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COMMISSION STAFF WORKING DOCUMENT

accompanying the

Proposal for a

DECISION 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 and
preparations (dichloromethane)**

(amendment of Council Directive 76/769/EEC)

Impact Assessment Summary

**{COM(2008) 80 final}
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Lead DG: Enterprise and Industry

Other involved services: AGRI, ENV, SANCO, JRC, EMPL, ECFIN, TRADE, JLS,
MARKT, RTD, SJ, TREN, SG

Agenda planning or WP reference: 2007/ENTR/016

1. BACKGROUND

This summary of the impact assessment report¹ accompanies the Proposal for a Decision to amend Directive 76/769/EEC related to restrictions on marketing and use of dichloromethane (DCM) in paint strippers.

DCM is not included in the priority lists under Regulation (EEC) No 793/93 on the evaluation and control of the risks of existing substances. However several studies on the risks from DCM in paint strippers² concluded that risk reduction measures are required throughout the EU.

The impact assessment analyses and evaluates the various measures in terms of their effectiveness, practicality, economic impact and monitoring, in order to reduce the risks during industrial, professional and consumer uses of DCM-based paint strippers.

2. PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES

Possible restrictions concerning the use of DCM in paint strippers were discussed at several meetings of the Working Group for the implementation of Directive 76/769/EEC at which representatives from the Commission, the Member States (MS) and the European Chemical Industry Council (CEFIC) were present. The European Consumers Organization (BEUC), the European Mine, Chemical and Energy workers Federation (EMCEF) and the European Trade Union Confederation (ETUC) were also consulted.

During these meetings, it emerged that MS were divided into two different camps with sharply divided views: on the one hand, UK, IE, IT, EL, PL - while supporting that additional workplace controls are necessary - saw no reason for adopting bans for either professional or consumer use. These MS believe that extensive restrictions will be disproportionate to the risks observed and that other measures will be sufficient to reduce the risks.

On the other hand, DE, FR, SE, DK disputed this reasoning and believe that the narcotic effects of DCM are particularly dangerous and that the observed accidents and fatalities demonstrate that the currently applied measures (such as vapour retardants) are not sufficient. They are, consequently, in favour of the adoption of strict measures for industrial uses and a total ban for professional and consumer uses.

Other legislations such as the General Product Safety Directive, the Worker protection legislation were examined to avoid any legal overlap or conflicts.

3. PROBLEM DEFINITION AND OBJECTIVES OF THE POLICY INITIATIVE

According to Annex I of Directive 67/548/EEC, DCM is classified as carcinogenic category 3.

The hazard potential of DCM lies primarily in its narcotic effect and subsequent depression of the central nervous system (CNS) at high concentrations. Even though acute toxic effects on the CNS are reversible fatalities have been reported on a number of occasions³. Between 1989 and 2007, 18 fatalities (9 for industrial use; 8 for professional use; 1 for consumer use) and 56

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

² TNO-STB study, November 1999; ETVAREAD expert group report, April 2004; RPA study, April 2007. These studies are available at the website http://ec.europa.eu/enterprise/chemicals/studies_en.htm

³ Scientific Committee opinion adopted in March 2005. http://ec.europa.eu/health/ph_risk/committees/04_scher/scher_opinions_en.htm

non-fatal injuries (6 for industrial use; 26 for professional use; 10 for both industrial and professional use; 14 for consumer use) have been registered in the EU.

The main factors which have contributed to fatalities in accidents involving DCM-based paint strippers are the following:

- Inadequate ventilation
- Inadequate personal protective equipment
- Use of inadequate tanks
- Use of the substance in situations where it should not have been used
- Heat-related accidents
- (possible) alcohol abuse
- Long-term exposure
- Unknown reasons

On the basis of these factors the impact assessment has analysed the different possible control measures to reduce the number of accidents and the risk of fatalities.

The objective of the Proposal is to reduce or eliminate the identified risks in order to achieve a high level of health protection for all users of DCM paint strippers (industrial, professional and consumer) and to establish harmonised rules throughout the EU to avoid barriers to intra-Community trade in DCM paint stripping products.

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.

In view of the divergent opinions among the MS on the need to act and the diverging actions taken by some (AT, DK, SE) but not all MS, the control of such risks cannot be achieved by leaving the responsibility to act solely to the MS. An action at Community level is the most efficient and proportionate way to eliminate or reduce the identified risks while preserving the Internal Market. Article 95 of the Treaty is the appropriate legal base for the Proposal.

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

The options to achieve the intended objectives to reduce the risks during the application of DCM-based paint strippers, were developed on the basis of the information and conclusions provided by the studies carried out for the Commission. Further information from the MS, industry, and other stakeholders were included. The following table summarises the findings of the assessment.

OPTION	Effectiveness	Efficiency
<u>No action</u>	<p>Very low: This option will not prevent accidents (fatal or not) which will continue for all uses.</p> <p>MS could continue to legislate nationally, applying different restriction measures with</p>	<p>Low: No extra costs for industry but the risk reduction objectives for the three uses will not be reached.</p>

	consequent obstacles to the Internal Market.	
<u>Voluntary action by industry</u>	<p>Very low: Difficulties to devise an agreement with broad industry coverage as opinions within industry are sharply divided.</p> <p>Difficulties for the MS to verify the compliance of the industry with voluntary action. Consumer health will not be guaranteed.</p>	<p>Very low: Significant administrative costs for industry for agreeing, setting up, enforcing and monitoring a voluntary commitment that would have to cover many SMEs.</p>
<u>Engineering controls: ventilation and tanks</u>	<p>High to average for industrial uses: risks during industrial uses will be reduced, but additional personal protective equipment will be necessary for worker protection.</p> <p>Average to low for professional uses: Practical difficulties for professional users operating outside industrial installations to check the levels of exposure to DCM and maintain sufficient ventilation. Measures regarding tanks are only applicable for certain professional uses and not for others.</p> <p>Very low for consumer uses: Difficulties in ensuring “good ventilation” when consumers need to use paint strippers indoors or in case of bad weather conditions. Measures regarding tanks are not applicable.</p>	<p>High to average for industrial uses: the installation of mechanical ventilation might require changes to existing equipment with costs especially for SMEs. Efficiency of modifications to tanks can be high for small articles, but becomes increasingly less efficient for larger articles due to higher capital investment.</p> <p>Average to low for professional uses: The costs for the necessary equipment will be high and will depend on the specific professional application. Expensive extra equipment might be necessary for specific cases and might require expert knowledge for correct application.</p> <p>Very low for consumer uses: Equipment necessary to always ensure 'good ventilation' would be excessively expensive.</p>
<u>Handling measures:</u> 1. Personal Protective Equipment (PPE)	<p>High for industrial uses: Protection against dermal exposure would be guaranteed through the use of gloves of appropriate materials. Protection against inhalatory risks would be guaranteed through</p>	<p>Average for industrial uses: Additional costs for the companies to provide effective PPE, which would have to be selected on the basis of the specific working conditions and existing engineering controls</p>

	<p>appropriate masks or respirators.</p> <p>Average for professional uses: Difficulties to assess the use of appropriate glove material (which depends on parameters such as exposure levels, mechanical work intensity and duration) for all the specific working conditions, especially for self-employed workers and for activities conducted outside industrial installations. Very unlikely that respirators would be worn when required.</p> <p>Low for consumer uses: no guarantee that consumers will use PPE properly or replace PPE as appropriate. Consumer health protection would not be guaranteed.</p>	<p>regarding ventilation and tanks.</p> <p>Average to low for professional uses: Additional costs to companies to select and buy appropriate equipment ensuring adequate protection under frequently changing working conditions.</p> <p>Low for consumer uses: Costs for necessary PPE are disproportionate, especially for small DIY jobs.</p>
<p>2. Container size limits and design requirements</p>	<p>Low for industrial, professional and consumer uses: reduction of container size and a requirement for narrow necks would be effective measures to reduce exposure from accidental spillages, but will not alter the way the product is used and will not reduce the related risks. Narrow neck containers would not permit the users to immerse a brush in the product and as result they would decant into wider containers with a high risk of exposure to DCM vapours.</p>	<p>Low for industrial, professional and consumer uses: considerable quantities of paint strippers are required in application with dipping tanks for industrial and professional uses. The additional costs due to the time that would be required to use multiple containers and the amount of packaging waste generated make this option less efficient.</p>
<p>3. Product composition requirements</p>	<p>Low for industrial, professional and consumer uses: Reduction of DCM content would require increased use of other ingredients which could potentially create other risks (e.g. flammable components).</p> <p>Addition of smelling substance could encourage users to wear “simple” masks without achieving the necessary protection against DCM.</p>	<p>Low for industrial, professional and consumer uses: a reduction of the concentration of DCM might affect the effectiveness of the relevant products without obtaining the same performance in paint stripping. This will require longer treatment times at higher costs.</p>

	Vapour retardants have already been used for many years and do not ensure adequate control of the exposure to DCM during use.	
<u>Mandatory training and licensing of users</u>	<p>Average to low for industrial uses: Worker protection legislation already requires employers to provide adequate protection for the management of risks from applications involving DCM.</p> <p>MS could be reluctant or unable to be involved in training and licensing schemes.</p> <p>High for professional uses: Training and licensing will lead to higher awareness of risks and necessary protection measures, in particular for SMEs and self-employed workers who are not covered by the Workers Protection legislation. This would be particularly effective for activities outside industrial installations.</p> <p>MS could be reluctant or unable to be involved in training and licensing schemes.</p> <p>Not applicable for consumer uses.</p>	<p>Average for industrial uses: Additional costs for those companies that choose to supply or use DCM-based paint strippers for organising training courses, disseminating information, testing and licensing of those intending to be employed in a DCM paint stripping business.</p> <p>More responsibility and administrative burden for the MS for controlling a training and licensing system.</p> <p>Average for professional uses: Additional costs for those companies that choose to supply or use DCM-based paint strippers for organising training courses, disseminating information, testing and licensing of those intending to be employed in a DCM paint stripping business.</p> <p>More responsibility and administrative burden for the MS for controlling a training and licensing system</p> <p>Not applicable for consumer uses.</p>
<u>Total ban</u>	<p>Low for industrial uses: A total ban of DCM-based paint strippers will eliminate the risk from DCM but the incremental reduction in risk through a total ban will be low, as other risk reduction measures can be equally effective in reducing risks.</p> <p>Average for professional uses: this option would be highly effective to protect professional users considering the number of fatalities registered. However</p>	<p>Average for industrial and professional uses: Significant losses for DCM manufacturers but gains for manufacturers of alternatives.</p> <p>Relatively neutral for paint stripper manufacturers many of whom already produce alternative formulations.</p> <p>A ban will impact user companies particularly with regard to: (a) the increased cost of alternatives; (b) the capital</p>

	<p>this option would be less effective if professionals would receive adequate training and appropriate PPE during their activities.</p> <p>High for consumer uses: As consumers do not have access to the same equipment (especially engineering controls and PPE) as professionals or industrial users, nor to training, and in some cases the working conditions at home may be much worse than under professional conditions, this measure would best ensure their protection against DCM exposure.</p> <p>A total ban would facilitate enforcement by Competent Authorities as they could not enforce other measures on consumers.</p>	<p>costs of adapting existing installations for use with the alternatives and (c) the losses in productivity as the alternatives will require longer treatment and repeated application. Significant costs for SMEs working with low profit margins.</p> <p>Average to high for consumer uses: Moderate losses for DCM manufacturers, but gains for producers of alternatives.</p> <p>Neutral for paint stripper manufacturers as companies producing paint strippers often do already provide DCM-based and DCM free strippers. So overall effect will probably be neutral.</p> <p>Overall reduced costs for consumers when taking into account cost of paint stripper <u>and</u> the required PPE to use DCM-based paint strippers.</p>
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6. CONCLUSIONS

The following combination of options emerges as the most balanced and proportionate:

- **DCM based paint strippers for industrial uses:**

The following mandatory requirements should be applied during industrial activities:

- Use of appropriate protective gloves
- Use of effective local ventilation or independent air supply respiratory protective equipment
- Appropriate engineering controls for strip tanks

A total ban for all industrial uses would be disproportionate considering the high costs for industry and the incomplete information on the alternatives. The other options such as container size limits and product composition requirements are not effective to prevent the exposure to DCM and reduce the risks.

- **DCM based paint strippers for professional uses:**

Uses by professionals outside industrial installations should be banned in general, but MS could opt to allow further use on their territories by specifically trained and licensed professionals. It would be the responsibility of the interested companies in the MS concerned

to create the necessary systems for training and licensing and it would be responsibility of MS to monitor the systems.

This measure would give to MS and interested companies the full responsibility and the administrative burden for setting up and controlling a training and licensing system and appropriate control measures.

The other options such as engineering controls, container size limits and product composition requirements are not effective to prevent the exposure to DCM and reduce the risks during many professional use situations.

- **DCM based paint strippers for consumer uses:**

A ban of the placing on the market of paint strippers containing DCM for consumer use is the only effective measure to eliminate the risks for consumers as it would be impossible to comprehensively monitor the actions and behaviour of consumer during Do-It-Yourself applications, or to ensure adequate training and use of the necessary protective equipment.

Considering the overall costs and benefits, this measure is proportionate.

None of the measures will have an impact on the EU budget.

7. MONITORING AND EVALUATION

MS 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. Furthermore, a Forum for Exchange of Information on Enforcement will be managed by the European Chemicals Agency and will coordinate a network of MS authorities responsible for enforcement of this Regulation