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D(2008) 7902

Opinion

Title **Impact Assessment on: Revision of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market**

(revised version of 9 September 2008)

Lead DG **DG ENV**

1) Impact Assessment Board Opinion

(A) Context

The IA provides analysis for the revision of the existing directive 98/8/EC (Biocides Directive), which seeks to harmonise the placing of biocidal products on the market whilst guaranteeing a high level of protection for humans, animals and the environment. The implementation of the Directive is too recent for evidence to be available on impacts on pest control and on the level of human/animal health and environmental protection.

An important element of the Directive is the principle of mutual recognition of authorisations. In accordance with that principle, a company, once it has obtained for a product a first authorisation in a Member State, may apply for the mutual recognition of that first authorisation by other Member States. However, as product authorisation has not yet started, no practical experience of the authorisation and mutual recognition procedures is available.

A draft version of the IA was discussed during the IAB meeting on 27 August 2008, after which the IAB recommended to resubmit a new version of the IA report¹.

(B) Positive aspects

The IAB recommendations have been followed to a large extent. The IA aims to monetise relevant cost parameters. Stakeholders' views have been clearly presented.

(C) Main recommendations for improvements

The recommendations below are listed in order of descending importance.

General recommendation: Following the IAB recommendations the quality of the IA report

¹ See IAB opinion of 3 September 2008, D(2008) 7014

has been substantially increased. Nevertheless, it can be further improved by strengthening the subsidiarity analysis, providing more clarity on the structure of the options and further assessing the impacts of the proposed options including a more thorough discussion of distributional impacts, as well as on methodological approach to assess the administrative costs.

(1) The subsidiarity discussion should be improved. While the general subsidiarity analysis has been strengthened, it should be further improved when assessing individual policy options, in particular as regards policy issue 5 (fees charged). The IA report should analyse in more detail the internal market implications of maintaining a decentralised fee system, rather than taking the positions of the Member States on this issue for granted.

(2) The assessment of impacts should be further developed. The IA report includes now rather aggregated figures of costs and benefits for the industry resulting from the proposed changes. While providing a fully developed impact analysis on the competitiveness of individual companies would be disproportionate, the IA report should nevertheless provide more information about the impacts on the various types of affected parties (e.g. big companies vs. SMEs, substance producers vs. product manufacturers, etc) and show how the benefits and costs of the proposed changes would evolve over time. Additionally, in line with the previous IAB recommendations, the IA report needs to be more specific about the level of data confidence and should be more transparent on the uncertainty involved when aggregating data. Furthermore, the IA report should provide a clear definition of the term market value. In any case it would be better that business compliance and administrative costs are clearly delimited and related to companies' sales or turnover. Finally, given the scale of the impacts (both for costs and benefits), effects on employment should be quantified.

(3) The structuring of options should be improved further. The IA still needs to provide greater clarity as to what would be the difference of some of the options when compared to the baseline scenario. This concerns in particular options (a) and (b) for policy issue 1 (scope) and policy issue 2 (product authorisation). Additionally, the problems described under some of the policy options (e.g. 4.2.1, 4.5.1) would be better presented already in the problem definition section.

(D) Procedure and presentation

The IA report exceeds the 30-page limit, which seems justified given the problems at hand. Additionally, the EU Standard Cost Model reporting sheet should be placed in an annex. The IAB would like to point out that according to the IA guidelines (Annex 10) the IA should have made use of the SCM.

2) IAB scrutiny process

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|-----------------------------|-------------------|
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| Author DG | ENV |
| External expertise used | No |
| Date of Board Meeting | Written procedure |
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