

Brussels, 9 November 2007 D(2007) 9977

Opinion

TitleImpact Assessment on a proposal for a Decision of the
European Parliament and the Council amending Council
Directive 76/769/EEC on the approximation of the laws,
regulations and administrative provisions of the member
States relating to the restrictions on the marketing and use of
certain dangerous substances (acrylamide)

(draft version of 5 October 2007)

Lead DG DG ENTR

1) Impact Assessment Board Opinion

(A) Context

Council Directive 76/769 seeks to establish harmonised rules to achieve a high level of protection of human health and to avoid divergent national legislations. It relates to restrictions on the marketing and use of certain dangerous substances. The proposal to amend this Directive to include acrylamide intends to prohibit its use and to prevent any future reintroduction of the use of acrylamide grouts. The objective of the proposal is to reduce identified unacceptable risks to consumer health and to avoid barriers to intra-Community trade in products containing acrylamide.

(B) Positive aspects

The impact assessment provides a well structured analysis and discusses an appropriate set of policy options, including voluntary action by industry. The potential impacts from the identified policy options are overall presented in a concise, proportionate and well balanced way.

(C) Main recommendations for improvements:

The recommendations below are listed in order of descending importance. Some more technical comments have been transmitted to the author DG.

General recommendations: While the overall quality of the impact assessment is good the scope of the problem should be better explained and impacts on trade and

Commission européenne, B-1049 Bruxelles / Europese Commissie, B-1049 Brussel - Belgium. Telephone: (32-2) 299 11 11. Office: BERL 6/29. Telephone: direct line (32-2) 2981898. Fax: (32-2) 2965960. administrative burden should be more thoroughly assessed.

(1) The IA report should specify more precisely the scope of the applications of acrylamide under the proposal, and give indications on the magnitude of the risk and the parties mostly affected by it (particularly if used under extreme situations).

(2) The links to the REACH legislation should be better explained. In particular the IA report should clarify why the other possibilities for regulatory regime under REACH (such as 'authorisation'') have been discarded as a policy option.

(3) Trade impacts should be presented more thoroughly. The IA report should analyse in more detail impacts with regard to the import of acrylamide in the various scenarios, including the impacts of a possible total ban on EU trade policy relations with third countries.

(4) An assessment of administrative burdens should be added. The IA report should give at least a rough estimate of the administrative costs related to the options 'voluntary action by industry' and 'mandatory specific conditions for the use of acrylamide in grouting applications' by applying the standard cost model.

(D) Procedure and presentation

An executive summary should be included. The report presents a highly scientific subject in an understandable way.

2) IAB scrutiny process

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Author DG	DG ENTR-G-2
External expertise used	No
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