



EUROPEAN COMMISSION
Impact Assessment Board

Brussels,
D(2012)

Opinion

Title **DG SANCO - Impact assessment on the placing on the market and production, with a view to placing on the market, of plant reproductive material**

(draft version of 15 December 2011)

(A) Context

The EU legislation concerning plant reproductive material (PRM) has led to guaranteed quality standards, as well as a highly competitive sector, supplying the European market with high quality products. The EU is the world's largest PRM exporter, with more than 60% of the worldwide export value. However, the sector is highly concentrated, and barriers to the internal market remain in place. The proposal aims at promoting the efficiency of the PRM management system by simplifying existing EU legislation (12 Council Directives) and by avoiding unnecessary burdens for operators and public administrations. Finally, PRM legislation should better reflect the role of plant reproductive material for biodiversity and climate change, and not only producer productivity. The current Impact Assessment focuses on the various options to replace the existing Directives.

(B) Overall assessment

The report needs a considerable amount of further work to present the necessary analysis in a more structured and accessible form, and a number of important issues should be clarified. Firstly, the report should demonstrate much more clearly which elements of the current system are problematic, and why they need to be addressed at the EU level, building on evaluation results, feedback from stakeholders' consultation and other available data. Secondly, the report should improve the intervention logic by clarifying the link between the underlying problems and the stated objectives. Trade-offs between objectives, for instance between strengthening competitiveness of producers (especially SMEs) and reducing the implementation costs for competent authorities, should be explicitly analysed. Thirdly, the presented options should be better differentiated on substance, especially as regards simplification and cost recovery regimes, and possible combinations of options should be identified and assessed. Fourthly, the expected impacts of the final combined options should be presented in a more quantitative and transparent way. Finally, stakeholder views on particular aspects of the problem as well as on the presented options should be referred much more clearly throughout the report.

Given the nature of these concerns, the IAB requests DG SANCO to submit a revised version of the IA report on which it will issue a new opinion.

(C) Main recommendations for improvements

(1) Strengthen the evidence base of the problem definition. The report should convincingly demonstrate which elements of the current system are problematic, why, and to what extent these problems derive from the content and implementation of the legislation, and why this has to be addressed at the EU level. In particular, the report should clearly show how the current legislation affects the functioning of the internal market, and where and how it generates distortions. In doing so, it should give clearer references to evaluation results and recommendations, differentiating clearly between the sub-sectors (ornamental, forestry, etc). The report should also strengthen the description of the current market structure, supported by providing more quantitative information on the situation in the EU and international market developments across the different sectors (players, structure, role of SMEs, etc). On that basis, a full baseline scenario should be developed, including a discussion of the effects of a better implementation and enforcement of the current EU regime. Finally the report should also present the relevant elements of the EU Plant Health Regime, and more clearly explain the problem of incoherence with the PRM regime. It should explicitly state that GMOs are dealt with in a parallel framework.

(2) Improve the intervention logic and the presentation of objectives. The report should clearly indicate which insufficiencies of the current system regarding the promotion of innovation and sustainability should be addressed, to justify presenting these issues as key objectives. It should clarify in greater detail which trade-offs exist between the objectives that the proposal aims to achieve and how the identified options will deliver on the objectives. Finally, the report should indicate to what extent introducing a full cost-recovery regime would constitute a proportionate measure in the light of the stated objectives.

(3) Better present the options and their possible combinations. The report should better differentiate between the options on substance, in particular concerning simplification and the proposed degree of harmonisation of recovery of costs by authorities. It should clearly state how options can be combined, and which elements are incompatible with others. The feasible combinations of elements from the original options, including the preferred option should be presented and assessed in a clearer fashion, stating explicitly what would change (and what would remain the same) in comparison with the baseline.

(4) Present the expected impacts in a more transparent way. The report should provide an overall assessment of all significant costs and benefits for the options presented, where possible in quantitative terms. Aggregate figures for costs and benefits should be broken across different actors (businesses, public authorities, etc.) and across sectors. Where exact figures cannot be given this should be explained and best possible indicative estimates should be provided. The report should clearly show how the shift of burdens from public authorities to enterprises may specifically affect SMEs (that are the main affected parties in a number of Member States), including those that are not exclusively active in the niche markets of conservation varieties. The analysis of the impacts on competitiveness should be strengthened, for instance by better taking into account the international dimension of the PRM sector, market entry and innovation issues and by strengthening the analysis of the effects on trade flows and investment needs. The analysis of social impacts should not only address public sector employment, but should also include an explicit analysis of possible impacts on employment in the

affected businesses. With regard to environmental impacts, the report should address key issues such as impact on biodiversity, land use and relation to the invasive species regime. The treatment of GMO material should be dealt with in greater detail. The presentation of the comparison of options should be strengthened by incorporating the available quantitative information on costs and benefits of the different options including the most feasible combinations of options. Finally, the expected impacts of the preferred option should be analysed in greater detail.

Some more technical comments have been transmitted directly to the author DG and are expected to be incorporated in the final version of the impact assessment report.

(D) Procedure and presentation

The references to stakeholder input received in the public consultation should be made more systematically throughout the report. The report should also provide a summary of the results of the stakeholder consultation, and it should clarify to what extent views differed across stakeholders' groups, in particular SMEs and competent authorities. The report should indicate more clearly how stakeholders' opinions have been taken into account. The executive summary should be modified in line with the recommendations concerning the main report.

(E) IAB scrutiny process

Reference number	2011/SANCO/008
External expertise used	No
Date of IAB meeting	18 January 2012