



COMMISSION OF THE EUROPEAN COMMUNITIES

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COMMISSION STAFF WORKING DOCUMENT

accompanying document to the

**Proposal for a
DECISION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**amending Council Directive 76/769/EEC as regards restrictions on the marketing
and use of certain dangerous substances and preparations 2-(2-
methoxyethoxy)ethanol, 2-(2-butoxyethoxy)ethanol, methylenediphenyl
diisocyanate, cyclohexane and ammonium nitrate
(amendment of Council Directive 76/769/EEC)**

IMPACT ASSESSMENT SUMMARY

**{COM(2007) 559 final}
{SEC(2007) 1237}**

Lead DG: Enterprise and Industry

Other involved services: Environment; Health and Consumer Protection; Employment and Social Affairs; Justice, Freedom and Security.

Agenda planning or WP reference: 2007/ENTR/015

1. BACKGROUND

This impact assessment¹ summary accompanies the Proposal for a Decision to amend Directive 76/769/EEC related to restrictions on marketing and use of certain dangerous substances and preparations.

Four of the substances [2-(2-methoxyethoxy) ethanol (DEGME), 2-(2-butoxyethoxy) ethanol (DEGBE), methylenediphenyl diisocyanate (MDI) and cyclohexane] were assessed for risks to human health and the environment under Regulation (EEC) No 793/93 on the evaluation and control of the risks of existing substances. Risks to consumer health were identified for the use of certain products containing the substances, and the risk reduction strategy recommended under the Regulation is for marketing and use restrictions under Directive 76/769/EEC. This impact assessment refines those recommendations and provides support for a legislative Proposal.

Ammonium nitrate is not a priority substance under Regulation No 793/93. However, risks due to explosions have been identified when it is used in high concentrations in fertilisers. These risks need to be addressed throughout the EU.

2. PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES

The draft Proposal was discussed at several meetings of the Commission's Working Group on Directive 76/769/EEC at which representatives from CEFIC, the European Chemical Industry Council, were present. BEUC, the European Consumers Organization, was also consulted.

Ammonium nitrate was discussed by a Commission Working Group on fertilisers. It was agreed by Member States and industry, represented by the European Fertiliser Manufacturers Association, that all high nitrogen ammonium nitrate fertilisers should conform to the harmonised EU safety requirements, and that Directive 76/769/EEC should be used (in order to cover both EC and national fertilisers).

Other legislation such as the General Product Safety Directive, the Regulation on Fertilisers, the Directives on the classification, packaging and labelling of dangerous substances and preparations, the Directive concerning transport of dangerous goods by road, were also examined to avoid any legal overlap or conflicts.

3. PROBLEM DEFINITION AND OBJECTIVES OF THE POLICY INITIATIVE

The EU risk assessments on DEGME, DEGBE, MDI and cyclohexane identified risks to consumers from certain applications and uses mainly due to dermal and inhalation exposure. For ammonium nitrate the risk is that of explosion when it is used in high concentrations in fertilisers. No risks to the environment have been found for any of the substances. The problems to be solved are:

- DEGME: risks for consumers during the use of DEGME in paints or paint strippers.

¹ The full version in English is available at the website : http://ec.europa.eu/enterprise/chemicals/studies_en.htm

- DEGBE: risks for consumers from the use of DEGBE in paints during spraying applications. A safe concentration limit of 3% DEGBE in spray paints has been established. For paints other than spray paints, no risk was identified for consumers.
- MDI: risks for consumers from MDI contained in certain products sold to the general public.
- Cyclohexane: risks for consumers from the use of cyclohexane in neoprene-based adhesives for carpet-laying on large floor areas.
- Ammonium nitrate: fertilisers with high nitrogen content which meet safety requirements other than those set at EU level may not be equally safe for farmers and distributors within EU. High nitrogen fertilisers can also be misused to make explosives.

The objective of the Proposal is to reduce or eliminate the identified risks.

4. RIGHT OF THE COMMISSION TO ACT

Council Directive 76/769/EEC seeks to establish harmonised rules to achieve a high level of protection of human health and the environment throughout the Community and to avoid divergent national legislation which may cause barriers to intra-Community trade. This cannot be achieved by leaving the responsibility to act solely to the Member States. As the problems identified occur in all Member States, action at Community level is the most efficient and proportionate way to eliminate or reduce the identified risks.

5. COMPARISON OF THE VARIOUS POLICY OPTION TO ACHIEVE THE OBJECTIVES

The various options to achieve the intended objectives take into account the existing market situations for the various chemicals, their actual uses, and the latest information from industry and from the Member States competent authorities as available to the Commission.

| DEGME | Effectiveness | Efficiency |
|--|---|--|
| <u>No action</u> | <p>Very low: The risks to consumer health would not be reduced.</p> <p>Member States could adopt diverging rules, with adverse impacts on the Internal Market.</p> | <p>Low: No extra costs for industry but the objectives will not be reached.</p> |
| <u>Voluntary action by industry</u> | <p>Very low: Difficulties to set up a voluntary agreement with all actors and to monitor SMEs and also imports.</p> <p>Consumer health will not be guaranteed.</p> | <p>Average: Administrative costs for industry for setting up, enforcing and monitoring a voluntary commitment can be significant.</p> |

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| <p><u>Additional use instructions on the products containing DEGME</u></p> <p><i>“For professional users only”</i></p> | <p>Average: It would dissuade consumers from using such products in cases where they might have access to products intended only for professional users.</p> | <p>Low: Additional costs for companies to label all products without benefits to consumer health as products are already sold in different channels for consumers and professionals.</p> |
| <p><u>Total ban for consumer use</u></p> | <p>High: Paints and paint strippers containing DEGME could not reappear on the EU market. Protection of consumer health would be guaranteed.</p> | <p>High: No additional cost for companies as paints and paint strippers containing DEGME are not currently on the EU market for consumer uses.</p> |

| DEGBE | Effectiveness | Efficiency |
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| <p><u>No action</u></p> | <p>Very low: The risks to consumer health would not be reduced.</p> <p>Member States could adopt diverging rules, with adverse impacts on the Internal Market</p> | <p>Low: No extra costs for industry but the objectives will not be reached.</p> |
| <p><u>Voluntary action by industry</u></p> | <p>Very low: Difficulties to devise an agreement with the involvement of large and small and medium sized enterprises and also imports.</p> <p>Consumer health will not be guaranteed.</p> | <p>Average: Administrative costs for industry for setting up, enforcing and monitoring a voluntary commitment can be significant.</p> |
| <p><u>Additional use instructions on certain paints containing DEGBE</u></p> <p><i>“Do not use in paint spraying equipment”</i> on paints other than spray with more than 3% of DEGBE</p> <p><i>“Only for professional users”</i> for spray paints containing DEGBE at 3%</p> | <p>High: Consumers will be alerted not to spray paints if they contain >3% DEGBE.</p> <p>Average: It would dissuade consumers from using such products in cases where they have access to products intended only for professional</p> | <p>Average: Companies will have some additional costs for the change of labelling of the products which can be reduced by foreseeing a longer transitional period.</p> <p>Low: Additional costs for companies to label all products without benefits to consumer health as products are already sold in different channels for</p> |

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| | users. | consumers and professionals. |
| <u>Concentration limit of 3% DEGBE in spray paints</u> | High: A limit of 3% for DEGBE in spray paints eliminates risks to consumers. | High: Very limited costs from the withdrawal or reformulation of those few remaining spray paints containing more than 3% of DEGBE. |
| <u>Total ban for DEGBE consumer spray paints</u> | High: No more spray paints with DEGBE will be available and consumer health will be guaranteed. | Very Low: Need to withdraw or reformulate all spray paints containing DEGBE will be costly. Loss of turnover and reduction in employment for companies unable to replace DEGBE in their formulations. |

| MDI | Effectiveness | Efficiency |
|---|---|---|
| <u>No action</u> | <p>Very Low: The potential risks for consumer health would not be reduced.</p> <p>Member States could adopt diverging rules, with adverse impacts on the Internal Market.</p> | <p>Low: No extra costs for industry but the objectives will not be reached.</p> |
| <u>Voluntary action by industry</u> | <p>Very Low: Difficulties to set up an agreement with all actors (in particular as alternatives are not available for all applications) and to monitor small and medium sized enterprises and also imports.</p> <p>Consumer health will not be guaranteed.</p> | <p>Average: Administrative costs for industry for setting up, enforcing and monitoring a voluntary commitment can be significant.</p> |
| <p><u>Appropriate PPE sold with products containing MDI</u></p> <p>PPE Dermal (gloves)</p> | <p>High to average: Systematic use of gloves will reduce dermal exposure significantly. Addition of a pair of gloves to the products is more effective than a sole indication on the label.</p> | <p>High: Polyethylene gloves are cheaper (0.15 € per can) and more comfortable to use than nitrile (3.5 €) or neoprene (10 €) materials and would be sufficiently effective to protect consumers. Overall costs for adding polyethylene gloves are only about 2% of product costs.</p> <p>Very Low: Mandatory masks</p> |

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| PPE Inhalatory (masks) | Low: Consumers will not wear a mask for short time applications and will not pay the high price for effective masks. | are not proportionate to the frequency (time period) of the use of MDI products and to the overall exposure. The most appropriate masks cost around 70 € (i.e. up to 10 times more expensive than a can of OCF). |
| <p><u>Appropriate use instructions on products containing MDI</u></p> <p><i>“May cause allergic reaction to individuals already sensitised to diisocyanates other than MDI”</i></p> <p><i>“May elicit asthma-like reactions in individuals with asthma”</i></p> <p><i>“May cause dermal reactions to individuals suffering from skin problems”</i></p> <p><i>“Use a mask with an antigas filter (I.e. type EN 14387:2004 mask with filter type A1) under conditions of poor ventilation”</i></p> | Average: Specific instructions would inform and protect consumers during the use of MDI products. The warning to use a mask under poor ventilation conditions will encourage consumers to improve ventilation and ensure that professionals use a mask where necessary. | High: Companies will face some additional costs due to the change in labelling. The impact can be reduced by allowing a longer transition period. |
| <u>Total ban for consumer use</u> | High: The risks from MDI products to consumers would be eliminated. | Very low: A ban of products containing MDI would not be proportionate to the risks for consumers. The direct loss from a ban of all MDI containing products will be about 200 million € turnover for the whole production chain. About 100 jobs lost in manufacturing companies and further job losses in DIY-stores. Some alternatives to MDI are available but they do not cover all the uses and they do not have the same performance as MDI. |

| CYCLOHEXANE | Effectiveness | Efficiency |
|-------------------------|--|---|
| <u>No action</u> | Very low: The potential risks for consumer health would not be reduced. | Low: No extra costs for industry but the objectives will not be reached. |

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| | Member States could adopt diverging rules, with adverse impacts on the Internal Market | |
| <u>Voluntary action by industry</u> | <p>Very Low: Difficulties to set up an agreement on voluntary action with all companies concerned and to monitor small and medium sized enterprises and also imports.</p> <p>Consumer health will not be guaranteed.</p> | Average: Administrative costs for industry for setting up, enforcing and monitoring a voluntary commitment can be significant. |
| <u>Regulatory reduction of the package size</u> | Average: Reduction of the packaging size to 650 g will reduce the surface area during application and exposure. | Average to high: A limit value of 650 g would not cause significant economic costs to industry. There would be a need to complement the measure by appropriate labelling instructions. |
| <p><u>Appropriate handling and use instructions added on the package</u></p> <p><i>“Do not use for carpet laying”</i></p> <p><i>“Do not use under conditions of poor ventilation”</i></p> | Average: specific warnings will dissuade consumers to use neoprene-based adhesives containing cyclohexane under poor ventilation conditions and for carpet laying. | High: Some additional costs to industry due to the change in labelling. The impact of these costs could be reduced by allowing a longer transition period. |
| <u>Total ban for consumer use</u> | High: Consumer health would be fully protected. | Low: High costs as there are currently no alternatives to replace cyclohexane especially for small-scale applications such as shoe repairing. |

| AMMONIUM NITRATE | Effectiveness | Efficiency |
|--|---|--|
| <u>No action</u> | Very low: The risks identified would not be reduced. | Low: No additional cost for companies but no benefits either. |
| <u>Voluntary action by industry</u> | Very Low: Voluntary compliance with the safety standards of Regulation | Low: Difficult to apply due to fragmented nature of industry |

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| | 2003/2003 is already possible, but it is not always used. Difficulties to monitor small and medium sized enterprises and also imports. | supply. Administrative costs for industry for setting up, enforcing and monitoring a voluntary commitment can be significant. |
| <u>Decrease of nitrogen content in all ammonium nitrate (AN) fertilisers</u> | High: addition of calcium or magnesium carbonate will reduce the AN content below the recognised safe limit of 28% to avoid detonation. | Low: Additional costs of 10% for transport and storage due to inert substances. No benefits as most soils do not require additional carbonate. |
| <u>Placing on the market of fertilisers with a nitrogen content >28% only if they comply with the safety requirements of Regulation (EC) No 2003/2003 and restriction for consumer use with a nitrogen content <20%</u> | High: Risks of inadvertent explosion are effectively reduced as all fertilisers will comply with the harmonised safety specification of Regulation 2003/2003. Only professional users will have access to fertilisers that can be misused. | High: minor additional costs for modifying the composition and properties of fertilisers and proving the compliance with the test of detonation. Negligible loss of sale to the general public and will be compensated through sale of other fertiliser types. |

6. CONCLUSIONS

– DEGME

A total ban of the placing on the market of paints and paint strippers containing DEGME for consumer use is an effective and efficient measure to eliminate the risks for consumers. From the analysis conducted there are no additional costs for industry, therefore this measure will be proportionate.

– DEGBE

Setting a limit value of 3% for DEGBE in spray paints to be sold to the general public is an effective and efficient measure to eliminate the risks to consumers. This measure will not cause high costs to industry as the content of DEGBE in most spray paints is already around or below 3%. The additional instruction “*Do not use in paint spraying equipment*” on all other paints containing DEGBE above the limit of 3% will avoid misuse by consumers. The costs for industry for a change in labelling are limited and can be reduced through a longer transition period. Therefore this measure will be proportionate.

– MDI

A requirement to add polyethylene gloves and specific warnings and use instructions to all products containing MDI sold to the general public are effective and efficient measure to reduce the health risks to consumers. Consumers can reduce dermal exposure and will be well informed to avoid misuse during the application of MDI products. The costs of polyethylene

gloves are low compared to the product price and the costs for change in labelling can be reduced through a longer transition period. Therefore these measures will be proportionate.

During the Commission's Working Group on Directive 76/769/EEC, it was agreed that a study is needed to collect more data on possible cases of respiratory allergy due to products containing MDI. Based on the results of this study, further protective measures will have to be considered if the risks for consumers will be confirmed.

– *Cyclohexane*

Additional labelling "*Do not use for carpet laying*" and "*Do not use under conditions of poor ventilation*" as well as a reduced package size to 650g for neoprene-based adhesives containing cyclohexane sold to the general public are effective and efficient measures to reduce the risks for consumers. The costs for industry for changing the labelling are not very high and can be reduced through a longer transition period. Therefore these measures will be proportionate.

– *Ammonium Nitrate (AN)*

Restricting the marketing of high nitrogen (>28%) AN fertilisers in such a way that they have to meet the safety requirements of Regulation (EC) No 2003/2003 is the most effective and cost efficient option to ensure that all AN fertilisers would meet harmonised safety standards. Sale to the general public will be restricted to fertilisers containing <20% nitrogen: the loss of sales will be negligible. Therefore the measure will be proportionate.

7. MONITORING AND EVALUATION

Member States have long-established mechanisms and have nominated authorities to monitor compliance with the restrictions of Directive 76/769/EEC. These same structures can be used under Regulation (EC) 1907/2006 to monitor compliance with the new restrictions of this Proposal which will therefore not create a significant administrative burden.