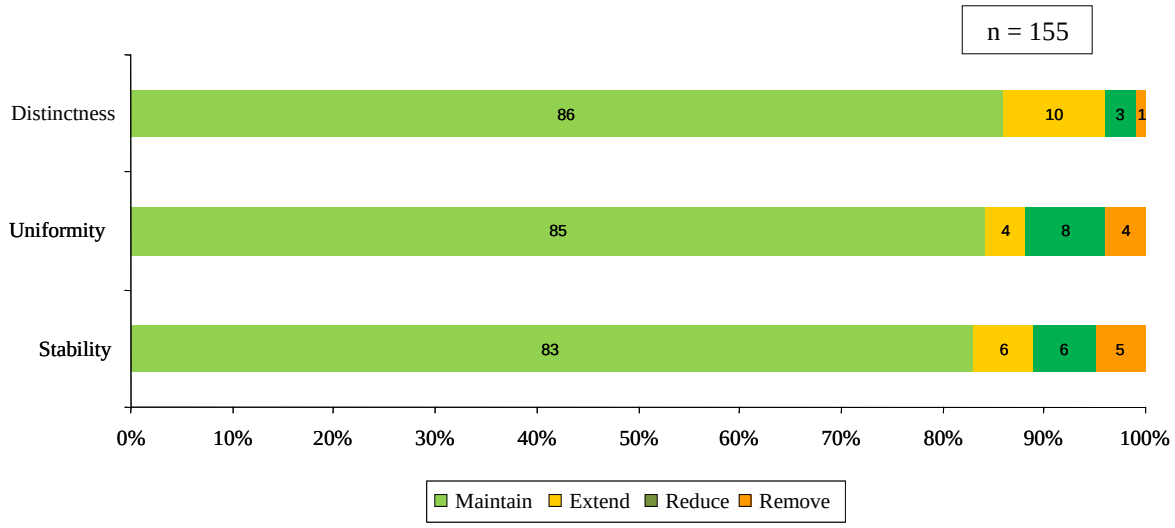
Overall, respondents to the qualitative survey and stakeholders interviewed believe that Distinctness, Uniformity and Stability are useful, as they are the baseline to describe the identity of a variety, which is crucial for seed certification and variety protection.

More than 80% of respondents consider that the acceptance criteria for Distinctness, Uniformity and Stability must be maintained in the future for National Listing purposes (Q 2.1.2.1., n=155).

[32] However both legislations do not have the same legal basis, i.e. the legal base for the Common Catalogues Directives is the articles 37 of the Treaty establishing the European Community whereas the one for Council Regulation (EC) 2100/94 is the article 235 of the same Treaty.

[33] According to this definition, the concept of 'Variety' is linked to the concept of 'Distinctness'. Such definition makes part of the the newly adopted fruit plants Directive 2008/90/EC (Article 2 (3)).

Graph 15 – Community DUS provisions in the future



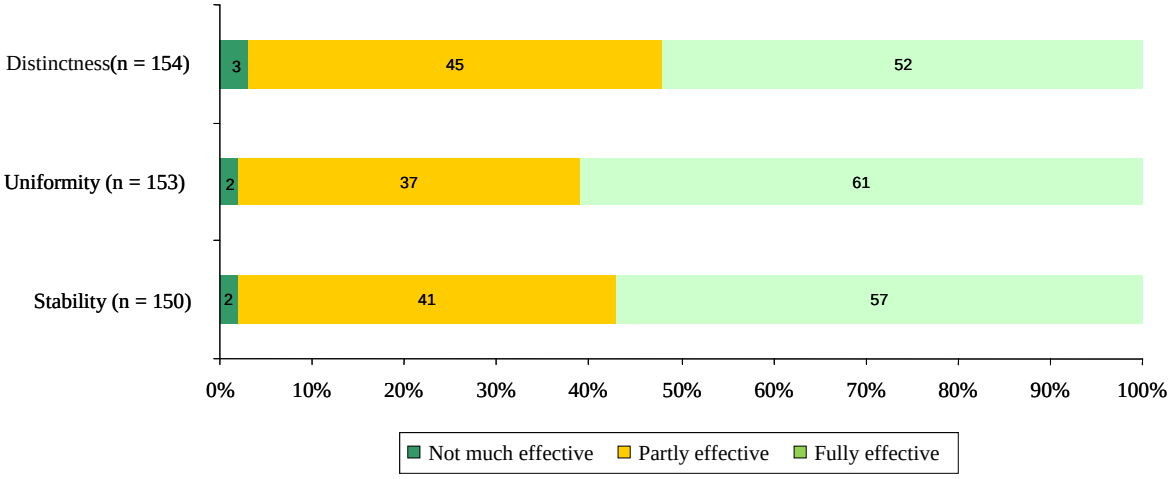
However, 34% of respondents to the qualitative survey (Q 2.1.1.2, n=141) have indicated that some DUS requirements have limited the marketing of varieties of interests to users. In particular, some stakeholders have mentioned that:

- DUS requirement limits the marketing of conservation varieties, amateur varieties, and landrace developed on the basis of composite-cross-populations, family populations and multi-lines varieties. Those adaptive populations do not fit into the DUS system as they build on genetic diversity instead of uniformity and stability;
- There were cases when a variety was removed from the market because of insufficient uniformity whereas Uniformity was no essential for the farmer;
- Distinctness requirement has limited the marketing of gradual improvements in the agronomical description of a same variety;
- Distinctness requirement has prevented the re-registration of varieties removed from the Common Catalogue 10 years after their acceptance in case of applications with a different denomination;
- In vegetables, the cost to test Distinctness and compare the variety with a large number of varieties, many of which are for relatively small markets, can be prohibitive and present a barrier to marketing;
- DUS criteria need to be adapted to the final use of the varieties: e.g. varieties targeted to be used as rootstocks for grafting should only be evaluated for the relevant characteristics;
- Concerning fibre flax and winter linseed, we have had many cases where DUS requirements prevented the registration of good varieties for the producers.

7.1.3.3. Effectiveness in achieving the objectives of DUS testing

Considering the responses to the qualitative survey (Q 2.1.1.1., n=154), 97% of respondents consider that the Community provisions for Distinctness have been partly (45%) or fully (52%) effective. As commented by one respondent, it seems that a very small minority of varieties have failed in commercial use, which perhaps proves that the system is working well.

Graph 16 – Effectiveness of the Community DUS provisions



National authorities estimate more frequently that such provisions have been fully effective than suppliers (71% of 34 respondents active in policy-making, 66% of 47 respondents active in registration, 73% of 30 respondents active in certification compared to 36% of 67 suppliers and 26% of 28 users having responded to the question).

Same observations are made as regards Uniformity and Stability:

As regards Uniformity, 98% of respondents consider that the Community provisions have been partly (37%) or fully (61%) effective. National authorities estimate more frequently that such provisions have been fully effective than suppliers (71% of 34 respondents active in policy-making, 66% of 47 respondents active in registration, 73% of 30 respondents active in certification compared to 36% of 67 suppliers and 26% of 28 users having responded to the question).

As regards Stability, 98% of respondents consider that the Community provisions have been partly (41%) or fully (57%) effective. National authorities estimate more frequently that such provisions have been fully effective than suppliers (81% of 32 respondents active in policy-making, 72% of 47 respondents active in registration, 73% of 30 respondents active in certification compared to 42% of 66 associations of suppliers and 35% of 26 associations of users).

To explain the possible lack of effectiveness of the DUS requirements, some suppliers and users respondents to the qualitative survey and stakeholders interviewed have mentioned the following:

- The lack of uniform interpretation and implementation of the CPVO and UPOV protocols may have resulted in different outcomes for the testing of the same variety in two different MS, because of difference in the quality of observation, recording and interpretation of results;
- Most of respondents indicated that differences exist in the completeness of the reference collections used by the MS to assess Distinctness, and that the major problem is linked to this issue;

- Distinctness should lead to the fact that all varieties present in the reference collection should be distinct. In the questionnaires, it has been commented of cases of non-distinct varieties registered under different names e.g. DNA analyses recently carried out by one MS has shown that 9 poplar clones approved in another MS were in fact only 2 varieties with different names in the national register. During the interviews with national officials in charge of DUS, FCEC has asked if they ever have tried to check if non-distinct varieties were present in the reference collections. One respondent explained that he did the exercise once leading to establishing that about 5 to 7% of varieties included in the reference collection are not distinct in WOSR according to his testing principles. Another one answered *"that it is better not to do the exercise!"* This is mainly explained by the difficulties of implementing a complete reference collection as explained in section 7.1.3., for instance, two comparable varieties have been tested and accepted in two different MS at the same time. This implies that non-distinct varieties are marketed in the Community;
- The definition of Stability stipulates that a variety is considered as stable when it keeps its characteristics as initially described during the multiplication cycles. In practice, as DUS test is generally done over two years, this can be insufficient to check real stability. However, it is widely accepted that a variety is stable if it is distinct and uniform;
- Stability is evaluated on a sample from the first generation and on a sample from the second generation of S&PM. Nevertheless, it is difficult to control if the sample comes from different generations or not;
- A couple of respondents have indicated that strict rules for Uniformity have occasionally inappropriately prevented the marketing of valuable distinct and stable varieties, in particular composite-cross-populations, family populations that could possibly offer better resistance due to their heterogeneity;
- The Community provision stipulates that the variety must be 'sufficiently' uniform, what may have lead to different interpretations by the testing authorities in the MS. For instance for WOSR, the reason is DE considers rapeseed as allogamous and FR as autogamous in the way the breeding is carried out with the self pollinating schemes);
- There have sometimes been problems in Uniformity, when a variety which has been bred in one MS is marketed in another. The problem is that a variety characteristic can be expressed in a different way in different climatic zones (e.g. continental vs. maritime) even though there are no problems in maintenance of the variety;
- DUS requirements are more appropriate for parental lines and less for hybrids. Uniformity is only relevant in relation to the description of the variety. For example outpollinating species or synthetic varieties can be described as having different types within them.

The analysis of the history of the DUS testing indicates that DUS is a key element of intellectual property. When DUS was listed as a EU provision, UPOV convention[34] was not in force yet. The UPOV further developed the concept of protection of new variety of plants which, in the opinion of interviewees, works well today. Considering that the criteria of distinctness is not fully effective (i.e. comparable varieties exist on the market, a MS has estimated that, on average, about 5 to 8% of varieties in reference collections are not distinct) and that an efficient alternative system exists now to

[34] The International Union for the Protection of New Varieties of Plants (UPOV) was established by the International Convention for the Protection of New Varieties of Plants ("UPOV Convention"). The UPOV Convention was adopted on December 2, 1961, by a Diplomatic Conference held in Paris.
The UPOV Convention came into force on August 10, 1968, having been ratified by the United Kingdom, the Netherlands and Germany. The UPOV Convention has been revised on November 10, 1972, on October 23, 1978, and on March 19, 1991, in order to reflect technological developments in plant breeding and experience acquired with the application of the UPOV Convention.

protect breeders rights, the FCEC questioned during the interviews the utility of distinctness for national listing purpose. Furthermore, as highlighted by some respondents, distinctness has prevented the registration of varieties of value and DUS is being used as a public tool for enforcement of PVRs which falls under the full responsibility of the breeders. Doing so, it prevents the development of generic products, which exist in most of other businesses e.g. PPP or pharmaceutical area. Additionally, a large amount of the DUS costs are linked to the management and growing of the reference collection. As the reference collection is mainly used for distinctness reasons, by suppressing distinctness as a provision for listing, implementation of a full reference collection would not be needed any longer leading to significant costs' reduction. Whereas some national key experts have agreed with the reasoning of the FCEC team on the utility of distinctness for national listing, most of them consider that distinctness must be maintained as based on the UPOV definition of a variety that stipulates that a variety doesn't exist if it is not distinct. Secondly, as DUS trials are being seeded for both national listing and protection purposes, no costs saving are anticipated.

It has also to be noticed that, even if based on common protocols, DUS national protocols differ on details, but also sometimes on fundamental aspects. The approach to assess Distinctness of a maize hybrid variety varies according to MS. For instance, in Germany, the candidate variety is compared to all other varieties whereas in France, the comparison is not being made on the variety itself but on the components of the variety. This fundamental difference may lead to the taking opposite decisions.

Finally, extremes are MS not implementing growing trials for assessment of D, U and S. Their assessment is based on information provided by the applicants.

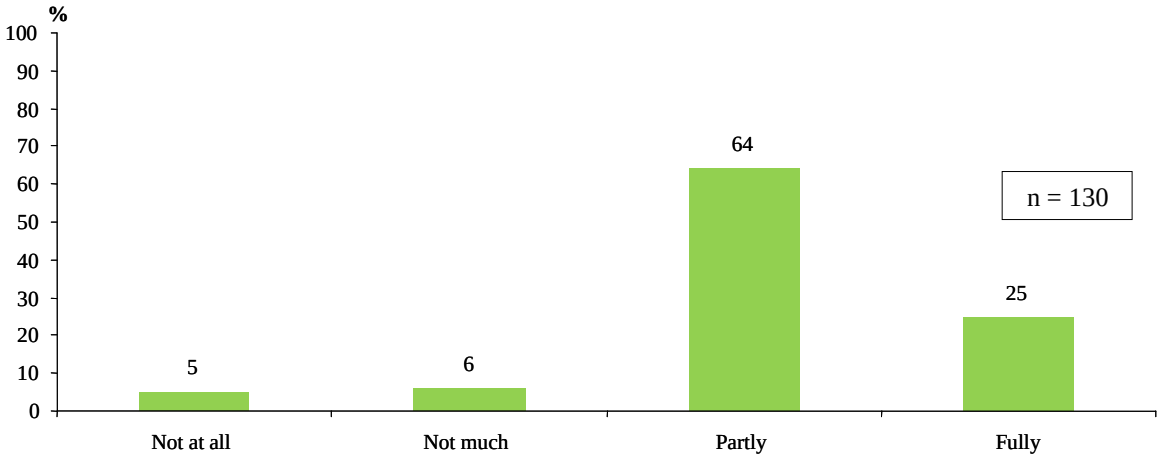
7.1.3.4. Efficiency in achieving the objectives of DUS testing

The major elements of the DUS costs are the maintenance of the reference collections and the execution of growing trials.

It seems that major differences exist in costs applied for variety registration from one MS to another mainly due to labour costs, number of sites and size of the reference collections. Several stakeholders consider that differences in implementing DUS between MS can be allowed as long as the level playing field for S&PM companies in different MS is not disturbed. For them, there is also the risk that the quality of the tests is insufficient in the MS with poor implementation of the rules or incomplete reference collections.

89% of respondents to the qualitative survey (Q 2.1.1.3., n=130) consider that the costs involved in fulfilling the obligations imposed by the Community DUS provisions are at least partly reasonable and proportionate.

Graph 17 – Extent to which the DUS costs are reasonable and proportionate (n = 130)



Among the 11% of respondents who consider that costs are not reasonable and not proportionate, some of them consider that the costs of DUS tests can be prohibitive for traditional varieties, peasant varieties or varieties part of the collective heritage or scarcely disseminated The remaining ones mainly consider that costs for some species, e.g. oilseed rape, are escalating due to expanding reference collections. One stakeholder mentions that costs are too high when there are only a few applications.

The interviews have highlighted the existence of alternative or customised approaches with reduced DUS costs associated to them, as follows:

- For the specific case of the *geranium spp.* ,the DUS testing takes place in a European site located in Germany and compares any new variety of this species with a sub-set of the reference collection, selected e.g. on the basis of the colour criteria;
- The analysis of Distinctness for some vegetable and ornamental varieties is organised in confined areas (e.g. in greenhouse), where the inspection of the characteristics of the variety is less influenced by the environment;
- In Canada, the DUS testing is carried out on the basis of as large as possible information, as provided by the breeder (e.g. pedigree, breeding method, etc.);
- In France, a new approach of the DUS protocol is explored based on the phenotypical distance and biomolecular distance to be more relevant in the sowing of the varieties that are more closed to observation.

As regards the distribution of DUS costs between the national authorities and the industry, 57% of respondents (Q 2.1.1.5., n=116) consider that the current distribution is fully appropriate. 34% consider that they are partly appropriate. Several respondents highlighted that there is currently not a level playing field in the payment system throughout the EU, what can distort in the market.

7.1.3.5. Results of the in-depth study on analysis for one crop of the feasibility of having DUS testing at European level rather than at national level (e.g. WOSR)

One of the options and future scenarios is the organization of DUS testing at European level instead of at national level in order to further harmonize the protocols and to reduce the costs. As winter oilseed rape acreage is mainly concentrated in North of Europe, the following MS have been selected: Czech Republic, Denmark, France, Germany, Italy, Poland, and the UK.

Key figures of the DUS testing networks:

Table 10 – Main characteristics of WOSR DUS testing national schemes

	CZ	DK	FR	DE	PL	UK
Average number of applications /year	75	60	80	128**	65	226
Duration of the testing (in year)	2 to 3	2 to 3	2	2 to 3		2
Fees per application	90 € per year*		700 € per year	770 € per year	160 €	1670£ per year
Size of the reference collection	543(incl. Lines)	520	700	423	137	650
Approximate number of FTEs dedicated to the management of the DUS testing	2 FTE + 5 part-time				2	

*: Costs of reference collection not included
**:including a few varieties submitted only for PBR

Effects of setting-up DUS testing at European level

Community legislation provisions impose the need for each MS to evaluate DUS for each new application. Distinctness, Uniformity and Stability are being assessed based on data reports that can come from several sources. There is no legal obligation to produce DUS report in the MS when the application has been filled. Bilateral agreements are in place, especially with small MS e.g. Belgium. Therefore, the existing Community legislation provisions are not a barrier to have a European approach to DUS.

Reflexions between MS already took place and started a couple of years ago with the aim of trying to harmonize the different system that would lead to a pan-European approach, but no significant progresses have been achieved so far. Main difficulties are based on the facts that the MS' systems are competing, especially the DE and FR ones and that discussions on criteria e.g. quality requirement, location sites, price, etc... are not really progressing. Each MS is defining its own system and doesn't want to compromise. New EU comers (PL and CZ) consider that harmonisation is required but that other existing tools e.g. bilateral agreements should be the preferred ones.

The main benefits to such approach are quite obvious and consistent for most of MS authorities interviewed in this respect. A European approach would lead to further harmonisation and to costs savings. Main disadvantages may be summarized in the fear to lose expertise that is required for certification purpose and control of a traditional activity.

Main advantages can be listed as follows:

- Harmonisation of the protocol (unique list of criteria, unique methodology for assessing Distinctness);
- Possibility to compile the complete reference collection based on EU provisions leading to uniformity and uniqueness. The actual figures on table 10 show that today, the reference collection size vary from 137 to 700 varieties;
- Costs saving for national authorities e.g. large reduction in the number of location sites to 2 or 3, management of a unique reference collection in a central place, exploitation of facilities and expertise.

List of main disadvantages mentioned during the in-depth interviews:

- Loss of link between DUS test for NL or PBR and certification, leading to fear for loosing DUS expertise and difficulties to further check seed quality during field examination and in post-control plots. Only MS that are not going to conduct DUS testing any longer on their territory will be affected;
- More possibility/difficulties to go and visit trials and to discuss with authorities for breeders. Not seen as a big issue for multinational that have a global approach, but more penalising for SMEs producing varieties for regional markets;
- Risks that all agro-climatic regions may not be represented in the network leading to the fact that certain varieties may not evaluated in areas where there are supposed to be marketed;
- Risks for higher costs especially for SMEs of NMS targeting regional markets.

CPVO is being seen as an alternative to move forward on the current slow discussion. It should act a facilitator and moderator in trying to find compromises between the different MS.

These in-depth study conclusions are consistent with the ones collected via the qualitative questionnaire as presented in table 11.

7.1.3.6. Analysis of recommendations

The following matrix summarises the identified problems/threats as well as the recommendations to address them, with description of the advantages/disadvantages, feasibility and acceptance as commented by the stakeholders during the survey and the interviews.

The recommendations in blue are suggestions formulated and tested in the questionnaire of the qualitative survey. Those in green are other recommendations made by stakeholders on their own initiative. For the recommendations in blue, the table provides the proportion of survey respondents who are 'in favour' and the one of those who is 'not in favour'.

Table 11 – Summary matrix – DUS

Identified problem/threat	Stakeholders concerned	Recommendations to address them	Advantages	Disadvantages	Feasibility and acceptance
Lack of uniform implementation and harmonisation of the protocols	Breeders, national authorities	Organise and coordinate the DUS testing at Community level instead of by national or regional authorities	- Harmonisation of DUS system; - Improvement of the global European quality; - Expected reduction of costs and of administrative burden (Less duplication of work); - More efficient management of the community of experts; - Equal treatment of breeders; - Unique and complete reference collections.	- Risk of insufficient consideration of climatic and day length conditions across Europe leading to ineffective DUS testing; - DUS testing carried out in different conditions as the breeding, selection, variety; development and maintenance breeding leading to possible conflicts; - Risk that DUS tests are still carried out at national level for certification and post-registration checks (what would eliminate the administrative and cost advantages linked to less duplication of work); - Expected longer time for decision-making process.	*Feasibility:* There are limits to a concentration of test sites. Depending of the crop, a minimum of 2 testing sites located in different MS is required in order to express GxE variability and to secure a back-up position. *Acceptance:* Survey results: 39% in favour, 61% not in favour; n=142 respondents *Reluctance of stakeholders:* - Loose of national expertise and staff in DUS testing; - Breeders should be able to communicate with testing authorities in their native language, to be able to visit trials etc., which contributes to transparency.
		Extend the bilateral agreements in order to rationalize the number of DUS testing sites in the EU Other recommendation made by stakeholders with comparable expected effects: - Extend the multilateral agreements.	- More harmonised protocols and testing provisions; - Concentration of the expertise on fewer examination offices per species; - Optimisation of the phenotype evaluation (having a critical mass and good reference collections); - Expected improved technical equipments per examination site (e.g. greenhouses, pathology laboratory facilities, molecular markers, data management, etc.); - Gain of effectiveness which could lead to a reduction of the number of cycles of examination and speed up the access to the market; - Expected reduction of costs and of administrative burden (avoidance of duplication).	As bilateral agreements are voluntary schemes, very little non-significant disadvantages exist.	*Feasibility:* - There are limits to a concentration of test sites. Depending of the crop a minimum of 2 testing sites is required. *Acceptance:* - Survey results: 84% in favour, 16% not in favour; n=135 respondents *Conditions for acceptance:* - Decision on bilateral agreements should be left to national authorities; - Ensure a Network of the only high performing examination centres, to cover all the agro-climatic conditions from North to South for the respective crops.
		Have a same and unique DUS testing for marketing and for the Community Plant Variety Rights system *"One key, several doors concept"*	- Harmonised decisions on DUS in all MS; - Time-saving and lower costs for the applicants; - Efficient administration of the applications.	In case of management by the CPVO: - CPVO is a private system which should not be related to the DUS testing system (public system); - Different legal bases for Common Catalogue and PVR.	*Feasibility:* - Such an increased importance of the DUS test requires not only a maintaining but also a further improved and harmonized implementation of the DUS testing provisions.

					In case of management by the CPVO: 1) Reorganization of DUS testing should be based on quality requirements, including the use of a proper reference collection; 2) Only Examination Offices meeting these quality requirements should be entrusted by the CPVO for the carrying out of DUS tests for a certain species; 3) The accreditation of testing institutes should be made by an independent body, not CPVO, since it will be the biggest commissioner of tests and cannot be considered as biased in the matter. *Acceptance:* - Survey results: 81% in favour, 19% not in favour; n=134 respondents; - Seems to be not necessary for national listing purposes (necessity of enlargement of reference collection or amendment of the definition of 'varieties of common knowledge').
DUS requirements and testing are in the hands of official authorities (more a fact than a problem)	Breeders	Organize DUS testing at breeders level, under official supervision Alternative recommendation made by stakeholders: - Establish an efficient official system involving both public and private organisations with expertise sharing.	- More use can be made of the information stemming from the tests performed by the applicants; - Expected cost reduction for industrial and international seed companies. - Official DUS examination conducted on centres with the input of private expertise should guarantee the impartiality and the credibility of the results. The delegation of a cycle on private stations could be an option, but only on voluntary basis, and under adequate official supervision.	- Additional burden and costs for the small breeders; - Expected difficulties in the management of reference collections; - Fragmented system that could lead to higher total costs and higher administrative burden to organise the tests; - Reduce the development of new varieties responding to new challenges e.g. in food, fibre and energy security; - Reduction of the independence (reliability of results) and transparency secured trough an official system.	*Feasibility:* - Difficult to implement because of the lack of adequate experience of some breeders in running DUS testing and lack of reference collection at breeder's premises. *Acceptance:* - Survey results: 37% in favour, 63% not in favour; n=122 respondents; - This recommendation is acceptable as an option but not on a mandatory basis. *Reluctance:* - Main aim of the breeder is breeding.
DUS testing relies on morphological features	Breeders, national authorities	Adapt the standards to the development of new breeding technologies In particular: - Support the morphological analysis with molecular tools and in particularly DNA markers. - Where useful, new	- Cheaper and faster technique; - Allow to identify 'biotypes' within even strongly inbred varieties; - Varieties that look the same can have totally different parents and would be allowed; - May help in the grouping of candidate varieties and in the management of reference collections as well as for the identification of genetic links (e.g. for	- The use of such new technologies in Uniformity could lead to very stringent constraints and reduce access to genetics and so to progress for the farmers; - New breeding technologies are potentially more discriminating than morphology.	*Feasibility:* - Totally new standards and statistical robustness of sampling etc. would need to be established to properly implement molecular methods for DUS for some species, especially out-pollinators, which would require a thorough re-examination; - The development, testing and implementation of molecular tools to support the morphological study should be done in

		phenotyping methods (pathological tests, chemical analysis and near infrared use, trait analyzers, etc.) could be used to complete the genotyping analysis.	herbicide tolerance, pathogen resistance, quality traits); - Could be useful to support verification of copy-varieties and PVR-infringements.		collaboration and consultation with breeders to standardize the operating protocols; - Any change to the standards must be internationally accepted as regards OECD. *Acceptance* - Survey results: 91% in favour, 10% not in favour; n=124 respondents; - On the condition that the modern techniques have been proven to be suitable for the species concerned and if they facilitate the verification of variety identity at lower costs; - The basis would stay on a phenotypical approach. New technologies (markers…) could be useful but they must be adopted only if the techniques are reliable and linked to a phenotypic trait.
Strict rules for uniformity	Stakeholders active in organic farming	Make uniformity an optional criterion and develop a traceability system with indication of the origin of the marketed variety, of the varieties used for its breeding as well as the specific breeding methods used. Inform the user accordingly.	- Allow the marketing of conservation varieties, amateur varieties and landrace and enlarge consequently the choice for the user.	- None for the stakeholders active in organic farming. - For the stakeholders active on conventional markets: more confusion for the user because of registration of uniform and not uniform varieties on the Common Catalogue.	*Feasibility:* - Conventional institutes can maintain the feasibility criteria, organic institutes can decide to or not depending on their experience.
Expanding reference collection	Breeders, National authorities	Reduce the size of the reference collection by: - Excluding the old varieties which are less performing; - When applicable, defining a sub-set to which compare the new variety. Consider criteria for reference collections on a crop-by-crop basis. Use molecular means to establish genetic distance between varieties and use these distances to sow only similar varieties at the beginning of the distinctness test (the first year).	- Reduced costs of distinctness analysis and maintenance of reference collection		

7.1.3.7. Overall conclusions and recommendations

The Community legislation provides precise provisions as regards the analysis of Distinctness, Uniformity and Stability of a new candidate variety. However, even if, the provisions were easy to understand, implementation has led to significant differences e.g. protocol, size of references collection, data analysis.

Major differences exist in the way MS have defined DUS protocols despite the existence of UPOV and CPVO guidelines, resulting in differences in the costs applied and in the results of the assessments of the varieties in those tests.

The difference in the size of the references collections is being seen as a major obstacle for a uniform DUS evaluation.

Overall, DUS tests are commonly considered as a robust tool to secure that only distinct varieties are being listed. However, several stakeholders have mentioned the limits of such system to register specific varieties such as landraces, populations, etc.

DUS costs are considered as reasonable and proportionate but room exists for costs reduction, especially when considering the costs linked to the conduct of distinctness testing. Some stakeholders have proposed several alternatives for the future (e.g. removing the old varieties, working with sub-set of varieties, using new technologies, etc) whose feasibility are worthwhile being further examined.

For the future, the majority of stakeholders are of opinion that more uniform implementation and harmonisation of the DUS protocols could be reached through the extension of bilateral or even the establishment of multilateral agreements.

Stakeholders active on niche markets consider that more flexibility could be introduced as regards the requirements of uniformity, so as to allow the registration of non uniform varieties. In such a case, it would be important to also develop a traceability system with indication of the origin of the marketed variety, of the varieties used for its breeding as well as the specific breeding methods used; and inform the user accordingly.

Those new breeding technologies (e.g. biomolecular techniques) are expected to positively support the DUS analysis on morphological features. Here again, in-depth feasibility and cost/benefit analysis according to crops should be carried out.

Some stakeholders also consider that cost savings could also be achieved in the current official DUS examination, if more use could be made of information from tests performed by the applicant.

Finally, having a same and unique DUS testing for listing and for Plant Variety Rights '*one key several doors'* would also lead to increased costs-savings and efficiency improvements, especially in the management of reference collections. However, further discussions should take place on this approach as some MS states expressed valid arguments against it, as demonstrated in the presentation of the case study on WOSR (see section 7.1.3.5).

7.1.4. VCU

Table 12 below summarises the Community VCU provisions.

Table 12 – Provisions of the EU S&PM legislation related to VCU

Crops	Directives	Community VCU provisions	
		Ref Art.	**Description of the obligation**
Beet seed Fodder plant seed Cereal seed Seed potatoes Seed of oil and fibre plants	Council Directive 2002/53/EC	Art. 4 (1)	The variety must be of satisfactory Value for Cultivation and Use (VCU).
		Art. 5 (4)	The value of a variety for cultivation or use shall be regarded as satisfactory if, compared to other varieties accepted in the catalogue of the Member State in question, its qualities, taken as a whole, offer, at least as far as production in any given region is concerned, a clear improvement either for cultivation or as regards the uses which can be made of the crops or the products derived there from. Where other, superior characteristics are present, individual inferior characteristics may be disregarded.

		Art. 7 (2, c)	The following shall be fixed in accordance with the Committee procedure, account being taken of current scientific and technical knowledge:
			- the characteristics to be covered as a minimum by the examinations of the various species;
			- the minimum requirements for carrying out the examination;
			- the necessary arrangements for the growing trials to be carried out with a view to assessing the value for cultivation or use; these arrangements may determine:
			  - the procedures and conditions under which all or several Member States may agree to include in the growing trials, by way of administrative assistance, varieties for which a request for acceptance has been introduced in another Member State,
			  - the terms of cooperation between the authorities of the participating Member States,
			  - the impact of the results of the growing trials,
			  - the standards relating to information on growing trials for assessment of the value for cultivation or use.

		Art 12 (1)	The acceptance shall be valid until the end of the tenth calendar year following acceptance.
	Commission Directive 2003/90/EC	Annex III	Characteristics as regards the examination of the value for cultivation or use: - Yield. - Resistance to harmful organisms. - Behaviour with respect to factors in the physical environment. - Quality characteristics. The methods used shall be specified when the results are submitted.

Vegetable Seed: **only industrial chicory**	Council Directive 2002/55/EC	Art. 4 (1)	In the case of industrial chicory, the variety must be of satisfactory value for cultivation and use.
Material for vegetative propagation of the vine	68/193/EEC	No	
Vegetable propagating and planting material other than seed	92/33/EEC	No	
Fruit plant propagating material and fruit plants	92/34/EEC	No [NB: concept of testing for pomological value is introduced in the newly adopted Council Directive 2008/90/EC]	
Ornamental plants	98/56/EC	No	
Forest reproductive material	1999/105/EC	No	

In cropping, the farmer is looking for the best return from his land based on local conditions of his own farm. Each season, he is adapting and improving his cropping plans by optimising his growing's practices adjusted to each piece of land. In this approach, looking for the best economic value for cultivation, the selection of agricultural inputs is key.

For this selection, the farmer is looking for the most reliable information on the economical and agronomical value for cultivation, on the most adapted varieties to be grown, as well as on how to cultivate them in order to express the best yield potential of these cultivars.

Any farmer in any crop is interested to know how the variety he has selected will perform on his farm and how much income he will get to it. Volume of information available to him varies, significantly, from one crop to another, from one MS to another, from one region to another.

This set of information includes data coming from regulated VCU or commonly called VCU trials but for, only, agricultural crops and industrial chicory.

Commission Directive 2003/90/EC lists in its annex III the characteristics (with no threshold specification) as regards the examination of the value for cultivation or use, as follows:

- Yield;
- Resistance to harmful organisms;
- Behaviour with respect to the factors in physical environment;
- Quality characteristics.

Overall, the VCU obligations are lightly defined at the level of the Community. The interviews have also shown that MS do not have a clear picture of their rights and obligations, for instance some key interviewees did not know that it is possible to make VCU evaluation in one MS on the basis of VCU trials carried out in another MS.

The overall absence of VCU requirements for vegetable seed (with the exception of industrial chicory) can be explained by the fact that such a requirement would be much too complex and costly to set up for the highly specialized and differentiated vegetable seed/crop markets. This is very much valid for certain species for certain usages where yield is not the leading criteria to be considered, less for others e.g. vegetables for industrial purposes (canned and frozen markets). Instead, vegetable seed companies have established their own highly efficient systems of variety trials, where new varieties are assessed in close cooperation with users in various climatic zones. The qualitative survey has shown that, overall, the European vegetable seed industry does not wish to see a change to this successful and well-established system by the introduction of any form of VCU requirement for vegetable varieties.

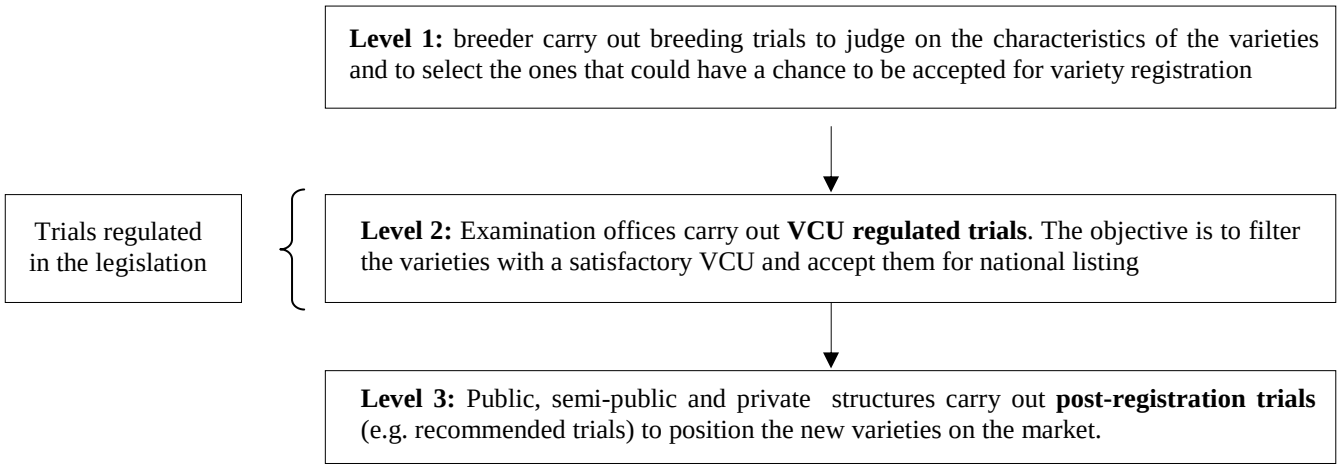
Because seeds are living materials in a living environment, the agronomical value of a new variety can vary according to:

- The testing location, which is characterised with specific climatic conditions, soil conditions and agronomic practices. The interaction between the trial location and the variety is formulated as G (Genotype) x E (Environment);
- The year: on a same location, the performance of the variety varies from one year to the other depending on the climatic conditions. Such interaction is formulated as G (Genotype) x Y (Year).

In conclusion, the value of cultivation of a given variety is never definitively established.

This has led the MS to develop and implement a 'chain of knowledge' as described in the following scheme. Major sectors of agricultural industry have organised their own information on variety performances through recommended list trials, post-registration trials.

Figure 7 – Chain of knowledge developed by the MS to assess the agronomical value of a variety



Each level may act as a filter and as a source of information for the next level. Tests at each next level tend to become more reliable from a farmers' perspective: for instance, VCU regulated trials are carried out on small plot trials whereas post-registration trials are carried out on large plot trials with optimal agronomical practices for the variety (sowing date, sowing density, etc.).

The importance of the VCU regulated trials in comparison to the post-registration trials is specific to each crop in each MS, depending mainly on the economic importance of the crop for the country. Consequently, big differences exist between MS on the structure of this chain of knowledge. In certain MS, masses of data are being collected each year while in others, only VCU regulated data are available for farmers' selection. In Romania, there are no post-registration networks, so the only source of independent information is the VCU data.

As European provisions are general, each MS implemented these provisions in its own legislation based on MS specificities and requirements, and leading to a large variability in the way varieties are nationally being assessed for their VCU, that could be called 'GxExL' (Genotype by Environment by Legislation), as being demonstrated in the GEVES comparative study of National listing systems of 2003[35].

7.1.4.1. Utility

Overall, the results of the qualitative survey indicate that large majority of respondents consider the VCU provision as useful and that they are not in favour of removing it from the EU legislation (Q 2.2.2.1.: 88% 'not in favour', n=114).

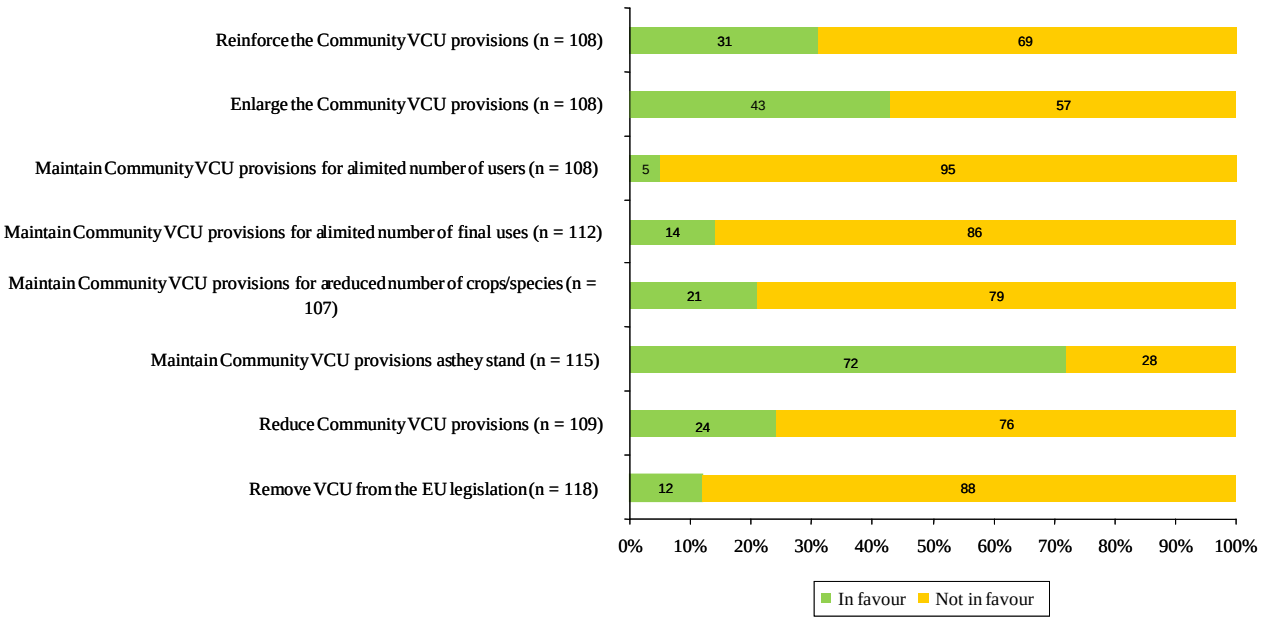
The main reasons they mention to explain this utility are as follows:

- They are one element of the process to get one variety marketable in the whole Community;
- They act to provide a first screening of the varieties and ensure that only the better varieties are registered;
- By assessing qualitative criteria, VCU networks allow to propose various products to the various market segments;

[35] Comparative Study of National Listing Systems for some Agricultural crops in the main European Countries, GEVES, 2003

- They make part of the chain of knowledge providing variety marketing information to users, directly if no post-registration scheme exists, indirectly in other cases;
- They allow the breeder to compare at an early stage his variety to all potential new varieties for a given year and, as a follow-up, to possibly adapt the production plans and market strategy;
- VCU regulated trials and the related establishment of official criteria give the opportunity to the national authorities to give 'the direction' in which breeding efforts should be made (e.g. resistance to diseases, low input agriculture, etc). This argument is largely valid when considering the history, much less today. Plant breeding has become an international and more scientific oriented activity. Most of breeders are aware about breeding orientations to be given to their R&D program based on market demands, but several, SMEs active in one or a few EU MS could loose the points of reference (i.e. the standards defined at EU and national levels) still at the basis of their strategy of innovation. Additionally, the presence of VCU as a provision of the Common Catalogue limits this argument as a breeder has always 2 ways for entering a market (national catalogue and Common Catalogue);
- The case on segmentation of maize markets (silage vs. grain) and the non-fast enough adaptation of the VCU Regulation in Germany, that has penalised the German market for a couple of years, demonstrates the limit of this argument;
- One respondent (i.e. national association of users) insists on the fact that food security remains an important driver for the future and will become more so as the global climate grows more volatile, as population growth continues, even if outside the EU, and as new markets in non-food expand worldwide. In its opinion, VCU together with DUS testing provides the solid base of information which is relied upon by future trials work, with the exception of the VCU testing for potatoes which could be replaced by the monitoring of disease resistance.

Graph 18 – Community VCU provisions in the future



43% of respondents (n=108) mention that they would like to see the Community VCU provisions enlarged to criteria such as food (and feed) as well as environmental safety aspects and 31% are in favour of reinforcing the Community VCU provisions. The comments they provide on these points are quite succinct but overall, they consider that enlarging or reinforcing the VCU provisions will bring

additional objective information on the characteristics of a variety, what facilitates the selection of the right variety by users, allow an official control of the fairness of commercial advantages claimed by the breeders and means more competitiveness for all the EU industry.

Some stakeholders have brought some nuances to their analysis of the utility of the VCU regulated trials, as follows:

- The utility of the regulated VCU trials increases with the extent to which they are developed and carried out in real conditions. The user looks for varieties adapted to the environment into which he plans to cultivate them;
- The relative utility of regulated VCU trials depends on the extent to which the post-registration trials are developed. If post-registration data exist for a variety, the user looks at them in priority to decide on the appropriateness of the variety. It's a balanced global system in the way post registration is feasible because the registration step deletes the non interesting varieties;
- The link between the Common Catalogue and the VCU provision, i.e. the VCU testing as a criterion to get a variety marketable in the entire Community, is a non-sense. VCU testing varies according to local environment and agronomical practices and does not have any pan-European value. During the interviews, some stakeholders made the same statement as regards the OECD guidelines, according to which a VCU testing is required for the inclusion of a variety in the OECD list. They have mentioned that some discussions already took place within the OECD with the aim of removing such a link but that they didn't succeed, not because of insufficient arguments but for fear of creating a precedent;
- The changes in usage of varieties in sophisticated markets make the assessment of yield superfluous and the one of usage too complicated. Assessment of these facets should not be matter of statutory assessment, which instead should focus on the characteristics affecting the sustainability of the crop e.g. chemical usage, wastage of harvested crop.

It is difficult in some cases to make VCU criteria meet industry requirements. The need to demonstrate that a variety has merit for the market of a specific MS has on occasions limited the marketing of varieties suitable for warmer climates. In particular for the seed potatoes sector, this approach has affected the ability of national breeders to produce varieties for the seed potato industry to compete in third countries markets.

These elements demonstrate that VCU is being perceived as a useful tool for traditional agriculture. However, when considering alternative agriculture, such as organic; VCU is being seen as an obstacle to release cultivar of interests for this specific market. Several stakeholders complain on the fact that conventional VCU trials are not able to select niche varieties like organic farming where low-input variety is preferred. In their opinion, the characteristics examined and the conditions for examination do not fit with the specificities of those varieties. For example, it is currently difficult to go through the convential VCU networks to test an organic variety under low-input conditions. However, the Proceedings of 2008 workshop on VCU testing of organic cereal varieties[36] mentions that '*In order to test the suitability of new varieties for organic farmers, during the last decade a number of EU countries (e.g. Austria, Germany, Netherlands, Switzerland) have started to study the necessity to adapt the VCU protocol for cereals to the specific requirements of the organic sector. These needs include the evaluation of varieties for plant traits that are not regularly observed in VCU, but are of key importance for organic farmers, such as e.g. weed competitiveness and resistance to seed borne diseases, and conducting the trials in organic fields'*. If certain MS have already integrated this approach of specific testing for specific varieties (e.g. AT for organic varieties), participants of the above mentioned workshop consider that these efforts have been too limited and that actual VCU costs are not proportionate, too expensive, to the market size of these varieties.

[36] Proceedings of the COST ACTION 860 – SUSVAR and ECO-PB Workshop on Value for Cultivation and Use testing of organic cereal varieties *What are the key issues?*, 28th and 29th February 2008, Brussels, Belgium.

This case example on organic varieties demonstrates the need for a VCU network to be flexible enough to integrate new type of varieties developed for other markets or/and with new technologies. Most of interviewees consider that the current VCU trial network is sustainable in the short to medium term (5 to 10 years) but needs to be constantly adapted to be able to tests other varieties than those aiming at increased productivity or better disease resistance only.

The survey results (Q 1.1.5.) indicate that 19% of respondents consider that the legislation has had a negative impact on the preservation of plant genetic resources in the EU, 28% consider that it has had no impact and 53% consider that it has had a positive impact. In the literature, the qualitative survey and during the interviews, several stakeholders highlight that the importance given to the yield characteristics for VCU trials may have contributed to missing an opportunity for increasing the intra-specific biodiversity for some species.

Distinction must be made here between the inter-specific biodiversity and the intra-specific biodiversity as follows:

- *Inter-specific biodiversity* refers to the diversity of the species domesticated and cultivated by the human being. In general, it is recognised that there is currently a loss of the inter-specific biodiversity but that it is not linked to the VCU trials, or to the legislation in general. If some crops have, nearly, disappeared in some regions, it's mainly due to the non-economic reliable value of the crop for the users. Alternatively, some other crops appeared in areas where there were not present in the past e.g. silage corn, and mainly due the breeding creativity. Maize cropping for feeding animals was not present in the Northern part of Europe 40 years ago. Breeders have developed new type of varieties and production schemes have been adapted to produce this new type of varieties;
- *Intra-specific biodiversity* refers to the diversity of the varieties within a species. Generally, stakeholders consider that the overall genetic diversity has not decreased but that it has been less exploited. Breeders have continued to enlarge the genetic variability (i.e. the germplasm) at their disposal to develop new varieties but this germplasm has been privatised by the industry. Some tools have been developed to counter such privatisation, like the breeder exemption (according to which a commercial variety, even if protected, may be used by a breeder in its selection programme) and the development of gene banks. Nevertheless, some narrow market requirements could have negatively impacted on the diversity of the cultivated/marketed varieties. For example, the continuous demand for new varieties with higher agricultural productivity could have pushed the breeders to focus their work on genes potentially contributing to better yield. Contrarily, the need for more disease-resistant crops has positively contributed to an increased diversity in crops like wheat.

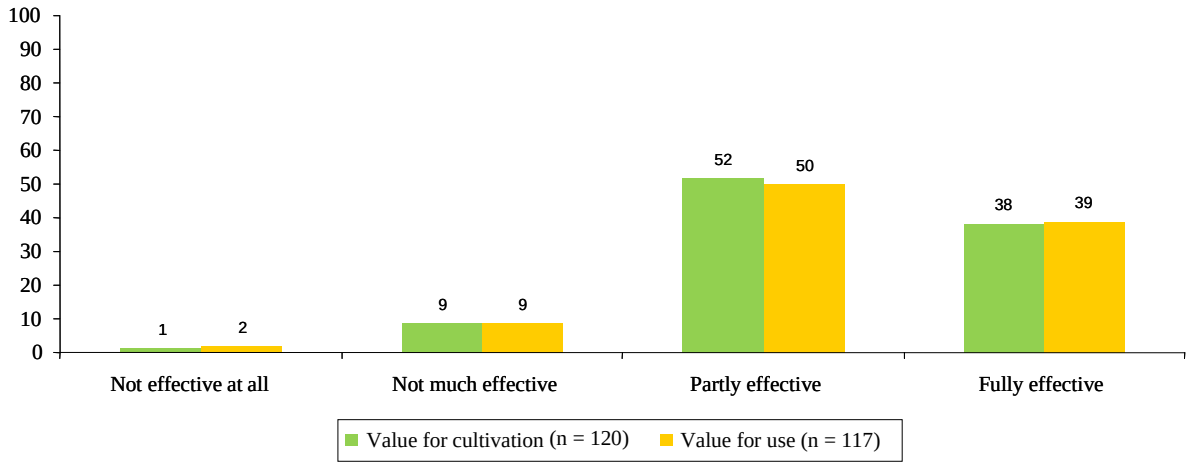
This point is of importance and requires further analysis as several contradictory studies show the complexity of the subject[37].

7.1.4.2. Effectiveness in achieving the objectives of VCU testing

Considering the responses to the qualitative survey (Q 2.2.1.1.), around 90% of respondents consider that the Community provisions for 'value for cultivation' and the ones for 'value for use' have been partly or fully effective.

[37] Cadot V., Le Clerc V., Canadas M., Belouard E., Foucher C., Richard E., 2006. *Estimation de la diversité des variétés inscrites au Catalogue français des espèces agricoles cultivées : réflexions préalables à la mise en place d'indicateurs de la diversité génétique disponible.* GEVES, september 2006, 50 p. and its critical analysis by S.L.Anvar. *les indicateurs de biodiversité: de l'importance du contexte réglementaire.* Courrier de l'environnement de l'INRA n° 54, septembre 2007.

Graph 19 – Effectiveness of the Community VCU provisions



National authorities estimate more frequently that such provisions have been fully effective than suppliers (65% of 26 respondents active in policy-making, 62% of 37 respondents active in registration, 58% of 24 respondents active in certification compared to 20% of 48 associations of suppliers and 44% of 25 associations of users).

The study of the evolution of the productivity also gives an indication on the effectiveness of the VCU in contributing to varieties with improved characteristics. Overall, it seems that gains of productivity has increased, due to 1) the cultivation of varieties with a higher potential (yield, quality, resistance to diseases), but also, 2) to the improvement on the agronomic practices. It is being recognized by interviewees that productivity increases are due for 40-50% to plant breeding efforts and for 50-60% to optimisation of agronomic practices.

For instance, the study of the evolution of the characteristics of forage maize during the last 20 years in Belgium has shown a continuous improvement in quantitative and qualitative characteristics, together with better disease resistance and harvest security, as follows:

- Increase for silage maize per year: total dry matter yield: 0,85% (rel.); total digestible organic dry matter yield: 1,2% (relative); dry matter content of the total plant: 0,8% (relative); resistance to lodging (scale 1-9): from 6,9 to 8,5, resistance for stalk rot (scale 1-9): from 7,0 to 8,9;
- Increase for grain maize per year: grain yield: 2,8% (rel.); dry matter content of the grains: 0,4% (relative); resistance to lodging (scale 1-9): from 7,0 to 8,2; resistance for stalk rot (scale 1-9): from 7,2 to 8,4. This evolution was due to progress in breeding; cultivation techniques were not changed during this period.

In its 2004 study[38] on the genetical progress of beet, oilseed rape, sunflower, soft wheat, barley, forage maize, alfalfa and turf-type perennial rye-grass on the 15 years preceding the study, the GEVES indicates an improvement for yield and diseases resistance in most of the studied species. Yield improvement was roughly of 1,3%. Quality improvement was also observed, upgrading varieties characteristics or giving them new opportunities on the market place.

These results should be analysed carefully as an indicator of effectiveness. Productivity has increased, but apparently not more or less than in EU crops where VCU is not mandatory e.g. vegetable seed. In countries where VCU doesn't exist, productivity has increased as well. When evaluating varieties during only 2 years on a specific limited list of criteria, some varieties with limited values for

[38] Aurélia Luciani, GEVES, Etude du progrès génétique chez différentes espèces de grande culture, septembre 2004

cultivation can be registered[39]; and others with true added value for cultivation are rejected as they may not express their full potential in VCU small plots trials[40].

Nevertheless, several stakeholders have mentioned during the interviews or the qualitative survey some limits to the current effectiveness of the regulated VCU trials, as follows:

- The legal provisions for VCU testing in principle are effective. However, because MS apply different thresholds for the judgement of a 'sufficient' VCU, the level of actually reached 'improvement' varies between them;
- In some MS, one can see that users are not relying on VCU results only to choose varieties. This highlights the fact that the guarantee they bring is not sufficient everywhere;
- Often the indices are too much focused on better yield or quality. In the future, a full assessment of market value must be made rather than over-reliance on yield or quality. Instead of agronomic value for cultivation, economic value for cultivation should be preferred;
- Quality standards are often too uniform and do not allow the breeding of varieties for specialities;
- In some case it is difficult to balance the evaluation of the variety between value for cultivation (a variety could be very productive in a restricted but specific area, and not in the large part of the member state territory) and value for use (often quality does not go with productivity);
- Because they are carried out on 2 years, The VCU regulated trials do not evaluate the 'yield stability', which is a key criteria for the farmer, and the processor in case of contractual relation with the grower. For instance, field peas are not cultivated by farmers not because of a lack of productivity but mainly because of a problem of yield stability, in space and time, for this crop. VCU is not addressing this criteria;
- The management of the national official VCU networks (e.g. the selection by official authorities of the trial locations, the control varieties, etc.) can be a matter of competition between some breeding companies, especially when trials are being executed by the breeders.

7.1.4.3. Efficiency in achieving the objectives of VCU testing

A high number of trials are necessary to predict the agronomical value of a new variety in comparison to control varieties on a reliable way. The costs of conducting those trials are expensive and depend on the area of the crop, the mechanisation of the variety testing (especially at harvest), the number and type of analyses and the number of varieties in the trials.

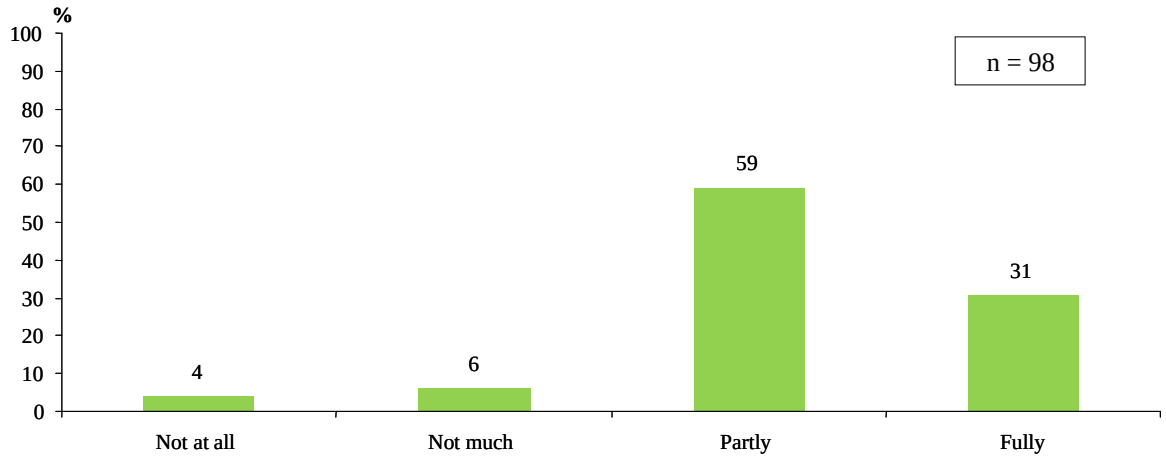
76% of respondents to the qualitative survey (Q 2.2.1.4, n=98) consider that the costs involved in fulfilling the obligations imposed by the Community provisions for VCU testing are at least partly reasonable and proportionate, mainly because the examined characteristics are in accordance with the specific conditions in the country and are a prerequisite to guarantee a sufficient production yield.

Considering the distribution of VCU costs between the public authorities and the industry, respectively 50% and 43% of respondents (Q 2.2.1.6., n=94) consider that it is partly or fully appropriate. Several respondents have highlighted that there is currently not a level playing field in the payment system throughout the EU.

[39] SYNERGY, an oil seed rape varietal association variety, has been registered after only 1 year of VCU testing in France, as the 1st year results were extremely promising, but failed completely in farmers field the year of market introduction

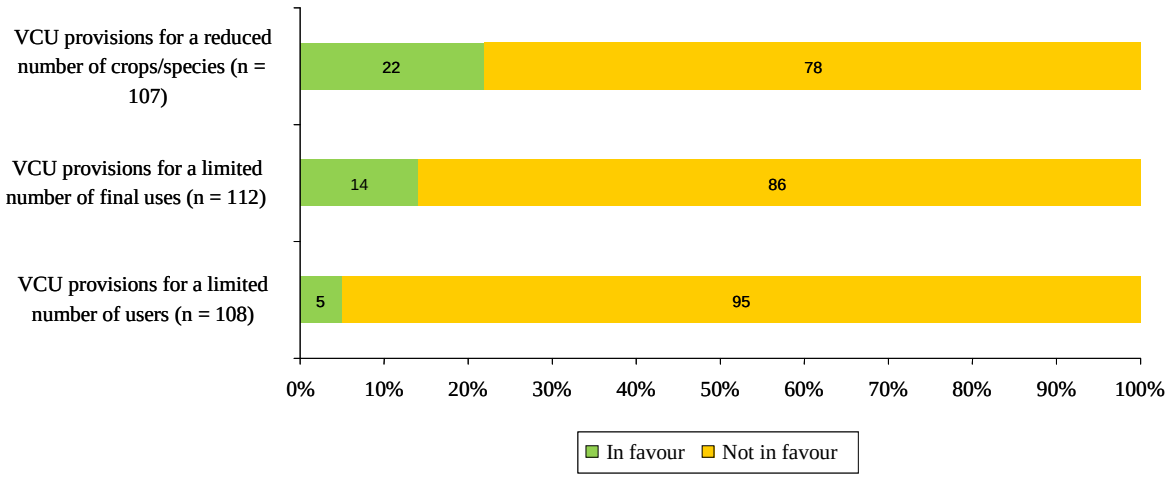
[40] THESEE, a winter wheat variety, has had to go through a 3rd year of VCU testing in France, as the 2 first years were not demonstrating that the variety was good enough to be listed ; and later became a market leader for a long period of time.
DEA, a maize variety, has never been accepted for addition to national list in Germany; but had a good commercial success in Germany by using the Common Catalogue access to the market.

Graph 20 – Extent to which the VCU costs are reasonable and proportionate



When asked about the possibility to restrict the Community VCU provisions (and the associated costs) to a reduced number of crops/species, or a limited number of final uses or a limited number of users, majority of respondents do not support such alternatives (Q 2.2.2.1.).

Graph 21 – Opinion of respondents on three possibilities to restrict the Community VCU provisions in the future



In particular, some stakeholders have considered that Community VCU requirements should be removed for minor species such as swede, mustard and fodder kale. Because the sugar beet market is generally almost entirely dictated by the needs of the sugar industry, VCU requirements should also be removed. As regards seed potatoes, two respondents insisted on the fact that the use of VCU testing is not seen as imperative and the allowance of market to decide appropriate varieties is seen as more beneficial. However, it remains important that growers are aware of any weaknesses varieties have in terms of diseases.

In their comments to the qualitative survey, stakeholders have highlighted some cases of reduced efficiency as follows:

- Currently, the VCU rules are completely dependent on the interpretation by the MS of the regulation. Different requirements may have limited the development by breeders of a specific MS

of varieties adapted to the environment in other MS. Also all MS do not have the required expertise to revise over time the VCU requirements for all species, including the minor ones. This has led to inconsistencies between MS for the testing of same species;

- The limitations of the existing system depend on the costs for releasing varieties in the respective MS. In MS with high costs, the VCU-testing leads to many varieties of the main crops which compete for the biggest areas. As a consequence, varieties with special characters to closed production chains or varieties with more diverse characters for less favourable growing conditions will not be developed, because the market potential cannot develop. The existing system limits the release of those varieties, thereby restricting their availability;
- The existing system can provide an obstacle for innovation because additional variety character analyses incur extra costs. As a consequence, new marketing ideas become more expensive, particularly as they have to start with smaller initial market;
- VCU testing is especially for SME too expensive and hinders them to register varieties. Big market players have enough financial backing to risk the registration of several candidate varieties in the same time with the aim that only some of them pass through. They can save a lot of time with these practices, which small companies cannot afford;
- Results of VCU testing are not enough used by everyone. Link, synergy between VCU for national listing and VCU for recommended list are often done by different examination offices and are not always fully exploited.

Assessing the true effectiveness of VCU is a difficult exercise. It is easy to demonstrate what has been achieved, as presented in the figures on productivity's increase over years in VCU trials (section 7.1.4.2); but difficult to predict productivity evolution without VCU as increase of productivity has been observed in crops (e.g. vegetables) and areas (e.g. USA, Australia) where regulated VCU is not mandatory.

The FCEC team believes it would be worth making a further analysis of the utility and efficiency of the VCU on a crop-by-crop basis and to better understand why VCU is so important in agriculture crops and not needed for vegetable crops (e.g. logic of keeping VCU for industry chicory and not having VCU for industrial vegetable crops).

7.1.4.4. Analysis of recommendations

The following matrix summarises the identified problems/threats as well as the recommendations to address them, with description of the advantages/disadvantages, feasibility and acceptance by stakeholders.

The recommendations in blue are suggestions formulated and tested in the questionnaire of the qualitative survey. Those in green are other recommendations made by stakeholders on their own initiative. For the recommendations in blue, the table provides the proportion of survey respondents who are 'in favour' and the one of those who is 'not in favour'.

Table 13 – Summary matrix - VCU

Identified problem/threat	Stakeholders concerned	Recommendations to address them	Advantages	Disadvantages	Feasibility and acceptance by stakeholder
- Lack of harmonisation between the VCU protocols of the different MS; - VCU trials are expensive.	Breeders, national authorities	Organise the official VCU testing at Community level, based on areas of adaptation (European networks according to agro climatic areas for national and regional decisions)	- Agro climatic areas can be interesting sometimes for certain species (e.g. Maize).	- Decision must be national for public policy of each member state. - VCU is limited to rather small regions. There is no added value from testing at EC level - The increasing diversity in the environment, climate, cultivation practices, and consumer demand (including the cultural aspect) will require a diversity of specific guarantee systems under the sovereignty of regions and states rather than a unique one.	*Feasibility:* Difficult to implement in practice. NL, BE and FR have tried to develop a harmonised testing protocol for linseed but they did not succeed *Acceptance:* Survey results: 36% in favour, 64% not in favour, n=117 respondents
		Allow recognition of other Member States' VCU data for national listing (bilateral agreements) Several stakeholders have enlarged this recommendation to multilateral agreements.	- Expected positive effect on the costs and administrative burden (avoiding unnecessary duplication of work where conditions are largely similar) - More harmonised VCU protocols.	- VCU is limited to rather small regions. There would be no benefit from data coming from other regions or MS. - In order to judge the VCU a certain minimum of testing years and testing intensity (locations, observations, examinations) is required. Cost saving efforts in individual MS may - from a statistical view - lead to crucial situations concerning the database for the assessment of VCU of a variety. - In small MS, small official teams in charge of VCU trials may disappear, what could cause more difficulties & increase time for decision-making.	*Feasibility:* - Bilateral agreements are possible when agronomical, climatic, phytosanitary and growing conditions are similar; - Full cooperation is required between the national networks both on the choice of the locations and on the way, trials are conducted and scored. This demands resources and willingness to cooperate. *Acceptance:* Survey results: 77% in favour, 23% not in favour, n=117 respondents

		Allow coordination between Member States of official observations and national decisions possibly under bilateral agreements.	- This alternative is a good and operational step to improve the European system; - Allow to go further than in the scenario of bilateral agreement, by treating data by agro climatic areas, and not by country. The valorisation of this new kind of information after registration could be transferred to a European level; - Improve the quality of information for users and breeders; - Reduce costs if the number of common observations is the majority and if the trials network is optimized at the European level. In this frame, the applicant could pay fewer fees for VCU, depending on the number of countries that are coordinated and the number of national registrations asked by the applicant; - Positive expected effect on the administrative burden and rapidity of decision-making process.	Same as above	*Feasibility:* - It is important that the decision on VCU remains at the national level; cooperation must only exist for the production of data but in no way decision should be made outside the country. - Each MS must be able to add observations; - Treatment of the information could be given to a European organisation in order that they communicate about it in a transparent and liable way. *Acceptance:* Survey results: 84% in favour, 16% not in favour, n=116 respondents
- VCU testing is mainly a tool of marketing for the breeder or a tool of decision for the user (not a problem but a fact); - VCU trials are	Breeders, national authorities	Organise the VCU testing at the level of the breeders, under official supervision Alternatives: - No organisation of VCU testing at the level of the breeders	*Organisation at the level of the breeders:* - Breeders operate very good trial networks and have experienced field officers. Therefore, they can really contribute to the system; - Positive expected effect on the costs (trials are done by breeders in the same platform as their own trials), administrative burden (as official involvement is reduced) and rapidity	*Organisation at the level of the breeders:* - Only breeders of a certain size will be able organise VCU testing. - Risk that the system is no more accessible to small innovative breeders or specific targets; - Expected negative effect on the quality and plant health of seed; - Job losses at official authorities	*Feasibility:* - Protocols, criteria and decision must remain the responsibility of the official authorities. Only the technical realisation should be the responsibility of the breeders; - In addition to breeders, farmers associations and institutes should be allowed to realize tests under official supervision; - Official supervision must maintain

expensive.		but more integration of the breeders, seed industry and other technical infrastructure in the testing network (e.g. by making use of existing infrastructure, expertise and data)	of the decision-making process. *Official supervision:* - Supervision from the authorities is bringing reliability and level playing field for all companies and users; - Public involvement permits the system to defend public policy about the orientation of genetic progress.	currently in charge of conducting trials; - Official VCU testing is interesting for those species and varieties where it is difficult for the farmer to easily determine himself the value of use and cultivation: qualitative aspects, rather than quantitative aspects (i.e. quality for feed, for good soil coverage, stress resistance etc).	some trials inside its own organism in order to maintain skills and expertise, and to benefit from stable data. Finally, official supervision must be able to purpose innovations and to pilot evolution of the system in order to keep its utility and competitiveness; *Acceptance:* Survey results: 67% in favour, 33% not in favour, n=118 respondents
		Stimulate the VCU testing at the level of the breeders without official control or supervision	*Organisation at the level of the breeders:* As option 'Organise the VCU testing at the level of the breeders, under official supervision'.	*Organisation at the level of the breeders:* As option 'Organise the VCU testing at the level of the breeders, under official supervision'. *No official control or supervision:* - Loss of credibility for the registration system, as users will have to rely on data impacted by private marketing strategies; - Loss of the guarantee of independence of the breeders and of their objectivity in the interpretation of the results of the VCU trials; - The orientation of genetic progress by collective interest (sustainability, adaptation to technologies …) would be impossible.	*Acceptance:* Survey results: 6% in favour, 94% not in favour, n=120 respondents
Conventional VCU trials are not able to select niches varieties like	Stakeholders on niche markets	Introduce flexibility in the VCU system, e.g.: - Periodically review the VCU criteria for relevance and ensure	Do not prevent the marketing of varieties suitable for niche markets, which may find VCU testing irrelevant and unnecessarily high cost burden;	- None for the stakeholders active on niche markets - More complex networks to be managed	*Feasibility:* - MS decision to go in that direction.

organic farming, GM variety, variety resistant to dryness, variety adapted to saline soil, low input variety		that they reflect end market requirements; - Set-up specific networks for specific varieties; - Consider private data submitted by applicants. - Cut down system for niche varieties making trialling effort and costs proportionate to the market In parallel, base registration regime on traceability from breeders to processors.	Do not restrict the development of new varieties.		

7.1.4.5. Results of the in-depth study: "Analysis for one crop of the effects of suppressing the VCU testing"

VCU is mandatory in EU provisions leading to the fact that VCU networks exist for the major crops in most of EU MS. A precise description of the different VCU networks is being presented in Annex 10. The following case study aims to establish what would be the consequences of suppressing VCU at national level for winter wheat.

The following MS were selected based on the importance of wheat: DE, DK, FR, HU and the UK.

Key figures of the VCU testing networks

VCU national schemes are very different from one MS to another, therefore the structure of the national networks are very specific. Comparison of the main indicators of the VCU networks is not leading to any significant conclusions.

Table 14 – Main characteristics of VCU national schemes for winter wheat

	DE	DK	FR	HU	UK
Average number of applications/year	120	30	75	50	60
Duration of the testing	3	2	2	2	2
Total number of yield trials	Y1:14, Y2:15, Y3:25	5 per year (+ Diseases trials)	18 per year	7	
Distribution of trials (authorities vs industry)	Industry:50% in Y1	2 authorities + 7 applicants per year	75% by industry	Authority only	50% industry
Average VCU acceptance rate	10%	About 2/3 of varieties are withdrawn from applicant after 1 year of testing	20%	80%	50%
Fees per application	1900 €/year	1200 €/year	5100 € for 2 years	1000 €/year	5000 € for 2 years
Average approximate costs to run the network	650 000 €	35 000€			
Approximate number of FTEs dedicated to the management of the VCU network	10		3	3	

Effects of removing regulated VCU testing at national level

The comments collected during these in-depth studies are not very different from the ones that are presented in the core analysis of the VCU provisions. Most of interviewees do not see the possibility to remove the VCU requirement, as it is a pillar for variety registration. In MS, such as HU, where no post-registration network exits, the main consequence would be that the farmers would not have any independent data at their disposal any longer. In other MS, removing VCU would require a re-organisation of the chain of knowledge as presented on Figure 7.

Other possible consequences can be listed as follows:

- Time to market will not be affected as DUS has to be completed before any listing decision can be taken;
- Loss of market transparency as the market could be flooded with varieties that have no value for the users;
- Access to the market for small players will be affected and reduced. VCU is being seen as a neutral platform for all breeders;
- Many more varieties will be marketed leading to confusion for users;
- Post-registration will have difficulties to select varieties to be tested;
- Breeders will lose references to plan their product positioning (selection of varieties to be marketed, development of seed production plans, positioning vs. competitors, etc...);
- Transfer of costs to the industry, as the breeder will have to run trials to further estimate the value for cultivation of the varieties to be selected for marketing;
- Disappearance of leverage public policy.

7.1.4.6. Overall conclusions and recommendations:

Value for cultivation is key for any farmer regardless the crop he is considering for planting. Therefore, he has taken lot of attention in selecting new varieties by looking at reliable information (e.g.data results) and visiting trials in his neighbourhood. As seed is a living material growing in a moving environment, the agronomic value of a new variety varies from one place to another (GxE) and depends also on the cropping conditions, the farmer is preferring data that are being produced as close possible to his farm and with the same cropping conditions than the ones he is using.

Depending on the agricultural sector organisation, the farmer has at his disposal lot of information for his selection (seed companies data, official and semi-official data, data from cooperatives, retailers, seed merchants, etc..) forming a "*chain of knowledge*". In other area and for minor crops, this set of data is sometimes limited to regulated VCU data (e.g. medicinal crops in Romania).

Regulated VCU trials aim to predict the agronomical value of a new variety in comparison with standard varieties. They are an obligation in the EU legislation for agricultural crops and industrial chicory only. Instead, vegetable seed companies have established their own systems which seems to function well so that, overall, the European vegetable seed industry doesn't wish to see the introduction of compulsory VCU for vegetable varieties.

The VCU obligations are lightly defined in the Community S&PM legislation. In practice, each MS has developed and implemented VCU protocols and networks to evaluate value for cultivation for a limited period of time (2 to 3 years). Great differences exist between MS as regards the VCU criteria and the importance given to the regulated trials in comparison to the post-registration ones and, therefore, a GxExL (Genotype by Environment by Legislation specific to the MS) situation is being observed. This has led to the absence of a level-playing field and to the appearance of significant differences between the VCU trials networks implemented by the MS.

However, VCU is perceived, on average, as an essential and robust tool for many agricultural species. It provides the solid base of information, which is relied upon for future trials work. VCU costs are considered as reasonable and proportionate but room exists for costs reduction. The VCU is an important decision tool for the user and an important marketing tool for the breeder. VCU requirement seems less appropriate or outdated for some crops such as sugar beet, as it is managed as an industrial crop.

VCU had been implemented to secure that only improved varieties would be marketed. This approach was based on the need to improve productivity in the 60's. As alternative agriculture e.g. organic farming, new technologies developed in the last 20 years, some limits exist to test non conventional and niche varieties.

The VCU must evolve to adapt to any type of agriculture, markets have diversified with varieties being developed for specific uses, and become more flexible to test varieties created by new technologies. Several projects (e.g. EU VCU approach on grasses, adapting VCU network for organic varieties in AT) and research activities (e.g. yield modelling in FR) are ongoing, and some results are already implemented, for adapting VCU networks to future needs. FCEC team considers that these efforts should be further developed with a pan-European approach (e.g. STREP project). Protection of the environment is, also, to be further considered; and development of varieties with environmental benefits should be promoted.
Stakeholders are in favour to a certain extent of increasing the role of the breeders in the operational (mainly technical) organisation of the VCU testing. They believe that the involvement of the official authorities are crucial to maintain credibility and a level playing field for all companies in order to avoid the exclusion of small innovative breeders. In some MS like France, Germany and the UK, breeders have been allowed to carry out the first year of the VCU trials under the official supervision of the authorities for main crops. Special attention should be focused on the neutrality of the VCU networks to avoid that this platform will become a place of competition between actors.

Great majority of stakeholders also support the suggestions of developing the coordination with the neighbouring MS, which have an overall objective of reducing VCU costs.

The European regulation is not a barrier to these developments; today there is no EU provisions preventing these evolutions. However, European provisions are not a lever for progress in this sought for and needed modernization. Being neither a barrier nor a lever, one may wonder about the usefulness of these European provisions and the need to make them evolve. Most of those interviewed prefer the *status quo* as there is a fear about the consequences at national level of modifying/abolishing European VCU provisions. FCEC recommend to carry out an impact assessment, as further study on this point would help to better understand the consequences of a change in European provisions.

The necessity to change the VCU to a more flexible system is a reflection that is being waged in many countries and particularly in Canada. Canadian authorities and breeders have considered removing VCU and replacing it with a more flexible system on a case-by-case basis.

The Canadian Food Inspection Agency has published in June 2008 its proposal for a more flexible variety registration system distinguishing between three parts with three levels of variety registration requirements as follows:

- Part I: variety registration requires pre-registration testing and merit assessment. It is intended for crops asking for stringent official control to ensure that varieties meet minimum performance standard;
- Part II: variety registration is based on pre-registration testing but not merit assessment. It is intended for crops for which official control is required to confirm the validity of pre-registration testing data but for which merit assessment represents a disproportionate regulatory burden relative to the benefit derived or does not effectively predict the usefulness of varieties in the marketplace;
- Part III: new varieties would be subject to only basic variety registration requirements, i.e. the application package would include a representative reference sample, the pedigree of the variety, a description of the characteristics of the variety, an indication of whether the variety is a PNT and data to support claims. The applicant must demonstrate that the variety meets health and safety standards and that it is DUS.

Overall, the benefit from the introduction of flexibility are more timely access for producers and end users to new varieties than with the previous system, increased innovation within the seed and crop sectors and cost savings due to the reduced regulatory burden.

The full text of the proposed regulatory text and regulatory impact analysis statement is available at http://www.inspection.gc.ca/english/plaveg/variet/vartoce.shtml

Finally, OECD Working Group is discussing the relevance of the following provision in the OECD Seed Schemes: *" The OECD certification applies [...] to varieties which [...] have an acceptable value in at least one participating country [...]"*.

7.1.5. Variety denomination

Provisions for variety denomination are developed in the Community legislation for agricultural crops, vegetable seed, fruit plant and ornamental plant, as presented in the following table:

Table 15 – Provisions of the EU S&PM Community legislation related to variety denomination

Crops	Council Directives	Community provisions on variety denomination	
		Ref Art.	Description of the obligation
Beet seed Fodder plant seed Cereal seed Seed potatoes Seed of oil and fibre plants	2002/53/EC	Art. 9 (6)	As far as the suitability of the denomination of a variety is concerned, Article 63 of Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights shall apply. Detailed implementing rules as to the suitability of denominations of varieties may be adopted in accordance with the Committee procedure.
Vegetable Seed	2002/55/EC	Art. 9 (6)	Idem Art. 9 (6) of Council Directive 2002/53/EC
Material for vegetative propagation of the vine	68/193/EEC	Art.5d (3)	If it is known that propagation material of a given variety is marketed in another country under a different name, that name shall also be indicated in the catalogue.
Vegetable propagating and planting material other than seed	92/33/EEC	Art.9.2. refers to Article 10 of Directive 70/458/EEC. This Article corresponds with Art.9 of Directive 2002/55/EC	
Fruit plant propagating material and fruit plant	92/34/EEC	Art. 9 (2)	Each variety shall be described and, as far as possible, bear the same denomination in all Member States, in accordance with accepted international guidelines.
Ornamental plant	98/56/EC	Art. 9 (2)	As far as possible, each variety shall bear the same denomination in all Member States, in accordance with implementing measures which may be adopted in accordance with the provisions on Committee procedures or, in their absence, in accordance with accepted international guidelines.
Forest reproductive material	1999/105/EC	No	

Commission Regulation 930/2000/EC[41] (amended by Commission Regulation 1831/2004/EC[42]) establishes the rules for the checking of variety denominations. Until the year 2000, no detailed

[41] Commission Regulation (EC) No 930/2000 of 4 May 2000 establishing implementing rules as to the suitability of the denominations of varieties of agricultural plant species and vegetable species

checking of the denomination was carried out. Today, such checking takes place within a pre-defined group of species, e.g. group 'sorghum and maize', group 'oilseed', etc.

The 'Whereas' (2) of this regulation specifies the possible impediments, which make a denomination unsuitable, as follows:

- Use precluded by the prior right of a third party;
- Difficulties as regards recognition or reproduction;
- Denominations which are identical or may be confused with a variety denomination of another variety;
- Denominations which are identical or may be confused with other designations;
- Misleading or causing confusion concerning the characteristics of the variety or other features.

Variety denomination can be in the form of a 'fancy name' or of a 'code'.

Article 3 (1) of the same regulation foresees cases where a variety denomination shall be considered to cause its users difficulties, as follows:

Table 16 – Cases where denomination shall cause its users difficulties

Fancy name	Code
Consist of a single letter	Consists of a number or numbers only, except in the case of inbred lines or of similarly specific types of varieties
Consist of, or contains as a separate entity, a series of letters not forming a pronounceable word, except where this series in an established abbreviation	Consists of a single letter
Contain a number, except where this is an integral part of the name, or where this indicates that the variety is or will be one of a numbered series of biologically related varieties	Contains more than 10 letters, or letters and numbers;
Consist of more than three entities	Contains more than four alternating groups of a letter or letters and a number or numbers
Consists of, or contains an excessively long word	
Contains an hyphen, a blank space other than between the entities of which it consists, another mark, an upper and lower case mixture within the entities, a subscript, a superscript, a symbol or a design	Contains a hyphen, a blank space other than for separation from a pronounceable word, another mark, a subscript, a superscript, a symbol or a design.

Furthermore, Article 6 (e) of the regulation stipulates that a variety denomination shall be considered to mislead or to cause confusion if it consists or contains:

- Comparatives or superlatives;
- The botanical name, or part thereof, of a genus or species of the plant kingdom;
- The common name of a genus or species of the plant kingdom within the group either of agricultural plant species or of vegetable plant species, to which the variety belongs;
- The name of a natural or legal person, or a reference thereto, so as to convey a false impression concerning the identity of the applicant, the person responsible for the maintenance of the variety, or the breeder.

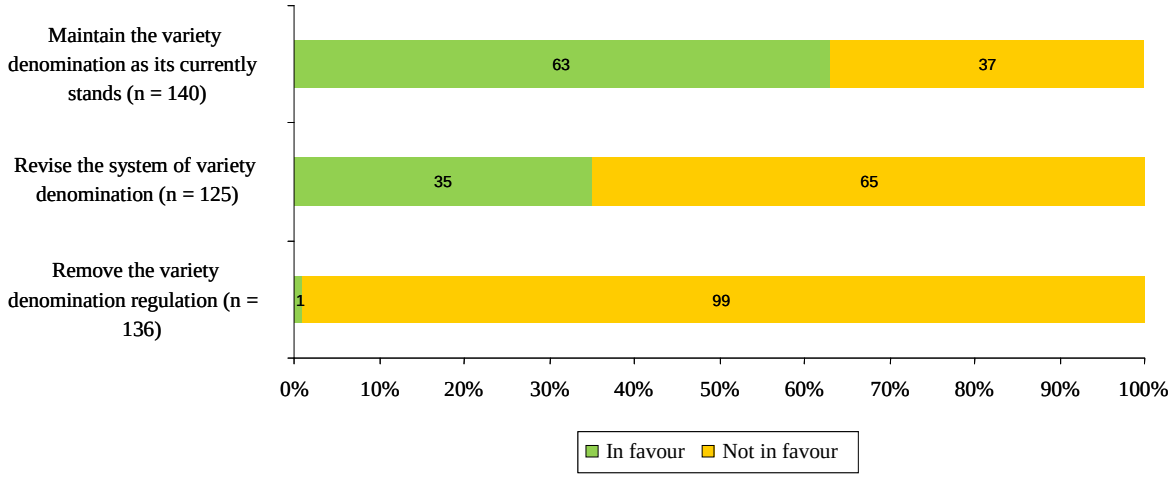
[42] Commission Regulation (EC) No 1831/2004 of 21 October 2004 amending Commission Regulation (EC) No 930/2000 establishing implementing rules as to the suitability of the denomination of varieties of agricultural plant species and vegetable species

The registration authority of the MS where the applicant submits its variety checks the suitability of the denomination at national level and possibly asks CPVO to check it at EU level, on the basis of its European database. The recent development of the CPVO database has improved the denomination check compared to the time when such check had to be carried out at the level of each other MS. The current role of CPVO on the matter of denomination is to provide an advice; it has no decision-power.

7.1.5.1. Utility

Overall, the current Community provisions on variety denomination are considered as useful; i.e. 99% of respondents to the qualitative survey (Q 2.3.2.2., n=136) are not in favour of removing them.

Graph 22 – Variety denomination in the future

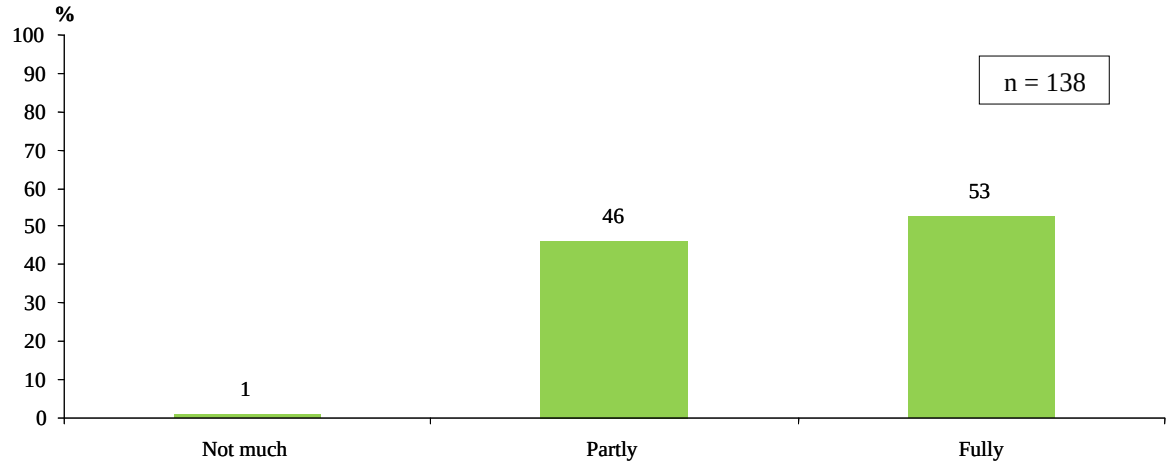


Around half of the survey respondents consider that the current system of variety denomination is sustainable in the future (Q 2.3.2.1., n=126). In their comments, several respondents have mentioned areas for improvement, mainly through the direct consultation of a centralised database or through the taking of decision on the suitability of denomination at EU level.

7.1.5.2. Effectiveness in achieving the objectives of variety denomination

The results of the qualitative survey (Q 2.3.1.1.) indicate that the majority of respondents (53%, n=138) consider that the Community provisions for the variety denomination have been fully effective in ensuring that varieties are designated in all MS of the EU by the same variety denomination. 46% of respondents consider that they have been partly effective to that aim.

Graph 23 – Effectiveness of variety denomination in ensuring the use of the same denomination in all MS



Stakeholders agree to say that the recent development of a database by the CPVO has contributed to more effective denomination checks, whereas there had been some problems in the past because not all MS had checked denomination correctly.

7.1.5.3. Efficiency in achieving the objectives

The majority of respondents to the qualitative survey (54%) (Q 2.3.1.3., n=125) answered that the time required for validation of a variety denomination by the official bodies (estimated from 3 months to 5 months) did not impact negatively at all or did not much impact negatively on the marketing of S&PM.

In particular, the recent development of a database by the CPVO has contributed to more efficient denomination checks; i.e. more harmonised and quicker denomination procedure.

Several respondents have however highlighted some remaining lack of efficiency as follows:

- Fancy name prevents the breeder from informing the user on e.g. the first year of marketing of the variety, the identity of the breeding company, etc.;
- Some variety names are difficult to pronounce or considered offensive in some (EU) languages (e.g. leek blauwgroene winter). In such cases, an official translation should be allowed;
- Very close names or even overlapping is existing due to worldwide activity;
- Some problems of synonyms and homonyms;
- The fact that the denomination and varieties are registered at the same time prevents the re-use of a nice name given to a variety that will never come to the market. It would be better to promote a system where names and varieties are registered separately and combined only at the end of the cycle (as already done e.g. in France);
- The prohibition to use a hyphen or the use of a name that contains comparatives or superlatives like PRO or SUPER limit the possibilities of applicants;
- Lack of harmonised denomination rules between the MS;
- Lack of harmonised rules between denomination (which are checked) and trademark (which are not checked) leading to confusion for the users in differentiating trademark from denomination;
- Lack of coordination between countries, what has led to the situation where e.g. a name approved in one country has been rejected afterwards in another one so that denomination had be changed after the registration of the new variety;

- The lengthy of the procedure, in particular when the initial proposed denomination has to be changed, can lead to a delay in registration and marketing of the variety;
- It becomes more and more complicate and time consuming to check the suitability of new names, even if some significant progress have been achieved by some MS in this matter;
- As regards ornamental plants, the lack of harmonisation in the interpretation of variety denomination rules between the PBR authorities and the International Cultivar Registration Authorities (ICRA) is causing problems. One cultivar (variety) should have one name (denomination) for proper marketing and for ensuring clarity so that the end consumer does not get confused. It would be appropriate in the future to officially recognise the scheme developed by the ICRA, which lists and describes cultivar on a world base.

7.1.5.4. Conclusions and recommendations

The recommendations in blue are suggestions formulated and tested in the questionnaire of the qualitative survey. Those in green are other recommendations made by stakeholders on their own initiative. For the recommendations in blue, the table provides the proportion of survey respondents who are 'in favour' and the one of those who is 'not in favour'.

Table 17 – Summary matrix – Variety Denomination

Identified problem/threat	Stakeholders concerned	Recommendations to address them	Advantages	Disadvantages	Feasibility and acceptance by stakeholder
Problem with the use of names	Breeders and users	Revise the system of variety denomination In particular: Enlarge the possibility of using codes and allow the combination of alphanumeric and figures for all crops and all varieties	- Less confusion on the market, clearer information provided to users on the variety they buy; - It becomes possible to identify of a variety through its denomination.	No	*Feasibility:* Not problem of feasibility as such codes are already used outside EU *Acceptance:* Survey results: 35% in favour, 65% not in favour, n=125 respondents
Lack of harmonised rules and coordination between MS	National authorities Breeders and users	Transfer the responsibility for denomination checking to the CPVO	See section 7.3.4 Role of CPVO below.		

The majority of stakeholders consulted during the qualitative survey and the interviews consider that the Community provisions for variety denomination are useful and must be maintained. However, they consider that there is room for improvement of the current system.

Overall, main recommendations to improve denomination in the future are to enlarge the possibility of using codes, according to the principle 'one denomination for one plant variety'. Also the current 'adviser' role of the CPVO could be reinforced, as presented at section 7.3.4. below.

7.1.6. Common Catalogues

The EU S&PM Community legislation on Common Catalogues refers mainly to Council Directive 2002/53/EC of 13 June 2002 on the Common Catalogue of varieties of agricultural plant species and Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed. Council Directives 68/193/EC (vine) and 92/34/EEC (fruit plants) also refer to a Common Catalogue but it does not seem to be implemented in practice. Some stakeholders consider that a Common Catalogue is desirable for vine and fruits varieties.

Finally, Council Directive 1999/105/EC on the marketing of forest reproductive material foresees the establishment of a community list comparable to the Common Catalogue.

Table 18 below describes the provisions of the Community legislation related to the Common Catalogue.

Table 18 – Provisions of the EU S&PM Community legislation related to Common Catalogue

Crops	Council Directives	Community provisions on Common Catalogue	
		Ref Art.	Description of the obligation
Beet seed Fodder plant seed Cereal seed Seed potatoes Seed of oil and fibre plants	2002/53/EC	Art. 1 (2)	The Common Catalogue of varieties shall be compiled based on the national catalogues of the Member States.
		Art. 3 (3)	Member States may provide that the acceptance of a variety for inclusion in the Common Catalogue or in the catalogue of another Member State is equivalent to acceptance for inclusion in their own catalogues.
		Art. 17	The Commission **shall**, on the basis of the information supplied by the MS and as this is received, publish in the C series of the *Official Journal of the European Communities* under the title 'Common Catalogue of Varieties of Agricultural Plant Species' a list of all varieties of which the seed and propagating material are not subject to any marketing restrictions as regards variety […].
Vegetable Seed	2002/55/EC	Art. 3 (3, 4), 17	Idem Article 1(2), 3 (3) and 17 of Council Directive 2002/53/EC.
Material for vegetative propagation of the vine	68/193/EEC	Art. 5e (2)	Based on the notifications from the Member States, the Commission shall publish a Common Catalogue of varieties.
Vegetable propagating and planting material other than seed	92/33/EEC	Art. 9(2)	Without prejudice to article 2 and paragraphs 3 and 4 of this article, vegetable propagating and planting material which belongs to *genera* and species listed in Annex II but which is not covered by Directive 70/458/EEC shall not be marketed within the Community unless its belongs to a variety officially accepted in at least one MS.

Fruit plant propagating material and fruit plant	92/34/EEC	Art. 9 (6)	It **may** be decided that a Common Catalogue of varieties may be established and published.
Ornamental plants	98/56/EC	No	
Forest reproductive material	1999/105/EC	Art. 11 (1)	Based on the national list provided by each MS, the Commission **may** publish a list entitled 'Community List of Approved Basic Material for the Production of Forest Reproductive Material'.

Council Directives 2002/53/EC and 2002/55/EC foresee the publication of the list of varieties in the Official Journal of the European Communities (OJEC) under the title 'Common Catalogue of Varieties of Agricultural Plant Species' or the title 'Common Catalogue of Varieties of Vegetable Plant Species'. Such provision doesn't exist for the forest reproductive material.

In practice, the EC publishes the modifications brought to the Common Catalogues every two months. Once a year, it publishes a complete version of the updated catalogues.

Council Directives on vegetable plants and ornamental plants do not contain any provision on the creation of a Common Catalogue. As commented by one association of suppliers active in the sector of vegetable plants, the Common Catalogue is not of great importance for plant propagators. Their main problem relates to the illegal marketing of unlisted vegetable seed. Either they decide to check whether the seeds they buy are from a listed variety, what causes them an unnecessary administrative burden, or they decide not to check this aspect and to bear the risk that the young plants they grow from those seeds are refused afterwards by the market.

7.1.6.1. Utility

The Common Catalogue is considered by all stakeholders as being a very useful instrument as it creates the free marketing of accepted varieties within the EU.

The results of the qualitative survey indicate that 83% of respondents consider that the Common Catalogue has had a positive impact on the free marketing of S&PM in the EU (Q1.1.4, n=211).

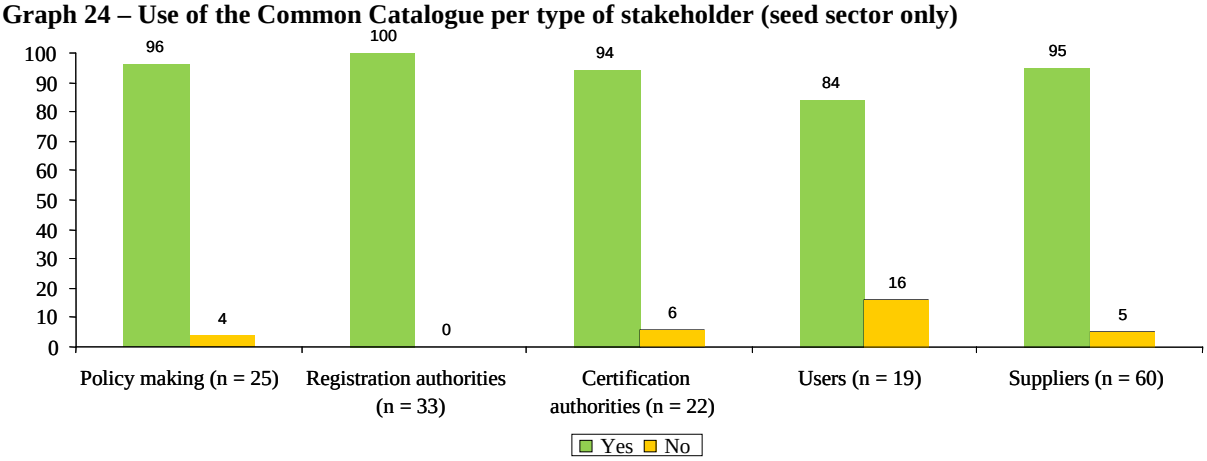
Nevertheless, the internal market also takes place in sectors where no Community provisions on the Common Catalogue have been established such as vegetables other than seed, fruit and ornamentals. The rules for those sectors are as follows:

- Vegetable propagating and planting material shall not be marketed within the Community unless it belongs to a variety officially accepted in at least one MS;
- Propagating material of ornamental plants **may** be marketed with reference to a variety, only if the variety concerned is legally protected by a plant variety right in accordance with provisions on the protection of new varieties, or officially registered, or commonly known, or entered on a list kept by a supplier with its detailed description and denomination. […]. Such list shall be available, on request, to the responsible official body of the MS concerned;
- Propagating material and fruit plants **shall** be marketed with reference to a variety to which they belong. The varieties to which reference shall be made must be either commonly known, and protected in accordance with the provisions on the protection of new varieties of plants, or officially registered on a voluntary or other basis, or entered on lists kept by the suppliers with their detailed descriptions and relevant denominations. These lists must be available, upon request, to the responsible official body of the MS concerned.

According to survey results, 93% of respondents of the seed sector (Q 2.4.1.1. n=125, seed sector only) use the Common Catalogue.

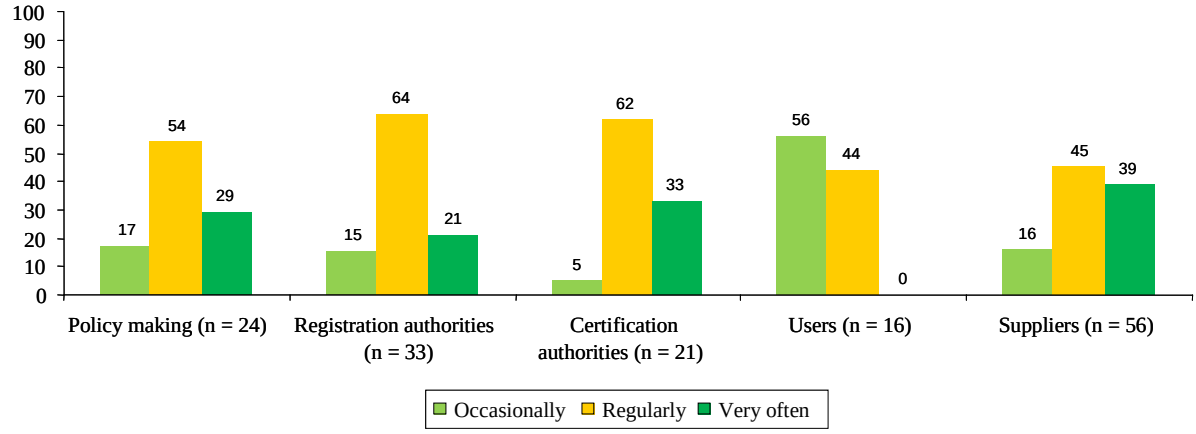
Only small differences appear when considering the types of stakeholders, as follows:

Graph 24 – Use of the Common Catalogue per type of stakeholder (seed sector only)



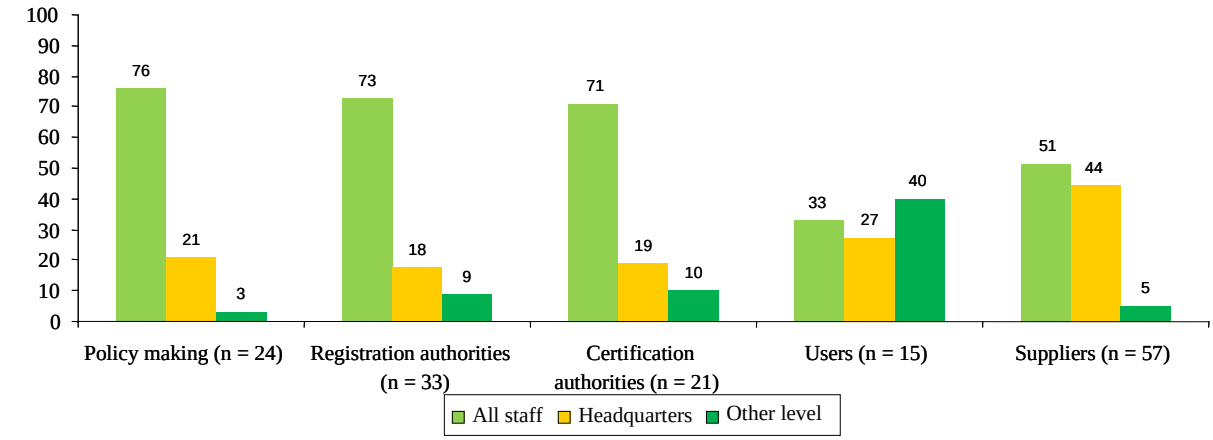
Among them, majority of national authorities have mentioned that they do it regularly. Associations of suppliers (56 respondents) tend to consult the Common Catalogue more frequently than associations of users (16 respondents) (Q 2.4.1.1., n=115, seed sector only).

Graph 25 – Frequency of use of the Common Catalogue per type of stakeholders (seed sector only)



The Common Catalogue is used by all staff for around ¾ of the responding national authorities and ½ of the responding suppliers. 6 of the 15 responding users mentioned that it was used at the level of their members (category 'Other level') (Q 2.4.1.1., n=115, seed sector only).

Graph 26 – Level of use of the Common Catalogue per type of stakeholders (seed sector only)



In their comments, respondents further precise the way they use the Common Catalogues, as follows:

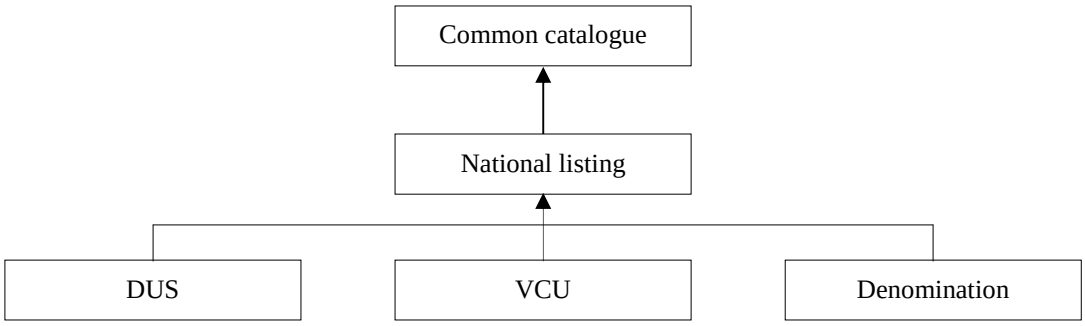
- To know which varieties are on the various national lists (official registration body);
- As an essential reference source of information for different operations such as research, development, marketing or commercialisation (members of an association of suppliers);
- To check if seed certification may be done and if free market is allowed for the variety;
- National catalogue is for some countries only an interim list for entrance into the EU-catalogue, the recommendation list being the finally used list; for other countries the national list is a recommendation list and, used as such, it is more than the entry-passport for the EU catalogue and the free market.

As regards the forestry sector, no statistical analysis of responses to the qualitative survey can be made as they refer to 8 respondents. The qualitative comments provided by this small group indicate that the Community list of registered material is mainly used by national authorities. For suppliers, it is more practical to use the national lists which contains more information and are easier to consult. The Community list is used to check the availability of the recommended sources of material.

The analysis the utility of the Common Catalogue also refers to the issue of the relevance of the VCU as a criterion for the Common Catalogue (as already approached at section 7.1.4.1. above)

As illustrated below, the Common Catalogue is based on the national listing which is based on the obligations of DUS, VCU (agricultural crops only) and denomination.

Figure 8 – Obligations at the basis of the Common Catalogue



Section 7.1.4. above has shown the importance of the VCU at national/local level but demonstrated the variability of implementation of EU VCU provisions at national level leading to a "*GxExL situation*". Such variability is however removed by the existence of the VCU provisions in the Directive on the Common Catalogue of varieties of agricultural plant species, as highlighted by several stakeholders during the qualitative survey and the interviews. Linking the free marketing within the EU (i.e. the publication in the Common Catalogue) to the VCU obligation doesn't make sense. Results of VCU testing vary according to local environment and do not have any value at Community level. Listing in the Common Catalogue is no guarantee of good performances outside the region of VCU testing. A variety of sufficient value in Greece, may not be of any value in other MS. Furthermore, some VCU data such as the 'zone' concept disappear when the variety is published in the Common Catalogue; e.g. a variety of maize that is of sufficient value for cultivation and use in a specific zone of France will appear as of sufficient value in France in the Common Catalogue without mentioning that it of value in only part of France.

Having VCU as a provision for CC creates a system of '*27 VCU keys – one door*' inducing the following key consequences:

- 2 accesses to a given market: National Catalogue or Common Catalogue. A breeder prefers to use the National Catalogue approach, but if he estimates that the variety will not be listed for a specific reason via the National Catalogue, he will apply for registration in another MS where conditions are more adapted to his variety and come back to market of interest via the CC;
- A variety can be marketed in a specific country without having local VCU results;
- Breeder' objective is to be on the CC and he can choose the country(ies) where he will apply, This situation is leading to the fact that national registration systems are competing *"fishing for applications"* in order to maintain their activity.

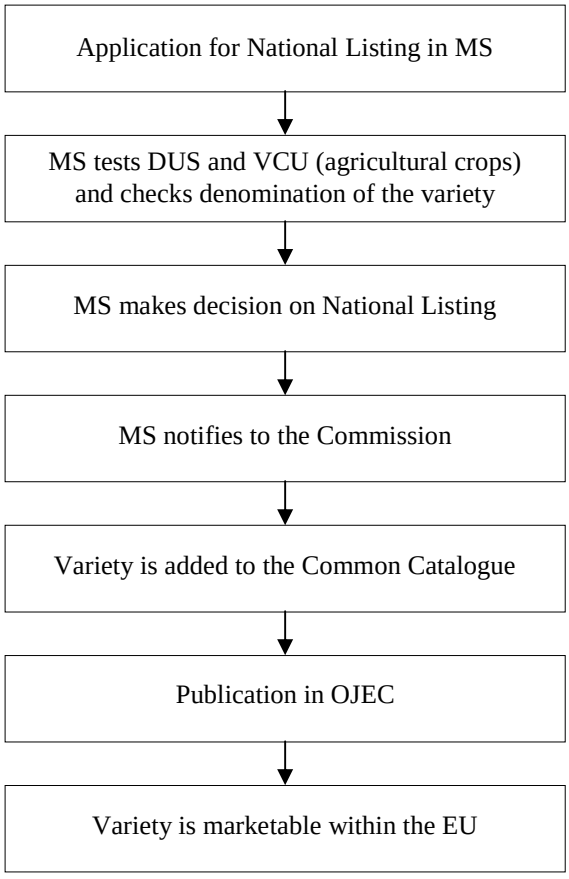
7.1.6.2. Effectiveness in achieving the objectives of the Common Catalogues

Because any variety listed on a national catalogue becomes automatically marketable on the entire Community, the related provisions of the seed Directives have been fully effective in ensuring the objective of free marketing.

7.1.6.3. Efficiency in achieving the objectives

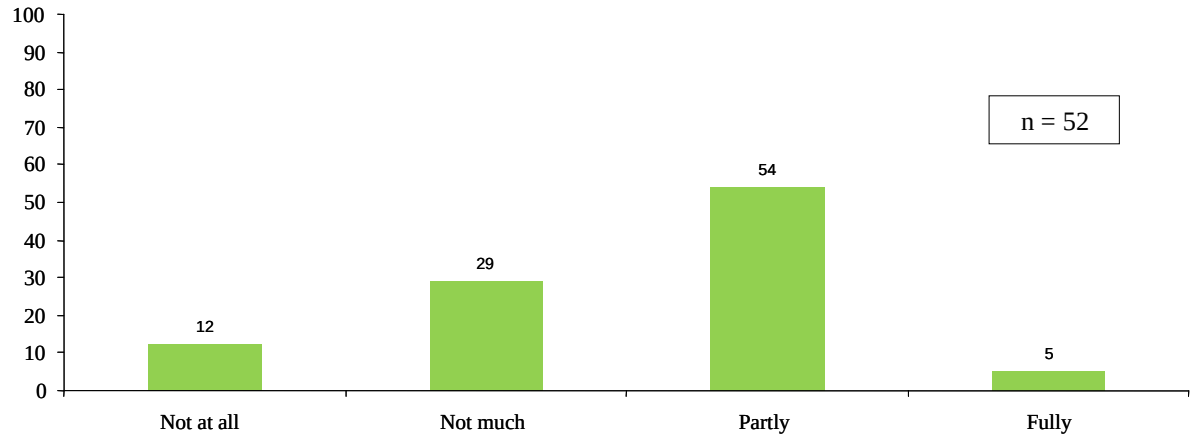
The analysis of the efficiency looks at the process by which a variety listed on the national catalogue becomes marketable within the entire Community, as presented in the following figure:

Figure 9 – Process for publication in the Common Catalogues of varieties



The results of the qualitative survey indicate that around 1 respondent out of 2 (Q 2.4.1.2. , n=106, seed sector only) consider that the lapse of time required between the national registration and the publication in the Common Catalogues has partly negatively impacted on the marketing of S&PM. This proportion increases to 71% when considering the group of suppliers only (n=52).

Graph 27 – Extent to which the lapse of time between national registration and publication in the CC has negatively impacted the marketing of seed (seed sector only)

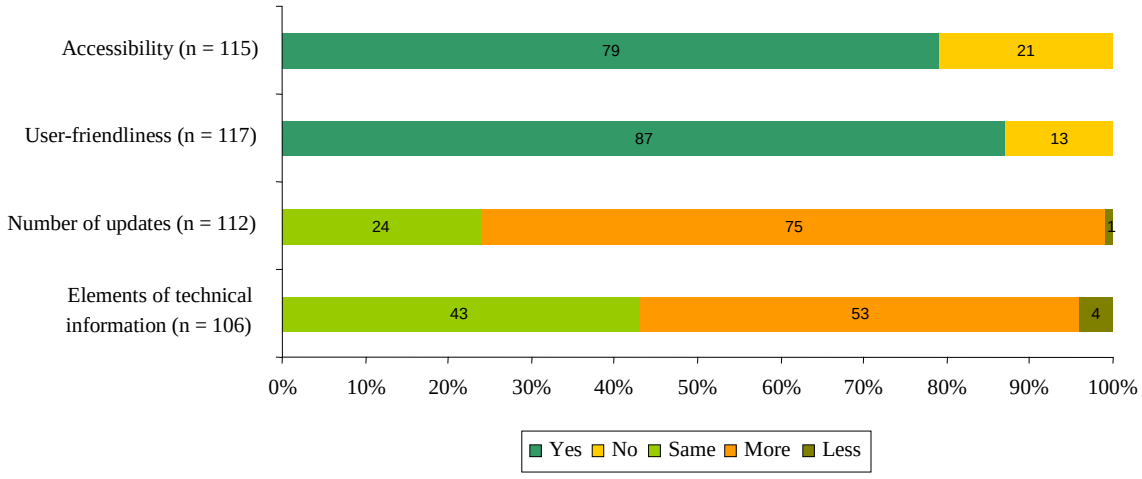


Their comments to explain the cases of negative impacts are as follows:

- The lapse of time between the two publications impact negatively on the marketing of seeds in a MS different from the listing one;
- A time lag can cause administrative issues surrounding certification processes as well as marketing. Simultaneous national listing and Common Catalogue listing should be possible using modern database and IT technology. It would also facilitate the listing in non-EU countries that are prepared to 'take over' EU DUS reports;
- There were cases of delayed notification by the listing MS;
- For many species and MS, administrative decisions to register new varieties are made very close to the planting season. In case such decision is not taken at the time when the users buy their seeds, the supplier looses one vegetative cycle of profits;
- Due to the current time lag between the national listing and the publication in the Common Catalogue, applicants are not able to introduce their varieties in the EU market when they are ready for it.

Results of the qualitative survey (Q 2.4.2.4.) also indicate some room for more efficient management of the Common Catalogues in terms of their accessibility, user-friendliness, number of updates and elements of technical information they contain, as follows:

Graph 28 – Extent to which it is desirable to modify the Common Catalogues (seed sector only)



Such demand for improvement is more frequently mentioned by responding associations of users and suppliers than by responding official authorities, with:

- 94% of them asking for modified accessibility (users: n=18; suppliers: n= 54);
- 100% of responding associations of users (n=18) and 98% of responding associations of suppliers (n=54) asking for modified user-friendliness;
- 78% of responding associations of users (n=18) and 92% of responding associations of suppliers (n=54) asking for more updates.

The demand for more technical information comes from national authorities as well as private bodies, in particular 61% of responding policy-making authorities (n=23), 53% of responding registration authorities (n=30), 47% of responding certification authorities (n=19), 60% of responding associations of users (n=15) and 44% of responding associations of suppliers (n=52).

As example of possible improvements, respondents mention the following elements:

- Include in the Common Catalogues all the information contained in the national lists (either directly or through links to e.g. technical sheets developed at national level on VCU results and DUS results, resistance of varieties to important pests and diseases, etc.);
- Include information on any legal restriction on the marketing or use of a variety;
- Add information on the type of selection method used for each variety (hybrid, GM, clone, etc.), the extent to which the variety is sterile, the extent to which it is protected or makes part of the public domain, the extent to which it is suitable for low-input farming or intensive farming;
- Allow for selection on the basis of interesting origins or parameters;
- Add the name and address of all maintainers;
- Add the official variety description of the variety to support field inspection and post-control activities and allow for its downloading in order to support variety listing outside the EU at minimum additional costs;
- Add information on the different starts of planting seasons all over the Community;
- Add a column of the "country of origin" to select interesting varieties for each user. Additional describing lists could relate to the use of the varieties (environments, farming system, processing) for different users. Make the Common Catalogue accessible to all authorised parties via the Internet;

- Develop a database system for the management and an easier use (selection on the basis of origins or defined parameters), increased transparency, permanent updates and lower management costs;
- Develop in parallel an automatic daily e-mail services of changes/additions/deletions to authorised people as well as a warning system when a variety gets deleted;
- Allow the search of a variety without knowing the species;
- Allow for electronic publication of the variety in the OJEC and recognize it as valid to authorize its marketing in the Community.

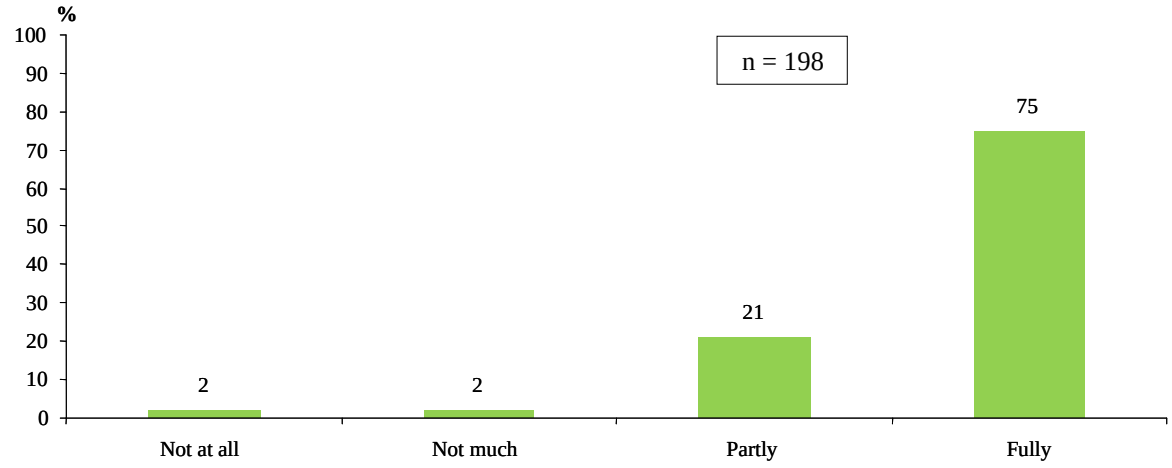
The most important improvement would lead in reducing the lapse of time for inclusion in the Common Catalogue. The delay that has been mentioned by most of interviewees is due to the requirement to have the variety lists published on the OJEC as mentioned on Article 17 of Council Directives 2002/53/EC and 2002/55/EC.

FCEC considers that it would be valuable to evaluate the feasibility for the Commission of reducing such a lapse of time.

7.1.6.4. Rules on variety maintenance: necessity, cost-effectiveness

The results of the qualitative survey indicate that ¾ of respondents (Q 1.1.9, n=198) consider that the rules on variety maintenance are necessary, as follows:

Graph 29 – Necessity for rules on variety maintenance (seed sector only)

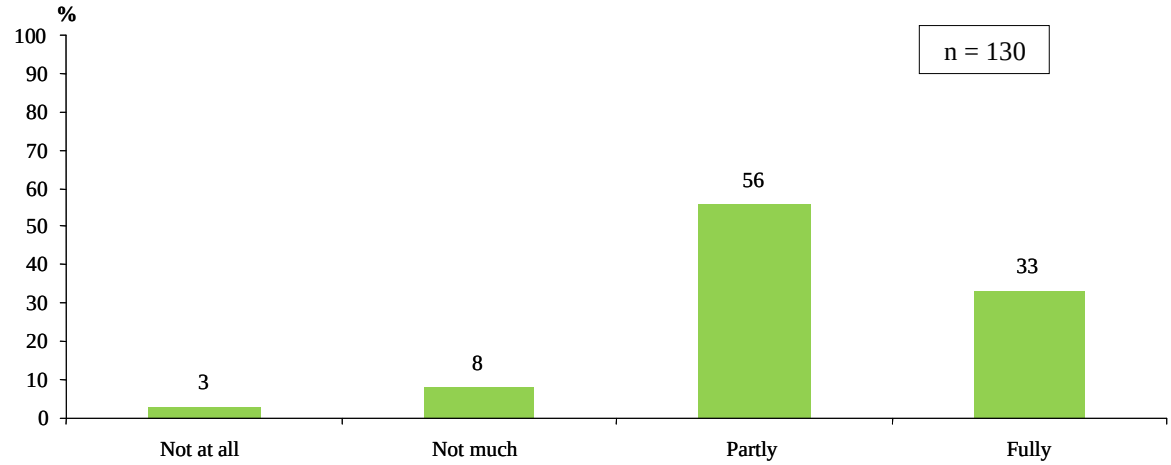


As commented by respondents:

- The breeder is the unique responsible for the identity of the variety, in respect to users and customers. Without any maintenance, transaction liability cannot be assumed;
- Keeping of variety identity needs good traceability which starts with maintenance;
- For commercial varieties, experience has shown that without a true variety maintenance, the breakdown of a variety is possibly leading to marketing and certification problems;
- The users require high stability of the marketed varieties in order to be sure to have products with stable attributes, stable genome and stable phenotypical attributes.

However, only 1/3 of respondents (Q 1.1.10, n=130) consider that such rules are cost-effective, as follows:

Graph 30 - Cost-effectiveness of rules on variety maintenance (seed sector only)



As commented by respondents:

- For the amateur vegetable markets, the rules are over-prescriptive and costly to apply;
- There is a lack of harmonized requirements of the definition for the maintainer and the body in charge of the control (Catalogue and/or certification bodies). Some provisions could become more tailored;
- Costs depend on the techniques used to establish and preserve trueness to type. It is proposed to provide the legal room for development/use of additional supportive tools (after careful evaluation) where this leads to more efficiency and cost-reduction. The use of modern techniques should only be possible where these tools have been proven to be suitable for the species concerned and if they facilitate the verification of variety identity at lower costs. It is not proposed to replace phenotypical evaluations by DNA-testing;
- Seed certification system can partly substitute the rules on variety maintenance;
- Annual variety maintenance costs can be reduced by applying a risk-based inspection scenario and using the data from the quality systems of seed suppliers;
- Maintenance rules should be omitted when the variety protection rights expire after 25 or 30 years. But even then free propagation is nearly impossible for farmers who still would favour such (old) varieties (this is in general a very small share of the market), since the official breeders fear that bad seed endanger their good reputation. This problem could be solved, by adding the appendix "ex" or "former" to the original variety name, so that it is clear to every farmer that this is not the officially maintained variety of the breeder anymore.

7.1.6.5. Analysis of recommendations

The recommendations in blue are suggestions for the future as formulated and tested in the questionnaire of the qualitative survey. Those in green are other recommendations made by stakeholders on their own initiative. For the recommendations in blue, the table provides the proportion of survey respondents who are 'in favour' and the one of those who is 'not in favour'.

Table 19 – Summary matrix – Common Catalogues (seed sector only)

Identified problem/threat	Stakeholders concerned	Recommendations to address them	Advantages	Disadvantages	Feasibility and acceptance by stakeholder
Lack of efficiency due to the co-existence of national and Common Catalogues	All stakeholders and public bodies in particular	Stop national catalogues and only work with Common Catalogues	- A unique Common Catalogue would be easier to use, to understand, and cheaper to implement. It would speed up the decision-making process and access to the full EU market for new varieties;	- Could bring confusion; - National level is the best level to inform, in their language, the users; - Problems with national listing of varieties intended exclusively for cultivation in third countries; - Problems with S&PM marketing on national level (keeping of quality control of seed production, etc.); - The national catalogue provides the farmers with useful information that will be lost if maintaining the Common Catalogues as they currently stand; - It would be more difficult to register niche varieties; - Expensive at Community level.	*Feasibility:* - Difficult to implement. Lists of assessment criteria for a Common Catalogue would not be relevant for the specificity of each national territory and national public policy. - Contacts between national authorities and the users are more close and easy than contacts with supranational authorities. *Acceptance:* Survey results: 11% in favour, 89% not in favour, n=120 respondents (seed sector only)
		Work with Common Catalogues and allow MS to have national catalogues on a voluntary basis	- Advantages in particular for small MS with a low number of applications for national list	- Any voluntary and non-harmonised system (leaving decisions to set up a national catalogue to the individual MS) decreases transparency and creates unnecessary confusion and potential for disagreements; - Voluntary national listing drives to the disappearance of national catalogue, which would destroy post-registration work; - Obligatory national listing is necessary as it is based on specific national conditions and markets; - Would be more expensive to everyone;	*Feasibility:* It could be difficult to bring all the data available and useful to the farmers. *Acceptance:* Survey results: 31% in favour, 69% not in favour, n=113 respondents (seed sector only)

				- Current system is efficient and permits each member state to develop its own policy, in conformity with CPVO protocols	
Common Catalogue is difficult to access and consult	Associations of users and suppliers	Online real-time Common Catalogue that is the automatic compilation of national authorised varieties	- Rapid consultation and search; - Transparent data to all stakeholders; - Permanent updating of the EU Common Catalogue that would better support free movement of seeds within the EU and would also support listing of varieties in some non-EU countries; - Possibility to include more technical information than currently done; - Efficiency gains and cost reductions.	- Huge mass of information which is difficult to decipher	*Feasibility:* Easy. Major change in administration. National catalogues with varying requirements will lead to variations in the registration depending on the cost of registration. Maintaining the current situation would continue the current administrative burden, costs and delays in the listing of vegetable varieties on the EU Common Catalogue.

7.1.6.6. Overall conclusions and recommendations

Common Catalogues exist for the varieties of agricultural and vegetable plant species, including their publications in the OJEC. A Community list also exists for the forest reproductive materials.

The Common Catalogue is perceived as very useful. The results of the survey indicate that most of the respondents from the seed sector use it at least on a regular basis. Associations of users tend to consult it less regularly and more frequently consider them not easily accessible and not user-friendly.

Nevertheless, as highlighted by some of them, linking the VCU obligation to the listing in the Common Catalogue leads to the *'27 keys – one door'* situation, in which 1) two approaches exist to access a given national market, i.e. the national one and the Common Catalogue one; 2) national variety registration authorities compete the one with the other; 3) an inconsistent provision allow applicants to have a biased access to the market.

For the future, large majority of respondents are in favour of maintaining both the national and the Common Catalogues. They are not in favour of stopping national catalogues or of allowing MS to have national catalogues on a voluntary basis.

Several stakeholders (in particular associations of users and suppliers) insist on the need to improve the contents, the accessibility, the use and the management of the Common Catalogues by adding information on origins or defined parameters of interest to the users; organising the data better in e.g. an excel file allowing for search facilities; make it accessible to all authorised parties via the Internet.

As expressed at section 7.1.4.5., removing the link between the VCU obligation and the Common Catalogue would not have major impact but it is worth making an impact assessment on such alternative to better know on the follow-up behaviour of national authorities (i.e. extent to which they will keep on the VCU as an obligation for national listing).

The most important improvement would lead in reducing the laps of time for inclusion in the CC. The delay that has been mentioned by most of interviewees is due to the requirement to have variety lists published on the OJEC as mentioned on the Art. 17 of Council Directives 2002/53/EC and 2005/55/EC. FCEC considers that it would be valuable to evaluate the legal need of this provision. If publication on the OJEC is not compulsory any longer, the inclusion on the CC of a new variety will be effective when MS notifies.

Seventy five percent of respondents consider that the rules on variety maintenance are necessary as they allow assuming transaction liability and the disposal of products with stable attributes. However majority of them consider that there it is needed to improve the costs-effectiveness of maintenance rules, either by adapting the strictness of rules according to markets, or by providing the legal room for the development and use of modern techniques when relevant, or by omitting them when variety protection rights have expired.

7.2. CERTIFICATION

7.2.1. Introduction

In the sixties, the certification of seed was made compulsory in Europe for marketing purposes, to ensure consistent seed quality to farmers and to allow free movement within the European Union. The Seed Certification system is an official system supported by EU legislation, National legislation and International protocols to ensure that seed is produced, multiplied and marketed according to predetermined standards and systems while maintaining the genetic integrity of the product. It is part of a wider system including plant breeding and plant breeder's rights, plant genetic resources, biodiversity and international trade.

The initial approach was to implement official controls at key stages of the multiplication processes to secure quality of the product and to control the identity of the variety. At its simplest, the system certifies that a sack, bag or box of seed contains what it is written on the label, and meets certain minimum quality criteria. The immediate objective of S&PM certification is to supply high quality S&PM to farmers, which is true to identity, high in varietal purity and germination capacity and free from major pests and diseases. Quality is most important in crop production, as high quality is essential for good crop yields and good returns.

Many factors have changed since the Community legislation was introduced, notably fewer, larger seed companies and better seed cleaning and agricultural equipment. As a result, seed production has become more sophisticated and reliable.

7.2.1.1. Concerned Council Directives of the S&PM Community legislation

Community provisions for certification are provided in the 11 basic Marketing Directives of the Community legislation.

Not all Directives impose the same certification obligations. Overall, distinction can be made between the marketing of seeds, of propagating materials and of forest reproductive materials as follows:

Seed

Directives 66/401/EEC (fodder plant seed), 66/402/EEC (cereal seed), 2002/54/EC (beet seed), 2002/56/EC (seed potatoes) and 2002/57/EC (seed of oil and fibre plants) require the multiplication of seed through a prescribed generation sequence, including the production of basic seed and certified seed (minimum of 2 generations corresponding to around 2 years of control). The crop to produce each generation must be shown on examination to meet prescribed minimum standards. The seed harvested from the crops must be sealed, labelled, sampled and tested to ensure it also meets prescribed minimum standards.

The certification system is designed to guarantee seed quality in the respects of varietal identity, varietal purity, analytical purity, germination capacity, weed and other crop seed content, seed-borne diseases. Rules in respect of sampling, sealing and labelling of seed aim to ensure that seed identity is clear and seed does not become contaminated.

Compared to the certification of other seeds, the certification of seed potato is mainly a phytosanitary certification (with a large panel of quarantine and non quarantine plant diseases).

Directives allow the sampling and testing of all categories of seed and the field inspection of certified seed to be carried out either officially (certification under official examination) or by licensed personnel under official supervision (certification under official supervision). In the case of certification under official supervision, a proportion of 5% of seed lots are checked for correct implementation of measures as regards field inspection, and seed testing.

Vegetable seed Directive (2002/55/EC) provides that the seed can be marketed under the categories ‘certified’ or ‘standard’. This last qualifier is the most common. In this case, the words "standard seed, EC rules and standards" is marked either directly on the packaging or on the commercial label and there is no official label. Only post-control examination of variety identity and purity are being officially checked by authorities.

Propagating material

The vegetable Directive 92/33/EEC and the ornamental Directive 98/56/EC require statutory control during the production process as well as accreditation of the operators.

The vine Directive 68/193/EEC and the fruit Directive 92/34/EEC authorize the production of two types of propagating material:

- Certified material, which must comply with obligation comparable to the ones applicable for certified seeds;
- Standard material (vine) which is examined ex-post as regards the varietal identity and purity and CAC material (fruit) which must satisfy minimum conditions.

The text of the proposal for the revised fruit Directive indicates that 'obsolete definition and conditions for the lowest category of material (CAC material) allows the marketing of plants which neither perform as expected in terms of production of fruit and health status'. Also it stipulates that 'the absence of some definitions (considered as not necessary at the moment of the adoption of the Directive) is a source of conflict due to misunderstandings or frauds. This implies an increase in costs for both suppliers and consumers and a lack of confidence in the market. The proposal foresees the definitions of categories of fruit plant, which should be in-line with the scientific and technical progress and in particular, with the international certification schemes (EPPO standards).

Forest reproductive material

Directive 1999/105/EC on the marketing of forest reproductive material stipulates that forest reproductive material may not be marketed unless it is of one of four categories specified by the Directive (source-identified, selected, qualified, tested) and that only approved basic material may be used for its production if the material is to be marketed. After harvesting, a master certificate of identity (with indication of the country and region of provenance) must be issued for all reproductive material derived from approved basic material.

When applicable, the S&PM Community legislation defines minimum standards to be satisfied by the (growing) crop to produce each generation of seed or propagation material as well as minimum standards to be satisfied by the seed or propagation material harvested. The control procedures are also defined by the Directives.

The following table summarises the certification obligations defined for each marketing Directive, as follows:

Table 20 – Certification obligations in each of the basic seed Marketing Directives

Crops	Council Directives	Certification schemes - Description of the obligations	
		Type of material	Type of examination
Beet seed	2002/54/EC	Basic seed → Certified seed	OE or UOS
Fodder plant seed	66/401/EC	Basic seed → Certified seed Commercial seed	OE or UOS OE or UOS
Cereal seed	66/402/EC	Basic seed → Certified seed	OE or UOS
Seed potatoes	2002/56/EC	Basic seed → Certified seed	OE
Oil and Fibre plants	2002/57/EC	Basic seed → Certified seed	OE or UOS
Vegetable seed	2002/55/EC	Basic seed → Certified seed or Standard seed	OE or UOS Only post-control official examination
Material for vegetative propagation of the vine	68/193/EEC	Initial propagating material → Basic → Certified or standard Material	OE OE
Vegetable propagating and planting material other than seed	92/33/EEC	Propagating material or Planting material	OE OE
Fruit plant propagating material and fruit plant	92/34/EEC	Pre-basic → Basic → Certified material or CAC material	OE or OE
Ornamental plants	98/56/EC	Propagating material	OE
Forest reproductive material	1999/105/EC	Basic material → Source identified or Basic material → Selected or Basic material → Qualified or Basic material → Tested	Formal inspection decided by MS OE *OE:* OE OE

certification under Official Examination; UOS: certification Under Official Supervision (applicable to the category 'certified seed')

7.2.1.2. Implementation in the MS

The implementation of Community legislation has generally led to the definition of higher standards for certification in the MS as well as to the use of different rules or methods for the analysis of e.g. identity or germination. In addition, the current EU provisions for seed potatoes are significantly lower than those set at Member State level, partly due to specific conditions in Member States.

There were also cases where MS have asked to Commission to be authorised to adopt more stringent provisions, e.g. concerning the presence of weed *Avena fatua* in cereal seed.

Not all MS have implemented the possibility to carry out the field inspection of certified seed by licensed personnel under official supervision, as presented in the following table on costs repartition:

Table 21 – Implementation of certification under official supervision in the MS

MS	Certification under official supervision	Additional information
AT	Yes	
BE	Yes	
BG	No	
CY	No	
CZ	Yes	60% of certificates for cereal seeds are provided by private laboratory
DE	Yes	
DK	Yes	
EE	Yes	
ES	No	
FI	Yes	Partly, for field inspection and seed sampling. Not for seed analysis.
FR	Yes	
GR	No	
HU	No	
IE	No	
IT	Yes	
LT	No	
LU	No	
LV	No	
MT	No	
NL	Yes	
PL	Yes	
PT	Yes	For cereals (winter cereals and rice) field inspection and seed, sampling is running under official supervision.
RO	Yes	
SE	Yes	20% for field inspection, around 60% for analysing
SI	No	
SK	Yes	
UK	Yes	

7.2.2. Certification costs (seed sector only)

7.2.2.1. General context

As stated by interviewees, seed certification costs represent between 1 and 2% of the total production costs. This proportion considers the standards implemented by the MS, which are generally stricter, then implying additional costs, than the minimum standards defined in the Community legislation.

Stakeholders generally agree to say that seeds produced in the EU have a high quality. Currently, in most of the MS, the focus tends to be on reducing the certification costs while maintaining the same level of quality for seed.

In addition, Stakeholders active on niche and emerging markets consider that the current certification costs for the testing of seeds of niche varieties, e.g. landraces, populations, organic varieties are too expensive and not proportionate to their market size.

The current distribution of the seed certification costs between the public and the private bodies in the MS is summarised in the following table:

Table 22 – Current distribution of seed certification costs between public and private bodies in the MS

MS	Certification costs are transferred to industry	Additional information
AT	Yes	Partial transfer of costs
BE	Yes	30% of costs are transferred to the industry
BG	Yes	Partial transfer of costs
CY	Yes	Partial transfer of costs
CZ	Yes	Partial transfer of costs
DE	Yes	Between 30% and 70% depending on the Federal Land concerned)
DK	Yes	Full transfer of costs (100%)
EE	Yes	Partial transfer of costs
ES	Yes	Partial transfer of costs
FI	Yes	Full transfer of costs (100%)
FR	Yes	92% for seed, 65% for vine
GR	Yes	The fee = (reference price) x (certified quantity) x 3%. The rate of the reference price is fluctuating between the farmers' price and the final selling price of the seed.
HU	Yes	Full transfer of costs (100%)
IE	Yes	Partial transfer of costs
IT	Yes	Full transfer of costs (100%)
LT	Yes	8% is financed by private sector
LU	Certification is mostly financed by national authorities	
LV	Yes	Partial transfer of costs
MT	No	
NL	Yes	Full transfer of costs (100%)
PL	Yes	Full transfer of costs (100%)
PT	Yes	Partial transfer of costs
RO	Yes	
SE	Yes	Full transfer of costs (100%)
SI	Yes	
SK	Yes	
UK	Yes	Full transfer of costs (100%)

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

7.2.2.2. Structure of the certification costs

The ToR of the evaluation distinguish between three types of costs, i.e. the administrative costs, the compliance costs and the enforcement costs, which they define as follows:

- Administrative costs i.e. those costs incurred by companies and public authorities in meeting legal obligations to provide information on their action or production to public authorities or private parties;
- Compliance costs i.e. those costs linked to changes in the method of production linked to legal obligations;
- Enforcement costs i.e. costs for public authorities and the Commission resulting from implementation.

During the interviews of stakeholders, it appeared that the public authorities and the private operators (suppliers of S&PM) do not distinguish between such categories of costs. Overall, they distinguish between costs per activity, grouped into costs centres.

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

Certification costs under official supervision

- Authorisation of companies, seed-testing laboratories and staff belonging to companies by certification authority
- Field inspection by accredited staff
- Seed lot sampling and seed sample testing by accredited staff
- Labelling of lots by accredited staff

Certification costs under official examination

- Registration of companies, seed-testing laboratories and staff belonging to companies by certification authority
- Official field inspection
- Official seed lot sampling and seed sample testing
- Official labelling of lots

Post-Certification

- Official post-control examination of varietal identity and purity
- Official recording of control by certification authority
- Official control of marketing
- Granting of equivalence and derogation
- Comparative trials

The breakdown of the total certification costs between the certification under official examination and the certification under official supervision is provided for some MS and some crops in the following graph:

Graph 31 – Breakdown of costs between certification under Official Examination and certification Under Official Supervision

7.2.2.3. Overall estimation of the annual certification costs in the MS

Certification costs for competent authorities represents 53% of the total costs linked to the implementation of the Community legislation and represents about 1,7% of the sum of the sizes of the internal commercial market for seed of the 8 selected EU MS (FR, DE, IT, UK, DK, SE, BE, and AT).

These figures consider the standards implemented by the MS, which are generally stricter than the minimum standards defined by the Community legislation. The figures do not segregate costs related to implementation of the Community legislation from costs generated by the national additional provisions, and therefore should be considered as costs dedicated for implementation of Community legislation and for the implementation of additional provisions.

The key elements that have been considered when segregating data on certification costs are 1) the structure of the certification schemes in each of the individual MS and 2) the current distribution of costs between the public and private operators.

Transfer of costs to the industry has been initiated in all MS, and percentage of transfer varies from 8% to full transfer of costs that have been reported by 8 MS.

Based on the answers from the qualitative questionnaire, 16 MS are reporting that competent authorities have partly implemented certification under official supervision but the budget figures clearly indicated that only 2 MS (FR, UK) have fully implemented that structure of certification under official supervision. The other national competent authorities reported supervision costs on activities such as laboratory accreditation and auditing, training requirements and labels printing representing a percentage of up to 20% of total certification costs.

Under certification under official examination, the 2 main costly activities for national authorities are seed lot sampling & analysis and field inspections. In most of MS, seed lot sampling and analysis represents more than 50% of the total certification costs. Field testing costs represent in between 20-30% on average. It should be highlighted that these ratios are quite similar for certification under official examination and certification under official supervision.

Post registration costs are mainly due to the official post-control examination of varietal identity and purity and represents from 40 to nearly 100% of these costs in major MS.

In order to fine-tune these global conclusions, a deeper comparison analysis has been conducted on seed potatoes in 3 MS (DK, FR, UK) as certification under official examination is compulsory on this crop. Field trials examination costs are quite homogeneous across MS, and differences can be explained by number of visits per production field, but large differences are being observed for sampling and testing of seed lots with a unit price varying from 1 to 4. Additionally, this study demonstrates that the number of samples par hectare varies from 0,3 to 1.

The limited data sets provided by the private operators have been considered too fragmented to draw reliable conclusions.

7.2.2.4. Tentative estimation of the part of the administrative costs – French example – and identification of opportunities for costs reduction

French authorities have provided very useful information that permitted to draw some general conclusions. The French authorities also highlighted that they have even more detailed figures which they cannot disclose for reasons of confidentiality.

Based on the data at its disposal, the FCEC team is of the opinion that there are no real opportunities in trying to further reduce the costs linked to the implementation of the Community certification legislation in each MS, mainly because:

- the certification costs represent around 1,7% of the size of the EU markets for seed and other planting material[43];
- constant efforts have been made by the MS in trying to reduce the certification costs (without modifying the certification obligations implemented in each MS).

[43] Calculated as the sum of sizes of the internal market of 19 selected EU MS

However, the FCEC team considers that there could be opportunities for reduction of the certification costs by promoting a different organisation of the inspection activity, as presented in sections 7.2.9., 7.2.10 and 7.2.11 below. The main options considered there are:

- Promote the integration of plant health and certification inspection schemes;
- Promote the implementation of certification under official supervision;
- Extend the certification under official supervision to pre-basic and basic crops.

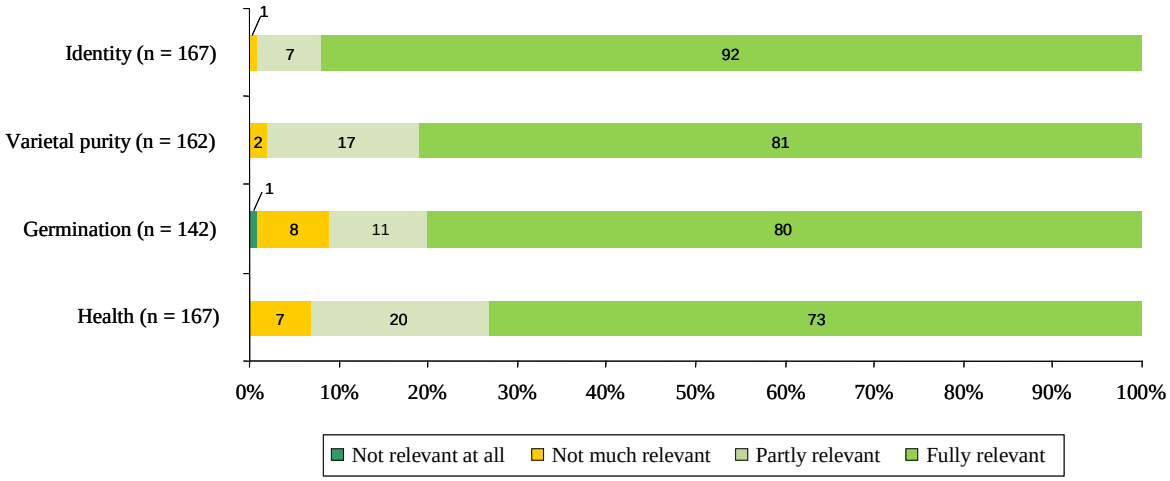
7.2.3. Utility

Overall, results from the survey and the interviews indicate that the certification system is useful as it establishes confidence in the supply chain. In particular, the certification of seed potatoes is considered as one of the best tools for the potato industry to get a production of quality and to mitigate the risk of contamination of production fields with harmful organisms and therefore to safegard the future of the production tools.

As regards the standards, the large majority of respondents consider that they are fully relevant (Q 3.1.3.). They believe that they should not be increased (Q 3.2.1., 72% of 120 respondents not in favour of increasing the standards) or decreased in the future (Q 3.2.1., 81% of 120 respondents not in favour of decreasing them).

A few stakeholders have suggested to consider in the future the possibilities of 1) dropping the standards that are not required in view of international compatibility; 2) restricting standards to health and identity, which are the most important ones; 3) restricting standards to the definition of maximum tolerances for negative characteristics; 4) decreasing the number of standards for less economically important species.

Graph 32 – Relevance of quality standards



Results relating to PM are less positive, in particular as regards the Health requirements which are considered as 'partly' relevant by 34% of PM respondents and 'fully' relevant by 57% of them (n=34).

To explain it, some respondents have mentioned again the lack of detailed EU requirements on the inspection/testing of certified fruit PM as well as the need to revise the health standard for fruit PM to better reflect the current plant health status. As regards vine PM, they consider that standards on the identity and varietal purity are very general but requirements on plant health and grading (as a quality characteristic) are quite clear.

Several respondents (from national authorities and from professional associations) have provided additional suggestions (Q 3.1.3. and 3.2.1.) as regards the standards for Seed and FRM in the future as follows:

Table 23 – Suggestions for future standards for Seed and FRM

Group of species	Standard	Suggestions
FRM	Overall	- Redefine or clarify some definitions like autochtonous, indigenous, origin etc.
	Health	- Establish more provisions.
	Varietal purity	- Reconsider the relevance of the % of different species allowed in the forest seed lot by taking into account that several natural hybrids exist, for example in oak species, which could be accepted or could even be considered as beneficial for planting in certain end-sites; - In particular, variety purity is a problem for *Qercus spp*., especially *Quercus robur* and *Quercus petraea*.
	Germination	- Specify the length of time seed germination reports for forestry seeds are valid
Seed	Overall	- Better harmonize the standards between MS; - Revise terms of 'lowest possible level' and 'sufficient quality'.
	Identity	- More specifically define the term 'Identity'.
	Health	- Establish consistency between plant health standards and marketing Directives. Currently there is a lack of quality standards for important seed-borne pathogens. For instance, non rules for *Claviceps purpurea* in fodder seed Directive, no rules for Powdery scab; - As regards seed potatoes, most of the standards concerning viruses and black leg in Annexe I of Directive 2002/56/EC are too low to avoid the extension of those parasites in the areas of production: For example, the standard of 4 % of plants presenting symptoms of severe and mild virus in the direct progeny of Basic seeds. Most of the EU countries have introduced stricter standards in their own certification regulation concerning those two parasites, which give less credibility to the EU Directive.
	Health standards for potatoes seed	- Establish an effective mechanism for reviewing and proposing amendments or additions to quality standards, particularly those of current UNECE Standard, with particular emphasis on the removal of the maximum variation in size band, marketing of Pre-basic seed potatoes and inclusion of tolerance for black scurf. Such a mechanism should be more responsive to the needs of a changing seed potato industry; - Consider the possibility of removing the Standards for Tuber defects and rules for tuber size which have no direct link with the quality. The same applies to e.g. scab standards which are a cosmetic rather than quality determining aspect.
	Varietal purity	- More clearly define varietal purity for allogamous crops; - Review varietal purity for tritical, which is not sufficient; - Increase the purity % for weat and barley.
	Germination	- Consider the possibility of removing official levels for germination in the (EU) legislation and replace them by 'true labelling', i.e. the seed suppliers must inform the users about the germination capacity of the seed according to a defined standardized methodology on the label; - Introduce a simple and effective method for reducing the minimum germination requirements when necessary in order to reduce the administrative burden of the current derogation arrangements; - Revise germination standards to set basic minimum for each crop species and make it mandatory to quote the actual germination level as tested by an official seed testing laboratory; - The high level of the germination norm (92%) for flaxseed is a key point for the producer and must be maintained. It is a major condition for the success of the crop; - Lower the germination standard for Sorghum; - Increase germination levels for professional use of vegetable seed; - Increase the germination level for wheat and barley; - Adapt the norm of durum wheat germination to agro climatic production conditions; - Revise the germination standard for maize seed (higher requirement).
	Weed	- Review some standards for weed seeds (e.g. remove not dangerous weeds) to make them more relevant to current conditions.
	Moisture	- Consider the possibility of removing the official EU provisions for seed moisture standard which seems difficult to harmonize and changing with time (time or climate).

As regards standards for plant health, several stakeholders consider that the principal provisions of the plant health Directive (2000/29/EC) to prevent the spread of pests and disease are undermined by the usage of Farm Saved Seed (in particular as regards seed potatoes).

In addition, as presented above at section 6.2. on consistency, several stakeholders have indicated the need to include standard on GMO adventitious presence.

One stakeholder insists on the need to revise the quality standard (in particular purity standard) by taking into consideration that some necessary phytosanitary active substances will be removed from Annex I of Council Directive 91/414/EC concerning the placing of plant protection products on the market leading to the fact that commercial products could not be re-registered for seed production in the future.

This analysis leads to the conclusions that the certification system is seen as a useful tool in ensuring S&PM of quality. However, it has to be noticed that in several crops e.g. winter wheat or potatoes, producing seed of quality has been achieved (at least the first generation) without official controls.

7.2.4. Coherence with OECD and UN-ECE standards

The primary purpose of the OECD Seed Schemes is to encourage the use of *"seed of consistency high quality in participating countries"* through *"the use of labels and certificates for seed produced and processed in international rules according to agreed principles"* In practice, the objective is to certify that seed lots produced under the Schemes are *"true to variety type*", based on the implementation of the production process.

OECD seed certification is applied to the following seven groups of species: grasses and legumes, crucifers and other oil and fibre species, cereals, beet, subterranean clover and similar species, maize and sorghum, and vegetables. Roots and tuber crops, fruit trees and flowers are not part of the OECD Schemes. Each seed scheme includes rules and directions aimed at the varietal certification of seed, except for the Vegetable seed scheme where generally traded seed, *"standard seed"* is not certified. Officials of participating countries (national authorities in charge of seed certification agencies) apply the OECD certification. OECD has defined standards for seeds but with no minimum standards, as in EU legislation, with the exception of beets.

Seed potatoes international standards are being managed by UN-ECE which principles are quite similar to the OECD ones.

According to survey results, the majority of respondents (56%, Q 3.1.7, n=110) consider that the EC standards are fully coherent with the OECD standards. The remaining ones (44%) consider that they are partly coherent. Overall, it seems that EU has minimum standards for specific purity and germination capacity, whereas OECD rules do not, except for sugar beet and fodder beet seed. Otherwise, the EU and OECD Rules are comparable.

Regarding the OECD standards for forest reproductive material, coherence has been searched for during the recasting of the Council Directive in 1999, as a follow-up to the renewal of the OECD scheme in the mid 1990s.

66% of respondents (Q 3.1.8., n=68) consider that EC standards are partly coherent with UN-ECE standards, and 31% of respondents consider that they are fully coherent. The UN-ECE Standards are an evolving framework, which deals with significantly more provisions and tolerances than are currently covered by the EC Directive, which has not really changed since its adoption from the UN-ECE Standard in 1963. For instance, contrarily to EC standards, UN-ECE standards include seed potatoes of the category 'Pre-Basic' seed and they cover slightly more quality aspects such as *Rhizoctonia.* It has been mentioned by several interviewees that UN-ECE rules are much more in line with the different national provisions and standards for international trade than the EC provisions.

Most of interviewees consider that further alignment of Community legislation to UN-ECE standards should be sought.

7.2.5. Effectiveness in achieving the objectives of certification

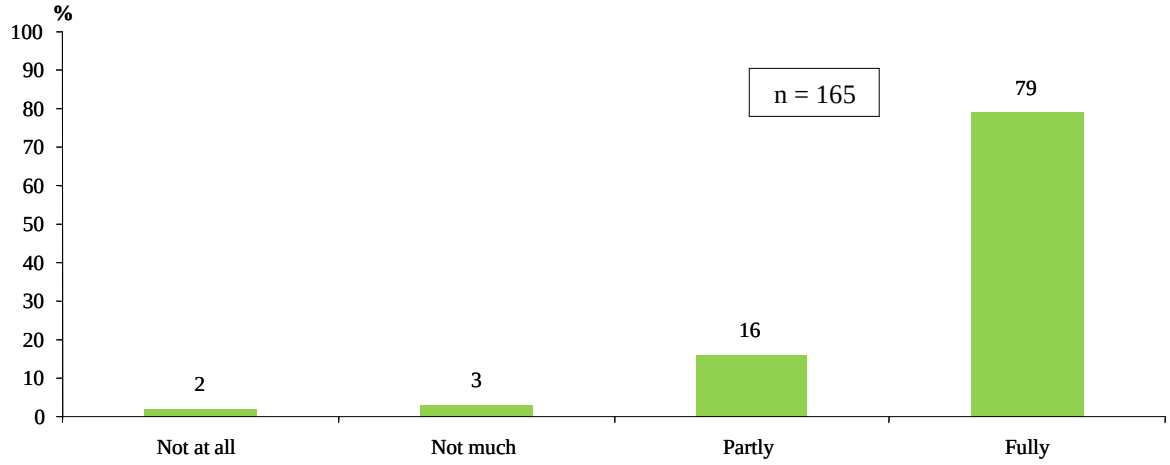
This section evaluates the effectiveness of the Community certification provisions in facilitating the free marketing of S&PM as well as in ensuring S&PM lots of sufficient quality.

79% of respondents to the qualitative survey (Q 3.1.2, n=165) consider that the Community provisions for the certification of S&PM have fully contributed to the free marketing of S&PM in the EU.

To explain the possible shortcomings, some stakeholders have commented as follows:

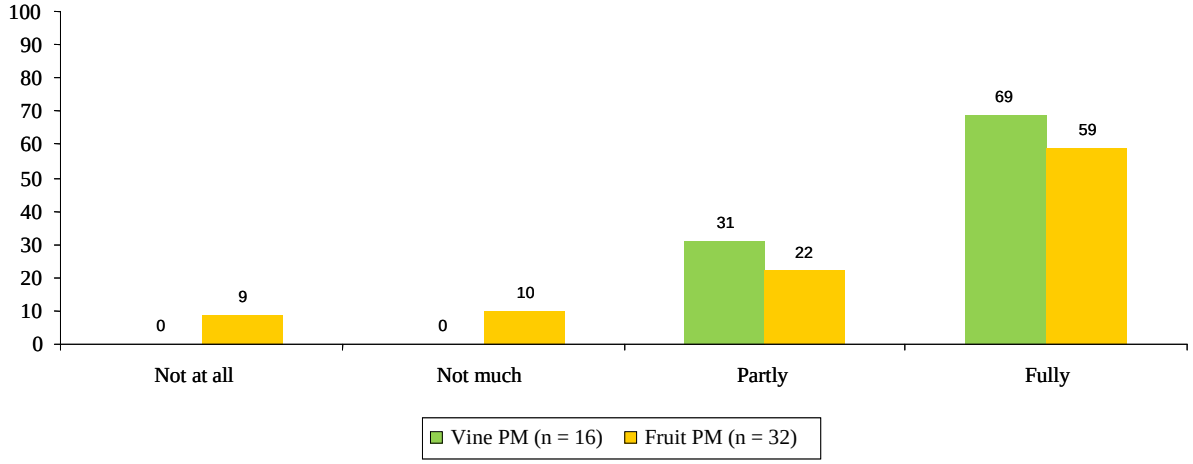
- The lack of harmonisation of implementing rules could have hindered the free marketing and the development of fraud and illegal import of seed. In particular as regards the marketing of FRM, the lack of harmonisation between the supplier document of the different MS. Forestry specialists indicated that S&PM forestry business collapsed completely in Germany, and mainly due to the illegal import of illegal seed from 3rd countries;
- The lack of legislation in the areas of grass seed mixtures (has been solved but with delay), thresholds for adventitious presence of GMOs and conservation varieties has made free marketing of these kinds of seeds difficult or impossible;
- Mandatory certification is a procedure too heavy and costly for most niche markets and therefore prevents their marketing and free trade.

Graph 33 – Effectiveness of the Community provisions for certification in facilitating the free marketing



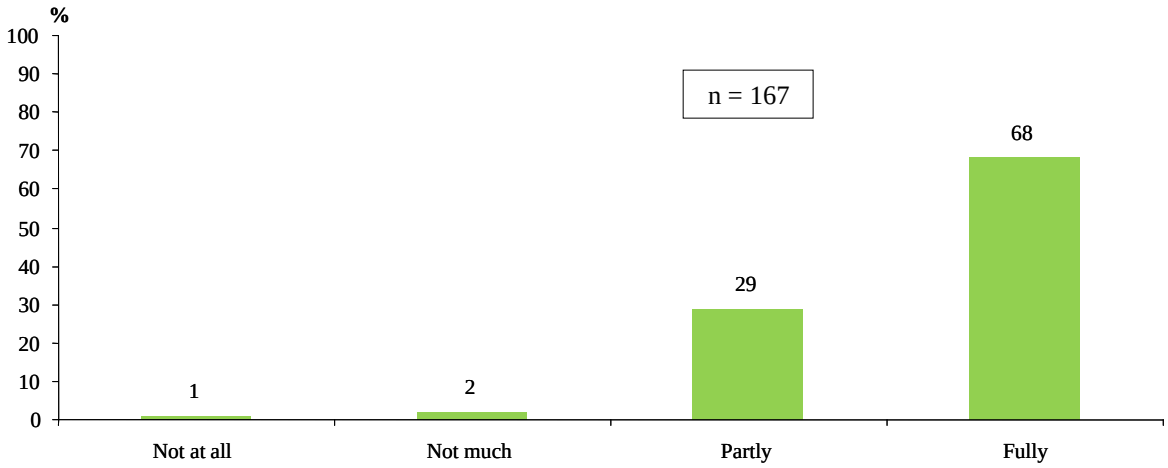
Less positive results appear when isolating the responses provided by people responding for the group PM, mainly because of insufficient Community provisions for the certification of fruit PM, whose certification system is mainly based on national schemes. The lack of readily available information on the national schemes and the difficulties in establishing equivalence between them has hindered the free movement of fruit certified material in the EU.

Graph 34 – Effectiveness of the Community certification provisions for vine and fruit PM in facilitating the free marketing



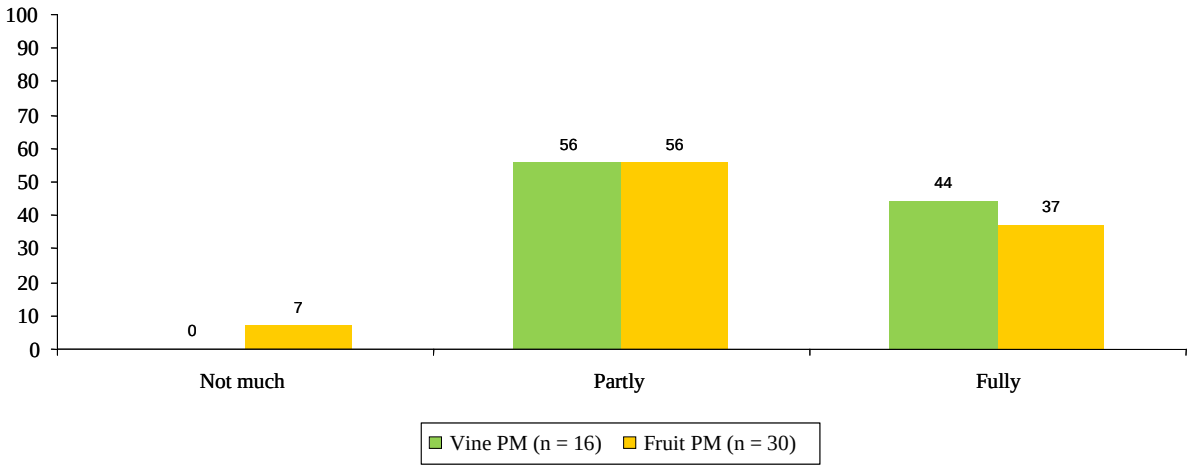
Survey results (Q 3.1.1., n=167) also indicate that the majority of respondents consider that the Community provisions for certification have been fully effective in ensuring S&PM lots of sufficient quality.

Graph 35 – Effectiveness of the Community certification provisions in ensuring S&PM lots of sufficient quality



Here again, less positive results appear when isolating the responses provided by people responding for vine and fruit PM, as follows:

Graph 36 – Effectiveness of the Community certification provisions for vine and fruit PM in ensuring S&PM lots of sufficient quality



The repondents'comments on a possible lack of effectiveness in ensuring quality have been as follows:

Overall

- Due to a lack of harmonisation in the implementation of the rules and due to different organisational structures the quality of the certification and S&PM can vary significantly;
- Industries own improvements have also played a significant role in ensuring quality. The market often demands seed that is 'cleaner' than the minimum standards for certified seed;
- Not all quality criteria relevant for farming are covered by the Community provisions;
- Quality requirements for seed-borne diseases are not included in Directives;
- Variability of requirements concerning the marketing and labelling of 'small packages'. The provisions in Council Directive 66/401/EEC for the marketing of fodder seeds are perceived as very complicated and therefore impede the marketing of these small packages (Art. 2F). In addition to their complexity, the respective rules for the marketing of small packages partly allow individual variations in the different member states. Harmonisation is required in this area.

Potatoes

- Legislation needs to 'catch up' with the requirements of the market place. Standards included in the seed potatoes Directive are adjusted with the lower standards from the MS which means that the quality isn't at the optimum level.

Cereals

- The problem is that wild oat zero tolerance is not applied in all EU MS. The control of wild oat is a matter of public concern only in a limited number of MS.

Fruit and vine PM

- The Directives not always cover all the phytosanitary problems due to the differences between member states;
- The certification system for fruit PM mainly depends on the national scheme developed at national level, which is based on the fundaments of the EU categories (CAC or Certified PM);
- It would be appropriate to specify in the Fruit Directive requirements in respect of root system, length of cuttings;
- For strawberries, Community certification provisions were fully relevant to ensure quality in the past, but nowadays the effect is little since the quality of propagation material of strawberries depends on the

requirements of the market. For producers of propagation material of soft fruits (burrs, berries and raspberries), Council Directive 92/34/EC is much more important because this market is still in a starting phase and requires a high qualified plant propagation. This is safeguarded by the requirements in the Directive.

Forestry RM

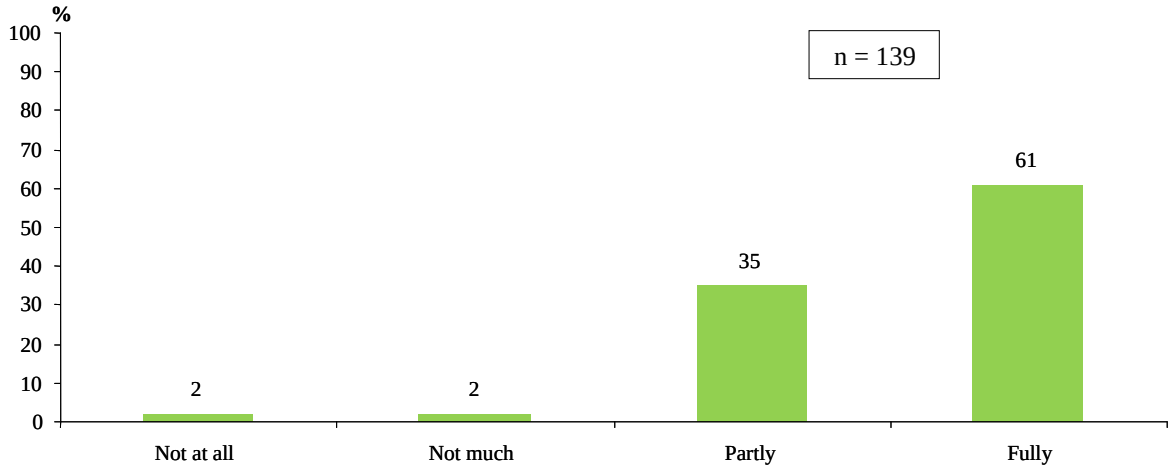
- The number of trees to be used for the production of FRM is not specified; neither are strategies for treatment and storage of seeds.

The FCEC team considers that these specific comments, which were sporadically formulated by experts, would be considered as matter to define some improvement items for Better Regulation.

7.2.6. Efficiency in achieving the objectives

96% of respondents to the qualitative survey (Q 3.1.4., n=139) consider that the costs involved in fulfilling the obligations imposed by the Community provisions for certification are at least partly reasonable and proportionate.

Graph 37 – Extent to which the certification costs are reasonable and proportionate



When considering the responses provided by the associations of suppliers only (n=51), results are less positive with 47% of them considering that certification costs are partly reasonable and proportionate and 49% of them considering that they are fully reasonable and proportionate.

The comments of this group of stakeholders are as follows:

- The seed certification could be made more efficient and thus more cost effective. Indeed, it seems appropriate that an increased transfer of financial responsibility from public authorities to private companies generally is linked to a corresponding increase of industry input to the efficient and cost-effective organisation and management of the system as such. Contrarily, one UK association having investigated other approaches to verifying seed quality, including the use of in-house verification and independent audit, believes that the certification process is generally cost effective with only minor improvements possible;
- Quality control by licensed seed producers is a matter of commercial liability and the costs are incurred in response to a seed seller's commercial risk management. Frequently, 'official' measures duplicate internal quality control procedures and add cost;
- There is a lot of redundancy in germination tests.

In particular, as regards the certification of fruit plant, one respondent indicates that any move towards greater equivalence (e.g. through a prescriptive Community scheme) should include arrangements to ensure that charges are applied on an equal basis, based on a EU legal framework.

In their consultation document of December 2006[44], the DEFRA also argues that the current legislation imposes a disproportionately high burden for minor species relative to the Community benefit.

As indicated by several stakeholders, the same statement could be made for niche varieties, for which mandatory certification is a procedure too heavy and costly.

Considering the distribution of certification costs between the public authorities and the industry, respectively 29% and 64% of respondents (Q 3.1.5., n=136) consider that it is partly or fully appropriate.

As highlighted by several stakeholders, the issue is mainly that the fact that some MS have a full cost-recovery system and others have official subsidized within the certification system creates unequal balance in the EU. Also, as commented by several actors, there is a current and unresolved debate about the extent to which certification schemes contribute to the 'public good' and should thus receive a proportion of public money.

As quality is, mainly, achieved in most of species covered by the Community legislation, efforts to improve the systems have been put on costs reduction during the last 10 years leading to significant costs reduction in most important crops. Most decisions on improving the certification system are based on this driver.

7.2.7. Quality of seed lots imported under the equivalence regime with 3rd countries

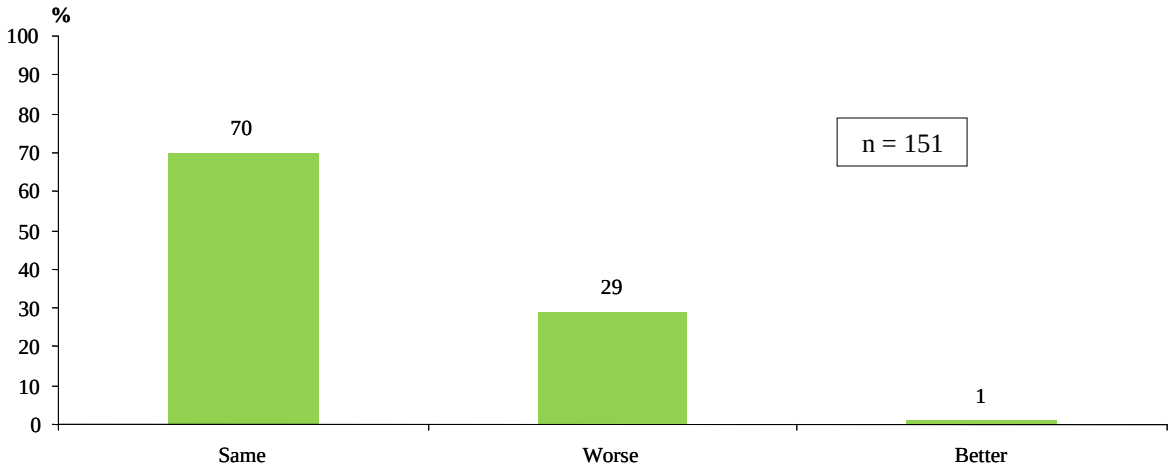
Council Regulation 2003/17/EC lays down the rules on the equivalence of field inspections carried out in third countries on seed-producing crops and on the equivalence of seed produced in third countries.

The marketing Directives foresee that S&PM lots imported under the equivalence regime have to satisfy the same legislative requirements than those produced in the EU and marketed in line with the marketing Directives.

Because vegetable seed is almost exclusively produced as standard seed, the equivalence regime has little relevance for the vegetable seed sector.

The survey results indicate that 70% of respondents (Q 1.1.8., n=151) consider that the rules on equivalence offer the same guarantee.

Graph 38 – Extent to which the S&PM lots imported under the equivalence regime offer the same guarantee as the S&PM produced in the EU



Respondents' overall comment is that the rules on equivalence ensure equal quality for imported seed lots on the condition that they are correctly implemented and enforced. Appropriate control of imports at

[44] DEFRA, Consultation on possibilities for Better Regulation in Plant Varieties, Seeds and Seed Potatoes, December 2006

boarder is crucial to check the correct implementation and enforcement. In addition, EU comparative trials could be useful to that aim. If, as mentioned by some respondents, the market did not indicate significant problems with the equivalence system, no definitive statement can be formulated, as it seems that no objective data exist on the subject.

Several respondents made other particular comments as follows:

- Continuous problems exist as regards the import of seed of unlisted varieties or of misdeclared product (e.g. EU import of bird feed and reselling as seed);
- The EU zero tolerance policy on GMO's could limit the possibility for the EU to import seeds;
- It is crucial that seed potatoes imported under this measure at least meet the same requirements as those of seed potatoes produced in the EU. However such imports must be considered in conjunction with requirements of the plant health Directive (2000/29/EC) which prohibits the import of seed potatoes from all countries outside the EC other than Switzerland. The only example for such imports is the derogation under Commission Decision 2005/850/EC which permits the import of Canadian seed potatoes to certain Southern Member States where the risk of harmful organisms establishing is less.

As regards the fruit PM, the proposal for the revised fruit Directive mentions that:

'*the existing conditions do not facilitate the adoption of clear and easily applicable rules for equivalence with third countries. At the moment, importation is subjected to temporary derogations, which do not satisfy both MS authorities and traders. In fact, some rules which refer to propagating material and the accreditation of suppliers create unnecessary obligations and do not give sufficient guarantees for the quality of material (e.g. identity of variety and health status)*'

and suggests '*A transparent certification system and a clear identification of the variety (complete and transparent labelling), which will improve the competitiveness and facilitate intra-Community trade and import based on equivalence and possible reciprocity'*.

7.2.8. Utility of the comparative tests and trials

All marketing Directives (with the exception of Directive 1999/105/EC on the marketing of forest reproductive material) stipulate that Community comparative tests and trials shall be carried out within the Community for the post-control of samples of S&PM placed on the market, whether mandatory or discretionary, including those relating to plant health. These comparative tests and trials shall be used to harmonise the technical methods of certification and to check satisfaction of the conditions with which the S&PM must comply.

Other aims of the trials are:

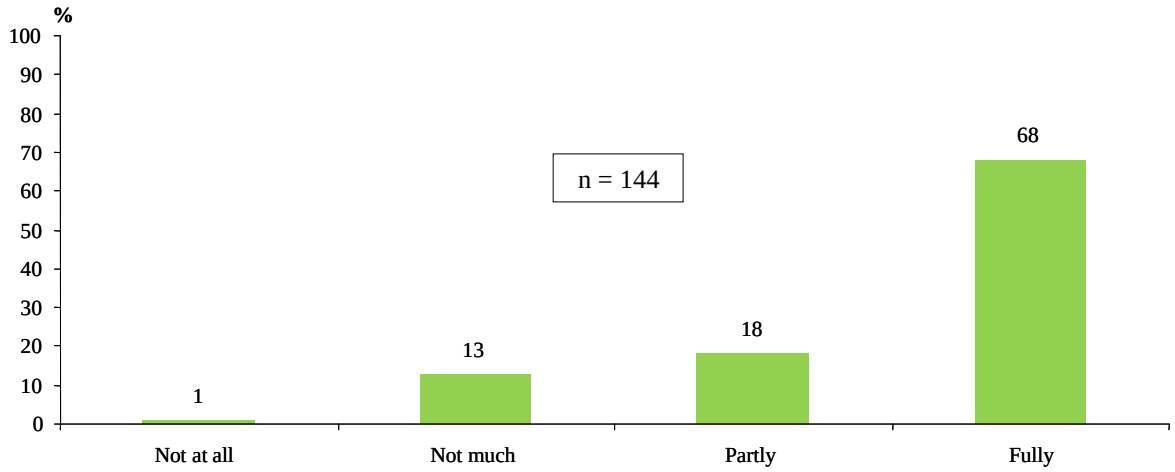
- Where appropriate to monitor the action taken by the Member States relating to samples that failed to meet the standards in the previous trial;
- To monitor whether changes in seed quality result from measures taken under official supervision;
- To develop in a harmonised way an understanding of the requirement that the seed shall have adequate identity and purity with regard of variety, together with the development of appropriate standards for the acceptance and rejection of seed lots.

Currently, comparative tests and trials are no more carried out by DG SANCO (mainly for reasons of scarcity of human resources and time-consuming procedures).

However, as indicated by the survey results, **majority of respondents (68%) consider them as fully appropriate for ensuring harmonisation of inspection practices (Q 3.1.9., n=144).**

They enable inspection services to get knowledge of the practices in other MS and by this they contribute to better quality of the work and to more harmonization of inspection practices.

Graph 39 – Appropriateness of the Community comparative tests and trials to ensure harmonisation of inspection practices.



Some respondents have mentioned that, in the past, there has not been enough feedback to policy makers[45] from comparative trials visits, therefore corrective measures have often not been implemented if obvious problems have occurred. A few respondents have also indicated that the compared samples are too small and too few to give narrow information on seed quality and inspection practices.

Most of respondents consider that comparative tests and trials are an important tool and should be fully re-established in the future. Some of them also make suggestions for improvement, as follows:

- Community trials could move to more methodological trials with the aim of European harmonization;
- To reach the same objective, other tools also could be suitable e.g. organisation of meetings in member states for inspectors with discussions on special items and visits to trials and breeding companies or growers;
- Material for the trials should be randomly collected by independent authorities;
- The tool should be made more efficient (e.g. the size and the number of samples) and results should be better exploited. In case of non-conformity, the member states should be obliged to implement corrective measures, e.g. through a system of penalties/sanctions[46];
- More communication should be done to policy-makers and the public in general;
- They are helpful but very expensive and need to be tightly focussed on specific issues.

Finally, some stakeholders of the forest sector regret not to have comparative tests and trials and believe it would be highly valuable to organize such tests in forestry.

[45] despite the fact that all reports on comparative trials are presented to and adopted by the Standing Committees

[46] Corrective measures (i.e. prohibition of the marketing of seed potatoes in whole or part of the Community) are foreseen in the Directive for the marketing of seed potatoes

7.2.9. Preliminary conclusions and recommendations

Overall, results of the survey indicate that ¾ of respondents are in favour of maintaining both the certification standards and the certification structure.

Such proportion is close to 100% when focusing on the 16 respondents having answered for FRM only. As explained by one of them, Directive 1999/105/EC is today a model in the world and could be extended to some other forest species in the future. In its opinion, it creates excellent conditions for successful afforestation, productive and well-adapted European forests. Forestry is also a very long-term investment and plantations cost a lot, so that only the right adapted material must be used. It is not suitable to let private seed companies and nurseries certify and sell FRM without any public control.

If they are in favour of maintaining the certification system, majority of respondents believe that some suggestions are worth further analysis and discussion in the future.

The table below summarises stakeholders' opinion for the suggestions most supported in the survey questionnaire (Q 3.2.1.).

Table 24 – Summary matrix – Certification

Identified problem/threat	Stakeholders concerned	Recommendations to address them	Advantages	Disadvantages	Feasibility and acceptance by stakeholder
Field inspection under official supervision is applicable to certified seed only (more a fact than a problem)	National authorities and suppliers	Extend the field inspection 'under official supervision' to pre-basic and basic crops	- Contribute to simplify the certification system; - More efficient and thus more cost effective; - More rapid decision-making system; - Increased responsibility for the supplier; - Would introduce flexibility; - Take advantage of the complementarities between the industry quality process and the official supervision.	- Possible negative effects for the multiplication of Basic seed in subsequent generations.	*Feasibility:* For seed potatoes there is at present no provision at all for field inspection under official supervision. *Acceptance:* Survey results: 64% in favour, 36% not in favour, n= 121 respondents It's most important to check the seeds which are to be sold to farmers. High quality of the seeds in the parental generation is in the companies' own interest.
5% of seed lots are checked for correct implementation of measures as regards field inspection, and seed testing	National authorities and suppliers	In the case of certification 'under official supervision', leave the level of check inspection, check sampling and check testing to MS' discretion, based on their own assessments of the risk to seed quality	- More compatible with a proportionate and risk-based approach to inspection; - Simplified certification system; - Simplified marketing of less economically important species; - Would provide a flexible system well adapted to the system in every MS;	- Would create a lack of harmonisation. It is important to have as similar regulations and quality requirements as possible in different MS.	*Acceptance:* Survey results: 50% in favour, 50% not in favour, n= 111 respondents As commented by several associations of suppliers: Potato seed companies have a preference to leave the level of check testing, inspection and sampling to MS discretion based on their own risk assessment. Seed companies active in breeding of cereals (including maize) and pulses, forage plants and grasses are not in favour of such an approach.
		In the case of certification 'under official supervision', target inspection level based on risk (taking into consideration the higher voluntary standards in place, industry inspections, track records, etc.)	- Increased flexibility for national authorities on how to organise the seed control and certification; - More effective inspections; - Higher probability to identify deviations in the systems;	- Would create a lack of harmonisation.	*Feasibility:* Requirements to set-up relevant and recognized indicators *Acceptance:* Survey results: 60% in favour, 40% not in favour, n= 111 respondents

Separate inspection for the purpose of certification and for the purpose of plant health	National authorities and suppliers	Integrate the inspection regimes for certification and for plant health	- More harmonised plant health system; - Would create more clear rules which will facilitate trade in the internal market and worldwide; - Decreased costs, staff resources and administrative burden through better organisation; - Would consist in a more streamlined and focused approach with industry and official concerns melded into a unified approach that better meets the needs of growers and the food industry; - Would simplify and introduce more consistency in the regulation implementation.	- Reorganising requirements and possible social consequences	*Feasibility:* - FRM: Plant health inspection is done in nurseries on seedlings; source quality inspection of FRM is done at collection in basic material and later compared to the identity of seed lots. Only the identity of the seedlings in the nurseries can and should be done by the same persons as plant health inspection, when seedlings have already been planted in well-marked nursery beds/rows; also, the forms could include both indications, on health inspection and origin of the material/certificate id. - Already in place in NL, and in DK for seed potatoes as examples. *Acceptance:* Survey results: 84% in favour, 16% not in favour, n= 150 respondents Less positive results when considering the 12 responses for FRM (50% in favour, 50% not in favour).
Reduced role of the industry in the certification process	National authorities and suppliers	Set up a certification with a system of an accredited third party private body approved by the MS	- Maintain the independence of the certification body; - Give more flexibility to companies; - Allow better adaptation to user's needs.	- Risk that no third party will be sufficiently independent to stay neutral in the seed market.	*Feasibility:* - It is necessary to have only one accredited third party per MS (no possibilities for seeds companies to choose) - Necessary to revise the part of Community legislation related to requirements for the laboratories. It must be possible to make use of ISTA or a national accreditation board to accreditate private laboratories, even when a private company owns the laboratory in question. In other areas like foodstuffs, such possibility exists and it works well. The laboratory capacities in EU have to be used in a more cost-effective way. This is especially important for small MS. *Acceptance:* Survey results: 51% in favour, 49% not in favour, n= 136 respondents. As commented by some associations of suppliers of seed potatoes, certification of seed potato is mainly a phytosanitary certification, concerning both quarantine and quality parasites and can't be delegated to private sector.

As regards the inspection 'under official supervision', another suggestion of the questionnaire has consisted in revising the minimum 5% check testing, check inspection and check sampling. This suggestion was not supported by 65% of the respondents (n=109) mainly because of the expected negative on the users if the minimum check will be less than 5%. However, several respondents have considered that such suggestion could have a positive effect on the simplification of marketing of less economically important species.

Respondents' opinion on the need to revise the standards in the future is presented at section 7.2.3. above on Utility.

As regards the number of species to be covered by the seed marketing Directives, no clear statement can be formulated based on the survey results, mainly because it depends on the own economic interest of each member country. Based on the examination of respondents' comments, the arguments in favour of increasing or decreasing the number of species are as follows:

Decrease the number of species covered by the seed marketing Directives

Species of minor economic importance or for which certification adds no additional value to the seed lots should be removed from the Directives. Indeed, the current legislation imposes a disproportionately high burden for those minor species relative to the Community benefit.

For instance, some respondents have indicated that:

- Some grasses species could be removed from Directive 66/401/EEC;
- The species and varieties of vine PM intended to cultures of amateur (not professional) could be put out of the Directive 68/193/EEC;
- Seed stands of species of FRM which have an ornamental aim or which are used for fruit growing should not be marketed under the forestry regulations (e.g. certain stands of *Prunus avium*);
- Subspecies with special end use/processing for niche markets (e.g. waxy barley, waxy wheat, special ingredients) could be taken from the list of Directive 66/402/EEC.

In addition, subspecies with special end use/processing for organic farming or adapted to local conditions could be taken from the current list and put on another list with lighter rules.

Increase the number of species covered by the Seed Marketing Directives

The list of species currently covered by each Directive could be review to include all species of which seed is commercially traded.

Such increase in species will have positive effects on the seed internal market, through the regulation of the marketing of new species with potential economic interest. It will however lead to more administrative burden and more certification costs.

For instance, some respondents have indicated that

- Specific Directives could include *Nicotiana tabacum* (Tobacco), *Cicer arietinum, Lens culinaris* (lentils), buckwheat and *Cucurbita pepo* (oil pumkin) *Melilotus alba,* more species of lupins and new oilseed crops, *Galega sp., Phalaris arundinacea, Camelina sp., Panicum miliaceum,* subterranean clover;
- Directive 66/402/EEC could include *Fagopyrum esculentum L.;*
- Directive 1999/105/EC could include *Abies borisii regis, Fraxinus ornus, Cupressus sempervirens, Platanus orientalis.*

In particular, one respondent from a NMS has mentioned that *Elytrigia elongata, Fagopyron esculentum, Panicum miliaceum, Coronilla varia, Bromus inermis, Festuca heterophylla* could be added to the list of Directive 66/401/EEC, as they have been certified in dramatically reduced number in this NMS since EU accession.

Finally, several suggestions of the qualitative questionnaire have consisted in reducing the scope of official certification or removing it. Overall, the rational behind them was that nowadays seed is produced under use

of quality assurance schemes so that the role of official authorities could be reduced or shifted to the producers. Those suggestions were not supported by the respondents. The suggestions in question as well as the reasons of no support are presented below.

Suggestion: Apply controls/certification standards to final generation S&PM only and leave companies to decide how to manage parental generation S&PM production to meet the quality standards of final generation certified lots of the category under which the S&PM is marketed – 79% of respondents not in favour, n=134

Respondents did not support such suggestion for the following reasons:

- It would increase costs for the industry;
- Certified seeds will not meet requirements, when pre-basic and basic material is not correctly identified;
- All the generations must be under official control, otherwise there could be a break in the quality process and marketing of one specie or one variety;
- Control the whole seed growing process is important in order to guarantee varietal identity; which will be one of the most important contributions to certification in the near future.

Suggestion: Apply controls/certification to parental generations only and leave companies to decide how to manage commercial S&PM production to meet the quality standards of final generation certified lots of the category under which the S&PM is marketed – 92% of respondents not in favour, n=134

Respondents did not support such suggestion for the following reasons:

- All the generations must be under official control, otherwise there could be a break in the quality process and marketing of one specie or one variety;
- A minimum of guarantee is needed for the certified product;
- Risk of non-conformity for variety identity and purity.

Suggestion: Set up a certification with a system of S&PM company accreditation – 64% of respondents not in favour, n=145

Respondents did not support such suggestion for the following reasons:

- Some small or medium sized companies would not have the capacity to implement accreditation systems;
- Some private operators to be more competitive could be tempted occasionally not to implement some regulations, making carrying risks to the whole industry and, when relevant, to the phytosanitary status of the environment;
- This suggestion, as well as any other suggestion consisting in reducing the impact of certification or its suppression, would lead to the suppression of the official certificate of quality guarantee required by the users for a means of production which is essential to the performance of their enterprise.

Some stakeholders have associated positive effects to this suggestion, in particular an increased flexibility on how to organise the seed control and certification possibly leading to reduced costs and an increased company's responsibility.

Suggestion: Limit the official certification scheme to a basic level defined in the legislation and have extra quality requirements left up to private companies – 83% of respondents not in favour, n=71

Respondents did not support such suggestion mainly because it doesn't guarantee the production of seed of sufficient quality in the Member States and in the EU in general and leads to a lack of transparency on the quality of the seed for the seed traders and their clients.

In particular regarding seed potatoes, the general fear is that if the same requirements are not applicable to all the producers, seed potatoes fields of less quality will affect the quality of potatoes grown on neighbouring seed potato fields. Another issues is the fear that seed potatoes of minor quality will be

marketed and that this will undermine in the end the reputation of MS producing potatoes with a good quality 'trademark'.

Suggestion: Set up a voluntary certification scheme to national or international (i.e. OECD) standards – 89% of respondents not in favour, n=141

Overall, respondents expect negative effects on the functioning of the internal market, on plant health and quality level of seed material.

However, some respondents consider that a voluntary seed certification would be best for small quantities, niche markets and direct sales between producers and users and that mandatory certification should be maintained for non direct sales and mass seed sales. In their opinion, such voluntary system would offer the required flexibility for alternative farming practices.

Suggestion: Remove the official certification system and pass on the full producer's liability – 94% of respondents not in favour, n=153

Respondents did not support such suggestion for the following reasons:

- There is a risk of reduction in quality standards (and of increase in quality diseases), which could lead to a loss of credibility among the retail and farming sectors and a decreasing use of certified seed;
- Giving all controls to the companies would reduce confidence of farmers/buyers in the seed quality and will create more difficulties for trade within the EU. Remove the official certification system would increase regulations on national level and would lead to barriers for international seed trades because of lack in harmonization;
- Producers' costs are expected to increase, which couldn't be assumed by small companies;
- The users will not be well informed about the quality of the seed.

7.2.10. Results of the in-depth studies *"Analysis for one crop of the extension of the certification activities carried out under official supervision"; "Analysis of the possible advantages of a private third party body set-up for supervision"*

Analysis for one crop of the extension of the certification activities carried out under official supervision

Several modifications have been brought to the initial texts of the Directives to strengthen the principle of responsibility of the companies and to limit inspections to a monitoring regime.

For example, Council Directive 98/96/EC lays down rules on certification procedures for field inspections under official supervision. A detailed evaluation of these procedures (Commission Decision 89/540/EC introducing a temporary experiment) has shown that the field inspections under official supervision should be extended to all crops for the production of certified seed. The evaluation has shown that the proportion of the areas entered for official certification to be checked and inspected by official inspectors could be reduced whilst still ensuring seed quality.

Council Directive 2004/117/EC amends basic seeds Directives as regards examinations carried out under official supervision based on positive results of a Community level temporary experiment (Commission Decision 98/320/EC) which aims at assessing whether seed sampling and seed testing under official supervision may constitute improved alternatives to the procedures of official examination, without a significant decline in the quality of the seed.

This role of the operator has thus been gradually cleared in the Community legislation for the production of certified seeds under official supervision, i.e. in charge of the company whose technicians are accreditated by the designated authority that monitors by official sampling at least 5% of crops or lots.

Despite these legislative adjustments, most of MS have kept certification under official examination as the main pillar of the their national certification scheme as presented in table 21 above.

Furthermore, it seems that mainly France and the UK have largely implemented a system of certification under official supervision. This implementation has occurred during a long period of time, and on a step-by-step and crop-by-crop basis. It has to be mentioned that for seed potatoes certification under official supervision is not yet allowed. Both MS uses the provisions for activities under official supervision to almost the full extent currently allowed by the Community legislation.

In MS where certification under official supervision has been implemented, this evolution is being perceived as largely positive in all respects, and especially in the reduction of costs and by adding flexibility to the systems.

The interviews carried out for this in-depth case study have not permitted to present a deep costs assessment, mainly due to the fact that the moves to official supervision have occurred over a long period of time. Furthermore the level of cost saving will vary significantly from company from company. However, costs savings have been observed and are presented below.

Main advantages of moving to a certification scheme under official supervision:

- Flexibility as regards planning and logistic for seed producers and seed companies, as they do not have to rely on inspectors checks to organise their day-to-day activity, and by having control procedures being undertaken at the most appropriate time rather than being delayed awaiting official personnel;
- Faster results for private operators that have not to wait for official results;
- Reduction of overlapping activities between quality system set up by the industry and official controls (e.g. in field inspection and seed testing), leading to costs reduction;
- Official supervision assures that seed meets the legal requirements;
- As the field examination has been taken over by seed companies, the costs have been removed from the official inspection services;
- Changes have put greater transparency into the system.

Effects on costs:

- Shift of costs from official authorities to private operators for field testing, leading to a significant reduction in the number of required official inspectors;
- For field inspection there may have been a cost reduction, but not for sample analysis nor for sampling;
- New costs for authorities for the training of private inspectors;
- Further costs savings would be achieved if official supervision would be extended to basic and pre-basic crops;
- UK considers that costs saving should be estimated at around 20-25%, but again with large variability across crops.

Additional consequences:

- Creation of public resources about expertise;
- Increased requirements to set-up training activities for the private inspectors;
- Increase of the responsibility of the seed companies.

Analysis of the possible advantages of a private third party body set-up for supervision

Considering the advantages and effects presented above, a limited number of MS considers that it is appropriate to further strengthen the principle of company responsibility for seed marketing by considering that supervision can be undertaken by a private third party body accredited based on standards such as EN 45 011, ISO 65, or ISO 9001:2000.

The accreditation of the certification body according to the mentioned international standards provides a guarantee that it has a quality system and it meets specific requirements in terms of organization and functioning. The accreditation may be granted to a private or public body, that can charge the seed suppliers for its services.

Planning that the monitoring can be done by an accredited private or public body mainly presents a double interest:

- On the one hand, it would lead to further EU harmonisation in the organization of certification bodies within the EU;
- On the other hand, it would enable MS that wish to disengage from public financing of certification: costs could indeed be transferred entirely to the industry, as supervision costs could be charged directly to the operators by the accredited body.

The answers to the qualitative questionnaire and the ones from the specific interviews FCEC has had on this matter demonstrate that this concept is not yet well understood within the EU. Even within the MS where the idea is promoted, it seems that not all crop sectors have fully understood the approach.

The main remarks collected are as follow:

- Accreditation is an extra activity to the system of certification under official supervision and will lead to extra costs for implementation and auditing;
- When looking at other agricultural sectors, accreditation is being perceived as a complicated system;
- Who should be accredited:
  - A single inspection public or private body appointed by MS competent authorities ? ;
  - Private seed companies as requested by the industry ?;

This approach is quite similar to the EU one for certification of organic products according to which each MS has the choice to decide if controls are made by an official body not accredited or by a public agency or by a private accredited body following agreed standards.

In conclusion, as mentioned previously in the analysis of this option in section 7.2.9, this approach is not known well-enough by operators, even in MS where it is promoted. This point certainly explains the reticence that has been collected during the in-depth studies. This approach has to be considered as an interesting one but should be further analysed to identify benefits and associated costs effects.

7.2.11. Results of the in-depth study "*Analysis of the interest to connect and bring together the seed phytosanitary requirements with the certification legislation for plant health*"

EU trade of S&PM depends, mainly, on marketing Directives, but also on plant health Directive (2000/29/EC) for species where plant health issues frequently occur. For seed potatoes, for example, it is widely commented that seed certification schemes consist mainly of a quality control on quarantine pests and quality diseases. Plant health Directive provides provisions to secure the zero presence of quarantine pests while the marketing Directives covers the 2 types of diseases, as described in section 6.2.3.

Historically, these 2 sets of regulation were managed independently by the MS, for an administrative and operational point of view, with 2 distinct official inspection bodies in each MS.

Plant health is being controlled by national plant protection services which have established national and regional inspection services covering the complete national territory. For plant health, any control is being managed by official services as delegating the inspection is not permitted by the plant health Directive. Inspection for certification purposes are being carried out by official bodies (certification under official examination) or by delegating to private operators who are monitored by officials (certification under official supervision) as described in the section 7.2 on certification purposes.

This structure leads to the fact that there are several inspectors for sometimes the same purposes at the farmer gate. Even if the inspection purposes are not fully similar, the products to be inspected are the same. It also has to be noticed that whereas the S&PM inspectors focus on controlling diseases in the crops field and on the crops products only, plant health inspectors have to inspect the agricultural areas and their crops as well as non-agricultural areas as plant pathogen can be hosted by the same or other related species in non-agricultural areas. In order to secure the zero presence of a given quarantine pest, host species have to be inspected regardless of whether there are in cropping areas or not. This approach of controlling non-agricultural areas is not familiar to S&PM inspectors of certain crops where lots of diseases are present, but in hybrid crops (e.g. maize, sunflower, sugar beet), S&PM inspectors are familiar to control non-agricultural areas (e.g. gardens, etc...) to prevent from any pollen shading from wild species that may pollinate seed production field.

Recent development of agriculture policies and budget reductions at national authorities in certain MS has initiated ideas, in some MS, on the possibility of integrating the plant health and certification inspection offices.

Neither of the 2 EU regulatory frameworks (S&PM and plant health) is a barrier nor a promoter to this approach. Each member state has the opportunity to initiate discussion on integrating these services or not.

Several MS have already achieved this integration (e.g. DK for potatoes, NL) and have been consulted to provide their feedback.

Main advantages to integrate plant health and certification inspection services:

- Costs reduction: 1 inspector for several tasks. *'One stop-one shop'* principle (1 inspection, 1 document, and 1 bill) would reduce administrative burden for seed producers and traders and accelerate the decision making process. The Danish approach has been to group the inspectors under the same legal structure and in the same offices inducing reduction of administrative costs and an optimisation of the inspection visits. In the NL, integration has been achieved on Sept 1, 2007 by moving 90 inspectors from the Plant Protection Service (agency of the Ministry of Agriculture, Nature and Food Quality) to the official inspection bodies for the marketing Directives (Naktuinbouw, NAK and Flowerbulb Inspection Service). These inspection bodies are independent organisations regulated by the Ministry of Agriculture, Nature and Food Quality (LNV). They implement on behalf of the Ministry of LNV the Seeds and Planting Materials Act and European legislation relating to propagation material in the flower, fruit and vegetable sector. Plant Protection Service kept 50 inspectors for tasks related to Directive 2000/29/EC;

- Move to crop quality approach: with 2 separated inspection offices, inspectors are focusing on the control and not on the quality of the end product. By integrating the 2 services, inspectors have to consider the crop as a whole as they have to control several dimensions of the crop and then need to have a complete view on the crop production scheme. The quality inspection is coming from the seed Directives, and the inspectors with a plant health background are profiting from the expertise of the S&PM inspectors (how and when to control imports, better efficiency of visual inspections, seed testing methodology, etc...);

- New pests will be better monitored if integration of the services as inspectors have a crop quality approach, therefore a closer link to producers, and less reluctances to notify appearance of new outbreaks of quarantine pests;

- Integration of S&PM and plant health inspection services to lead to discussion on the quality of the product and inconsistencies between the 2 regulatory frameworks would become more visible and would lead to discussions at EU and MS levels;

- Anticipation of crop production evolutions and adaptation;

- Reinforce traceability from suppliers to farmers, which is not achieved via regulation, especially for latent diseases in potatoes, for example;

- Introduction of more consistency in the regulations implementation.

This approach implies to develop training expertise to secure that all inspectors have an 'optimal' knowledge of the 2 regulations provisions.

When certification is being carried out 'under official examination', integration of services is possible and of the responsibility of the competent authorities. When the certification schemes are 'under official supervision', a difficulty is based on the fact that phytosanitary inspections have to be made by officials only or by supervised body as long as these bodies are 'exclusively' involved in plant health inspection. This point may limit the wishes to move to an integrated system.

The answers to the qualitative questionnaire show that authorities and stakeholders are largely in favour of this integration (Q 3.2.1.: 84% in favour, 16% not in favour, n= 150 respondents) and that the benefits to be anticipated are well known. These statistics should be analysed carefully as it has been noticed, based on interviews, that EU 15MS are much more in favour of this approach than EU 12MS, even if the statistics are not highlighting this segmentation. Additionally, respondents from crops with plant health issues (e.g. potatoes) are not more in favour of this approach than respondents from other crops where less phytosanitary problems occur.

As presented before, it is up to the MS discretion to decide on this integration. The Community legislation is not a barrier to this approach. Having clarified this point, it has to be highlighted that very few initiatives have been taken in this direction. The major reason is based on the social impacts and consequences on restructuring national inspection services.

One way for the Commission to promote this model is to consider integration of the regulatory frameworks at EC level. Both regulations are being managed by the same SANCO unit so that harmonisation and integration should not be too difficult. Additionally, the plant health legislation is planned to be reviewed in 2009; therefore it is the correct time to evaluate the possible integration of the legislative texts at EU level.

This integration of regulatory provisions (certification and plant health) will promote integration of services, and the FCEC team considers that a pre-feasibility should be carried-out prior to the evaluation of the plant health legislation in order to integrate results in that evaluation, if the Commission wishes to go that direction.

7.2.12. Overall conclusions and recommendations

The original aims of certification were the quality insurance and the free trade of S&PM produced in the EU.

Currently, the official certification consists in the control of the S&PM production processes. Statutory certification exists for seed and forestry reproductive material. Vegetable seed and ornamental propagated material are only examined in post control plots, as regards varietal identity and purity. Vine and fruit propagating material can be subject either to a high level of official examination and be sold as 'certified propagating material' or be subject to post control only (as done for vegetable and ornamental propagating material) and be sold as 'standard propagating material'.

1. The seed Directives allow the MS to carry out the field inspection, sampling and seed testing 'under official supervision' instead of 'under official examination'.

Illegal imports and illegal usage of S&PM are perceived as an actual threat to the S&PM sectors. Forestry specialists consider that the S&PM forestry sector collapsed in Germany in the 80's due to illegal seed import and fraud.

Most of interviewees consider that an audit of the implementation of the Community legislation for certification would lead to a more uniform baseline and would add to further harmonisation and improved information between MS.

2. Overall, the certification scheme is perceived by most of stakeholders as an essential tool as it ensures the quality of S&PM. However, it is observed that in several crops e.g. winter wheat or potatoes, producing seed of quality (at least the first generation) has been achieved without official controls but this should not be considered as an indication that certification is superfluous.

3. A large majority of survey respondents consider that the standards are fully relevant. However, stakeholders from the fruit sector consider that the standards for the certification of fruit PM need to be better defined and to better reflect the current plant health status. EU rules are generally aligned with international standards and guidelines (OECD), with the exception of the seed potatoes standards (UN-ECE). Considering that the UN-ECE standards represent an up-to-date framework with adequate provisions covering all the categories of seed potatoes, including the 'pre-basic' seed, further alignment of the EU provisions to those standards should be sought.

4. Comparative tests and trials should be re-established as they provide a key platform to exchange experience for certification leading to further harmonisation. In the future, they could be made more relevant by ensuring corrective measures are taken in case of non-conformity with the standards.

5. Certification costs currently represent between 1 and 2% of the total production costs for certified crops. As the S&PM currently produced in the EU are of high quality, certification is moving from a quality-driven activity to a cost-driven one. Indeed, as far as the Community legislation permits it, some MS have taken initiatives to make the process more efficient and reduce accordingly the costs and administrative burden. For instance, several MS like FR and the UK have set up certification 'under official supervision'; The Netherlands and DK have merged the certification and phytosanitary inspection bodies on a crop-by-crop approach.

6. The qualitative survey has suggested several options for reducing the importance of the certification by the official authorities. Overall, the large majority of respondents did not support such alternatives, mainly because they would reduce confidence of farmers/buyers in the seed quality, would increase the current lack of harmonisation between MS and would create more difficulties for trade within the EU, even if the examples presented in the previous paragraph shows that costs optimization could be achieved.

7. However, a majority of stakeholders have been in favour of making the certification process more cost-effective mainly by 1) extending the field inspection 'under official supervision' to pre-basic and basic crops; 2) in the case of certification 'under official supervision', targeting the inspection on the basis of risk 3) integrating the inspection regimes for certification and for plant health. There was greater agreement (around 50% in favour and 50% not in favour) to the suggestion of 'leaving the level of check inspection, check sampling and check testing to MS' discretion in the case of certification 'under official supervision'.

8. Regarding the idea of 'setting up a certification with a system of an accredited third party body approved by the MS', answers are balanced too (around 50% in favour and 50% not in favour). This last idea should be further examined and explained as it seems that the principles and the potential benefits of this approach are not sufficiently known.

9. An extra proposal was presented by one association of users which consists of using the certification platform to control conformity of seed products to other requirements, and especially the GM quality requirements. Discussing this idea with suppliers' representatives and some national authorities led to the conclusions that the conditions should be further discussed and feasibility analysed.

10. Finally, on the basis of the analysis of the current situation and of the discussions with stakeholders during the interviews, the FCEC team believes that it is worth analysing the extent to which more flexibility could be introduced in the certification of seed in the future by e.g. introducing different categories of seeds to which would correspond different certification requirements, as done already for forestry reproductive materials (i.e. definition of four categories) or for vine and ornamental propagating materials (i.e. production of certified or standard propagating material).

7.3. OVER-ARCHING ISSUES

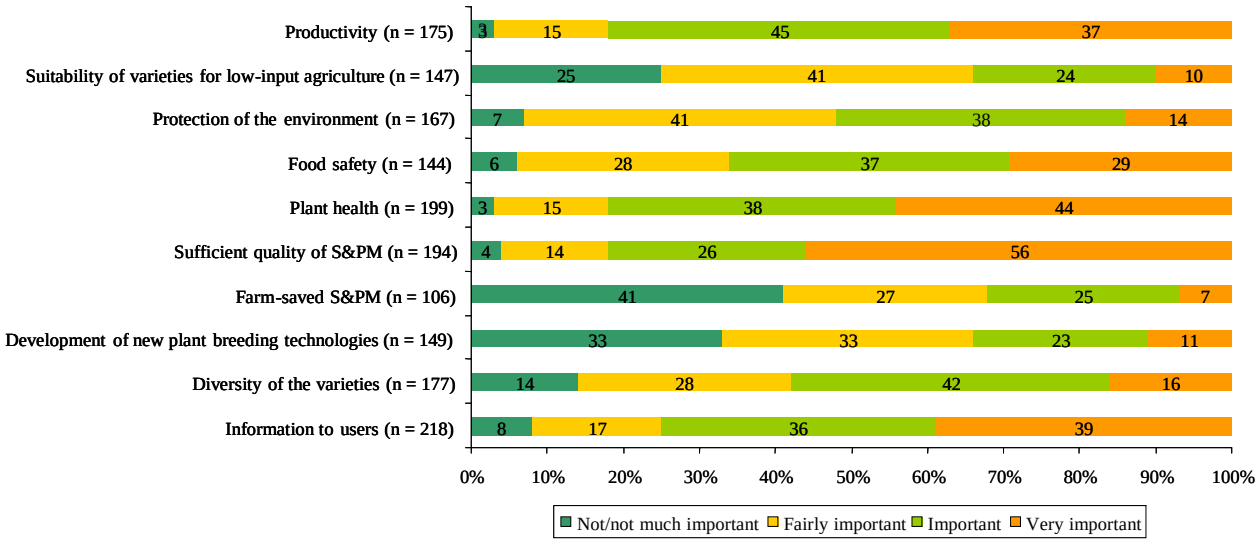
7.3.1. Main aims to be pursued when revising the Community legislation

This section of the report examines the extent to which the revision of the Community legislation provides the opportunity to consider any new aim, any new driver, instead or in addition to the initial aim of 'improving the productivity of agriculture' felt at the time when the Community legislation was created. Productivity is still important but food security is, mainly, achieved even if some analysts expect shortage production of e.g. oil in the short-term. If the Community legislation have to be recast, it is important to understand what should the drivers of this evolution and simplification.

During the qualitative survey, respondents were asked to score the importance of the following possible drivers: productivity, suitability of varieties for low-input agriculture, protection of the environment, food safety, plant health, sufficient quality of S&PM (identity, purity, etc), farm-saved S&PM, development of new breeding technologies (GM, molecular breeding, etc.), Diversity of the varieties, information to users (traceability of S&PM lots).

The survey results have been as follows:

Graph 40 – Aims when revising the Community legislation



Respondents' arguments for consideration of those possible aims in the future Community legislation are as follows:

Productivity, food safety, sufficient quality of S&PM must remain the focus of the EU regulations

- With growing worldwide demand for quality food, a growing use of plant material for non-food uses and limited and decreasing area of production, maintaining and increasing the productivity of European agriculture must remain the focus of the Common Agricultural Policy in general as well of its implementing legislation like e.g. the seed marketing and variety protection legislation;
- Directly related to the productivity, are issues such as seed quality, seed/plant health, and respective information to users.

Suitability of varieties for low-input agriculture, diversity of the varieties, protection of the environment is more and more necessary

- The legislation must be sufficiently flexible to acknowledge the diversity of the biology of crops and the diversity of increasingly differentiated markets. Niche varieties resistant to the extreme climatical

conditions or resistant to diseases (culture without or lower pesticides) contribute to the protection of environment, plant health and the food safety;

- Improving agro-biodiversity in the field will be one of the main issues in the future to better mitigate climate change and reduce chemical inputs;
- The varieties for low-input agriculture are capable to valorise the natural nutrient existing in the soil (without or lower chemically nutrients) and by this contribute they contribute to the protection of the environment and for food safety;
- Conservation of forest genetic resources should be considered in the EU directive, by including in the list naturally occurring tree and other woody species.

Plant health to increase

- Plant health is important and should be ensured by regulation which applies to all plants, not only the species listed in the Common Catalogue.

Farm-saved S&PM is not in favour of the progress breeding

- The continuous growth of farm saved seed use without equitable remuneration of the breeders more and more deprives breeders and seed producers of their deserved income. The risk is that, in the long term, all farmers active in certain crops will suffer from lower income due to the lack of R&D investment and breeding progress (and thus more limited choice of less competitive varieties).

Development of new breeding technologies increases the genetic progress

- Clearly, the legislative framework must not hinder the inclusion of new technologies. Currently, the lack of labelling thresholds for adventitious presence of GMO in seed prohibits the use of GM technology within the existing well-developed plant breeding, variety development and seed production patterns.

Information to users to help them to be more competitive and to facilitate achieving compliance with various regulations

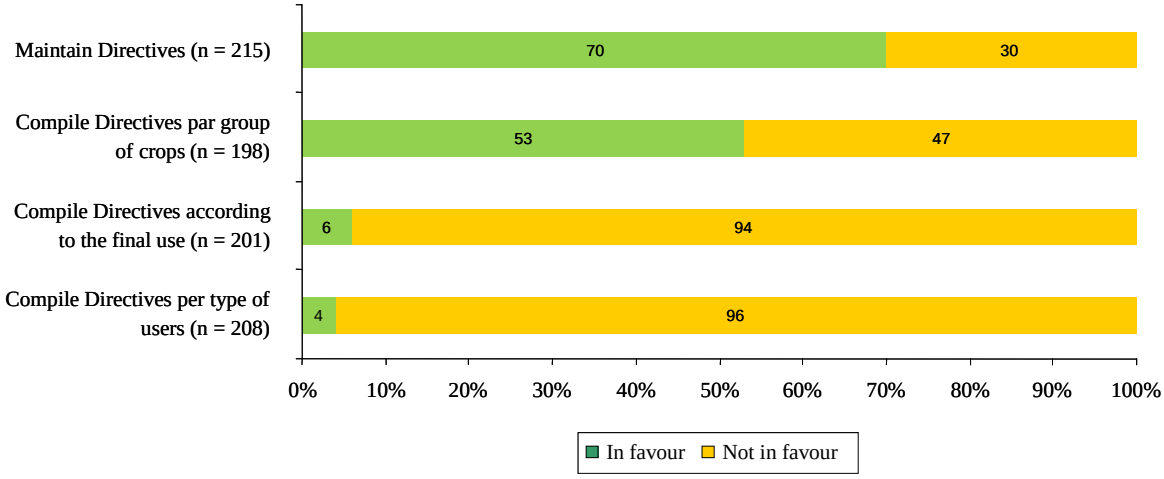
- Information to users leads to consumer protection, to the consumers knowledge and decision making inside the market;
- Transparency is essential to consumer confidence;
- Traceability is increasingly important in the modern sophisticated world of food retailing. Certification schemes can play a central role in providing such traceability;
- Forestry has a very long-term return on investment. Sessile oaks are harvested 200 years after plantation. Damages due to the use of not adapted provenances may only be seen after decades, with heavy time and investment losses. Good and accurate information of the end-user (planting forest owner) is a key-goal of forest tree plantations. On the condition of a good FRM traceability, the achievement of an updated European register of forest basic material is necessary to help forest managers to choose appropriate genetic material when they will have to adapt their forests to the effects of climatic change;
- A clear and transparent system for the identity of cultivars in ornamentals (in particular the bulb sector) is needed.

Finally, as regards productivity, some stakeholders have specifically mentioned that, for the farmer, productivity means ‘price x yield’ and is not only a question of ‘yield’.

7.3.2. Structure of the legislation

Overall, the quantitative results of the survey (Q1.2.2.) have not indicated a strong desire to modify the structure of the Community legislation.

Graph 41 - Structure of the S&PM Community legislation in the future



Stakeholders generally agree that it is important to have consistency within Directives covering seed and within Directives covering PM. However, PM and seed are too different to pursue consistency or parallelism of legal acts between those two groups, as different types of material and often different businesses are involved. Also vine and seed potatoes are specialised areas, which warrant separate attention.

In addition, the existence of two Directives for vegetables brings complexity and requires adaptation to market demand. Indeed the possibility of seed certification is provided by Directive 2002/55/EC but is not used by the vegetable seed industry, which mainly markets 'standard seed'.

Stakeholders from the forestry sector have mentioned the problem with the expression 'non-forestry purpose' (see section 6.1.3. above). As a solution, one respondent has indicated that a common Directive on forest and ornamental trees could improve the information of tree S&PM users. In its opinion, there is on the European market increasing confusion between ornamental trees and forest trees (there are no such problems with fruit trees). A solution could be to clarify in the same Directive all possible approval and certification categories of forest and ornamental trees.

Respondents' opinions on the advantages of compiling Directives per group of crops are as follow:

- It could simplify the system and increase consistency between the provisions of various genera and species which have certain common characteristics regarding quality and plant health requirements, requirements regarding variety identity and purity, official checks and/or inspection, certification, etc.;
- It could increase clarity and reduce the amount of legislation.

For several stakeholders, content and proper implementation of the legislation is more important than the way the respective texts are presented technically (e.g. 6 texts or 1 text with a respective variation of annexes).

Nevertheless, the examination of the 12 Directives (see section 6 above), the analysis of respondents' comments to the survey as well as the interviews have mentioned their complexity as well as the lack of flexibility to quickly adapt them to a changing market environment.

To reduce the complexity of the Community legislation, the FCEC team believes that improvements can be brought at two levels:

- To revise the legislative text of each Directive in order to clean it and by this, to increase its readability, consistency and understandability. Several proposals have been made for that purpose at section 6 above. This first option is mainly short-term. It will facilitate the operational management and the implementation of the Community legislation without changing its intervention logic;
- To look at Directives which could possibly be entirely removed or compiled with other Directive(s) to better fit the current market demand.

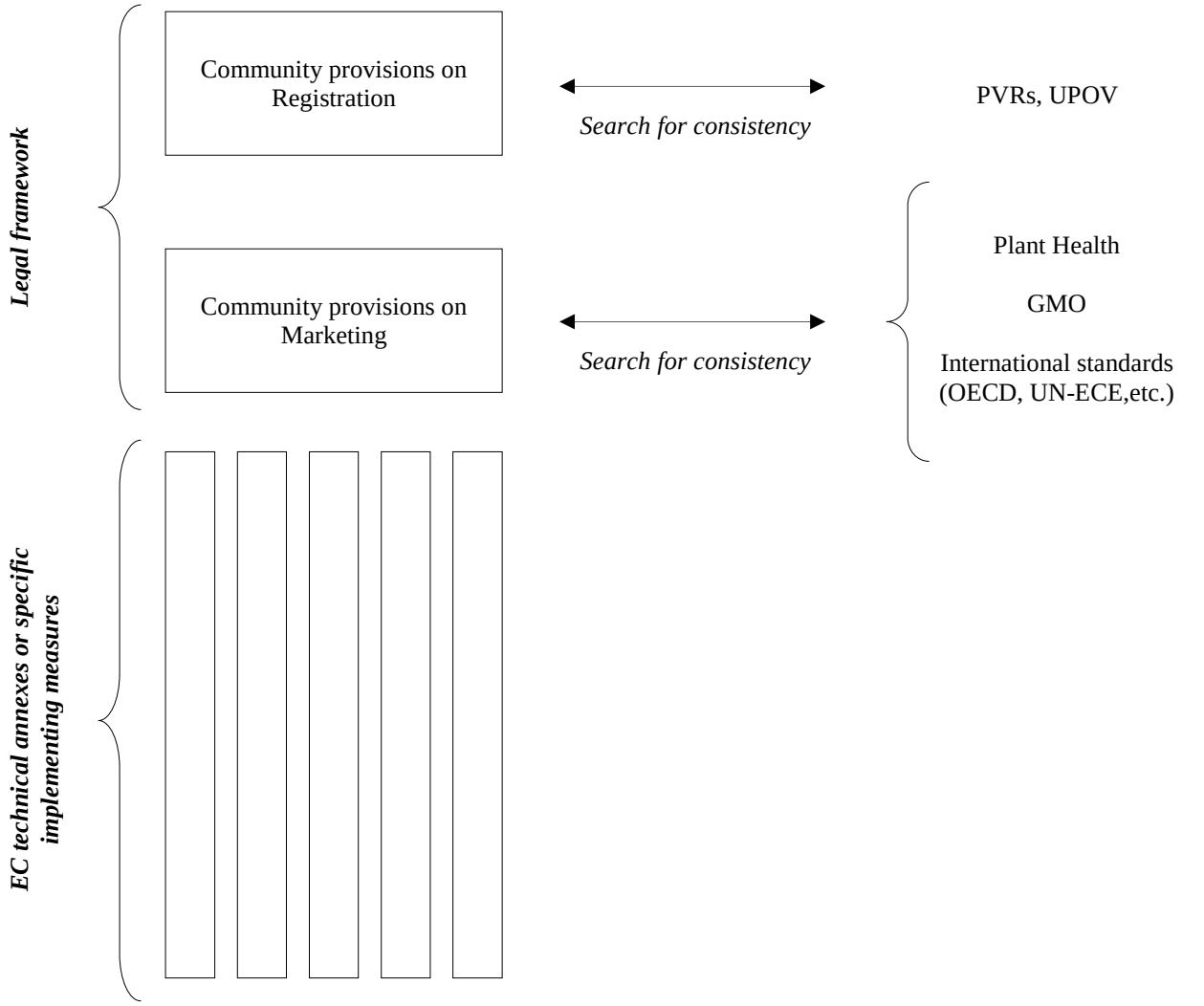
To make the Community legislation more flexible and facilitate the regular and ongoing review of the standards, provisions and tolerances within the Directives, two alternatives are suggested: either to transfer all technical measures to technical annexes or, as suggested in the proposal for the new fruit Directive, transfer all technical measures to specific implementation measures.

The above-mentioned options are mainly short to medium term and do not imply an in-depth reshape of the legislation. They maintain the current structure distinguishing between the Common Catalogue Directive and the marketing Directives and do not impact on the current points of references of stakeholders.

However, the FCEC team considers it would be worth further examining the proposal for a new structure of the Community legislation as formulated by some respondents to the survey and some interviewees. Apparently, this approach is, also, in discussions in Canada where a regulation review is ongoing as already presented.

This proposal distinguishes between two pillars subject to general Community provisions as well as specific technical annexes according to species, as follows:

Figure 10 - Proposal for a new structure of the Community legislation



According to such structure, a first piece of horizontal framework legislation (called 'Registration') would set the general standards for registration of seed varieties and plant propagating material based on adapted VCU requirements, identification of varieties based on DUS as well as on variety denomination and on the Common Catalogue.

The second part would present the legal requirements for 'Marketing' S&PM and should comprise the general provisions with regard to certification. To this horizontal legislation will be attached individual technical annexes per species or groups of species and its usage e.g. in the case of beet species one for sugar beet and another one for fodder beet where minimum standards for marketing should be defined. This segmentation per usage for a given species should be implemented, only, when the segmentation is non-disputable and when one variety cannot move from one usage to another, or when a variety cannot be marketed for 2 different usages.

Furthermore, some stakeholders consider that it is important to cover all plant health aspects in one piece of legislation. FCEC team supports this idea as the same unit at SANCO level is managing both plant health Directive and seed Directives.

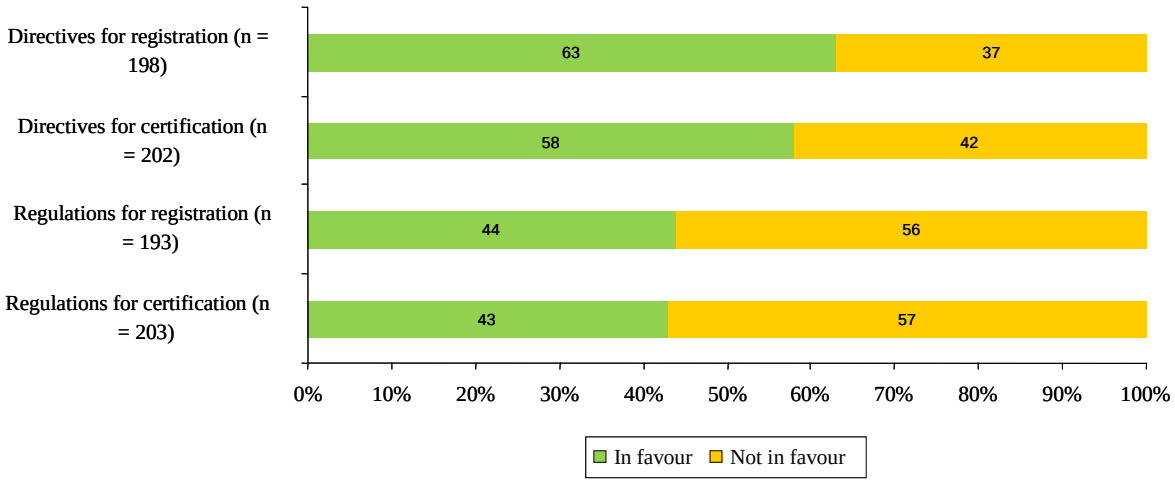
Such proposal consists in a revision of the intervention logic of the Community S&PM legislation i.e. the legal framework has a horizontal structure and covers aspects common to all species; i.e. identity, registration and marketing.

This proposal was discussed with several stakeholders during the last interviews. Overall, interviewees support the idea of separating the legal dimension from the technical one. However, it is a long-term option that requires further consultation and discussion.

7.3.3. Legal instrument

The opinion of the respondents to the question on the most appropriate legal instrument to regulate the marketing of S&PM at EU level in the future is not clear (Q1.2.3).

Graph 42 – Legal instrument to regulate the marketing of S&PM at EU level in the future



The arguments they provide to maintain Directives or to replace them with Regulations are as follows:

- Directives seem more dynamic and easier to adapt than regulations;
- Regulations generally are the stronger instrument to achieve uniform implementation across all Member States and therefore, specifically in a growing European Union, may be regarded the better instrument to assure a true Common Market for seed and avoid intra-Community barriers to trade caused by differences of interpretation by national bodies;
- Regulation is mainly adapted for DUS and certification.

In particular, some respondents consider that, overall, leaving to each country the possibility of adapting European rules to their geographic, social and economic conditions could enhance the diversity of the entire seed system. They suggest setting up minimum rules and giving each country the freedom of implementing them.
Considering the proposal for a new structure of the Community legislation as presented at section 7.3.2. above, the FCEC team believes that it is important that harmonised rules are defined as regards 'Identity', therefore is recommending for a regulation as legal instrument.

Regarding Registration, Directives remains more appropriate as significant MS specificities have to be considered.

In case the legal framework consists in Directive(s) for the Community provisions on marketing, the technical specifications would be transferred to implementing measures as suggested in the proposal for a new fruit Directive. In case it consists in Regulation(s), these specifications could consist in technical annexes.

7.3.4. Role of the CPVO

Current role of the CPVO

Council Regulation (EC) 2100/94 has created the Community Plant Variety Office, the CPVO. It is based on article 235 of the Treaty establishing the European Community. It has its headquarters in Angers, France. It is a so-called Community agency; i.e. a body governed by European public law but distinct from the Commission. It has its own legal personality and its own financial resources. Its status as an independent entity guarantees better transparency and accountability towards its main stakeholders, the breeders.

As a preliminary remark, it should be highlighted that any extension in responsibilities of the CPVO would require a preliminary alignment of the legal basis. Today Council Regulation (EC) 2100/94 is based on article 325 of the Treaty, whereas seed marketing Directives are based on article 37 of the Treaty. It has often been reported during the interviews that any alignment would consist of an important effort.

The core business of the CPVO is to grant European Plant Breeders Rights. The Community systems exist in parallel with the national PVRs system of the EU MS. It is up to the breeder seeking PVR protection in the EU to decide what type of protection he prefers. CPVO staff runs a technical examination on any application to ensure that in respect of a candidate variety the criteria of D, U and S are complied with. The CPVO doesn't itself carry these examinations. They are entrusted to bodies deemed competent by the CPVO Administrative Council. At present time, more than 20 examination offices have obtained the qualification 'competent'. The latest statistics show that the number of applications received by the CPVO is higher than the sum of national applications received by the national PVR authorities within the EC over the same period.

In December 2005, Commissioner M. Kyprianou asked DG SANCO to investigate on the possibility to utilising CPVO experience in the S&PM marketing sector as regards variety denomination, management of the CC and technical tests (i.e. DUS tests) and to explore the possibly of extending its activities in this sector.

A working group with experts of the MS, the CPVO and the Commission was created in 2006 to analyse the possible extension of the role and activities of the CPVO. The first meeting of this working group took place on the 12th of January 2007 and was followed by 6 meetings respectively in February 2007, April 2007, July 2007, October 2007, January 2008 and March 2008.

During the first meeting, the working group identified a list of 7 items to be discussed, as follows: 1) variety denominations, 2) DUS and VCU testing, 3) Common Catalogue and national listing, 4) comparative trials, 5) conservation varieties, 6) protection of geographical indications as well as 7) additional items (i.e. the maintenance of varieties in 3rd countries).

Up to now, the discussion of the WG have focused on the items 1 and 3 and have resulted in 1) a proposal for a centralised checking of variety denomination using the current CPVO database for the purposes of National listing, Community listing, National PVR and Community PVR as well as 2) 5 options for a possible role of CPVO in managing the Common Catalogues and in National listings.

Proposal for centralised checking of variety denomination

According to this proposal:

- CPVO makes recommendations to the National authorities on the proposed denomination for National listing and National PVR which are sent by the MS to the CPVO;
- Decisions and responsibility on variety denominations for National listings and National PVR remains with the MS;
- Centralised checking must involve all the MS;
- The services of the Commission would only be involved in centralised checking of variety denomination for National listing and National Plant Variety Rights in the case of disagreement between the CPVO

and a given MS. In such as situation the opinion of the services of the Commission should be asked before publication to avoid conflict after the MS has approved variety denomination.

The pro's and con's of the proposal were discussed by the WG as follows:

Table 25 – Pro's and con's of a centralised checking of variety denomination by CPVO

Pro's	Con's
The CPVO database is already used extensively by MS for checking denominations and is an efficient tool for centralised checking. MS could limit their activities to maintain their own denominations database or could no longer maintain them, saving time and cost. This might help MS as the number of varieties with national PVR continues to decline. Divergence of opinion between CPVO and MS should be dealt with before a variety is added to a national list or granted under national Plant variety rights (PVR) and there is a subsequent application for Community PVR. This should be of considerable benefit to breeders and, although difficult to quantify, it may also save time and cost for CPVO and MS. MS should retain responsibility for decisions on national listing and national PVR, so no change to the legislation as regards responsibility is required. With CPVO making a recommendation but not having responsibility, MS should retain the possibility to react to the CPVO when there are different views. Centralised checking should favour exchanges and co-operation between CPVO and the MS. The system should work for all plant species: i.e. for agricultural, ornamental, vegetables, fruit, and wine and forestry species. Centralised checking should improve coherence in the application of Community rules on variety denomination. Centralised checking should eventually be an advantage to include all relevant variety lists, since it should improve communication and reduce problems of duplicated names.	To achieve the full benefits, centralised checking should require all MS to participate, which might be difficult to reach. National expertise in variety denominations should be reduced or lost, reducing the quality of advice to national applicants, and possibly weakening the EU's position in UPOV (on this point, there were different views on the likely impacts, some members of the working group expressing concern, and others feeling that it could be managed and was not a significant issue). It should be necessary to consider other variety lists, not currently included by the CPVO in its database. Some issues for synonyms, mainly links between original denominations and their synonyms, will not be fully addressed. The working group recognised that there is not yet sufficient information for detailed discussion on eventual costs for such a system (CPVO representative suggested that one full-time extra. official would be enough to deal with it: but who should pay?).

Source: compiled on the basis of the main conclusions of the Working Group on checking of variety denominations, the management of the Common Catalogues and the procedures for variety listings – 6 march 2008

The initial view of the WG to the question of the CPVO managing the Common Catalogues was that there is no added value in transferring this work to the CPVO. The management of the CC has to be improved as already concluded in section 7.1.6. but that these improvements could be achieved quite easily by the Commission services.

The 5 options currently identified by the WG for a possible role of the CPVO in managing the Common Catalogues and in National listings are as follows:

- Option 1: no change compared to the current situation;

- Option 2: CPVO managing technical and administrative tasks for listing new varieties in the Common Catalogues at the place of the Commission services, after it has been listed in National Catalogues, with official notifications for listings in the Common Catalogues continuing from the MS to the Commission;
- Option 3: CPVO fully managing technical and administrative tasks for listing new varieties in the Common Catalogues, at the place of the Commission services, with direct notifications for listings in the Common Catalogues from the MS to the CPVO;
- Option 4: CPVO would manage the Common Catalogues with a split of technical tasks between CPVO and the MS concerning DUS and VCU tests; CPVO should manage DUS tests for National and Common listings but MS should continue to proceed with VCU tests;
- Option 5: possibility for centralising of variety listing for the Common Catalogues at CPVO level only on the base of DUS requirements. MS can voluntarily produce national variety recommendations lists on the base of their own VCU tests.

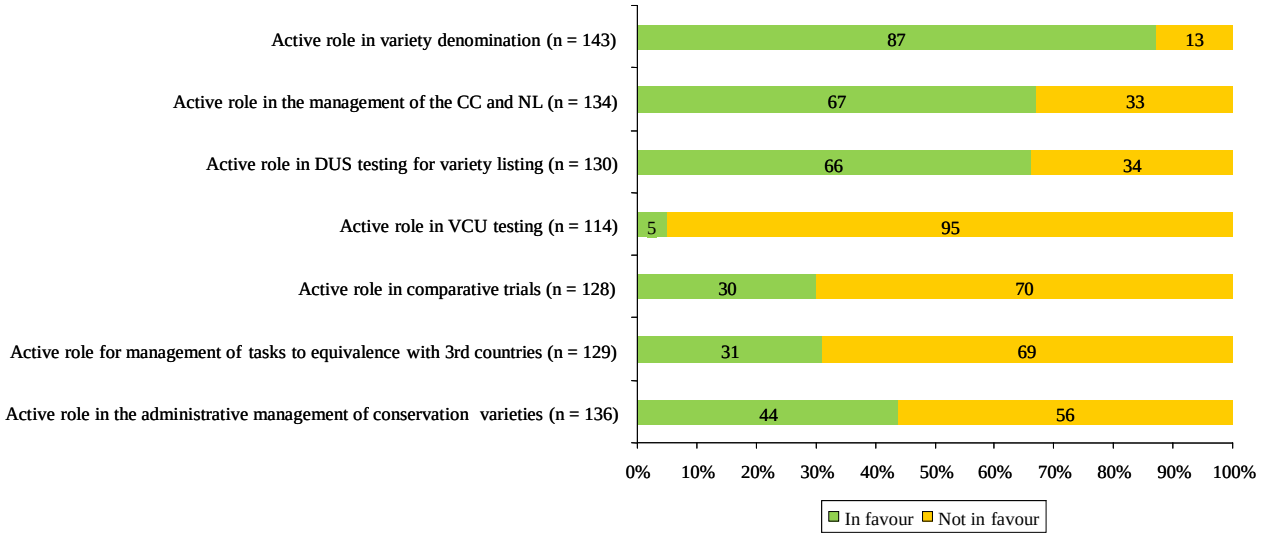
The WG was clearly in favour of the approach *'one key – several doors'* as suggested in option 4, i.e. the adoption and the auditing of quality requirements for DUS testing not only as concerns the Community PVR system but also or possibly in respect of national PVR and listing systems. However, no common position was reached by the members of the WG on a possible role for the CPVO in respect of DUS testing for national listing and national PVR granting purposes. They consider that such roles might be a long-term effect after the implementation of the *'one key – several doors'* approach.

With the aim of validating or further investigating on the relevance of the proposals discussed by the CPVO WG by a larger group of stakeholders; the qualitative survey also included questions on the role of the CPVO in the future, in addition to considering applications for protection of variety rights (Q4.1.).

Role of the CPVO in the future

The large majority of respondents have considered that the CPVO would have an active role in variety denomination (87% of 'In favour', n = 143), in the administrative management of the Common Catalogue and national listing (67% of 'In favour', n = 134) as well as in the DUS testing for variety listing (66% of 'In favour', n = 130). However, they generally do not support the suggestions of providing the CPVO with an active role in VCU testing, for the management of comparative trials, for the management of tasks to equivalence with third countries as well as in the administrative management of conservation varieties.

Graph 43 – Role of the CPVO in the future



Overall, the majority of respondents to the survey support the current conclusions of the CPVO Working Group and consider that the tasks of the CPVO could be extended to administrative tasks of general use. Such administrative tasks refer mainly to the management of the denominations database and of the common catalogues as well as the monitoring and auditing of the national bodies in charge of DUS testing.

In their opinions, the advantages would be increased efficiency, transparency and cost savings. Consequently, the seed industry should be able to place new varieties on the market earlier and administration should be simpler and less costly.

However, some stakeholders have questioned the benefits of moving the administrative tasks (in particular the management of the Common Catalogue) to the CPVO. Indeed, if the Commission was organised better i.e. will such move add to a reduction of the total costs and administrative burden or not?

Also, some respondents consider that it could be 'bad policy' to confuse the objectives of intellectual property rights (protect innovations) and the objectives of commercial regulation (protect users). Requirement and criteria for the protection of intellectual property under private law must not prevail or substituting for regulation by the public law of fair-trading.

Respondents' specific comments on the possibilities to extent the role of the CPVO in the future are as follows:

Variety denomination

- The centralised database recently set up by the CPVO is a precondition to assure a harmonised and consistent implementation of the provisions as regards denomination of varieties in Member States. Consulting this website must be obligatory for both, listing and granting of national and EU PBRs. Responsibility for the management of the database and thus the verification of the proposed denominations should be transferred to the CPVO. The final decision may then be up to the responsible national authority or the CPVO itself (EU PBRs).

Management of the Common Catalogue and the national listing

- CPVO should be in charge of the format of the EU Common Catalogue and its electronic supporting tools.

DUS testing for variety listing

- For some stakeholders, the variety listing procedure is a national responsibility which cannot be transferred to the CPVO. CPVO can play a coordinating role for DUS and denomination;
- The CPVO could have a central role in setting up the operational standards for DUS testing, in coordinating the organisation of such DUS testing by national Examination Offices and in accrediting and auditing the national Examination offices for variety registration. The Examination Offices should be in charge of DUS-testing and initiation of National Listing, leading to the automatic addition to the EU Common Catalogue. Also accredited DUS Examination Offices should mutually accept each other's test reports. A test report for an application for national plant variety protection should also be used when evaluating Community plant variety protection;
- In particular, one respondent consider that there is good synergy in having variety administration, VCU and DUS testing located in the same unit. Splitting those tasks could generate more problems than it will bring benefits,
- For other stakeholders, the important elements for the internal market are variety identity and registration so that listing could be done without VCU requirements. In such a system, the CPVO could play a central role in DUS testing for PBR and listing, i.e. the Common Catalogue will be a Common List on which all varieties that are authorized for marketing in the EU are listed.

VCU testing

- VCU testing should be continued on a national level for three reasons: 1) the VCU testing is closely related to the geographic and climatic conditions of the single MS- significantly more than the DUS

test; 2) the VCU testing is an essential part of the variety registration procedure which is fully under national responsibility. Considering this, there are no financial advantages for applicants if the CPVO would be involved in the VCU area; 3) in view of the provision, that national registrations must be notified to the Commission within 4 weeks, no harmful time lag (in theory) for the applicants does occur.

Comparative trials

- Comparative trials are connected with exchange of knowledge and harmonisation of certification between Member States. CPVO has no role to play in the field of certification and therefore no role to play in the management of the comparative trials;
- The CPVO is not structured to perform this task.

Management of tasks to equivalence with 3rd countries

- The responsibilities for the granting of equivalence are well established and effective under the current legislation which should thus remain unchanged in this respect;
- Also, equivalence is more linked with certification and CPVO has no role to play in the field of certification;
- The task of the Commission in this area currently consists in the drafting of proposals for decision to be taken by the Council of Ministers. Drafting proposals for legislation is not a task for CPVO;
- The granting of equivalence is essentially a political issue.

Administrative management of conservation varieties

- Some stakeholders consider that in the case where the role of the CPVO is extended to the management of the Common Catalogue, its role as regards the management of conservation varieties would concern the inclusion of the conservation varieties in the Catalogue to assure transparent information. In their opinion, listed conservation varieties should become part of the regular listing system and be included in the Common Catalogue with mention of their specific status of conservation variety and consequent specific limitations for their use;
- For other stakeholders, the administrative management of conservation varieties should be kept by the national authorities because it needs to be very closed to the concerned territories where the conservation varieties come from.

In particular, one respondent from the forestry sector has mentioned that protected S&PM are very rare in forestry (only some poplar clones) so that CPVO is not a key actor in this field. In its opinion, the question of the extension of the responsibility of the CPVO in forestry should be first discussed in a meeting of the Standing Committee on seeds.

Also, some respondents active in the field of ornamental plants at European or international level have indicated that – with the exception of cutflowers- only a small percentage of ornamental crops are protected by plant breeders rights.

In conclusion, stakeholders opinion on the possible extension of the role of the CPVO supports the conclusions of the CPVO Working Group, i.e. increased harmonisation and better efficiency could be achieved from centralising the denomination checking at the CPVO; having the CPVO responsible for the definition and auditing of the DUS requirement would contribute to create a level-playing field in the implementation and interpretation of the DUS protocols.

Most of survey respondents consider additional efficiency gains could be achieved through the management of the Common Catalogue by the CPVO but one alternative is the development of an online real-time Common Catalogue at Commission level. Interviewees more familiar to the practices in this area are not so much convinced of the added values of this change.

Today the CPVO has a unique responsibility on PVRs and would be called Community Plants Variety *Rights* Office. Its customers are the breeders and its activities are fully of the private domain. Several key

players are of the opinion that transferring responsibilities from the public domain (marketing Community legislation) may cause concerns. FCEC considers that that point should carefully be taken into consideration.

Furthermore, any modification of the role of the CPVO will need legislative change to implement.

Finally, the first attempt to list possible extra responsibilities that the CPVO could undertake have been sorted according to their ease of implementation and not on their possible benefits. Only 2 ideas have been deeply discussed (Variety Denomination and Common Catalogue), which are not those which are regarded as adding more value to the system. These first discussions should be extended to any other added-values concepts (e.g. '*one key-several doors'*).

7.3.5. Definition of the terms 'marketing', 'seed' and 'seed marketing'

The analysis of the Community legislation indicated a few cases of inconsistencies, discrepancies or gaps in the current legislation. One of those cases relates to the definitions of 'seed' and 'marketing' in the current legislation, and some of these problems are depicted in Annex 7.

7.3.5.1. Definition of 'seed'

There is no definition of 'seed' anywhere as such in the current legislation. Although reference is made to the concepts of 'standard seed', 'basic seed', 'commercial seed' and 'certified seed', which are described – as applicable - in Article 2 in each of the seeds marketing Directives, the overall definition of 'seed' as such is missing.

Furthermore, from our interviews it appears that there is generally confusion in this field, with the terms 'grains' and 'seeds' used often interchangeably in the market place and even by policy-makers (when we move away from the close circle of experts in this area).

This suggests that there is scope for including a definition for seed. The simplest proposal appears to be to include a generic definition of seed in its botanical term, as commonly understood by professionals. This implicitly differentiates between seed to be used only for the production of new plants / multiplication, from grains used also for food/feed processing. The definition should be consistently introduced in all Directives (including the Common catalogue).

Introducing a definition for seed would also be consistent with the PM Directives, where a definition for PM is given.

The use of Farm Saved Seed (FSS). Interviews with stakeholders in the UK in particular have identified a problematic situation that arises for the use of FSS, the movement of which appears to be extensive between farms especially in the co-operative sector. The problem arises because this movement is not covered as such by the seeds marketing Directives (FSS is uncertified seed), or by the plant variety rights legislation which states that seed can only be used on the holding on which it was produced. The seed marketing legislation and the plant variety rights legislation were drafted at a time when one farmer farmed one farm and so the spirit of the legislation was that a farmer could save seed on his one farm. This is clearly not the case nowadays and the legislation that was written back then does not reflect current agricultural practices, at least in the UK[47].

In the UK, associations of users appear to support the farming community on this, against the wishes of the suppliers who do not want to see any change in the seed marketing legislation allowing farmers to market

[47] In the UK current agricultural practices often involve large farming cooperatives that can farm between 6-20 farms, all of which are registered as separate businesses, but cooperate in the form of cost-sharing (i.e. by sharing seed costs, fertiliser costs, machinery and equipment etc.). With the current legislation, these cooperatives cannot use their FSS/uncertified seed on the different member-farms to optimise seed costs within the business.

FSS/uncertified seed (for fear of potential loss in FSS royalties). Thus, there are currently discussions also involving national authorities on best approach to resolve the situation.

The Commission's point of view is that this is an issue that relates and should therefore be dealt with in the context of the legislation on plant variety rights. The Commission considers this issue to be separate from the seed marketing Directives, the aim of which is to provide high quality material for users by ensuring the identity of seeds throughout the transaction. The seed industry do not favour any change in the way FSS is treated in the Directives – if anything in the event of a definition for seed they would favour a wording that ensures reference to 'seed belonging to a variety that is listed in the Common Catalogue'.

7.3.5.2. Definition of 'marketing'

From our review of the Community legislation and interviews (with industry, national authorities and the Commission), the following issues were identified and analysed:

- There is no definition at all for the term 'marketing' in the Common Catalogue Directive 2002/53. This is due to the fact that the Common Catalogue is regarded as a 'support' Directive for the seed marketing Directives, to avoid replication of the provisions relating to registration of varieties in each of the seed marketing Directives. As Directive 2002/53 does not deal directly with the marketing of seeds, it was not considered necessary to include such a definition. However, there may still be a case to include this definition in Directive 2002/53, for the purposes of consistency, clarity and thoroughness;
- The current definition of marketing followed in the seed marketing Directives is consistently used throughout all Directives (Article 2.1(a) in all Directives, with the exception of the fodder plant and cereal seed Directives where it is covered by Article 1a). However:
  - The current definition does not appear to include imports even if there is a general understanding, excepted for the industry, that importing is included in marketing. In common with many of the other issues highlighted by the analysis of the Community legislation, this is due largely to the long history and evolution of the legislation in this sector. In the early 1960s when the legislation was, first drawn, direct imports of seeds from other continents were inconceivable; nearly 50 years later, the seeds business has grown to become very international with large-scale players in both the seeds and agricultural sectors, and a very high level of information exchange and awareness for both seed growers and farmers.

    The Commission's current position is that, in view of the fact that the seed marketing Directives are based on the parallel system of OECD certification for seed produced by OECD member countries, the provisions on equivalence applying to imports from third countries (Article 16 of the various seed marketing Directives) sufficiently cover imports. Under Article 16, the Council acting by qualified majority on a proposal from the Commission may grant equivalence to imports from third countries if it determines that the EU conditions on field inspections and other examinations are met.

    On the other hand, in the case of the PM marketing Directives, where no such certification exists at OECD level, in addition to the fact that equivalence may be granted under comitology procedures, the need has arisen to include more specifically imports in the marketing definition. For example, in the current proposal recasting Directive 92/34 (on the marketing of fruit plant PM and fruit plants)[48], the act of importing will be specifically listed in the definitions of 'marketing' and 'supplier' of the Directive. In order to increase the harmonisation and transparency of the legislation, the proposals include a new definition of marketing covering all the initiatives concerning the commercial exploitation of PM (Article 2(10), and the addition of the action of importing to the list of actions of a supplier (Article (2.9). The other PM Directives would eventually follow in the same direction.

    Given these changes in the PM sector, it would appear to be more consistent to also revise and update the seed marketing Directives accordingly. This appears to be the case not only for the

[48] COM(2007)31f of 29 January 2007.

definition of 'marketing', but also for the definition of 'supplier', which is currently missing from the Directives.

We investigated the potential consequences of the lack of specific reference to imports in the definition of marketing. There are allegations from industry that illegal imports of seeds into the EU appear to be taking place and this may well be due to the absence of more clear legislative provisions on these flows. In particular, two problems with imports were explored further:

- Imports in the sector of vegetable seeds. Because this is a low volume / weight – high value product, it appears to offer better potential for 'illegal' trade (compared to other seeds). Such imports have occurred in several MS: this appears to involve imports of seeds by farmers for own use, and subsequently used for seed regeneration. It appears that the authorities are unable to act because these types of import flows as such are not falling under the seed marketing Directives. Thus, this is not considered illegal trade or fraud as such, but seems to be due to a lack of specific coverage in the Directives. The industry does not have now a figure of the size of this trade, but this is likely to be very modest. Nonetheless, in a sector worth overall some 800,000 million Euros, it is feared that some individual vegetable sectors may be disproportionately affected. In the longer term, it could also give rise to concerns on plant health and unauthorised GMO introduction;
- Imports of grass seeds. This problem appears to involve imports of grass seeds under different customs codes (low quality seed imported as bird feed). The problem is compounded by the fact that, again, this trade flow involves small volumes (this is a very light seed), and there is no OECD certification on this. Although it is hard to document as such[49], if proven this would in effect constitute clear-cut fraud that is mainly associated with customs import procedures and checks. It may therefore be difficult to improve if at all with the seed marketing Directives, as this does not appear to be due to a weakness in the current legislation. Promoting the self-control and responsibility of companies in the sector seems to be the first priority here.

It is the opinion of the industry the '*any import of seed in the Community with a view to distribution or use shall be deemed to constitute marketing'*.

- The wording provided in the definition 'whether or not for consideration' is confusing and may not be easily understood. It seems this is the result of translation from the original French/German text into English. It effectively means 'whether in return of payment or free of charge', which is the wording followed in other EU legislation. There seems to be a case therefore to rephrase this to what it actually means. To provide for all situations where a transaction may have occurred resulting in the physical exchange of the seeds but without involving payment, and to keep the spirit of legislation as open as possible, this could be re-phrased to 'whether or not the transaction is finalised'. Initial discussions with the Commission and the industry have shown the latter phrase to be the most pragmatic and acceptable option.

7.3.5.3. Conclusions

There appears to be significant scope for a clarification and improvement of the definitions on seeds and on marketing that are followed in the Directives. These would include notably adding a generic definition for seed, including imports in the scope of marketing, and updating the Directives for technical progress. In this context it is important to note that:

[49] It appears that uncertified grass seed imported into the EU eventually moves inside the European market as certified seed. However, it is not possible to confirm this trade flow on the basis of official statistics. Unconfirmed reports indicate that such illegal imports are possible because the official quantities used for statistics are not the quantities actually being imported (containers can hold up to 20 % more than the official weight, and this surplus can then be repacked for sale); other unconfirmed reports indicate that EU seed companies multiply uncertified varieties in some of the New Member States which in turn is mixed with certified seed in bags to be marketed in the EU. ESA members have written to the Italian and Spanish competent authorities on this in 2006, but no follow up action appears to have been taken.

- It is essential for any revisions in the legislation to take place for the entire package of the seeds and PM Community legislation. Given the interconnections in the Community legislation and the fact that many plants have multiple uses (for example, a plant can be considered for fruit bearing, ornamental or forestry purposes), only this parallel approach can ensure the integrity and consistency of the entire Community legislation in this sector;
- The legislation should also be reviewed in the context of overall EU policy objectives of relevance to the sector of seed and PM, notably the Common Agricultural Policy (CAP), and the environment, especially as these unfold into the future. For example, it is not clear at the moment which Directives would apply to crops used for biomass, although this sector is forecast to experience substantial growth in the near future. There is also a need for better coordination of the policy management between DG AGRI and DG SANCO. For example, current Pillar II (rural development) measures refer to the requirement to use certified seed or to VCU requirements at seed level, while it is not clear whether these are not fully consistent and whether there is duplication with the current seed Community legislation.

7.3.6. Quality of the information to the users

Users agree that the most useful information on S&PM is the performance of the variety (Value for Cultivation and Use), quality and traceability of S&PM (varietal purity, identity, plant health status, germination capacity, etc.).

As regards the certified lots of S&PM, current information to the user consists in the official labels, or plant passport. For standard S&PM, such information is provided on the supplier's label.

As regards the official label, the information required depends on the species, as follows.

The seed marketing Directives define the conditions for the labelling of pre-basic seed as well as the ones for the labelling of seed intended for certification (basic seed and certified seed). Packages of seeds intended for certification must also be accompanied with a document.

For instance, the required information for certified seed contains the EC rules and standards; the authority responsible for field inspection and Member State or their initials; the reference number of lot; the month and year of sealing; the species; the variety; the category; the country of production; the declared net or gross weight; the nature of the additive and the approximate ratio between the weight of pure seeds and the total weight where weight is indicated and granulated pesticides, pelleting substances or other solid additives are used; the name of the variety to which the seed belongs in the case of varieties which are hybrids or inbred lines; where at least germination has been retested, the words 'retested … (month and year)' and the service responsible for such retesting. Label for seed potatoes must specify the size.

Label for certified vine PM must contain data on EC Standard; country of production; authority responsible for certification or checking and Member State or their initials; name and address of the person responsible for sealing or his identification number; species; type of material; variety and, where appropriate, the clone. For the rooted grafts this indication applies for the rootstock and the top-graft; reference number of batch; quantity; length (only for the graftable rootstock cuttings); crop year. Derogation exists as regards small quantities to final consumer.

Each lot of forestry reproductive material shall be identified by the master certificate code and number; botanical name; category; purpose; type of basic material; register reference or identity code for region of provenance; region of provenance — for reproductive material of the 'source-identified' and 'selected' categories or other reproductive material if appropriate; if appropriate, whether the origin of the material is autochthonous or indigenous, non-autochthonous or no indigenous, or unknown; in the case of seed units, the year of ripening; age and type of planting stock of seedlings or cuttings, whether undercuts, transplants or containerised; whether it is genetically modified.

Forestry reproductive material are accompanied by a label or other document from the supplier ('the supplier's label or document') giving, in addition to the information indicated above, the following information: master certificate number(s) or reference to the other document available; name of supplier;

quantity supplied; in the case of reproductive material of the 'tested' category whose basic material is approved under Article 4(5) of Directive 199/105/EEC, the words 'provisionally approved'; whether the material has been vegetatively propagated.

In the case of forestry seeds, the supplier's label or document shall also include the following additional information: purity; the germination percentage of the pure seed, or, where germination percentage is impossible or impractical to assess, the viability percentage assessed by reference to a specified method; the weight of 1000 pure seeds; the number of germinable seeds per kilogram of product marketed as seed, or, where the number of germinable seeds is impossible or impractical to assess, the number of viable seeds per kilogram.

Derogations exist in case of small quantities of seed.

Results from the survey and the interviews have indicated that 75% of respondents (Q 1.2.1., n=218) consider that the information to users is a very important or important aim to pursue when revising the Community legislation.

In particular, stakeholders from the forestry sector have complained about the lack of harmonisation between the supplier's documents and stressed the need to further clarify them.

7.4. OTHER ISSUES

7.4.1. Impact of the S&PM Community legislation on the marketing of conservation varieties

Previously, there has been no Community legislation in place for the marketing of seed of conservation varieties. A new Council Directive (2008/62/EC) has recently been approved enabling this, which must be implemented by all Member States by June 2009. With no Community legislation to evaluate, this case study concentrated on the reasons behind the drafting of the new Directive and the potential impact of it. The new Directive is to

"*provide for certain derogations for the acceptance of agricultural landraces and varieties which are naturally adapted to the local and regional conditions and threatened by genetic erosion and for the marketing of seed and seed potatoes of those landraces and varieties*".

7.4.1.1. History behind the new Directive

Following interviews within the Commission it appears that the UK had been very interested in looking at Better Regulation in relation to the Seed Marketing Directives in general. At the same time there had been difficult discussions going on within the Commission about the marketing of seed of conservation varieties.

It was considered that there were two different types of varieties for different markets. Firstly, the new commercial varieties that comply with DUS and VCU guidelines laid down by UPOV and secondly, the old traditional varieties that do not comply with DUS and VCU but still have a very valuable role to play in local food production, local markets and in rural areas and communities.

It was felt that a positive step should taken to enable the marketing of seed of conservation varieties to take place, but without creating a second class market for the marketing of seed generally.

It was intended that the new Directive would only apply to a small number of varieties with a small market value that might be affected by genetic erosion. The new Directive was meant to apply to varieties grown in specific regions and would not apply to the main commercial varieties which were clearly not affected by genetic erosion.

Any system that would be set up had to have the confidence of everyone and the new Directive was drafted to provide the basis for a system to give people that confidence.

7.4.1.2. General background

Currently, for a variety to be certified and marketed in the EU it must pass the current DUS and VCU testing system used to assess new varieties bred in commercial breeding programmes for the main markets. If a variety passes these tests it can be listed on the Common Catalogue and certified seed for that variety can be produced and marketed. This system is based on the UPOV guidelines and has evolved with the development of new commercial varieties with improved morphological and agronomic characteristics. The new commercial varieties are bred for very specific markets and have very specific characteristics.

There are a large number of older traditional varieties or conservation varieties, landraces and other varieties that do not pass this rigorous and very specific testing system. As a result these conservation varieties cannot be legally marketed and as a result could potentially become susceptible to genetic erosion.

Often these conservation varieties and landraces are adapted to local climatic and regional conditions and their loss could result in the loss of local food production and local markets which help to maintain the social structure of small communities in the regions. Local food production also reduces transport costs and makes food more affordable for the local people. It also creates a local economy and encourages tourism in the region, as tourists are interested in the traditional ways.

It is also known that there are very successful systems already up and running in Switzerland and Austria, where they test local varieties in local climatic and agricultural conditions.

7.4.1.3. Specific examples of traditional varieties and conservation varieties

Blue potato

In the Dolomites the local people grow a blue potato variety that is retained as a traditional crop. The variety suits the environment, soil type and climate and the local people find that they can store seed potatoes of this variety very well there. However, they need some structure of legislation to be able to market the seed to other farmers to use and those farmers that buy the seed potatoes need some protection.

The local traders know each other, so they know who produces good quality seed of the blue potatoes but if a farmer bought seed of a variety from another region of the country, they would not know what they were buying. Even with conservation varieties the farmer needs proof that a variety he has requested is what he actually receives. This is why there is a need for some type of structure and legislative control.

Yellow tomato

In a particular region of Italy, there are some old varieties of tomatoes grown. These tomatoes are a population of tomatoes that are grown and marketed locally as a "brand" of tomato called ROMA. When sampled, 70% of the tomatoes do not show up as "the same variety" Roma suggesting that they are a changing population. The tomato Roma is identified by an "old description" and not by a DUS test. It can therefore be accepted as a conservation variety under the description method of identification. When sold there is no guarantee of quality, variety specificity or germination but they are highly sought after in the region.

Both the blue potatoes and the yellow tomato are important examples of local production, for local markets of conservation varieties with true genetic diversity. However, neither would fit into the modern commercial production system and would not pass the DUS and VCU systems.

Varieties for thatching straw

There are two long straw winter wheat varieties that thatchers have been using in the UK for the last 25 years. These are Maris Widgeon and Maris Huntsman. It appears that it is no longer viable for these varieties to be maintained economically and they therefore may be taken off the National List. As a result thatchers will no longer be able to produce thatching straw from these old varieties and the commercial breeding companies have no interest in investing in a breeding programme for a small market of about 14,000 tonnes per year. Loss of local varieties could lead to imported varieties being used, which may not be as suitable.

In addition, thatchers also use a large number of conservation/old winter wheat varieties some of which were bred in the 1800's. They are ideal for thatching but the problem again is that they cannot produce enough seed and therefore enough of the thatching straw for their industry to use. The reason for this is that the varieties do not pass the criteria for DUS and VCU as they currently stand. DUS testing is specifically for food production, not straw production. Uncertified seed of these varieties cannot be moved between the farmers to increase the amount of land on which seed production can occur. The thatches are trying to develop their own system of variety assessment for thatching varieties. This includes things such as straw length, thickness, lodging etc. Seed stocks of these older varieties are tested regularly for purity, using gel electrophoresis.

UK amateur vegetable market

At the moment there are a large number of hobby vegetable breeders and producers in the UK. These breeders grow their vegetables on allotments or in small back gardens and sell them at markets. In addition, there is a large trade in small packets of different varieties of vegetable seed at markets and even garden centres. It is thought that there may be as many as 1500 varieties of vegetable seed that are sold in this way and this system has worked well for over 25 years. These varieties do not pass the DUS system.

Shetland cabbage/kale

In the Scottish Highlands and Islands, the crofters and local people use old varieties and landraces in local food production and other such industries. One example is the Shetland Cabbage which has been grown in the Shetland Islands at least since the 17th Century. It was first used as a vegetable and then also for cattle and sheep feed. The cabbage seed is not sold commercially and the survival of this old landrace now depends on the local crofters' farm saving seed and exchanging it annually.

7.4.1.4. Legal basis for new Directive

There is already a provision within each Seed Marketing Directive for the different crop species which allows "something" to be set up to enable seed of these types of varieties to be marketed and for genetic resources to be conserved within Member States. The relevant Articles included within each Seed Marketing Directive are listed at the beginning of the New Directive for the marketing of seed for conservation varieties. For example, in the Common Catalogue of varieties of agricultural plant species it is Article 4(6), Article 20(2) and Article 21 of Council Directive 2002/53/EC of 13th June 2002 (seen below).

Article 4(6)

6. In the interest of conserving plant genetic resources as specified in Article 20(2) Member States may depart from the acceptance criteria set out in the first sentence of paragraph 1 in so far as specific conditions are established in accordance with the procedure referred to in Article 23 (2) considering the requirements of Article 20(3)(a) and (b).

Article 20

1. Specific conditions may be established in accordance with the procedure referred to in Article 23(2) to take account of developments in relation to the conditions under which chemically treated seed may be marketed.

2. Without prejudice to Council Regulation (EC) No 1467/94 of 20 June 1994 on the conservation, characterisation, collection and utilisation of genetic resources in agriculture (13), specific conditions shall be established in accordance with the procedure referred to in Article 23(2) to take account of developments in relation to the conservation in situ and the sustainable use of plant genetic resources through growing and marketing of seed of landraces and varieties which are naturally adapted to the local and regional conditions and threatened by genetic erosion.

3. The specific conditions referred to in paragraph 2 above shall include in particular the following points:

(a) landraces and varieties shall be accepted in accordance with the provisions of this Directive. The procedure for official acceptance shall take into account specific quality characteristics and requirements. In particular the results of unofficial tests and knowledge gained from practical experience during cultivation,

reproduction and use and the detailed descriptions of the varieties and their relevant denominations, as notified to the Member State concerned, shall be taken into account and, if sufficient, shall result in exemption from the requirement of official examination. Upon acceptance of such a landrace or variety, it shall be indicated as a "conservation variety" in the Common Catalogue;

(b) appropriate quantitative restrictions.

Article 21

Specific conditions may be established in accordance with the procedure referred to in Article 23(2) to take account of developments in the area of the conservation of genetic resources.

7.4.1.5. General views on the new Directive

Generally, the people and organisations interviewed felt that the new Directive could be more restrictive than helpful and that it would not achieve what it is meant to. It was also felt that there would still be a large number of varieties left "outside the system".

It was considered that it would be very difficult to define a "region" when implementing the Directive. Each definition of "region" could be very different within each Member State with very different consequences.

Commercial variety perspective on the Directive

It is considered that the Directive has been drafted for political reasons. There is concern that the Directive could undermine the main commercial system of introducing new varieties onto the market, leading to a cheap, quick way for varieties to be listed for marketing. Also, (under Article 6) the period of two-year gap between a variety being listed on the Common Catalogue, then being removed from the CC and becoming a conservation variety is too short. A gap of 10 years was considered to be more suitable.

With respect to Article 14 of the new Directive, it was considered that the quantitative restrictions of 100 ha are too high. Potentially these conservation varieties could take up a large part of the market for some crops species.

With respect to Article 15 there was concern that the reporting of seed quantities to the Commission would be both time consuming and expensive. In addition, it was questioned what use the data would have.

Organic, low-input and commercial variety perspective

There was concern that the actual implementation would be too restrictive because the final implementation would be greatly influenced by the main commercial breeders and would not be implemented as it is truly meant to be.

With respect to Article 14 of the new Directive, it was considered that the quantitative restrictions are limiting because some organic farmers may want to expand their businesses to grow 300ha or more of one particular conservation variety. Farmers themselves are involved in participatory breeding programmes i.e. farmers and researchers but not commercial breeders. In France alone there are farmers and researchers working on developing their varieties for more than 30 crop species. These farmers want to do their own crosses using "old" and new varieties for the organic market, but they do not see how they will be able to do this under the new Directive. Farmers are concerned whether they are able to continue to use these "old varieties" and use these positive traits in developing new varieties for organic agriculture and low input production, under the new Directive?

The older varieties are very important for low input agricultural systems and appear to have the ability to adapt to varied climatic and soil conditions. Whereas the new commercial "mono varieties" are bred for "high input" systems and potentially cannot cope with extremes. Farmers need to be able to choose varieties to suit their soil type, structure, and climate and farming methods. In low input agriculture the differing genotypes are needed to adapt towards the different environments.

The interpretation of "regional" varieties will be very difficult. There are some organic varieties, for example wheat that can move between Member States, so the "region" can cover different countries.

At the moment the commercial breeding systems strongly influence the interpretation of both DUS and VCU characteristics and the testing systems. With environmental issues becoming more important there is a stronger case now for a wider interpretation of both DUS and VCU for varieties that are going to be used for organic and low input agriculture. The for this reason being that these systems have appear to have better soil structure; the varieties have better root systems and need less of a blanket requirement for additional nitrogen, in fact the whole treatment of the varieties in these trials would be different to the current system. A positive example of this can be found in Austria which has a separate VCU system for organic varieties to adapt to new requirements in value for cultivation and use.

Finally, there is specific wheat breeding programme in progress in the UK for plant populations, rather than specific varieties, for use in organic agriculture. It is thought that these populations provide a better yield and stability in organic farming compared to the pure lines. The populations are evolving all the time and adapt to different climatic and soil type conditions. Clearly these populations will not be able to pass the DUC and VCU testing systems that are currently in place and therefore would not be able to be marketed.

7.4.1.6. Implementation

The idea of the Directive is that each Member State could implement its own schemes for their conservation varieties. Groups wishing to produce and market seed of the old conservation varieties could submit a proposal to their own Government Department outlining their own requirements.

7.4.1.7. Conclusions

All the organisations that the FCEC spoke with had their own individual concerns about the introduction of this new Directive. The main one being: Will it actually achieve what it is meant to or will it actually be restrictive? This of course will depend on the importance that each Member State places on the implementation and how it is actually done.

FCEC view is that there appears to be an increasing move towards developing varieties and use of varieties that are not in the mainstream commercial agricultural industry. FCEC believes that the two different systems of the large commercial breeding companies and the smaller market or regional breeders and producers could run side by side because they are targeting completely different markets.

FCEC concern is that the new Directive may well be restrictive if implemented in the wrong way and FCEC is not certain that Member States will understand how to implement it with the flexibility, freedom and adaptability that the Commission intended.

The only way to check this would be for any new schemes / improvements in the marketing of theses types of varieties set up as a result of the implementation of the new Directive to be submitted to the Commission. This would show that the new Directive was actually achieving what it was set out to do.

8. SCENARIOS FOR THE FUTURE

In view of the stakeholders' opinions on the past/current performance of the Community S&PM legislation and on possible alternatives for the future, three approaches to the further development of the Community legislation were identified as follows:

- 'Status quo' scenario;
- 'Suppress' scenario;
- 'Modify' scenario.

The characteristics of the three scenarios considered as well as a preliminary assessment of their economic, social and environmental impacts are presented below.

8.1. 'STATUS QUO' SCENARIO

In the 'Status quo' scenario, the structure and provisions of the Community legislation will be maintained as they currently stand. The 'status quo' scenario assumes the continuation without change of the current arrangements. The difficulties discussed throughout this report persist.

The arguments in favour of this scenario are as follows:

- The internal market for S&PM exists and is generally perceived as functioning quite well;
- The Community legislation is adapted to the needs of the majority of the users;
- Costs reduction has already been an objective of the S&PM sectors over the years. Indeed, because of the reduced profitability of those sectors, national authorities and private bodies have worked together to better adapt the national regulations to the market demands, in particular as what concerns the marketing of conventional seeds;
- The costs linked to the implementation of the Community legislation are generally considered as reasonable and proportionate, in particular as regards the certification costs.

Despite the fact that the S&PM Community legislation has achieved good performances, the FCEC team consider that the 'Status quo' scenario is not advisable because it is not in line with the Better Regulation initiative and because majority of stakeholders have expressed their wish to maintain the S&PM legislation at Community level but to adapt it, as illustrated by a series of initiatives already taken to that end at EU or MS level (the Commission Working Group on the possible extension of the role of the CPVO, the DEFRA consultation (UK) on possibilities for Better Regulation, the promotion of the certification 'under official supervision' in several MS, the integration of plant health and seed inspection services in some MS, etc.).

8.2. 'SUPPRESS' SCENARIO

In the 'Suppress' scenario, the current Community provision for the registration and marketing of S&PM are suppressed. It is then up to the MS to decide if they maintain the implementing regulations developed at national level for national listing and certification or if they are left to self-regulation by the markets. MS will decide for each sector/crop by taking into consideration the competitiveness of the concerned S&PM sector on the EU market, the number of employees in the related official registration and certification authorities; the contribution of the legislation in this sector to the national economic, environmental and social policy.

The arguments in favour of this scenario are as follows:

- The main need felt at the time when the Community legislation was created was to improve the production volumes to secure food security. This was expected to be achieved by improving the crops

productivity through ensuring the marketing of S&PM lots of high quality. Now that food security in EU is achieved 'a priori', the rationale for keeping the Community legislation becomes questionable;

- Under self-regulation, industry would compete in terms of product quality, price and consumer choice; Any increase in competition and choice is expected to benefit consumers;
- Seed is the most 'officially' controlled agricultural input versus PPPs, fertilisers, machinery whereas it is certainly the sector where there is the least risk for users and consumers;
- New priorities (other than the productivity) and new crops (other than conventional crops) have emerged. The Community provisions (some of them dating back to the 60's) do not fit their needs;
- Free marketing of some S&PM (e.g. vegetables) is achieved with not any Community provision for VCU or certification, and these sectors are considered as competitive as the fully regulated sectors;
- As the catalogue, via VCU results, is being used as a marketing tool by all companies and especially SMEs, one might ask if it is the role of the public authorities to support the marketing strategy of such private operators;
- Some 3rd countries, e.g. USA, have developed a competitive S&PM sector with not any provision comparable to the ones developed at EU level. It must however be stressed that in the USA, the legislation governing the relations between buyers and seller is quite different from the EU legislation;
- In VCU, the *G x E x L* situation demonstrates that the current EU provisions are not a policy lever any longer;
- The certification requirements are, often, higher in national certification schemes than in the EU provisions, which demonstrate that the current EU provisions are not, any longer, a policy lever.

Survey results have clearly indicated that the large majority of stakeholders do not support the 'Suppress' scenario.

Furthermore, a high degree of uncertainty is related to the implementation of such scenario, in terms of its feasibility and sustainability because 1) it is not possible to know at this stage how the different MS will react; 2) it would get extremely complicated to implement a harmonised system of Common Organisation of the Markets for agricultural products in a situation where the source material (S&PM) were harmonised at national level only.

Finally, suppressing the Community legislation would lead to the loss of a possible policy lever for the EU, that could be used to enforce other regulation (e.g. GMOs).

8.3. 'MODIFY' SCENARIO

The main arguments in favour of the 'Modify scenario' are as follows:

- The S&PM sectors have become more complex and suppliers & users have become more responsible;
- New priorities (i.e. organic farming) and new crops have emerged;
- The examination of the structure and provisions of the Directives has highlighted their complexity and pointed to some inconsistencies, incoherences or gaps;
- The large majority of stakeholders consider that official authorities (at EU or national level) still have an important role to play in guaranteeing the equal access to all EU players on the S&PM Internal Market, the productivity of the agriculture in the EU and the quality of S&PM produced and marketed in the EU in the future;
- Modernisation of the S&PM regulatory frameworks is ongoing in several places in the world. A 'Status quo' may result in a loss of competitiveness;
- MS are highly creative in the modernisation of their S&PM regulatory schemes. A 'status quo' may result in a marginalisation of the Community legislation; as already highlighted for potatoes.

The results from the stakeholders' consultation support the 'Modify' scenario. In terms of strategic focus, the evaluation has highlighted the need to move forward a policy which is more focused on crop sectors specificities and by taking into account the development of complementary food markets. This can be achieved via a simplification of the current Community legislation with the additional objectives of introducing flexibility within the regulatory framework in order to address the specific needs of the different sectors in a fast changing environment and to adjust costs to the size of the targeted markets.

The evaluation team has identified a range of modifications for the future, which were discussed with the stakeholders and authorities during the interviews. It should be noted that these modifications are complemented by a series of specific recommendations that are presented in Annex V.

The proposed modifications aim to support the following main objectives for a revision of the Community legislation:

- Simplify the current Community legislation by 1) removing the inconsistencies; discrepancies and gaps; 2) replacing the current structure of the Community legislation with a structure distinguishing between the pillars 'Identity', 'Registration' and 'Marketing' and splitting the technical aspects from the legal provisions;
- Introduce more flexibility within the regulatory framework to 1) address the specific needs of the different sectors in a fast changing environment and to 2) adjust costs to the size of the targeted market;
- Reduce the differences between MS as regards the implementation of the Community legislation and contribute thereby to the creation of a level-playing field;
- Promote costs reduction approaches and introduce flexibility in the operating system e.g. to promote the implementation of certification under official supervision and the integration of plant health and certification inspection schemes;
- Secure long-term consistency with the other EU policies, and especially on GMOs, Plant Protection Products, Plant Health, Human Health/Food Safety;
- Finalise the current discussion on the extension of the role of the CPVO and further identify additional synergies with the CPVO expertise leading to significant benefits to the S&PM sectors;
- Reinforce provisions dedicated to inform users, in particular in the forestry area.

9. PRELIMINARY IMPACTS OF THE SCENARIOS FOR THE FUTURE

Because of data limitations on the expected impacts, the following impact assessment of the 'Suppress' and 'Modify' scenarios is a preliminary assessment. It consists in a general qualitative assessment rather than a quantitative cost-benefit analysis and needs to be further discussed and examined in consultation with the stakeholders.

9.1. PRELIMINARY IMPACTS OF THE 'STATUS QUO' SCENARIO

The strong and weak points identified for the current Community legislation remain.

9.1.1. Economic impact

Trade, competitiveness

- There is a general perception that the current Community provisions offer an equal access to all suppliers (large companies and SMEs). Maintaining such legal platform contributes to keeping a large number of market players in the EU, producing S&PM of high quality and well-positioned on world markets;
- Community rules are considered as disproportionate to the market size of some minor crops or niche varieties and are barriers to the timely and cost-effective development and trade of such varieties;
- The absence of some definitions (e.g. variety) or the confusion linked with some expressions (e.g. 'not for forestry purpose') can be a source of conflicts or frauds;
- The lack of threshold for the adventitious presence on GMOs in non-GM seed put EU farmers at a disadvantage in the world markets;
- The non-modernisation of the S&PM legislative framework may influence negatively the competitiveness of the EU in term of trading, but also in term of seed production. Suppliers may be further interested in to move their production plans in 3rd countries (already largely the case for vegetables seed and more and more the case for spring crops such as maize);
- In particular, the insufficient control of the fraudulent imports of FRM has negatively impacted on the EU forestry sector in the past. There is the risk that such negative effect increases with the 'status quo' scenario.

Competition in the internal market

- The Directives on the Common Catalogue is considered as having positively contributed to the free marketing of S&PM in the EU. The observed increase in trade of seed of agricultural crops (within the EU but also with the external world) is expected to continue if the Directives are maintained;
- The lack of harmonisation and the national additional requirements have contributed to the absence of a level-playing field.

Specific regions or sectors

- It is difficult and expensive for suppliers of varieties for low-input agriculture, peasant varieties and other niche markets to fulfil the existing conditions and criteria defined for registration and certification purposes. The 'status quo' scenario will not favour the establishment of alternative systems for the listing and marketing of such varieties;
- The absence of bilateral or multilateral agreements for the conducting of DUS tests (and into a lesser extent the one of VCU tests) will oblige the new MS to support all the costs for the implementation of the Community legislation in their country;

- The existence of a testing system common to all candidate varieties provides crucial marketing information to all breeders, including SMEs wich have the possibility to compare at an early stage their candidate varieties to those developed by large companies with important marketing resources.

Consumers

- Consumers of S&PM produced according the rules defined for the conventional agriculture have currently access to a large choice of products of good quality;
- Contrarily, the Community provisions have not encouraged the development of non-conventional commercial varieties (i.e. peasant varieties) and the germplasm has been privatised (more recently tools have been developed to counter such privatisation as the breeder exemption and the gene banks). Those elements have limited the choice for consumers interested in those varieties;
- The implementation of the Community provisions represents a minor part of the total costs of production of S&PM. The 'status quo' scenario will consequently not impact on the costs of products sold to consumers;
- The official label required for the marketing of certified S&PM is considered as adequately informing the consumers. Problems still exist for the ornamental PM and the FRM, for which additional legislation at Community level is required and will not be provided in the 'status quo' scenario.

Costs and administrative burden

- In some cases, the Community legislation imposes a disproportionate regulatory burden on developers of new crop varieties;
- The different implementation of the Community legislation in the 27 MS (e.g. the GxExL situation for VCU) creates additional costs and administrative burden for the marketing of varieties at European level. Such weak point will intensify with the possible adhesion of new MS or the adoption of the co-decision procedure for the S&PM area;
- The mixing of technical and legislative components in the Community legislation makes it difficult (so costly and time-consuming) to adapt to changes in the market environment.

Innovation and research

- The Common Catalogue Directive provides valuable indications to the SMEs on the expected characteristics of any new variety;
- The Community legislation creates impediments to innovation and to the timely availability of niche varieties;
- With the 'status quo' scenario, the Community legislation will not fully benefit from recent advance in plant breeding technologies.

9.1.2. Social impact

No important changes are expected.

As explained for the economic impact, the current Community legislation provides equal access to all market players in conventional agriculture. Contrarily, it imposes disproportionate costs for breeders of niche varieties of varieties of minor economic importance.

9.1.3. Environmental impact

- The eradication costs of pests or new pests (quarantine or quality ones) can further increase as a consequence of the inconsistency between the Community legislation and the plant health legislation;
- The 'status quo' scenario maintains the problem of the suitability of the Community legislation for the marketing of niche varieties contributing to an increased intra-specific biodiversity;

- No link exists between the Community legislation and the legislation on contaminants in food (in particular mycotoxins) what does not allow to attack the problem of production of mycotoxins at the source.

9.2. PRELIMINARY IMPACTS OF THE 'SUPPRESS' SCENARIO

9.2.1. Economic impact

Trade, competitiveness

- Different approaches in the MS could lead to the principle of the internal market being compromised and threatened by a hidden national protectionism;
- In the case of self-regulation by the market, large companies with a European or international dimension will sufficiently know about the EU and world market demand to orient their breeding efforts and keep competitive. Contrarily, SMEs active in one or a few EU MS could loose the points of reference (i.e. the standards defined at EU and national levels) previously at the basis of their strategy of innovation;
- Under self-regulation, industry would compete in terms of product quality, price and consumer choice; Any increase in competition and choice would benefit consumers;
- Mechanisms would need to be ensured (at national or EC level) to satisfy requirements for the international trade of S&PM which requires that varieties be registered on an official list;
- Mechanisms would need to be ensured (at national or EC level) to satisfy requirements for the international trade of seed potatoes and beet seed for which respectively UN-ECE and OECD minimum standards exist.

Competition in the internal market

- Competition may be driven by price rather than quality, resulting in lowering of quality in certain sectors;
- Competition is based on market conditions and will become stronger;
- Loss of tools for enforcements of PBRs for breeders i.e. DUS and certification;
- Technical rules will create obstacles to the circulation of the S&PM.

Specific regions or sectors

- The impact on the regions and sectors will depend on how the MS and the industry will react as a follow-up to the removal of the Community provision, as follows:
  - If the majority of the MS decide to keep their national legislation, stronger competition will force them to make the testing of varieties more efficient by taking into consideration the importance of the species for their national economy as well as the extent to which agreement can be reached with other MS in order to reduce the number of testing stations;
  - If the majority of the MS remove their national legislation, breeders and their associations will be forced to invest to test or to promote their varieties. In sectors where some large companies have an important market share, SMEs will probably not survive. In sectors characterised by a large number of SMEs, competition will increase and reduce the profitability of the breeders;
- The market is expected to evolve to a higher concentration of firms as well as further specialisation of the production and of marketing channels.

Consumers

- For some crops, the removal of minimum quality requirement will lead to the marketing of products of different quality and price, probably inducing an other professional organisation in charge of controls;
- The removal of the Community legislation has the potential, at least in the first years, to reduce consumer acceptance and confidence in EU seed;
- This scenario eliminates EU ability to ensure the integrity and safety of seed produced and marketed in the EU;
- It becomes possible to market a same variety under several names, what increases confusion and reduce market transparency;
- Emergence of new costs for farmers to prevent the risks of unfair selling, because of the need to organise legal protection or to buy 'safer' S&PM at higher price;
- Loss of traceability;
- Higher transparency in supplier-buyer relationship and responsibilities.

Costs and administrative burden

- In the case of self-regulation by the market, no more common rules will apply to identify and characterise a variety. This could lead breeders to protect their varieties more frequently what means additional costs;
- In case some MS have maintained their national legislation, the removal of the Common Catalogue Directive obliges the breeders to pay for national listing in those MS;
- In S&PM sectors characterised with a large segmentation of actors, the absence of a minimum level of harmonisation could increase the costs supported by suppliers to find or adapt certain standards based on a voluntary approach;
- Administrative costs and burden could decrease in the absence of Community rules to be applied. However, new costs and administrative burden could appear 1) for the MS because of the need to conclude agreements with other MS to facilitate trade as well as 2) for the users because of the need to protect against unfair selling.

Innovation and research

- In the case of self-regulation by the market, SMEs active in one or a few EU MS could loose the points of reference (i.e. the standards defined at EU and national levels) previously at the basis of their strategy of innovation;
- MS and/or breeders could take the opportunity to adapt the standards and the testing of varieties to new breeding technologies.

9.2.2. Social impact

- Risks that the small/medium size suppliers do not survive or need to re-orientate their activity;
- Incentive for 3rd countries players that are familiar with lighter regulatory frameworks to enter the EU market;
- The decision of any MS to remove its national legislation will lead to job losses in the official authorities as well as in the accreditated organisations working for them.

9.2.3. Environmental impact

- MS and/or breeders will have the opportunity to adapt the costs for the testing and or marketing of niche and peasant varieties to the size of such market and possibly contribute to increase the genetic diversity of the commercialized varieties;
- There is the risk that some suppliers will consider the plant health aspects as economically not important, what could negatively impact on the environment because of spreading of pests or appearance of new pests and/or increased S&PM treatments by the farmers;
- The possibility of un-harmonised national rules on health status is also expected to increase the risk of spreading of pests or appearance of new pests (quarantine and quality).

9.3. PRELIMINARY IMPACTS OF THE 'MODIFY' SCENARIO

Section 8.3. above identifies several objectives for a revision of the Community legislation.

For each of them, the following table establishes a link with the implementing options as identified in the analysis of the past/current performance of the Community legislation (section 7) and assesses their easiness and timescale for implementation as well as their preliminary economic, social and environmental impacts.

Table 26 – Preliminary assessment of the options under the 'Modify' scenario

Objective	Implementing options	Easiness and timescale for implementation	Preliminary economic impact	Preliminary social impact	Preliminary environmental impact
Simplify the current Community legislation	**Clean the Directives; i.e. remove the inconsistencies, discrepancies and gaps.** **To be applied in priority to the old Directives.**	Easy, short term	Simpler implementation because of better understanding. Limited requirements to further modification and harmonisation of the national legislative framework. Clarity in the Community legislation leading to correct implementation at MS level, better adequacy to international standards and possibly improved free marketing. Limited contribution to reduced costs and administrative burden.	No	No
	Replace the current structure with a structure distinguishing between the pillars 'Identity', 'Registration', and 'Marketing' and transferring technical rules to technical annexes or implementing measures	Partly easy, medium term	In the short term, negative impact on the free marketing as national authorities and market players need to adapt. In the long term, positive impact due to simplification, increased harmonisation, reduced costs and administrative burden and more rapid adaptation to the changing market environment (leading to increased competitiveness). In line with the *Better Governance* approach.	Requirement to align national structures to new model. Negative impact on NMS that will have to modify their legislative framework for a second time in a short period of time.	No

	Separate the legal from the technical discussions	Partly easy, short term	Better decision-making, based on better knowledge and targeted discussions, leading to faster decision.	Alleviate the strategic discussions of the technical considerations and conversely. Consequently, increased motivation of the actors and more place for strategic proactive discussions on new challenges and changing market environment.	More adapted platform for discussion on the environmental challenges.
Introduce more flexibility within the regulatory framework	**Make the official rules for uniformity of a variety more flexible** **To make the VCU rules evolve to adapt to any type of agriculture and to test varieties created by new technologies**	Difficult, long term	Reduced costs and regulatory burden for crops with revised rules. Appropriate, timely and cost-effective responses to changing conditions in the agricultural sector. Costs adjustment to the size of the targeted market. Increased investment in research in new varieties due to greater predictability in the eligibility of the varieties for registration. Buyers of S&PM will have to carefully research varieties before making purchasing decisions.	Increased number and diversity of registered varieties better responding to farmers' different agronomic needs. For the varieties, which do not require VCU, testing anymore, reduction in the personnel previously in charge of the trials, sample and site evaluations of those varieties.	Greater diversity in the types of varieties available
	Adapt the requirement for the marketing of seed to defined categories, as done for the FRM and PM.	Not easy, long term	Increased suitability of the system to peasant and niche varieties. More choice for consumers. Better adaptation of the certification costs to the size of the targeted market.	No	Increased genetic diversity of commercial varieties

Reduce the difference between MS as regards the implementation of the Community legislation and contribute thereby to the creation of a level-playing field	**Promote the coordination of VCU testing and the extension of bilateral or multilateral agreements for DUS testing**	Not easy, mid term	Reduced number of testing sites avoiding duplication of work and by this, reduced costs and administrative burden. Increased transparency of the system. Improve uniformity of the DUS reference collections. Minimize current problems base on different implementation of provisions Improve harmonisation	Reduced number of testing sites leading to possible job losses	No
	Restart the comparative tests and trials	Easy, short term	Improved harmonisation of the certification protocols leading to better control of fraud	Improved knowledge of the practices in other MS contributing to better quality of the work of inspectors Motivation of actors	No
	Audit the current implementation of the Community legislation on certification and DUS	Not Easy, short term			
	As regards seed potatoes, further align the EU rules with the international standards of UN-ECE	Easy, mid term	Simplification of legislative framework leading to costs reduction Improve harmonisation within EU Reduce the duplication of administrative efforts for EU and international competent authorities	No	Better fit to the international phytosanitary requirements and/or guidelines (IPPC)
Promote cost reduction approaches and introduce flexibility in the operating system	**Promote the implementation of the certification 'under official supervision'**	Easy, mid term	Increased flexibility to organise certification. Increase flexibility in the day-to-day management of the operations Increased efficiency of the certification system (i.e. efficient	Increased motivation of the actors. Supervision from authorities maintain the confidence in the market Restructuration may lead to	No
	Promote the integration of plant health and certification inspection services	Partly easy, short term			

	Promote the implementation of certification 'under official supervision'	Easy, mid term	use of existing infrastructure, expertise and data leading to reduced costs) leading to reduced costs, reduced administrative burden and more rapid decision-making.	job losses at authorities level	
	Extend the certification 'under official supervision' to pre-basic and basic crops	Partly easy, short term			
	Support the morphological analysis of the variety with molecular tools and in particular DNA markers	Partly easy, mid term	Better management of the testing and of the reference collections leading to reduced costs Improve traceability of S&PM lots Reinforce concept of Distinctness	Training of officials	Allow the listing of more varieties (e.g. varieties which looks the same but have different parents)
Secure long-term consistency with EU policy on GMO, Plant Protection Products, Plant Health, Human Health/Food Safety	**Integrate plant health and Seed certification legislation**	Not easy, mid term	More efficient organisation of the inspection leading to costs and time- savings. Reduced administrative burden with the use of one European document to attest S&PM certification and healthiness	Training of inspectors. Better organisation of the work of inspectors and producers, leading to increased flexibility	Better control of plant pests and diseases
	Make use of the certification inspection platform to monitor the implementation of quality control for GM varieties	Difficult, long term	Better consistency between S&PM and GMO legislations leading to better understanding of their obligations by the producers. Reduced costs because of fewer conflicts on quality. Eliminate duplication of costs for inspection and administrative burden for both private operators and competent authorities	Training of inspectors Elimination of redundant activities lead to jobs losses	No
	Implement in the S&PM Community legislation provisions leading to risk reduction of	Partly easy, mid term	Global chain approach to the problem of mycotoxins.	Food safety expertise required at S&PM Reduced presence of	No

	contaminants in food			mycotoxins in cereal.	
	Identify additional link between S&PM Community legislation and the Food law	Difficult, long term	Integration of the food value chain leading to costs savings	No	No
Finalise the current discussion on the extension of the role of the CPVO and further identify additional synergies with the CPVO expertise	**Checking of variety denomination by the CPVO, based on their centralised database. MS remain responsible of the final approval**	Easy, short term	More efficient mechanism leading to reduced administrative burden. Elimination of inconsistencies	No	No
	Adoption and auditing of quality requirements for DUS testing by the CPVO	Need to be further discussed and examined	Harmonised decision on DUS testing Improved efficiency in time and costs Leads to the promotion of bilateral agreements	No	No
	Extension of discussion to the principle '*one key-several doors*', i.e. same and unique DUS testing for listing and for Plant Variety Rights	Need to be further discussed and examined	Harmonised decision on DUS testing Improved efficiency in time and costs Efficient administration of the applications	No	No
	Develop a traceability system with indication of the origin of the marketed variety.	Not easy, long term	Allow enlarging the choice to consumers. Improved enforcement of PVRs	Users become more responsible.	
Improve the information to the users	**Clarify the supplier' documents in the forestry area**		Better harmonisation leading to improved marketing	No	No
	Better define the rules for small packages				