



European Commission

Directorate General for Health and Consumers

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

Assignment 5 of the Framework Contract for evaluation and evaluation related services - Lot 3: Food Chain (awarded through tender n° 2004/S 243-208899)

Final Report

Submitted by:

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10.10.2008

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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 Organisation for Economic Co-operation and Development (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 exercise (Simpler Legislation for the Internal Market), 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 Small and Medium-sized Enterprises (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 (characteristics 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. Genetically Modified Organisms (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 (United Nations - Economic Commission for Europe).

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 France and the United Kingdom have set up certification 'under official supervision'. The Netherlands and Denmark have merged the certification and phytosanitary inspection bodies on a crop by crop approach.

A Working Group (WG), 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 a unique responsibility on Plant Variety Rights (PVR). 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 lapse of time for its inclusion in the Common Catalogues 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 (Department for Environment, Food and Rural Affairs - 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 markets. 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 flexible 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 UNECE.

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 constraints 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 explicitly 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.