EUROPEAN COMMISSION
IMPACT ASSESSMENT BOARD

Brussels, 15 June 2007
D(2007) 5416

Opinion

Title **Impact Assessment on a proposal for a Directive of the European Parliament and of the Council amending Council Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances**

(draft version of 30 May 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 legislation. It relates to restrictions on the marketing and use of certain dangerous substances. The proposal to amend this Directive to include five further dangerous substances (DEGME, DEGBE, MDI, cyclohexane and ammonium nitrate) intends to either eliminate or reduce identified unacceptable risks to consumer health and to avoid barriers to intra-Community trade in products containing these substances.

(B) Positive aspects

The impact assessment provides a well structured analysis and discusses a broad 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: Overall the quality of the impact assessment is good. The section on problem definition should be clarified for the substances ammonium nitrate and MDI and the absence of environmental impacts for any of the substances also needs further clarification. Moreover the identified options should

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.

E-mail: impact-assessment-board@ec.europa.eu

address, explain how restricting access to products for "professional use only" ensures that consumers are not unduly exposed to health risks.

(1) The impact assessment should explain in more detail why the existing safety requirements for ammonium nitrate at the national level are not sufficient and thus require EU regulatory action on the basis of Council Directive 76/769. References to respective scientific or empirical evidence should be provided. For the substance MDI the analysis of consumer risks of respiratory sensitisation should be elaborated to clarify whether there is indeed a need for policy measures.

(2) The absence of any environmental impacts should be clarified. The problem definition mentions that no adverse environmental impacts are identified for any of the five dangerous substances. It should be explained in more detail why no such impacts are expected in practice due to the envisaged restrictions on the marketing and use and it should be underlined that the management of possible intrinsic (environmental) risks associated with these substances is sufficiently covered by other legislation.

(3) The effectiveness of the preferred policy options with respect to specific consumer health risks needs further clarification. In particular for the DEGME substance it should be made clear how exactly consumers in practice are prevented from getting access to products for "professional use only".

(4) A brief description of the typical consumer groups affected by the use of the problematic substances should be provided. The illustration of typical consumer usage situations would facilitate the understanding of the problem context for the non-experts and allow a better assessment of the appropriateness of the envisaged consumer protection measures.

(D) Procedure and presentation

An executive summary should be included. Moreover it should be clarified whether the Commission's minimum requirements for public consultations have been met and whether the preferred policy options received general stakeholder support.

2) IAB scrutiny process

Reference number	2007/ENTR/015, catalogue item
Author DG	DG ENTR-G-2
External expertise used	No
Date of Board Meeting	13 June 2007
Date of adoption of Opinion	15 June 2007