



COMMISSION OF THE EUROPEAN COMMUNITIES

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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 (Dichloromethane)

(amendment of Council Directive 76/769/EEC)

(presented by the Commission)

{SEC(2008) 192}
{SEC(2008) 193}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

Council Directive 76/769/EEC of 27 July 1976 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 establishes a framework for harmonised rules throughout the European Union concerning the placing on the market and use of dangerous substances and preparations.

Directive 76/769/EEC is used to manage the risks to human health and the environment from dangerous substances. Dangerous substances and preparations listed in Annex I to Directive 76/769/EEC may only be placed on the market and used under specific conditions.

It is proposed to manage the risks on Dichloromethane (DCM) by listing this substance in Annex I of Directive 76/769/EEC.

1.1. Dichloromethane, its chemical properties and its risks to human health

Dichloromethane (DCM), CAS number 75-09-2 and EINECS number 200-838-9, is a colourless, halogenated aliphatic hydrocarbon compound with a penetrating ether-like or mild sweet odour. It is mainly used in the production of pharmaceuticals, solvent and auxiliary applications, paint strippers manufacture and adhesives.

DCM is not included in the priority lists under Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances. However risks from DCM in paint strippers have been assessed in several studies¹ which concluded that risk reduction measures are required throughout the EU. Paint strippers are used to remove coats of paints, especially blistered or cracked coats on various substrates, particularly metal and wood and are applied by industrial and professional users, as well as consumers.

The main risks from DCM to human health are related to its vapours and its toxic effects to the central nervous system. These effects associated with bad working/operational conditions (e.g. inadequate ventilation, inappropriate personal protective equipment) have contributed to a number of registered accidents and fatalities during the last 18 years in the EU.

According to the Scientific Committee on Health and Environmental Risks² (SCHER), exposure to DCM released from paint strippers is of concern for human health especially for the more susceptible populations such as children due to a potential for higher exposure. The

¹ Methylene chloride: Advantages and drawbacks of possible market restrictions in the EU. TNO-STB study finalised in November 1999. http://ec.europa.eu/enterprise/chemicals/studies_en.htm ; Effectiveness of vapour retardants in reducing risks to human health from paint strippers containing dichloromethane by ETVAREAD expert group. Final report published in April 2004 http://ec.europa.eu/enterprise/chemicals/studies_en.htm; Impact assessment of potential restrictions on the marketing and use of dichloromethane in paint stripper. RPA study finalised in April 2007. http://ec.europa.eu/enterprise/chemicals/studies_en.htm

² Scientific Committee on Health and Environmental Risks opinion on “Effectiveness of vapour retardants in reducing risks to human health from paint stripper containing dichloromethane ETVAREAD final report April 2004. Adopted by SCHER during the 4th plenary session of 18 March 2005. http://ec.europa.eu/health/ph_risk/committees/04_scher/scher_opinions_en.htm

high concentrations of DCM measured during paint removing activity are unacceptable for the risks to human health.

Various alternatives to DCM-based paint strippers are already available on the market: physical/mechanical stripping, pyrolytic/thermal stripping, and chemical stripping involving other chemicals than DCM. The chemical alternative paint strippers are the most widely used, however they also have their own hazard profiles and, depending on their concentration in the formulation, they could pose other risks to the user.

During the last four years discussions have taken place between the Commission, Member States and other stakeholders. Despite strongly divergent opinions on the risks associated with DCM and on the safety of alternatives, an agreement has been reached on the need for marketing and use restrictions at Community level under Council Directive 76/769/EEC to limit the risks from DCM.

1.2. Intended effects of EU legislation

Due to the fact that there is a need for limiting the risks during industrial, professional and consumer uses of DCM-based paint strippers, certain restrictions on placing on the market and use should be applied. The present Decision would amend Annex I to Directive 76/769/EEC by adding Dichloromethane. This will ensure harmonised rules applied at Community wide level.

The most significant proportion of fatalities associated with the use of DCM-based paint strippers in Europe over the last 18 years were linked to industrial and professional uses under conditions of inadequate ventilation and with inappropriate application of personal protective equipment.

For the activities conducted in industrial installations some mandatory requirements should be applied such as: the use of appropriate protective gloves, the installation of local ventilation or independent air supply respiratory protective equipment, and modification of the strip tanks, to ensure reduction of exposure of workers.

Professional uses should be banned in general, but Member States could opt to allow further use on their territories by specifically licensed professionals for those activities where they believe that the replacement of DCM is particularly difficult or inappropriate. Licenses should be subject to specific training requirements.

A total ban of the placing on the market of paint strippers containing DCM for consumer uses should be applied as the only effective measure to eliminate the risks.

2. RESULTS OF CONSULTATIONS WITH THE INTERESTED PARTIES AND IMPACT ASSESSMENT

2.1. Consultations

In 2004 the Commission started discussions at the meetings of the Commission Working Group responsible for the implementation of Directive 76/769/EEC (hereinafter referred to as the "Limitations Working Group"). In November 2005 the Commission organised a forum on "paint stripping agents" with the involvement of the manufacturers of DCM-based paint strippers and of DCM alternatives. Due to the remaining divergent opinions of industry and authorities, the Commission contracted out another study to collect more information in order

to assess the impact of potential restrictions on the marketing and use of DCM-based paint strippers at Community wide level.

The recommendations of this study³ were discussed during the Limitations Working Group meeting on 3 July 2007. Representatives from companies in favour of continued use of DCM and from companies in favour of the alternatives, the European Consumers Organisation (BEUC), the European Mine, Chemical and Energy workers federation (EMCEF) and the European Trade Union Confederation (ETUC) attended this meeting or were consulted.

2.2. Impact Assessment

A detailed impact assessment has been prepared and was sent to the Impact assessment Board on 5 October 2007 which expressed its opinion on 9 November 2007. All the comments of the Board (IA quality checklist and final opinion) have been included in the final impact assessment version⁴

A number of options ranging from the 'No-Action' option, over voluntary actions by industry to legislative restrictions of various degrees have been evaluated and the most effective and efficient options for the three use categories are the following:

– *For industrial uses*

DCM-based paint strippers activities should be conducted only in industrial installations with mandatory requirements concerning the protection of personnel, such as appropriate gloves, exhaust ventilation or air respiratory equipment and engineering controls for strip tanks. These measures will further support the enforceability of the legislation for workers protection by effectively reducing exposure to DCM and thus the number of accidents and fatalities.

– *For professional uses*

The use of DCM-paint strippers by professionals in non-industrial settings should be banned in general, but Member States could opt to allow further use on their territories by specifically licensed professionals for those activities where they believe that the replacement of DCM is particularly difficult or inappropriate. This measure will give Member States and interested companies the full responsibility and the administrative burden of setting up and controlling a training and licensing system with appropriate measures. The number of accidents and fatalities will be reduced.

– *For consumer uses*

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

³ Impact assessment of potential restrictions on the marketing and use of dichloromethane in paint stripper. RPA study finalised in April 2007. http://ec.europa.eu/enterprise/chemicals/studies_en.htm

⁴ Commission Staff working document: « Impact Assessment Report » available at: http://ec.europa.eu/chemicals/studies_en.htm

3. LEGAL ELEMENTS OF THE PROPOSAL

3.1. Legal basis

The legal basis of the Proposal is Article 95 of the Treaty.

The present Decision would provide rules for the placing on the market and use of DCM-based paint strippers for the three categories of use (industrial, professional and consumer).

It would also establish uniform rules for the circulation of DCM-based paint strippers and it would avoid obstacles to trade because of differences in legislation between the Member States. This proposed amendment to Directive 76/769/EEC would improve the conditions for the functioning of the Internal Market and it would guarantee a high level of protection of human health.

3.2. Subsidiarity and proportionality principles

Council Directive 76/769/EEC relating to restrictions on the placing on the market and use of certain dangerous substances and preparations, seeks to establish harmonised rules throughout the EU and to avoid divergent national legislation, which is liable to cause barriers to intra-community trade. This cannot be achieved by leaving the responsibility to act solely to the Member States.

The measures proposed in the present Decision are also proportionate considering the overall costs and benefits for all use categories in relation with the final aim of improving the protection of human health.

3.3. Choice of instruments

The Commission has chosen Council Directive 76/769/EEC as the best instrument to preserve the Internal Market and at the same time ensure a high level of protection of human health and the environment. It is therefore in conformity with Article 95(3) of the Treaty.

Directive 76/769/EEC will be repealed on 1 June 2009 by Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. The amendment to be made to Annex I of Directive 76/769/EEC by this Decision will be applied after 1 June 2009 and will be introduced in Annex XVII of Regulation (EC) No 1907/2006.

It is more appropriate to amend the Annex I of Directive 76/769/EEC using a Decision rather than a Directive as transposition of the proposed restrictions into national law would be accomplished only a few months before Directive 76/769/EEC is repealed or even only afterwards. Transposition will therefore not serve any useful purpose. In this situation a Decision is a more appropriate legal act than a Directive.

4. BUDGETARY IMPLICATION

There are no budgetary implications arising from the present Decision.

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(amendment of Council Directive 76/769/EEC)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission¹,

Having regard to the opinion of the European Economic and Social Committee²,

Acting in accordance with the procedure laid down in Article 251 of the Treaty³,

Whereas:

- (1) The risks posed to human health by Dichloromethane (DCM) in paint strippers have been assessed in several studies⁴ which concluded that risk reduction measures are required throughout the EU to reduce the risks posed to human health during the application of DCM at industrial, professional and consumer level. The results of those studies were evaluated by the Commission's Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE - later named SCHER) which confirmed that the exposure to DCM released from paint strippers is of concern for human health⁵.

¹ OJ C , , p. .

² OJ C , , p. .

³ OJ C , , p. .

⁴ Methylene chloride: Advantages and drawbacks of possible market restrictions in the EU. TNO-STB study finalised in November 1999. http://ec.europa.eu/enterprise/chemicals/studies_en.htm; Effectiveness of vapour retardants in reducing risks to human health from paint strippers containing dichloromethane by ETVAREAD expert group. Final report published in April 2004 http://ec.europa.eu/enterprise/chemicals/studies_en.htm; Impact assessment of potential restrictions on the marketing and use of dichloromethane in paint stripper. RPA study finalised in April 2007. http://ec.europa.eu/enterprise/chemicals/studies_en.htm

⁵ Scientific Committee on Health and Environmental Risks opinion on Effectiveness of vapour retardants in reducing risks to human health from paint strippers containing dichloromethane. ETVAREAD Final Report 01 April 2004. Adopted by the SCHER during the 4th plenary session of 18 March 2005. http://ec.europa.eu/health/ph_risk/committees/04_scher/scher_opinions_en.htm

- (2) In order to achieve a high level of health protection for all use categories (industrial professional and consumer) the marketing and use of DCM-based paint strippers should be restricted.
- (3) DCM-based paint strippers are used by consumers at home to remove paints, varnishes and lacquers both indoors and outdoors. The safe use of DCM by consumers cannot be ensured by training or monitoring. Therefore, the only effective and proportionate measure to eliminate the risks for consumers is a ban on the marketing and use of DCM-based paint strippers.
- (4) In order to ensure a proportionate enforceability of the phase-out along the supply chain of paint strippers containing DCM, different dates to prohibit the first placing on the market and the final supply to the general public and professionals should be fixed.
- (5) As consumers, may have access to DCM-based paint stripper despite the ban through the distribution chain intended for professional and industrial users, a warning phrase should be included on the product.
- (6) The fatalities registered in Europe over the last 18 years for industrial and professional uses are mainly attributed to inadequate ventilation, the inappropriate personal protective equipment, the use of inadequate tanks and the long-term exposure to DCM. Therefore restrictions should be imposed to control and reduce the risks involved in professional and industrial uses.
- (7) Professionals are generally covered by the provisions of the legislation for workers protection. However, many professional activities are often conducted in customers premises which often do not have all the appropriate measures to manage, control and reduce the risks to health. Moreover, self-employed workers are not covered by the provisions of the worker protection legislation and would require adequate training before conducting paint stripping activities based on DCM.
- (8) The placing on the market and use of DCM-paint strippers by professionals should therefore be banned in order to protect their health and to reduce the number of fatalities and non-fatal accidents. Nevertheless, when the replacement of DCM is deemed to be particularly difficult or inappropriate, Member States should be able to allow further use of DCM by specially licensed professionals. Member States would be responsible for granting and monitoring such licences, which should be based on compulsory training with specific requirements.
- (9) The number of fatalities and non-fatal accidents registered during industrial activities is an indication of inadequate enforcement of the workplace legislation. The exposure to DCM remains high and further risk reduction measures should apply to workers in industrial installations. Preventive measures such as good ventilation of the workplace, appropriate personal protective equipment and additional modification of tanks should be adopted.

- (10) Personal protective equipment should comply with the requirements of Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States⁶.
- (11) Directive 76/769/EEC should therefore be amended accordingly.
- (12) This Decision is without prejudice to the Community legislation laying down minimum requirements for the protection of workers, such as Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work⁷ and individual Directives based thereon, in particular Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (codified version)⁸ and Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)⁹,

HAVE ADOPTED THIS DECISION:

Article 1

Annex I to Directive 76/769/EEC is amended in accordance with the Annex to this Decision.

Article 2

This Decision shall enter into force on the third day following that of its publication in the *Official Journal of the European Union*.

Article 3

This Decision is addressed to the Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

⁶ OJ L 399, 30.12.1989, p. 18.

⁷ OJ L 183, 29.6.1989, p. 1. Directive as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

⁸ OJ L 158, 30.4.2004, p. 50.

⁹ OJ L 131, 5.5.1998, p. 11.

ANNEX

In Annex I to Directive 76/769/EEC, the following point xx is added:

“(xx) Dichloromethane CAS N°: 75-09-2 EINECS N°: 200-838-9	(1) Paint strippers containing dichloromethane in a concentration equal to or greater than 0.1% by mass shall not be placed on the market for the first time after [12 months after the entry into force of the Decision] for supply to the general public or to professionals, and shall not be supplied to them after [24 months after the entry into force of the Decision]. (2) By way of derogation to paragraph (1), Member States may authorise the supply of paint strippers containing dichloromethane to licensed professionals. (3) The licence referred to in paragraph (2) shall be granted to professionals trained in the safe use of paint strippers containing dichloromethane. The training shall cover: (a) awareness, evaluation and management of risks to health, (b) use of adequate ventilation, (c) use of appropriate personal protective equipment¹. (4) Paint strippers containing dichloromethane in concentrations equal to or greater than 0.1% by mass may be used in industrial installations only if the following conditions are met: (a) effective exhaust ventilation or respiratory protective
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¹ Such personal protective equipment shall comply with the requirements of Council Directive 89/686/EEC.

	equipment with an independent air supply², (b) enclosed strip tanks covered when not in use, (c) appropriate protective gloves for operators.³ (5) Without prejudice to other Community legislation concerning the classification, packaging and labelling of dangerous substances and preparations, paint strippers containing more than 0.1% by mass of dichloromethane shall be legibly and indelibly marked by [<i>24 months after the entry into force of the Decision</i>] as follows: “Reserved for industrial and professional uses”.”
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² Such respiratory protective equipment shall comply with the requirements of Council Directive 89/686/EEC.

³ Such protective gloves shall comply with the requirements of Council Directive 89/686/EEC.