EUROPEAN COMMISSION
IMPACT ASSESSMENT BOARD

Brussels, 03 -09- 2008
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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**

(draft version of 1 August 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.

(B) Positive aspects

The report is written in a clear and focused language and generally well structured. It aims at monetising all relevant costs.

(C) Main recommendations for improvements

The recommendations below are listed in order of descending importance. 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.

General recommendation: The IA report needs to strengthen several key elements: the problem definition, policy options and their assessment. In particular the presentation of data on costs, including administrative costs should be significantly improved. The stakeholders' views on the most crucial issues should be presented clearly in the report. Given the scope of the necessary changes, the IAB invites DG ENV to send a new version of the IA report, on which the IAB will issue a new opinion. These recommendations were

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largely accepted by DG ENV during the IAB meeting. Additionally, alternate IAB Member, Robin Miège, offered his help to the authors.

(1) The problem definition should be strengthened. Given that there has been no experience with the authorisation procedure under the current directive, the IA needs to provide solid arguments on the timing of the revision. The relation to forthcoming regimes (such as REACH) or other relevant planned policy initiatives ('new' new approach) should be explained, and the impact of these initiatives taken into account when constructing the baseline scenario. The IA would also benefit from explaining the regulatory background and the rationale for regulating the substances and products in question.

(2) The baseline scenario needs to be made more robust. The baseline scenario needs to be reconstructed; it should include all actions (including other relevant policy initiatives) that have been decided (even if they are not implemented yet) as well as any business as usual actions that would happen without revision of the directive. For the issue of treated materials, the figures regarding market share compared to other products should be added. Finally, in the baseline scenario there should be more information about the underlying reasons for the current heterogeneous fee structure, as well as the length of the procedures at the member state level, possibility of appeal (should the authorisation not be granted) and the impact this may have on innovation.

(3) The policy options need to be restructured. Following clarification of the baseline scenario, the policy options need to be better differentiated (for instance option a and b for policy issue 2 or a and b for policy issue 4). The IA needs to clarify which options are mutually exclusive, and how simultaneous implementation of the measures would impact on cost (savings) for business (e.g. applying data sharing and more possibilities for data waving).

(4) Assessment of impacts needs to be made significantly more transparent. All cost figures need to be clarified (annual, one-off, discount rate used, etc) and put into context (e.g. how do they relate to business turnover?). In particular the assessment of new costs arising from extending the scope to treated materials should be more robust. While providing an aggregated cost figure for all treated materials would probably be highly speculative, the IA should nevertheless provide quantification of the scope of the overall problem (e.g. import figures) and a more detailed analysis based on examples. This analysis should also look at competition and competitiveness aspects and in particular assess whether expected reductions will be sizeable enough for new businesses (SMEs) to enter the market. These additional costs need to be compared with environmental, health and competitiveness benefits. The IA should distinguish those costs that will arise from implementation of the current directive (and these should be part of the baseline) and those that would arise from options examined here. The impact on administrative costs (including possible reductions) needs to be assessed using the EU Standard Cost Model. Overall impacts on simplification should be presented more prominently.

(5) Results of the stakeholder consultations should be better reflected in the report. The IA should provide a clear overview of stakeholder views in relation to the most important policy options, such as enhancing the scope to treated materials.

(D) Procedure and presentation

The report needs to be redrafted according to the recommendations listed above. Particular attention should be paid to the clarity of presenting costs and costs reductions. In particular, the IA and the executive summary should include an overall figure for the cost implications of the preferred option.

2) IAB scrutiny process

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