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Accompanying document to the

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 REPORT

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RTD, SJ, TREN, SG.**

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**This report commits only the Commission's services involved in its preparation and does not
prejudge the final form of any decision to be taken by the Commission.**

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Note: This impact assessment has been sent to the Impact Assessment (IA) Board on 5 October 2007 which expressed its opinion on 9 November 2007 in written procedure.

This IA has been revised in order to take into account the comments in the final opinion of the IA Board and the comments of the IA quality checklist received by DG Enterprise and Industry before the Board issued its opinion.

The Bibliography included in Section 9 lists all documents that have been used in the preparation of this impact assessment. They are accessible either by internet or upon request from DG Enterprise and Industry.

BACKGROUND

This impact assessment presents the possible policy options with their comparative advantages and drawbacks that could be adopted to control the risks from all uses (industrial, professional and consumer) of Dichloromethane (DCM) in paint stripping applications. The analysis and results of this impact assessment accompany the legislative Proposal related to restrictions on the marketing and use of DCM in paint strippers.

DCM, also known as methylene chloride, is a colourless, halogenated aliphatic hydrocarbon compound with a penetrating ether-like or mild sweet odour. The key markets are: production of pharmaceuticals, solvent and auxiliary applications, paint stripper manufacture and adhesives.

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 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.

Several discussions were conducted during the last four years with Member States and other stakeholders, which hold strongly divergent opinions on the risks of DCM and the safety of the alternative products available on the market. A general consensus has emerged that there is a need for marketing and use restrictions at Community level under Council Directive 76/769/EEC to limit the risks from DCM. However, despite significant efforts the wide-ranging and thorough debate among Member States and the stakeholders at several meetings of the Commission Working Group responsible for the implementation of Directive 76/769/EEC did not lead to full agreement on the specific risk reduction measures to be adopted. This impact assessment includes a detailed analysis of the possible measures as discussed during the meetings and evaluated in the studies conducted for the Commission.

The purpose of this impact assessment is to analyse and evaluate 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 – referred to as “use categories” - of DCM-based paint strippers.

1. SECTION 1: PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES

A first study on the potential advantages and drawbacks of possible restrictions in the EU of DCM² was finalised in November 1999. The risk characterization for exposure to DCM in paint stripper concluded that there was a need for risk reduction measures for all three use categories. The study also mentioned some potential risks/hazards from the alternatives in terms of their toxicological properties and disadvantages in the form of longer duration of stripping time (lower efficiency).

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 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

A second report was finalised in April 2004 by a team of experts on vapour retarding additives (ETVAREAD)³. As most of the fatal accidents occurred as consequence of acute inhalation of the vapours of DCM during its application in paint strippers, the expert team analysed the effect of different vapour retarding chemicals which would reduce the exposure to vapours of DCM when used in paint stripping preparations.

The results of both studies were evaluated by the Commission's Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE - later named SCHER) which concluded that the exposure to DCM released from paint strippers is of concern for human health⁴.

In 2004 the Commission started discussions at the meetings of the Commission Working Group responsible for the implementation of Directive 76/769/EEC concerning possible restrictions on the marketing and use of dangerous substances and preparations (hereinafter referred to as the 'Limitations Working Group'). In November 2005 the Commission organised a forum on "paint stripping agents" with the involvement of manufacturers of DCM-based paint strippers and of DCM alternatives. During the discussion two main divergent opinions were expressed. UK and IE supported the use of DCM-based paint strippers with the addition of vapour retardants in the DCM formulations and also supported the use of smaller container and narrow neck bottles to avoid the spillage of DCM. DE, on the other side, was in favour of a total ban in order to protect human health during paint stripping applications.

Due to the lack of information from most Member States, the Commission contracted out another study⁵ 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 study recommended a ban on the marketing and use of DCM-based paint strippers unless used in industrial installations under strictly controlled conditions (such as gloves, mask, adequate air ventilation, enclosed dip tanks). These recommendations were presented and discussed during the Limitations Working Group on 3 July 2007. Representatives of industry - those in favour of DCM and those favouring 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.

BEUC, EMCEF and ETUC did not express any official comments to the Commission on possible restriction of DCM in paint strippers. From the information available to DG ENTR in 2004 as part of the European Health and Safety Week "Building in Safety", the Danish Painters Union held an experts conference on organic solvents and water based paints. Participating were some 40 representatives of trade unions from 10 European countries (Denmark, Norway, Sweden, Finland, Estonia, Lithuania, Germany, Austria, the Netherlands and Belgium), the Nordic Federation of Building and Wood Workers and the European Federation of Building and Wood Workers. Also participating were a Member of the European Parliament and representatives of research institutions and governments. The Declaration of the conference states that "the use of particular hazardous chemical substances

³ 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

⁴ 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

⁵ 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

(e.g. dichloromethane) in paints, strippers and products for floor treatment shall be banned, for instance by including such substances to the Chemical Agent Directive, Annex III, or the Directive relating to restrictions on the marketing and use on certain dangerous substances and preparations (Directive 76/769/EEC)”.

During this meeting of the Limitations Working Group meeting it emerged that Member States were still divided into two different camps. While it is not exceptional that differences of appreciation of risk will occur when considering the risks from individual substances, in this case, opinions are especially divided.

On the one hand, UK, IE, IT, EL, PL while supporting additional workplace controls where necessary, saw no reason for adopting bans for either professional or consumer use. These Member States believe that extensive restrictions will be disproportionate to the risks observed and that other measures will be sufficient to reduce the risks. They consider that further controls to reduce exposure in industrial premises are appropriate, and they also believe that an outright prohibition on the use of DCM-based products by individual users, either consumer or professional, is not justified. The Member States who support DCM-based paint strippers suggest that, when used with simple and common sense precautions (such as the addition of vapour retardants, better information of users, etc.), their safety is comparable to other alternatives. Accordingly, in their view, restrictions based only on the acute narcotic effects and the classification as carcinogenic class 3 (which means cause of concern for man owing to possible carcinogenic effects but in respect of which the available information is not adequate for making a satisfactory assessment) are not proportionate to the risks.

On the other hand, DE, FR, SE, DK dispute 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, which are already used) 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.

Nevertheless the last study conducted for the Commission provided the information necessary to justify action at Community level. This information, in addition to that already gathered, provides the main basis for this impact assessment.

Other legislation such as the General Product Safety Directive and the Workers protection legislation were also examined to avoid any legal overlaps or contradictions.

All these potential measures have been discussed with other relevant Commission services such as DG Environment, DG Health and Consumer Protection and DG Employment to arrive at a general agreement for the measures to be adopted to manage and reduce the risks from DCM-based paint strippers.

2. SECTION 2: PROBLEM DEFINITION

According to Annex I of Directive 67/548/EEC on classification, packaging and labelling of dangerous substances, DCM is classified as carcinogenic category 3, which means cause of concern for man owing to possible carcinogenic effects but in respect of which the available information is not adequate for making a satisfactory assessment. There is some evidence from appropriate animal studies, but this is insufficient to place the substance in category 2.

In terms of human toxicology, the hazard potential of DCM lies primarily in its narcotic effect and subsequent depression of the central nervous system (CNS) at high concentrations. The acute toxic effects on the CNS are reversible; however fatalities have been reported on a

number of occasions⁶. Between 1989 and 2007, 18 fatalities (9 for industrial uses; 8 for professional uses; 1 for consumer) and 56 non-fatal injuries (6 for industrial uses; 26 for professional uses; 10 for both industrial and professional; 14 for consumer uses) have been registered in the EU.

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

- Inadequate ventilation
- Inadequate personal protective equipment
- Use of inadequate tanks (occasionally open tanks)
- Use of the substance in situations where it should not have been used (e.g. in underground storage tanks without ventilation – most likely due to lack of knowledge of the users)
- Heat-related accidents (accidents which took place in a closed space on a warm day)
- (possible) alcohol abuse
- Long-term exposure
- Unknown reasons

On the basis of these factors this impact assessment has analysed the different possible control measures to reduce the risks of fatalities as well as reduce the number of accidents.

The following table summarises the number of accidents and fatalities attributed to these factors. A single incident may have involved more than one factor:

Factor potentially contributing to accidents or fatalities	Number of accidents	Number of fatalities
Inadequate ventilation	19	14
Inadequate personal protective equipment	9	9
Use of inadequate tanks (occasionally open tanks)	9	9
Heat-related accidents	2	3
(possible) alcohol abuse	1	1
Long-term exposure	1	0
Unknown reasons	5	1

The provisions set up under Directives 89/391/EEC and 98/24/EC on the protection of workers from the effects of chemical agents present at the workplace⁷ are generally considered to give an adequate framework to limit the risks of DCM to the extent needed and shall apply. However self-employed workers (not subordinate to a third person) are not

⁶ See footnote 4.

⁷ OJ L131, 5.5.1998, p.11

covered by this legislation on health and safety at work, even though they can be subjected to health and safety risks similar to those experienced by employed workers.

It should be noted that there are strong variations in the exposure limits (OELs) adopted in EU Member States and discussion on the establishment of a common European Occupational Exposure Limit are currently ongoing but have not yet been concluded. However the Scientific Committee on Occupational Exposure Limits (SCOEL) noted in its draft report on Occupational Exposure Levels and Biological Limit Values for DCM that high levels of exposure of DCM have led to unconsciousness and, in some cases, death. Other effects include irritation of the eyes and respiratory tract, lung oedema and acute effects on the heart, liver and kidneys. The formation of COHb as a result of DCM metabolism decreases the oxygen-carrying capacity of the blood, giving symptoms of oxygen deprivation such as light-headedness, headache or loss of consciousness. The SCOEL recommends to set a limit value of 100 ppm (353 mg/m³) for an eight hours Time Weighted Average (TWA) and based on possible short-term prenarcoic effects, a limit value of 200 ppm (706 mg/m³) for a 15 min Short Term Exposure Level (STEL). A Biological Limit Value (BLV) of 4% of COHb (Carboxyhaemoglobin) is also recommended by SCOEL.

According to SCHER⁸, a major concern from the toxicity of DCM is the risk to especially susceptible populations. Children are more susceptible due to a potential for higher exposure, as they have a higher ventilation rate than adults and the concentration of DCM may be higher at floor level. People with a predisposition to cardiovascular disease may be at a higher risk than healthy individuals, due to the toxicity of carbon monoxide formed by biotransformation of DCM.

The risks from DCM in paint strippers have been assessed in several studies⁹ with the conclusion that further risk reduction measures are required and must be applied to all the three use categories (industrial, professional and consumer).

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 and they contain a large variety of chemical ingredients such as methyl-2-pyrrolidone, dibasic esters, benzyl alcohol, dimethylsulphoxide, 1,3 dioxolane, sodium hydroxide. These substances have very diverse hazard profiles and, depending on their concentration in the formulation, they could pose other risks to the user than DCM. Methyl-2 pyrrolidone has been recently classified as toxic to reproduction category 2 and due to this new classification sale of formulations containing this substance to the general public will be prohibited under Directive 76/769/EEC. Some dibasic esters may be considered to be skin and eye irritants and marginally more toxic to the aquatic environment than DCM. 1,3 dioxolane is highly flammable.

Annex I contains a list of the main alternatives to DCM and their hazard properties based on their classification at EU level. None of those alternative substances already available on the market appears to combine those characteristics of DCM that are of particular concern:

- Central Nervous System effects
- Limited evidence of carcinogenic effects
- Priority substance status under the Water Framework Directive

⁸ See footnote 4

⁹ See footnotes 1 and 2

- High concentration in formulations

Furthermore, so far, only very few accidents involving alternatives have been recorded (see Annex 2). Should this change in the future in terms of severity of accidents or number of fatalities, the Commission will immediately re-examine the situation and propose measures on other substances as appropriate.

It is evident that DCM has a unique profile of adverse effects to human health coupled with being a priority substance under the Water Framework Directive. Also, because of its high concentration in paint stripping products, its high volatility and narcotic effects, DCM poses a direct risk of death as a result of misuse (a characteristic not necessarily shared by most of the alternatives). On balance, there are alternatives with a better human health and environmental hazard and risk profile. Still, it should not be assumed that the use of alternatives would not be accompanied by the need for a proper assessment of the risks, likely to give rise to the use of appropriate engineering controls and Personal Protective Equipment (PPE) for workers.

The cost analysis of some alternatives has highlighted that some of them are more expensive and require repeated applications as they are less effective than DCM and also because they have a different mechanism of action.

A general decline has been observed for recent DCM sales registered in EU, in the same way as for other chlorinated solvents, which is expected to stabilise by late 2007 once the Solvents Emissions Directive 1999/13/EC is fully implemented. Sales figures for “virgin” DCM for the manufacture of paint strippers during the last 10 years are the following¹⁰:

Table 1:

Year	Tonnage of “virgin” DCM sold for paint stripper manufacture
1995	ca.20,000
2001	ca.18,500
2002	ca.18,000
2003	ca.19,000
2004	ca.15,000
2005	ca.13,000

Overall, the main destinations of paint strippers produced from “virgin” DCM appear to be: France, Germany, Italy, Belgium, the Netherlands, Luxembourg, Spain, the United Kingdom and Ireland. The total sales for the year 2005 broken down by Member State and a comparison of sales for the years 2002 and 2005 are provided below:

Table 2:

Country	Sales (tonnage) in 2002	Sales (tonnage) in 2005	2002-2005 change (%)
UK/Ireland	4,267	3,228	-24%
France	4,779	2,530	-47%
Benelux	2,824	2,511	-11%

¹⁰ See footnote 5.

Germany	1,067	1,524	+42%
Spain	2,203	1,441	-36%
Italy	1,532	1,254	-18%
Rest of EU-15	1,056	716	-32%

Emissions of DCM are regulated under Council Directive 1999/13/EC on volatile organic compounds¹¹, which controls the direct and indirect effects of emissions into the environment and the potential risks to human health. In addition, other European legislation, such as the IPPC Directive, is in place which prevents and controls the pollution from professional activities involving DCM¹². So far and because of such controls already in place at EU level, no environmental risk has been identified during the production and use of DCM.

3. SECTION 3: RIGHT OF THE COMMISSION TO ACT

Directive 76/769/EEC relates to restrictions on the marketing and use of certain dangerous substances and preparations and is a well-established instrument at Community level to control risks from dangerous substances and preparations. In order to avoid divergent national legislation which will cause barriers to intra-Community trade and to achieve a high level of protection of human health and the environment throughout the Community, Council Directive 76/769/EEC is considered the most efficient instrument to manage identified risks.

A number of European countries have already put in place national measures to control the risks of DCM. In Austria, a ban on sales of DCM-based paint strippers was introduced in 1992; in Denmark DCM as a substance classified as carcinogenic category 3, has been made subject to the same rules as the carcinogens category 1 and 2 listed under Directive 2004/36/EC (Carcinogens Directive for workers). Under the Danish national legislation, DCM-based paint strippers must be substituted by less hazardous preparations if available on the market. In Sweden DCM is prohibited for marketing and use since 1 January 1996 with a general exception for use in research and development, and for individually authorised cases. In January 2007, Germany notified to the Commission draft legislation within the framework of Directive 98/34/EC. This draft Order had the objective of introducing a general ban on the placing on the market and the use of paint strippers and exterior cleaners with a total content by mass of more than 1% DCM with exemption for those activities conducted under closed systems in industrial installations. As the scope of the notified draft Order covered a field to be harmonised at Community level, the Commission requested the German authorities in accordance with Article 9(3) of Directive 98/34/EC to defer adoption of the notified draft for 12 months until 29 January 2008.

In view of the divergent opinions among the Member States on the need to act concerning the registered cases of fatal and non-fatal accidents in several Member States during the last 18 years and the diverging actions taken by some but not all Member States, the control of such risks cannot be achieved by leaving the responsibility to act solely to the Member States. An action at Community level is the most efficient and proportionate way to eliminate or reduce such identified risks. Article 95 of the Treaty is the appropriate legal base for the Proposal.

¹¹ Directive 1999/13/EC known as VOC or solvent emission (SE) Directive; Directive 2004/42/EC on limitation of emissions of VOCs due to the use of organics in certain paints and varnishes and vehicle refinishing products; Thematic Strategy on air Pollution.

¹² IPPC Directive 96/61/EC and guidance on the use of Best Available Techniques is explained in detail in the relevant BREF on surface treatment using organic solvents.

Transition to REACH:

On 1st June 2009 Directive 76/769/EEC will be replaced by Regulation N° 1907/2006 (REACH Regulation) – in particular by Title VIII and Annex XVII on restrictions. The provisions of the proposal accompanied by this impact assessment will be included into Annex XVII of REACH, which contains restriction measures. As DCM is classified as carcinogenic Category 3, it is not of sufficient priority to be considered under the authorisation procedure of REACH. This means that if the Commission waited for entry into force of the relevant parts of the REACH Regulation before presenting its proposal on DCM, it would also have to be dealt with in accordance with the restrictions procedure.

REACH will also not affect the already existing national measures concerning DCM. The only national derogations (more stringent restrictions) which will be phased-out are those which have been approved in accordance with Article 95 of the Treaty and appear in the inventory of national restrictions to be established by the Commission by 1 June 2009 (see Article 67 (3) of the REACH Regulation. National restrictions adopted in the so-called ‘non-harmonised’ area, i.e. where no Community restrictions exist, are not affected by this provision.

4. SECTION 4: OBJECTIVES

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 paint stripping products containing DCM.

5. SECTION 5: POLICY OPTIONS

Different options to achieve the intended objectives are analysed in order to reduce the risks during the application of DCM-based paint strippers. The options take into account the available information on current practices for the different uses (industrial, professional and consumer), the existing legislation at EU and national levels and the views of stakeholders as available to the Commission at the time of writing this impact assessment. The options were developed on the basis of the information and conclusions from the three studies on DCM carried out for the Commission.

Option 1: No action

This would mean that the status quo, i.e. no restrictions at Community level concerning the placing of the market and use of paint strippers containing DCM for industrial, professional and consumer uses, would continue.

Option 2: Voluntary action by industry

A voluntary commitment would be made by producers of paint strippers containing DCM. The actions taken would involve modification of the process or products in order to reduce the risks, to better control emissions of, or to gradually reduce the use of DCM-based paint strippers. These measures would be monitored by the industry. The results achieved would have to be assessed by the authorities at regular intervals.

Option 3: Engineering controls: ventilation and tanks

The occurrence of (often fatal) accidents is frequently linked to inadequate air ventilation or the use of (open) dip tanks. In this option, users would be required to control the local

ventilation and to modify the design and operation of stripping tanks in order to ensure a reduction or elimination of exposure to DCM.

Option 4: Handling measures: Personal Protective Equipments (PPE), container size and design, product composition

Mandatory use of gloves made of suitable chemical-resistant material and appropriate personal respiratory protection equipment would specifically provide dermal and respiratory protection during the use of DCM.

Restrictions of sales to containers smaller than a certain volume would harmonise the present differences between the Member States and would reduce the quantity of DCM which may be released/evaporated and potentially inhaled. Containers would be redesigned with additional requirements such as a spill-proof mechanism or a narrow neck to prevent or reduce the accidental spillage of DCM.

A mandatory change in the composition of DCM formulations with the addition of vapour retardant additives or nasty smelling substances could reduce the exposure levels to DCM.

Option 5: Training and licensed user

The manufacturers of DCM paint strippers would be obliged to set up training and qualification systems for industrial and professional users as part of a licensing system.

The licensing of the users would be based on providing verifiable proof that they have completed the necessary training and that the manufacture has provided accurate, harmonised, up-to-date information, advice and training on using DCM-based paint strippers. Member State Competent Authorities would be required to oversee the operation of the training and licensing system and that licences are issued only when they are satisfied that these are of the required standard to ensure adequate control of the risks.

Option 6: Total ban

DCM-based paint strippers would be banned for all industrial, professional and consumer uses.

As summarised in Table 3, the policy options described above will be considered for all use categories except the option “training and licensed user” which is not applicable for consumers.

Table 3:

Options Use category	1. No action	2. Voluntary action by industry	3. Engineering controls: ventilation and tanks	4. Handling measures: PPE, container size and design, product composition	5. Training and licensed user	6. Total ban
Industrial	√	√	√	√	√	√
Professional	√	√	√	√	√	√

Consumer	√	√	√	√	-	√
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6. SECTION 6: ANALYSIS OF IMPACTS

The analysis of the impacts of the various policy options has been conducted taking into consideration the following criteria: effectiveness and proportionality to reduce the identified risks, practicality, economic impact and monitorability. Advantages and disadvantages have been examined for each option for all three categories of uses (industrial, professional and consumer).

The marketing data and estimated stem from the latest information available to the Commission at the time of writing this impact assessment. The sources of this information are listed in section 9. On the basis of the last survey the uses/applications of DCM-based paint strippers can be summarised in the following Table 4.

Table 4:

Industrial uses	Professional uses	Consumer uses
Removal of air drying <i>paints</i> from wood and metal objects.	In situ <i>paint</i> removal of paint from woodwork, brickwork, plasterwork, stonework, concrete, cast iron.	Removal of <i>paint</i> from woodwork, brickwork, plasterwork, concrete, cast iron at home (indoors and outdoors).
Paint removal in furniture strip-shops; including stripping and restoration of antique furniture.	In situ (indoors and outdoors) removal of <i>coatings</i> from buildings, facades, timber and steel structures, including conservation work and historical building maintenance.	Removal of paint in domestic dwellings on wood and metal articles such as wooden doors, skirting rails/boards, window frames, hand rails, staircase, especially for removal of varnishes, lacquers, nitro lacquers, polyurethane lacquers and plastic coatings.
Removal of coatings from machine and automotive parts (this may include the cleaning of walls in spray booths or cleaning of floors around the spray booth).	Stripping walls and floors, window frames, doors, skirting boards.	
Stripping paint from aircraft and occasionally from rail vehicles.	Graffiti removal including removal of graffiti on behalf of local authorities usually from wall surfaces and removal of graffiti from vehicles.	

Option 1: No action

Figures concerning sales of DCM paint strippers have been presented in Section 2. The general trend is towards a reduction in sales. This is evident for both total sales (around 13,000 tonnes down from 20,000 tonnes in 1995) and per country sales with the most notable reductions in France, Spain, and UK/Ireland as well as in the rest of the EU-15. There is, however one notable exception, Germany, where sales have increased by 42%.

It is not clear whether significant amounts of DCM are imported into the EU for the manufacture of paint strippers; only one manufacturer of DCM-based paint stripper has indicated that they use DCM imported from a non-European country. Consequently, it would be disproportionate to investigate this further and establish a regulatory dialogue on DCM issues with key trading partners. In any case, the proposal will also be notified to the WTO under the TBT agreement, which will give 3rd countries the possibility to comment

DCM is also recycled from the pharmaceutical industry and may end up in paint stripper manufacture. Starting from total sales of “virgin” DCM to the pharmaceutical sector of more than 50,000 tonnes per year and using the different assumptions which regard the number of pharmaceutical companies recycling DCM, the recycling rate, the output rate of the recycling process and the percentage of distillate used in the manufacture of paint strippers, the tonnage of reclaimed DCM that is used in the manufacture of paint strippers is calculated to be between 1,500 and 11,000 tonnes DCM per year (tonnes of DCM recycled/reclaimed and sold for use in paint strippers). The upper limit of 11,000 tonnes is an agreed estimation in all the studies conducted on DCM¹³.

As described in Section 3, a number of European countries (Austria, Denmark, Sweden) have put in place national measures to control the marketing, use and exposure of DCM in paint strippers. Recently also Germany has notified to the Commission a draft of legislation for restrictions on the placing on the market and use of DCM-based paint strippers. Without action at Community level, there is the likelihood that Member States would continue legislating nationally and apply different restriction measures which would create obstacles to the internal market and lead to different levels of protection of human health.

There are already existing legislative measures, for instance, worker protection legislation, specific national measures such as the establishment of occupational exposure level (OEL) as well as environment-orientated legislation (VOC/IPPC/WFD)¹⁴ which could set out a sufficient framework for controlling directly and indirectly the risks from DCM-based paint strippers to the users. However, the statistics on fatalities and injuries show that this is not the case. Nor do they appear to prevent the misuse of DCM-based paint strippers and failure to take elementary safety measures (such as sufficient ventilation and use of PPE). Of particular concern is the fact that accidents and fatalities associated with the use of DCM-based paint strippers continue to be registered as described below (this information is collected from industry sources and consultation with Competent Authorities):

Table 5:

Use category	Fatalities	Non fatal injuries	Location and year of fatalities
Industrial use	9	6	FR: 3 (1997,2002,2007) DE: 1 (2000) ES: 1 (2000) UK:4 (1989,1999x2,2006)

¹³ RPA study, TNO study and ETVAREAD study. See footnote 1.

¹⁴ See footnotes 9 and 10.

Professional use	8	26	FR: 2 (1990,1992) DE: 5(1989x2,1990,1999,2002) UK: 1(2002)
Industrial/Professional use	0	10	
Consumer use	1	14	FR: 1 (1993)
Totals	18	56	

In conclusion the option “no action” is inappropriate as it will not prevent further accidents (fatal or not); nor will it harmonise the internal market as Member States could continue to adopt diverging national provisions.

Option 2: Voluntary action by industry

Setting up a voluntary commitment, ensuring participation by all actors concerned and guaranteeing monitoring of compliance by all EU companies including small and medium-sized enterprises, would create a significant administrative burden to companies and the relevant industry associations.

It is not possible to quantify with any certainty the administrative burden to companies for this Option. There is no reliable information on how many companies would actually participate and how they would organise and monitor compliance. Using the standard cost model would therefore be highly speculative. However, it is reasonable to assume that the costs could be significant, as it would be necessary to involve a relatively high number of medium and small sized companies which are not usually members of EU or national associations or federations. They all would have to make resources available to participate in voluntary schemes.

In addition, there is a clear difference of opinion between the manufacturers of DCM-based paint strippers and users and the manufacturers and users of alternatives on technical and practical issues which has given rise to a variety of claims and counter-claims which remain unresolved. It is highly unlikely that voluntary action to obtain a gradual reduction of the use of DCM, the elimination of its use in unacceptable situations, or with regard to product composition and container design could be agreed under these circumstances. Effectiveness of voluntary action could therefore not be guaranteed.

Option 3: Engineering controls: ventilation and tanks

A significant proportion of fatalities associated with the use of DCM-based paint strippers in Europe over the last 26 years were linked to industrial and professional uses with inadequate ventilation and the use of dip tanks key factors contributing to the accidents.

The following engineering controls generally exist to reduce exposure to and risks from DCM during the use of DCM-based paint strippers:

- (1) Natural ventilation, which is usually relied upon in outdoor applications and in well ventilated (draughty) spaces; and/or
- (2) Artificial ventilation (by extraction of vapours or venting with fresh air), which may be applied in spaces with little natural ventilation.

There is currently no comprehensive information available on the practices in industrial installations with regard to the use of engineering controls. A requirement to install mechanical ventilation meeting certain minimum criteria, for instance, would, necessitate

some physical modification to existing equipment with related costs – unless the requirements would already be met by the existing installations. It is, however, not known how many installations exist or would have to be modified.

There are strong variations in the current occupational exposure limits (OELs) adopted in EU Member States: the limit value for 8h-Time Weighted Average (TWA) varies between 10 mg/m³ in Hungary and 350 mg/m³ in Greece, the Netherlands, the Slovak Republic, Slovenia and the United Kingdom; also the short-term exposure limit (STEL) values may be as low as 10 mg/m³ in Hungary or as high as 1,750 mg/m³ in Greece and the Netherlands. Discussions on the establishment of a common European Occupational Exposure Limit are currently ongoing but have not yet been concluded. As described in Section 2 the SCOEL recommends to set a limit value of 100 ppm (353 mg/m³) for an eight hours Time Weighted Average (TWA) and based on possible short-term pre-narcotic effects, a limit value of 200 ppm (706 mg/m³) for a 15 min Short Term Exposure Level (STEL). A Biological Limit Value (BLV) of 4% of COHb (Carboxyhaemoglobin) is also recommended by SCOEL.

The advice given by manufacturers to professional users is normally that the user must ensure “adequate” ventilation. This in effect means that the national OELs should be respected. There is one key issue, though: how do users establish in practice whether the national OELs are exceeded. It is unlikely that those involved in professional uses (especially micro-enterprises of 2-3 employees or self-employed 1-man companies) would have the necessary equipment.

Respecting OELs, especially in open applications (such as removal of paint from external building walls) is problematic. It is also very difficult in practice for those involved in professional uses (working outdoors or requiring continuous movement from one location to another) to respect an OEL (or even to conduct measurements to check the levels of exposure). The users have limited knowledge of the role and importance of OELs as it is a measure more relevant to a stationary industrial installation where reliable measurements may be undertaken, evaluated and acted upon.

Respecting OELs is not feasible for consumer uses - in fact in some case the working conditions at home may be much worse than those for tradesmen. For example, paint stripping may be undertaken in a basement, or in an enclosed area with closed windows, or in the presence of vulnerable persons such as children, elderly relatives or those with specific health conditions. There may be difficulties in interpreting the requirements of good “ventilation” when the consumer needs to use the paint stripper indoors in a room without windows (for example, a basement) or when the weather is such that opening windows and doors to increase ventilation is not an option, for instance, in winter or in colder climates in Northern Europe. It is also unlikely that consumers will pay much attention to the ventilation issues especially when there is no mechanism for enforcement at Member State level.

In industrial installations, exposure to DCM could be significantly reduced by a requirement to allow use only in closed systems. Cost for installing a closed system to completely prevent the exposure of the operator to DCM vapours, have been estimated at up to € 100,000¹⁵. This cost per installation is a significant capital investment and would be disproportionate and prohibitive for many SMEs who are active in the paint stripping industry. There are also practical issues related to the use of truly 'closed systems', for example it would be extremely difficult to introduce a closed system when very large work-pieces need to be stripped (such as car bodies, airplane parts).

¹⁵ See footnote 5.

Furthermore, the actual stripping in the tank is not the only step where exposure to DCM can occur, and again operations in small companies (e.g. those involved in furniture stripping) could hardly be completely 'closed': (a) disposal of waste residues is often carried out manually, unless a sophisticated filtering system is installed; (b) items of furniture need to be turned over, brushed, scraped and (c) washing off dipped items after stripping will result in excessive fumes, so this part of the process would also have to be enclosed (with the associate cost and inconvenience). A requirement for the use of closed systems by all users involved in industrial uses would therefore result in disproportionate costs. Costs would be kept more reasonable through certain engineering controls around the dipping tank, and better ventilation of workshops and/or PPE for operators to control exposure.

All tanks used for dip tank application should normally be fitted with effective local exhaust ventilation. General mechanical ventilation should be installed to provide air circulation. This should be designed to operate in conjunction with local exhaust ventilation at the tanks. Heated wash tanks which follow the solvent tank should be kept at the lowest suitable temperature to limit solvent evaporation. All tanks should be covered when not in use and to avoid high continuous exposures, workers should not spend all their time on one stage of the process. No one should work alone in an immersion stripping workshop.

Alternative systems based on high boiling point solvents or caustic soda need to be heated (usually at 80-90°C), while DCM stripping tanks are used at room temperature (20°C). This need to heat the tank when a company would have to switch from DCM to an alternative could, therefore, mean that existing tanks have to be significantly modified at considerable additional costs. It has been suggested that the cost of the tank for the alternative system could be up to four times the cost of a tank for a "traditional" DCM-based stripping system¹⁶.

The costs associated with certain more limited technical modifications of the actual DCM dip tank – without moving to a completely closed system – would be more modest and would be justified by the use of these tanks for certain essential industrial uses. However this engineering control option would have to be combined with measures to ensure better ventilation in the workshops and the requirement to provide a separate ventilated area for drying stripped articles.

Measures relating to dip tanks are also of no relevance to consumer uses.

In summary, good ventilation of the workplace and further engineering controls for dip tanks are important measures which should be applied in view of the high volatility of DCM and the associated risks. This measure can be implemented in fixed installations during industrial uses which are able to create the necessary infrastructures. During professional uses this measure is feasible, but needs to be adequately controlled as professionals themselves (and in particular also self-employed workers, who are not subject to the worker protection legislation) do not necessarily have the capacity to assess the exposure levels to DCM and to guarantee appropriate engineering controls especially outside the industrial installations. For consumer uses assuming well-ventilated working conditions is unrealistic. A completely closed system is not feasible for any of the use categories.

Option 4. Handling measures: Personal Protective Equipments (PPE), container size and design, product composition

Personal Protective Equipments (PPE)

¹⁶ See footnote 5.

Users wearing the appropriate personal protective equipment (such as gloves and masks) at all times would be sufficiently protected.

For industrial and professional users, the use of PPE should be reasonably straightforward, as long as the adequate equipment is provided by the employer to his employees. In practice, there may be a potential difficulty for users with limited knowledge to make informed choices on PPE except where it is clearly set out in national legislation or unless sales of DCM-based paint strippers are only allowed if accompanied by the appropriate equipment.

From the information gathered¹⁷ from professional users, even though in cases of limited ventilation airborne concentration of DCM vapours may be unacceptably high, it appears that in practice independent air supply respirators are not always used, and often no real respiratory protection is provided to the user (only a visor that protects from splashes on the face and eyes but very limited protection from inhalation of DCM vapours). It is also important to note that even when the paint stripping is undertaken outdoors, the exposure levels may exceed by far the national OELs. Therefore, outdoor use, where the likelihood that workers would use independent air supply respirators is very low, does not automatically preclude the possibility of adverse effects. Working habits have an important role to play in the practices of users especially those of employees of small and micro-enterprises which more often than not do not have the benefit of the presence and knowledge of a health and safety expert. Employees may often be reluctant, especially in hot weather, to use respiratory equipment – even much less complex and uncomfortable one than independent air supply respirators, such as masks.

Industrial and professional uses could be made subject to the use of appropriate gloves and masks and, where necessary, independent air supply respirators; the users would then be protected from dermal and inhalation exposure to DCM. Additional costs for the companies would have to be considered, however. The costs of gloves will depend on the material used and it can vary from € 9.60 to € 50 per pair, masks with specific vapour filter will cost around € 70 and for supplied air respirators the mask alone will cost around € 92-184 without additional costs for the compressors.

There are relevant European standard for gloves giving protection from chemical risks where some parameters such as penetration and permeation are assessed. In the case of DCM, gloves with a polyvinyl alcohol (PVA) coating have a much better chemical resistance to DCM than fluororubber and the 5-layer laminate type (EVA); however PVA-coated gloves cannot be used where water is present. On the other hand the EVA laminate is the less costly (€ 9,60 price per pair compared with € 25,30 of the PVAs and € 50 for fluororubber) but it has little mechanical strength and a short breakthrough time. The use of gloves must be appropriate to protect at specific working conditions defined by parameters such as the exposure levels, the mechanical work intensity and duration. Overall, a worker might, in theory, have to use different gloves for different parts of his work and it is possible that in the course of the day he may encounter conditions which require other type of gloves.

However, it is unrealistic to expect the user to change gloves part-way through a job; logistically the use of more than one type of gloves is also far from ideal: companies would need to have a stock of several types of gloves. This may cause problems in professional uses where the packs of gloves would need to be carried around to where paint stripping will take place. Overall, the use of a variety of gloves would complicate paint stripping work and companies prefer just one type of gloves which offers sufficient protection under all

¹⁷ See footnote 5.

circumstances instead of considering the most appropriate protective gloves which would guarantee good permeation resistance, good mechanical properties and be water resistant.

Furthermore, over-reliance on PPE would contravene the spirit of existing workers legislation which places more emphasis on substitution and engineering controls before considering PPE. If implemented in a very constraining manner, it could require users to use respiratory protection equipment at all times, although adequate ventilation may be in place.

Consumers are very unlikely to accept such measures as it would make the use of DCM-based paint strippers very uncomfortable and disproportionately costly. The costs of a pair of gloves could be between € 9.60- € 50 and the cost of DCM-based product is around € 10.3/litre. Even if it was mandatory to sell appropriate gloves packaged together with the paint stripper, the authorities would have no way of checking whether the PPE is actually used by consumers. Similarly, a retailer may guarantee that the consumer has bought the relevant PPE but cannot guarantee that the consumer will actually use it.

In conclusion, a restriction requiring PPE would result in additional costs, which for consumer uses might be disproportionate, and, although the use of PPE would be essential for protection of human health there is no guarantee that PPE will be used properly or replaced as appropriate, again especially for consumer uses for the reasons mentioned. For industrial uses in fixed installations, availability and use of appropriate PPE are more likely, whereas for professional users the situation is probably mixed: in particular small companies and self-employed workers might not have sufficient awareness and/or the necessary equipment. Any requirements concerning the use of PPE for professionals will therefore have to be combined with other measures to be truly effective.

Container size and design

The most widely used container sizes are 25 litres for industrial uses, 5 litres for professional uses and 1 litre for consumer uses.

A reduction of the container size and a requirement to use only narrow-neck bottles would be effective measures in reducing exposure from spillages and to make access to DCM-based paint strippers more difficult in general. However, spillages are not one of the main reasons behind accidents resulting from industrial or professional use of these products. Apart from container size, there are many other factors that may influence exposure, in particular the competence and actions of the user. A restriction on size or bottle design will not address or alter the way the product is used by the user.

When discussing the size of containers and how this may impact upon the exposure of the user to DCM and the associated risks, the following should be considered:

- the size of the container cannot be the same for all three categories of use, industrial, professional and consumer, because these types of uses have different requirements, and use patterns: a 0.5 litre container may be suitable for a consumer who needs to remove the paint from a window frame but not for an industrial use which involves the use of a dipping tank with a capacity of several cubic metres or the stripping of paint from large surfaces (e.g. aircraft, vehicle, large furniture)
- companies involved in professional uses may consume a few thousand litres per year and containers of 5 or 25 litre are more appropriate; therefore
- a possible restriction on the size to 1 or 0.5 litre is of relevance to consumer risk reduction only.

According to the SCHER opinion on the ETVAREAD study¹⁸, unacceptable risks may result even when only 0.35 litre DCM is used for paint stripping. On the other hand, consumers will determine the quantity they buy primarily in function of their stripping needs, i.e. the consumer will purchase a quantity appropriate for the job at hand even if it means buying multiple small containers (if only small containers are available at the retail outlet).

For industrial and professional uses a restriction of the container size to 0.5 litre or 1 litre would be unrealistic as considerably greater quantities of paint strippers are required (for example in dipping tanks). The time that would be required to use multiple containers and the amount of packaging waste generated make this measure particularly unattractive.

Undoubtedly, narrow-neck containers, apart from preventing accidents involving mishandling the container, can also reduce the release of the contents if the container is tipped over and can further reduce the release of vapours if the container is left uncapped. However, they are not effective in reducing exposure associated with the actual stripping process and the normal actions of the user (i.e. decanting its content, using the brush on the substrate, scraping the paint stripper and the coating off the surface, etc). In fact, narrow-neck containers do not allow the user to immerse a brush into the product. As a result, the user needs to decant the contents (or part thereof) of the container into a tub or bucket or a jar so that in the end exposure would not be reduced.

In conclusion the reduction of the packaging size and other measures limited to container design would be unrealistic for industrial and professional users due to their specific applications which require considerable quantities of paint strippers. Only during consumer uses could such reduction be considered efficient to reduce exposure from accidental spillage, but exposure from actual use would most likely not be reduced or controlled.

Product composition

The majority of paint-stripper preparations available on the EU market contain between 60% and 90% DCM; there are also products available in the EU market, which contain 10-25% DCM and some with less than 10%. Nevertheless, given that DCM is the “active ingredient” in paint stripper preparations, it can be assumed that a reduction in concentration might affect the effectiveness of the products. Moreover, the effectiveness and the human health/environment hazards and safety issues of the added other components would have to be taken into account.

The inclusion of a “nasty smelling substance” has been suggested by industry as risk reduction measure. However, the effectiveness of such a risk reduction option is uncertain. In particular, the inclusion of a “nasty smelling substance” may encourage users to wear “simple” respiratory equipment (masks) to avoid the unpleasant smell of the added substance without achieving the necessary respiratory protection against inhalation of DCM vapours themselves.

Vapour retardants that are added to DCM-based formulations help prevent DCM evaporating before achieving the removal of the coating and can therefore reduce the exposure of the operators. The use of vapour retardants is not a recent phenomenon. Waxes (the most commonly used type of vapour retardants) have been used for decades (since at least the 1940s) and the technology has not changed significantly over the last 20-30 years. Waxes need to remain undisturbed in order to create a protective film (“skin”) which prevents the quick evaporation of DCM from the formulation. When the user interacts with the product

¹⁸ See footnote 4.

(decanting, dipping brush in container, applying paint stripper, removing paint stripper), this “skin” is disturbed/broken and DCM vapours are released. Some formulators of DCM-based paint strippers have argued that the “skin” is re-formed very quickly which prevents excess exposure of the user to vapours.

Products intended for consumer and professional use normally already contain vapour retardants. Non-vapour retarded products are generally used in industrial applications. This does not, however, mean that no vapour retardants are used: waxes or other agents (water or plastic balls) may be added in dip tanks to create a protective layer on the top. Other cases where non-retarded formulations are needed include applications where the paint stripper is used for cleaning purposes, for instance cleaning the nozzles of spraying equipment. In such cases, the presence of vapour retardants would hinder rather than facilitate the cleaning operation. The tests presented in the ETVAREAD report and the available monitoring data suggest that despite the use of vapour retardants, airborne concentrations of DCM during the use of paint strippers may exceed the nationally established OELs (occupational exposure levels) and there are parameters far more important than vapour retardants that influence the exposure of the operator to DCM vapours (e.g. the temperature during the application, the area of the treated surface, conditions of ventilation etc).

In addition, since the use of vapour retardants is state of the art since several decades it is reasonable to assume that the accidents have occurred although vapour retarded products have been used¹⁹.

In summary, while vapour retardants may contribute somewhat to the control of exposure of the user to DCM, this contribution is insufficient to guarantee that a formulation does not pose a risk. Moreover, the existing methods for measuring the evaporation rate of products containing vapour retardants are not standardised or necessarily reproducible and have little relevance to real conditions of use of DCM-based paint strippers.

Option 5: Training and licensed user

Only well trained users are fully aware of the risks linked to DCM and the measures that can be applied to reduce exposure to acceptable levels.

In this option, producers of DCM-based paint strippers would be made responsible for organising training courses, disseminating information, testing and licensing of those employed in a paint stripping business wishing to use DCM-based paint strippers. The aim of licensing of users is to ensure that those using the products have the necessary knowledge to do so safely while respecting the current legislation and taking all necessary measures to protect themselves. The effectiveness of the training/licensing system would partly depend on the information provided to the participants. Industry would have to develop up-to-date and scientifically robust training manuals to ensure that the users of these products have adequate protection.

Communication of new information down the supply chain should be straightforward which makes this measure quite simple to implement. A licence would provide a guarantee of competence and responsibility of the user, i.e. some guarantee that the required risk management measures would be taken to protect the health of users of DCM-based paint strippers. Whilst the details of the procedures would be left to companies, minimum training requirements will have to be defined by the legislator and will include: a) the use of personal

¹⁹ See footnote 3.

protective equipment; b) good ventilation conditions, c) full awareness of risk including its assessment and management during activities involving DCM-based paint strippers.

While the authorities would be overseeing the operation of this system, industry would exercise the key functions. This would be in line with the principles of the new chemicals legislation, REACH, which gives primary responsibility for the safe use of chemicals and communication of the necessary information to the actors in the supply chain. Authorities would also have to monitor the use of DCM paint strippers (i.e. only by licensed operators).

It is clear that provision of information, advice and training can be as effective as most other measures if the users really take the information into account and apply what they have learned. This is more likely if training is profound and is repeated regularly. A licence would provide some guarantee of competence and responsibility of the user i.e. some guarantee that the required risk management measures are definitely known, which would increase the likelihood that they are applied for human health protection. The option aims at influencing the long term behaviour of the user so that the use of DCM-based paint strippers under the appropriate conditions is the result of conscious choice rather than the result of authority enforcement or fear of a penalty. This option would give more responsibility to professional users and it would ensure that those using the product have the necessary knowledge to do so while respecting the current legislation and taking all necessary measures to protect themselves.

In terms of drawbacks, just as in any sphere of worker protection, providing the information and checking that training has been followed cannot provide an absolute guarantee that the users of the substance will act more responsibly. Misuse of DCM-based paint strippers occurs not only due to the lack of knowledge but also out of habit, boredom or lack of time (i. e. the risks are assessed quickly and superficially and protection measures are inadequate) or cost consideration (adequate measures, for instance, using the correct type of gloves and replacing them as appropriate would add to costs of companies). In fact, there is no evidence that those who died in accidents involving DCM were not necessarily experience or had not received training. On the other hand there is no evidence either that they actually had been trained, were fully knowledgeable and did apply the required or recommended safety measures.

However, it is reasonable to assume that the costs for companies to follow training and to obtain a licence and the possible sanction of a loss of the licence in case of breach of the requirements will give a strong incentive to ensure that the necessary precautions are taken and accidents are minimised.

The adoption of such training and licensing systems would be rather considered for professional uses than for industrial uses. Industrial activities are usually conducted in industrial installation where workers are generally protected by the provisions set up under the workers legislation if these are appropriately enforced. As described above, proper application of the workers protection legislation for professionals outside industrial installations is much more difficult, in particular in small companies, and the category of self-employed workers is not covered by the workers legislation. A specific system of training and licensing could well improve the situation for these particular groups of workers.

Based on the costs observed in the UK, a formal training course is estimated to cost around € 1,400 and this should be suitable for between 10 and 20 people. A day's training can cost at € 140 per employee with a cost of € 56 (8hours x €7) for lost time (equivalent to lost production). Assuming that 1 day's training will be required in the first year and half a day's annual training in subsequent years. This means a cost of € 196 in the first year and € 98 in the following years for each employee.

Assuming an employee turnover rate of 20%, then the recurring costs will be 1 day training for all the workforce plus 20% of the total workforce having to be trained from scratch.

There are no numbers available concerning companies and workers that would be required to follow training and obtain a licence. Assuming a total number of 10,000 employees throughout the EU, training costs are likely to be € 196 x 10,000 = € 1.9 million in the first year and (€ 98 * 10,000) + (20% of 10,000*196) = € 1.3 million in subsequent years. Higher numbers of employees would lead to higher costs.

For the actual licensing process, costs will vary, depending for example on the number of licensed applications, costs to the licensing body as well as the degree of monitoring that authorities deem to be necessary. Using low and high uptake scenarios

- low = applications from 100 businesses and 800 individuals, no site inspections by authorities
- high= applications from 200 businesses and 2600 individuals, 20% inspections by authorities

and the unit time cost estimates, some illustrative licensing scheme costs have been calculated (on the basis of cost figures from the UK) on an annualised basis and are summarized in table 6:

Table 6

Stakeholder	Low (1000 €/y)	High (1000 €/y)
Individuals	3,36	21,84
Licensing authority	22,68	306,46
Local Authority	0,86	1,82
Total	26,9	330,12
Illustrative licence fee (€)*		
<i>per individual</i>	15,4	96,6
<i>per company</i>	109,2	277,2

* covering relevant licensing body and (local) monitoring authority costs

The costs associated with the licensing process would be passed onto applicants via licence fees and the illustrative fees reported in the table are just that. The actual costs are expected to be closer to the lower scenario, because in the case of professionals working mostly directly at their customers' sites inspections are not particularly meaningful.

Extrapolation to the EU with an assumption of 10.000 individuals and 800 businesses would result in costs of € 1.34 million.

Competent Authorities in several Member States may generally be unable and/or reluctant to be involved in participating in such as scheme. The current legislative framework requires that companies (employers) are responsible for assessing and taking the necessary action to address risks to their employees. Therefore, any measure which may require additional input by the authorities may place an additional burden on their available resources. In particular in Member States where only few companies or individuals would be interested to follow training and acquire a licence, Member States might not be able to recover their costs.

Therefore, instead of requiring the setting up of training and licensing schemes in all Member States, the option could be modulated to allow this as an alternative to a ban for professional

use of DCM-based paint strippers. This modulated option would give some Member States and industry which consider that the benefits of DCM outweigh the risks, such as the UK and Ireland, the possibility to allow continued use. In turn, they would have to accept full responsibility and the administrative burden of setting up a licensing system and appropriate control measures. In this way, the Member States will be best placed to assess, in close consultation with interested companies and worker organisations, the likely costs and benefits of the option 'training and licensing', compared to the option of a ban for professional users where no such costs would arise. It is likely that these costs and benefits will vary between Member States and that the number of actors involved will show wide variations.

In a cross border context this option does not pose particular problems. The decision on whether to allow the use of DCM based paint strippers by licensed operators would lie entirely with the Member States. In Member States which choose not to allow it, no company could use DCM based paint strippers, whereas in Member States which choose to allow it, all companies having the required licence would be entitled to exercise their business. Companies from neighbouring Member States would not be barred from participating in the required training and obtaining the licence.

There are several precedents under Directive 76/769/EEC which give the possibility to the Member States to authorise some derogation from a more general ban on a case-by-case basis, for example, the ban on pentachlorophenol established by Directive 1999/51/EC. Member States are entitled to authorise on their territories specialised professionals to conduct some specific uses. Up to now the Commission has never received any complaint from the Member States authorities or from the users themselves about cross-border problems in the application of such measures.

Option 6: Total ban

A total ban of DCM-based paint strippers is likely to have an impact particularly with regard to: loss of sales of DCM manufacturers, impacts on paint stripper manufacturers, increased cost for users for alternative chemical preparations and the capital costs of adapting existing installations for use with the alternatives. Some of these costs could indeed be significant especially for SMEs working with low profit margins. Other potential costs include the costs of an increase in the duration of the operations and the need to heat the dip tanks with some alternatives (wherever a tank dip system is operated)

Impacts on manufacturers of DCM

The figures in Table 7 reflect the total revenues from the sale of DCM for the manufacture of paint strippers that would be lost in case of a ban. In the absence of more information across all Member States, it has been assumed that sales of DCM relating to paint strippers are divided equally among the three use categories, industrial, professional and consumer (33%). In addition, prices for DCM for other applications would most likely go down, as the market would (at least initially) be oversupplied.

Table 7

Decreases in sales volume		€ per tonne DCM	
Value of lost sales	Use category	European market	
		€1,000*	€1,300**

	Industrial	€4,330,000		€5,630,000	
	Professional	€4,330,000		€5,630,000	
	Consumer	€4,330,000		€5,630,000	
	Total	€13,000,000		€16,900,000	
Losses due to per unit price reduction					
Value of lost revenue by % price drop	10%	€9,800,000	€12,740,000	€23,100,000	€30,030,000
	50%	€49,000,000	€63,700,000	€115,500,000	€150,150,000

**€ 1,000 is an assumption of price per tonne based on the figures quoted by formulators; ** € 1,300 represents an estimation which implies the average price per tonne of DCM which is higher than the figures quoted by users.*

Assuming a profit margin of between 10% and 25% the actual losses arising from the ban would range from about € 1.3 million to € 3.2 million per year. Taking a 33% split between industrial professional and consumer uses, the loss in profits per use category would be between roughly € 430,000 and € 1.1 million.

Impacts on manufacturers of paint strippers

The paint stripping sector as whole is characterised by stable demand, as it is an essential process for the metal treatment sector, construction, home decoration (Do-It-Yourself) and building restoration and maintenance markets. Any restrictions (or price increases) imposed on a particular paint-stripping product are thus unlikely to have a significant impact on demand - rather it will result in an increase or redistribution of costs amongst relevant manufacturers and users. In this regard, it should be borne in mind that several manufacturers of DCM-based paint strippers in the EU also manufacture DCM-free alternatives and may already have a well-established position in the alternatives market. This would allow them to compensate some or all of their losses from a restriction on DCM-based formulations with sales of alternatives (which naturally would increase once DCM-based products are removed from the relevant markets).

The majority of companies producing or using DCM paint strippers are not expected to experience significant impacts on employment levels. However, for some producers of paint strippers this depends on whether a suitable alternative could be developed. One company provided information that its operations could, in theory, be relocated to a non-EU destination following a restriction on DCM. However, this company currently has a range of alternatives in its product portfolio (already achieving good sales in the market). While the success of any company in switching from DCM to alternatives cannot be predicted, it is reasonable to expect that those companies with pre-existing alternative products in their portfolio may have a relative competitive advantage.

A total ban on DCM-based paint strippers would probably lead to a situation that out of the total of 40,000 tonnes of DCM-based paint strippers (this tonnage includes also the recycled DCM from the pharmaceutical industry), some 10,000 tonnes (25%) will be replaced by mechanical stripping (with the associated benefits for the companies that supply relevant

equipment and services) and the remaining 75% will be replaced by alternative chemical paint strippers. If a 1:1 tonnage replacement is assumed (i.e. the remaining 30,000 tonnes of DCM-based formulations will be replaced by 30,000 tonnes of alternative formulations) and the cost of alternative formulations range from € 3-8/kg, then the size of the new market for alternatives could potentially be valued at € 90 million to € 240 million.

Regarding innovation, there is a mixed reaction from consulted companies on whether any potential restriction may spur or hinder innovation. Impacts on trade and competition are not expected to be damaging even if there may be significant changes in the internal market. It may also open up the market to some SMEs who have invested significantly in exploring the potential for alternative paint strippers.

Impacts for industrial use:

The cost of DCM-based paint strippers for industrial use are estimated at around €1.5/kg while the alternatives may cost from €3 to €8/kg (factor 2-5); The key factor which will influence the overall cost of the alternative formulation for an industrial user is the quantity required/used. Using some simplistic calculations from the data provided by industry, it would appear that the average (additional) cost of using alternative formulations could be around €3.000 to 10.000 per year per industrial user (based on a user requiring 600 litres of DCM and 750 litres of an alternative formulation per month)

Impacts for professional use:

A case study has been developed based on a typical job undertaken by a company involved in professional uses. The company removed paint from the front of a residential property.

Depending on the alternative formulation used, it is assumed that the user may need 0.5 to 1.5 times the quantity of DCM-based paint stripper (in this case, 100 litres). The information available suggests a cost of DCM-based paint stripper to the user of €1.5/kg (€1/litre) and a cost of DCM-free paint strippers from €3 to €8/kg. These figures are equivalent to ca. €2/litre to €6/litre.

Table 8 contains the cost by companies involved in professional uses with and without DCM-based paint strippers.

Table 8:

Cost component	DCM-based	DCM-free
Cost of paint stripper	€100	€ 75 to €600
Cost of respiratory protection	€400 to €2,400	€200
Cost of gloves	€ 100	€68 (based on two days)
Cost on increased duration of paint stripping	€0	€100
Cost of waste disposal	“baseline”*	“baseline”*
TOTAL	€600 to €2,600	€450 to €1,000
Total without respiratory PPE	€ 200	€ 250 to € 800

* At the end of each job, the operators need to dispose of any waste in the appropriate manner in accordance with hazardous waste legislation. The presence of DCM requires that any waste be disposed properly; however

this does not automatically mean that such disposal requirements would not apply with any of the alternative paint strippers. In fact, the nature of the removed paint could make the waste hazardous and would require appropriate waste disposal action irrespective of the paint stripper used.

The larger part of the overall costs are due to the costs of appropriate PPE – in particular for respiratory protection. As not always appropriate PPE is used, companies might perceive costs for using DCM-free paint strippers to be lower than those for alternatives, even though this is not necessarily correct.

For user companies, the effects on employment should be neutral to positive: some of the alternatives will be more labour intensive (longer application times, repeated use of the products, etc.), and job quality should improve as the hazards involved are probably lower and will reduce the requirements for uncomfortable personal protective equipment.

Impacts on consumer use:

In a model scenario, when DCM-based paint strippers is used in DIY renovation work at home for stripping three doors (both sides), the quantity required will be around 4,5 litres (3x1.5 litres) of product (one manufacture notes on its package “one litre covers from 2 to 3 square metres enough for 1 to 2 standard door sides). If an alternative formulation is used, then the consumer might need between 2.25 litres (4.5x0.5) and 6.75 litres (4.5 x 1.5) depending largely on the specific product used and the thickness and age of the paint that needs to be removed).

Assuming that the unit cost of alternative formulations could be 2 to 3 times higher than that of DCM-based formulations, the cost of purchasing the paint stripper could be around €45²⁰ (€10x4,5) for the DCM-based and from €45 (€20x2.25) up to €122 (€27x4.5) for the alternative formulations, depending on the alternative formulation and its characteristics and price.

With alternatives, less sturdy gloves would be required and these would also cost less: fluororubber gloves (to be used for DCM) cost €50-€90 per pair, whereas the ones suitable for the alternatives possibly cost €2 to €5. Although these two types of gloves have different breakthrough times, it is assumed for simplicity that the consumer uses one pair of glove throughout the stripping of the three doors irrespective of the type of gloves.

Table 9 summarises the cost for a consumer using DCM-based and DCM-free paint strippers.

Table 9

Cost component	DCM-based	DCM-free
Cost formulation	€45	€45-122
Cost of PPE	€50-90	€2-5

²⁰ The price of DCM-based paint strippers appears to be 10 times higher for consumers as opposed to non-consumer uses. Possible explanations for this could include the size of packages sold for consumers as opposed to professional/industrial uses. Where possible, professional and industrial users buy in bulk and avoid paying any premiums to distributors, wholesalers and retailers (premiums that cannot be avoided by consumers when they buy a can of paint stripper off the shelf at a DIY store). Especially when the professional user establish a personal relationship with the manufacturer and engage in ‘repeat business’, then the price he has to pay may be even lower. Even for consumers, the price of €10/litre may be just about average but paint strippers sold in 5 litre packages eventually cost around 3 times cheaper than 0.5 litre packages (only €6.8/litre as opposed to €18/litre).

Cost of (additional) lost time	€0	€7-13
TOTAL	€95-137	€54-140
<i>Total without PPE</i>	€ 45	€ 52 - 135

Overall costs demonstrate that a ban on consumer use of DCM-based paint strippers will not create significant costs, provided the costs for required PPE are taken into account.

The perceived price advantage from using DCM-based paint strippers relates only to the relative costs of stripping formulations. If a requirement were placed on consumers to use DCM-based paint strippers only when the appropriate PPE is used (i.e. fluororubber gloves and – in certain use situations an independent respirator, as necessary), the cost of stripping with DCM-based paint strippers would increase significantly, as would the inconvenience to the user. Furthermore, since national authorities would not be able to enforce such a restriction, a straightforward prohibition of consumer uses of DCM-based paint strippers would be more effective as a risk reduction measure.

Effects on human health from chemical alternatives

In terms of risks to human health and the environment, each paint stripping method may have adverse effects on human health and the environment. Not all alternative paint strippers may be considered to be safer than DCM-based paint strippers. In practice, inappropriate use of any of the alternative paint stripping methods can result in serious adverse health effects. For instance, if mechanical methods are not used appropriately, chemical methods may be preferable given the greater knowledge of the effects that their known components have on health and the environment.

The chemical replacement of DCM-based paint strippers may result in more widespread use of flammable products which may in turn result in a higher incidence of fires with the associated loss of property, life or injury. The use of volatile substances such as methanol, xylene, toluene, ethyl acetate and dimethyl ether, could, in theory, be abused for sniffing with serious social problems. It is impossible to forecast the magnitude of these risks with any certainty as no single substance can replace DCM in all applications.

However based on the available information on the hazard profiles of alternatives as described in Section 2 and summarised in Annex 2, it is evident that DCM has a unique profile of adverse effects to human health coupled with being a priority substance under the Water Framework Directive. Also, because of its high concentration in paint stripping products, its high volatility and narcotic effects, DCM poses a direct risk of death as a result of misuse (a characteristic not necessarily shared by most of the alternatives). On balance, there are alternatives with a better human health and environmental hazard and risk profile – in particular for untrained users such as consumers – although it is impossible to quantify these in a meaningful way.

Conclusion:

With regard to consistency with existing legal requirements, a risk reduction measure will ideally deliver the required reduction in risks by building on and supplementing existing EU legislation and where possible using frameworks and possibilities that are already available. In other words, where the required reduction in risks can be achieved through existing

legislation or by limited modification of existing legislation, such a measure would be considered more favourably than an outright ban which may create significant disruption.

For industrial uses, a ban does not seem to be justified in the light of the significant adverse economic impacts and the other available risk reduction options. For professional use, the situation is less clear and depends on the degree of knowledge of the user, the protective equipment available to him and the correct implementation of the workers protection legislations which does, however, not cover self-employed workers.

The options analysed to reduce the risks of DCM paint strippers other than a ban, which might well be efficient for the industrial and professional sectors include measures which will be difficult or impossible to put into practice for consumers and which will imply relevant costs to the final products (protective equipment such as masks and gloves, use of appropriate equipment to guarantee good ventilation, training, education, licensing). Therefore, a total ban can be justified for consumer use.

7. SECTION 7: COMPARING THE OPTIONS

DICHLOROMETHANE IN PAINT STRIPPERS	Effectiveness	Efficiency
<u>No action</u>	<p>Very low: This option will not prevent accidents (fatal or not) which will continue for all uses (industrial, professional and consumer)</p> <p>Member States could continue legislating nationally and apply different restriction measures which would create obstacles to the Internal Market.</p>	<p>Low: No extra costs for industry but the risk reduction objectives for the three use categories (industrial, professional and consumer) will not be reached.</p>
<u>Voluntary action by industry</u>	<p>Very low: Difficulties to devise an agreement with the involvement of large, medium and small sized enterprises. Opinions within industry are sharply divided and likelihood to agree on voluntary action is very low.</p> <p>Difficulties for the Member States Competent Authorities to verify the compliance of the industry with voluntary action.</p> <p>Consumer health will not be guaranteed.</p>	<p>Very low: Administrative costs for industry for setting up, enforcing and monitoring a voluntary commitment can be a significant burden to companies.</p>

<p><u>Engineering controls:</u> ventilation and tanks</p>	<p>High to average for industrial uses: risks during industrial uses will be reduced as a significant proportion of accidents (fatal or not) registered has been associated to inadequate ventilation. Worker protection can be further improved by engineering measures related to tanks (i.e. cover when they are not used).</p> <p>Average to low for professional uses: Practical difficulties for professional uses (working outdoors or movement from one location to another) to maintain and 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 in a room without windows or when the weather conditions do not permit open windows or doors.</p> <p>There is also no means of monitoring consumer behaviour in the home and as such, the practicality of this measure is questionable.</p> <p>Measures regarding tanks are not applicable.</p>	<p>High to average for industrial uses: the installation of mechanical ventilation might require some physical modification to existing equipment with costs for the companies, especially for the SMEs. No extra costs for those who have the installations already in place. 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 and might require specific and appropriate knowledge for their application.</p> <p>Very low for consumer uses: Buying the necessary equipment to always ensure 'good ventilation' would be excessively.</p>
<p><u>Handling measures:</u> 1. PPE</p>	<p>1. PPE</p> <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 appropriate masks (if necessary in combination with local</p>	<p>1. PPE</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 regarding ventilation and tanks.</p>

	<p>artificial or natural air ventilation and engineering measures for tanks), or respirators.</p> <p>Average for professional uses: Difficulties to assess the use of appropriate glove materials when comparing 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 the industrial installations. Very unlikely that respirators would be worn when required.</p> <p>Low for consumer uses: there is no guarantee that consumers will use PPE properly or replace PPE as appropriate. The consumer health protection would not be guaranteed.</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 (possibly necessitating multiple sets of equipment).</p> <p>Low for consumer uses: Consumers are very unlikely to accept such measures as it would make the use of DCM-based paint stripper very uncomfortable and extremely costly especially for small consumer jobs (e. g. the cost of a pair of gloves depends on the material and it can be between €9,60 and €50).</p>
<p>2. container size and design</p>	<p>Low for industrial, professional and consumer uses: the reduction of the container size would be an effective measure in preventing exposure from accidental spillages, however a restriction on size will not address or alter the way the product is used by the user and consequently will not reduce the risks. The narrow neck container would not permit the users to immerse a brush in the product and as result they would decant the content with a risk to be exposed to the DCM vapours.</p>	<p>Low for industrial, professional and consumer uses: A restriction on the size would be unrealistic as considerable quantities of paint strippers are required for example in application with dipping tanks for industrial and professional uses. The time that would be required to use multiple containers and the amount of packaging waste generated make this option less efficient for all three categories of uses with relevant costs.</p>
<p>3. product composition</p>	<p>Low for industrial, professional and consumer uses: Some ingredients could introduce other hazards (e.g. the addition of flammable components) and they would require further protective</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</p>

	<p>measures without necessarily increasing the overall benefits to health protection.</p> <p>The addition of smelling substance could encourage users to wear “simple” masks without achieving the necessary protection against DCM.</p> <p>Vapour retardants have been in use for many years and cannot ensure adequate control of the exposure to DCM as evidenced by recent fatal and not-fatal accidents.</p>	<p>in paint stripping. This will require longer treatment times at higher costs.</p>
<u>Training and licensed user</u>	<p>Average to low for industrial uses: Workers legislation already requires employers to provide adequate protection for the management of risks from applications involving DCM.</p> <p>Competent Authorities could be reluctant or unable to be involved in participating in such as scheme.</p> <p>High for professional uses: This will lead most likely to higher awareness of risks and necessary protection measures, in particular in small companies and for self-employed workers, which are not subject to the Workers Protection legislation. An adequate training would be an effective measure to protect them during DCM activities which are mostly conducted outside industrial installations.</p> <p>Competent Authorities could be reluctant or unable to be involved in participating in such as scheme. But some of them would benefit of this system if they would like to avoid a total ban.</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 Member States 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 Member States for controlling a training and licensing system</p> <p>Not applicable for consumer uses.</p>
<u>Total ban</u>	Low for industrial uses: A	Average for industrial and

	<p>total ban of DCM-based paint strippers will eliminate the risk from DCM but the incremental reduction in risk through a total ban of DCM will be low, as other risk reduction measures already in place or outlined above can be more 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 this option would be less effective if professionals would receive adequate training and appropriate personal protective equipments 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 could ensure their protection against DCM exposure.</p> <p>A total ban would facilitate enforcement by Competent Authorities as they would not have to try to enforce use restrictions or other measures on consumers.</p>	<p>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 total ban will impact user companies particularly with regard to: (a) the increased cost of alternative chemical preparations; (b) the capital 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. These costs would be more significant 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. 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 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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In conclusion, 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 the activities conducted in industrial installations:

- Use of appropriate gloves

- Effective local exhaust ventilation and mechanical ventilation or independent air supply respiratory equipment in areas where activity takes place before and after stripping
- Additional modification of the strip tanks (e.g. top and sides enclosed and coverage when not in use)

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 those concerning container size and the product composition, are not effective to prevent the exposure to DCM and reduce the risks during industrial uses. Therefore these recommended measures will also be proportionate.

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

Uses by professionals outside industrial installations should be banned in general, but Member States could opt to allow further use on their territories by specifically licensed professionals. It would be the responsibility of the interested companies in the Member States concerned to create the necessary systems for training and it would be responsibility of Member States to grant the licence to professional users.

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

This administrative burden is the price to be paid to ensure a better protection of health in order to avoid a total ban. Therefore these measures will also be proportionate.

- **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.

The costs to consumers of DCM-free products will be higher than DCM-based products. However the impact on consumers will be minor were they to be obliged to buy the relevant PPE to use DCM. Considering the overall costs and benefits, this measure is proportionate.

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

8. SECTION 8: MONITORING AND EVALUATION

Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on marketing and use of certain dangerous substances and preparations establishes a framework to control and limit the risk of certain dangerous substances as such or contained in preparations during specific uses and applications. This legal instrument permits to have harmonised rules throughout the European Union and to apply the relevant controls on the market in terms of production, import, distribution and use.

Member States have put into place long-standing mechanisms and have nominated authorities to monitor compliance with the restrictions of Directive 76/769/EEC. These same structures can be used to monitor compliance with the new restrictions of this Proposal which will therefore not create a significant administrative burden. Although the Directive does not contain any mechanism or indicators for progress achieved, a satisfactory level of feedback is

obtained through cases registered by the poison centres, recommendations/complaints by the Member States and by industry.

As already mentioned the Regulation (EC) No 1907/2006 will repeal Directive 76/769/EEC on 1 June 2009. The Regulation has established a European Chemical Agency for the purposes of managing and carrying out technical, scientific and administrative aspects of the Regulation and to ensure consistency at Community level in relation to these aspects. In particular, a Forum for Exchange of Information on Enforcement will be managed by the Agency and will coordinate a network of Member States authorities responsible for enforcement of this Regulation.

Member States are also already obliged to monitor compliance of industrial and professional users with existing worker protection legislation. Those opting for training and licensing schemes for professional users will probably face higher costs as they will have to devote more efforts, whereas those deciding not to foresee such schemes for professional users will face equal or even lower compliance monitoring costs.

There will be no transposition costs for the Member States, as the proposed Decision will not require any transposition by the Member States. With effect of 1 June 2009, the restrictions will be included into Annex XVII of the REACH Regulation and will then become directly applicable.

9. SECTION 9: REFERENCES

- (1) Methylene chloride: Advantages and drawbacks of Possible Market restrictions in the EU. Final report November 1999 conducted by TNO on behalf of DG III. http://ec.europa.eu/enterprise/chemicals/studies_en.htm
- (2) Effectiveness of vapour retardants in reducing risks to human health from paint strippers containing dichloromethane. Final report 01 April 2004 conducted by the Expert team for Vapour Retarding Additives (ETVAREAD) http://ec.europa.eu/enterprise/chemicals/studies_en.htm
- (3) Impact Assessment of potential restrictions on the marketing and use of Dichloromethane in paint strippers. Final report April 2007 conducted by RPA on behalf of DG Enterprise and Industry. http://ec.europa.eu/enterprise/chemicals/studies_en.htm
- (4) 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

Annex 1: Hazardous properties of DCM alternatives

EINECS Name	DCM	N-methyl-2-pyrrolidone* (See footnote)	Dibasic Esters	Benzyl Alcohol	Dimethylsulphoxide	1,3-Dioxolane	Sodium Hydroxide
Vapour pressure	475 hPa at 20°C	0.32 hPa at 20°C	0.008-0.3 hPa at 20°C	<0.1 hPa at 20°C	0.55 hPa at 20°C	93 hPa at 20°C	<10 ⁻⁵ hPa at 25 °C (calculated)
Classification	Xn: Harmful Carc Cat. 3 R40: Limited evidence of a carcinogenic effect	The agreed new classification will be: Xi: Irritant R36/37/38: Irritating to eyes, respiratory system and skin R61: Repr. Cat. 2	Not classified in Annex 1 of Directive 67/548/EEC	Xn: Harmful R20/22: Harmful by inhalation and if swallowed.	Not classified in Annex 1 of Directive 67/548/EEC	F: Flammable R11: Highly Flammable	C: Corrosive R35: Causes severe burns
Danger symbols	Xn: Harmful	Xi: Irritant	-	Xn: Harmful	-	F: Flammable	C: Corrosive
Repeated Dose Toxicity	Oral: liver/kidney damage reported	Oral: Mice NOAEL: 2,500 ppm in males and 7500 ppm in females, based on the kidney histopathology Oral: Mice NOAEL 1,000 ppm based on the liver responses at higher doses.		Considered to be of moderate toxicity	Oral: NOAEL 1,100 mg/kg bw (rat, 18 months); 8910 mg/kg bw(monkey, 18 months)	Oral: NOAEL for gavage were 75 mg/kg/day. Most sensitive organ system appear to be the blood-forming organs	Corrosive action on dermal, bronchial, intestinal and renal tissues observed
Carcinogenicity	Classified as category 3 carcinogen	Has been reported to have no oncogenic potential.	None reported	None reported	None reported	No known completed and reported studies	Systemic carcinogenicity is not expected to occur because NaOH is not expected to be systemically available in the body under normal handling and use conditions. No suitable studies are available to

							assess the risk on local carcinogenic effects.
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* Following adoption of the 30th ATP of Directive 67/548/EEC, which will officially classify the substance as reprotoxic Category2, the substance will be included in Annex I of Directive 76/769/EEC with a ban for sale and use of the substance and preparations containing it by consumers.

Annex 2: Information on fatalities and non-fatal accidents of DCM-alternatives

(information provided to DG ENTR at the time of writing this impact assessment)

Country	Fatality	Accidents	DCM alternative	Year
The Netherlands	1(worker)	1 (worker) * (worker)	Explosion of paint stripper vapours (unnamed volatile and extremely flammable fluid)	2004
US		1 (worker)	Caustic soda	2003
		1(worker)	Caustic soda	1991
		1(worker)	Sanding of lead-painted doors	2003
		1(worker)	Percussion method	1978
France		1(worker)	Caustic soda	missing
Spain	1	2(worker, consumer)	Caustic soda	2002/2003/2004
Germany		Inflammation of a tower no injuries registered	Acetone	1998
		Evacuation from an administrative building. Some employees complained for nausea due to Toluene	Toluene	1994/5
Italy		1 (4-year child)	G-Butyrolactone	missing

* a number of cases (not quantified) of Chronic Toxic Encephalopathy caused by solvents (hydrocarbons; chlorinated solvents seem to be exempt)

In addition to these data DG ENTR received other data on accidents due to DCM alternatives registered by some National Poison Centres. No fatalities were registered in Austria, Belgium, Czech Republic, Germany, UK from the use of DCM alternatives. These data are listed in the report (3) of Section 9