

Opinion of the European Economic and Social Committee on the 'Proposal for a Decision of the European Parliament and of the Council amending Council Directive 76/769/EEC as regards restrictions on the marketing and use of certain dangerous substances and preparations (Dichloromethane)'

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(2009/C 77/05)

On 10 March 2008, the Council decided to consult the European Economic and Social Committee, under Article 95 of the Treaty establishing the European Community, on the

Proposal for a Decision of the European parliament and of the Council amending Council Directive 76/769/EEC as regards restrictions on the marketing and use of certain dangerous substances and preparations (Dichloromethane).

The Section for Single Market, Production and Consumption, which was responsible for preparing the Committee's work on the subject, adopted its opinion on 15 July 2008. The rapporteur was Mr Sears.

At its 447th plenary session, held on 17 and 18 September 2008 (meeting of 17 September), the European Economic and Social Committee adopted the following opinion unanimously.

1. Summary and recommendations

1.1 This proposal seeks to amend Council Directive 76/769/EEC by adding restrictions on the marketing and use of dichloromethane (DCM) when used as a major component of paint strippers for industrial, professional and consumer use.

1.2 This is the last such amendment of Council Directive 76/769/EEC before it is replaced on 1 June 2009 by Regulation (EC) 1907/2006 (REACH).

1.3 The EESC recognises the considerable scientific and political difficulties faced by the Commission in proposing and reaching agreement on a proportionate and cost effective amendment which, as Directive 76/769/EEC requires, will preserve the Internal Market and at the same time ensure a high level of protection for human health and the environment.

1.4 The EESC agrees that there is compelling evidence that, where high concentrations of vapour occur due to the high volatility of DCM, these can lead to unconsciousness and death. These result from poor industrial practice, including inadequate ventilation. The evidence for a serious ongoing risk to consumers through occasional domestic use is less compelling. The proposal for a ban on sales is therefore disproportionate and, given the known but so far unquantified risks of the alternative products and processes, seems unlikely to lead to any overall reduction in the, rather low, rate of accidents being recorded.

1.5 The EESC also notes, as did the consultants employed by the Commission, that the special hazards of DCM are not fully covered by existing pictograms or Risk and Safety phrases. The same comment applies to the risks to children, more common in a domestic setting. This is a failing of the labelling system,

not of the products or people concerned. Recommendations on packaging and labelling are therefore made to rectify this situation.

1.6 Other problems are identified, most noticeably the absence of agreed Occupational Exposure Limits and guidelines or regulations on good industrial practice. The German TRGS 612 is considered an excellent model in this respect.

1.7 A number of other general points are made for consideration by the Commission, European Parliament and Member States in the hope that agreement can be reached. Failure to do so will lead to a fracturing of the internal market. Users, in and outside the work place, will remain at risk.

2. Legal Basis

2.1 As previously noted, Regulation (EC) No 1907/2006 of 18 December 2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) will come into effect on 1 June 2009. This will repeal and replace a number of existing Council and Commission Regulations and Directives, including Council Directive 76/769/EEC of 27 July 1976 on the marketing and use of certain dangerous substances and preparations.

2.2 Annex I of Council Directive 76/769/EEC sets out the specific restrictions on the marketing and use of certain dangerous substances and preparations that have been agreed and put in place over the last 30 years. On 1 June 2009 these will become the cornerstone of Annex XVII of Regulation (EC) No 1907/2006 (REACH).

2.3 Previous amendments to Council Directive 76/769/EEC (i.e. to add further restrictive measures) have been in the form of Directives requiring implementation by member states. This proposal by the Commission is, however, for a Decision, which will have immediate effect, rather than for a Directive. It will not therefore require transposition into national laws which would also have to be repealed on 1 June 2009 when Regulation (EC) No 1907/2006 (REACH) comes into force.

2.4 All subsequent proposals for restrictions on the marketing and use of dangerous substances or preparations will be under Regulation (EC) No 1907/2006 (REACH).

2.5 The substances (and any preparations containing them) for which restrictions on marketing and use have been deemed necessary have generally resulted from evaluations of certain 'priority substances' nominated by Member States and published in four priority lists between 1994 and 2000 under Council Regulation (EEC) No 793/93.

2.6 A number of substances not included in these lists have also been assessed for their impact on human health and the environment, and/or proposals made to restrict their marketing and use, as new problems have been addressed at the request of the Member States. DCM comes under this heading. A number of Member States, for a variety of reasons, have already imposed or sought to impose restrictions on its use, in particular as a component of paint strippers. Other member states view these measures as being disproportionate, costly and likely to lead to less satisfactory outcomes for users. There is some evidence (or a lack of evidence) to support or contradict both positions.

2.7 The first full review of the proposal in Council took place in early June. If a compromise can be found within the coming months, then the proposal is likely to go ahead as planned. If this is not the case, then the proposal will fail. In this case the Internal Market for DCM-based paint strippers will remain fractured and may become more so. DCM would then in due course be assessed under Regulation (EC) No 1907/2006 (REACH) — with its use in paint stripping being one of many exposure routes to be considered. It is obviously unclear what the outcome of this would be or when any final recommendation could be made.

3. Background

3.1 DCM is a colourless low boiling halogenated aliphatic hydrocarbon with a mild sweet odour. It has been widely used for many years as a powerful solvent with low flammability in the production of pharmaceuticals, aerosols and adhesives and in other processes such as paint stripping, metal degreasing and as an extraction solvent for foodstuffs.

3.2 Although regarded as one of the safer low molecular weight halogenated hydrocarbons, DCM must still be used with care. It is classified in Europe as a Category 3 carcinogen, i.e. it is 'a substance that causes concern for man owing to possible carcinogenic effects but for which the available information is not adequate to make a satisfactory assessment'. It must therefore carry the R40 phrase ('limited evidence of a carcinogenic effect'). It is also a priority substance under the Water Framework Directive.

3.3 Of greater concern however is that it is also a powerful narcotic, depressing the central nervous system, and leading to unconsciousness or death. This has led to a series of accidents and fatalities, generally associated with unsafe working practices and gross over-exposure, generally during open tank industrial or large scale professional use. Usage in closed systems, where this is feasible, removes these risks.

3.4 Production levels of DCM in Europe (from sites in Germany, France, Italy, Spain, the Netherlands, UK and Romania) are declining slowly as other products become available. Of the approximately 240 000 tonnes currently manufactured in Europe, approximately 100 000 tonnes are exported. 30-50 % of the remainder goes to the pharmaceutical industry and 10-20 % for sale as 'virgin' DCM in paint strippers. Recycled DCM from the pharmaceutical industry provides a similar tonnage. This proposal deals solely with the use of DCM in paint stripping.

3.5 Paint stripping is familiar to most householders as an essential process to conserve and decorate wood, metal, stone and plaster objects and surfaces in and outside their properties. There are also a number of more specialist markets, including fine art restoration, graffiti removal and the repainting of large mobile objects such as trains or planes.

3.6 Paint strippers are divided somewhat arbitrarily into three categories: 'industrial' (i.e., with on-site continuing high volume usage); 'professional' (multiple site specialists, builders and decorators) and 'consumers' (individuals occasionally undertaking home maintenance).

3.7 The numbers of actual incidents for each group are hard to determine. Given that the symptoms of a DCM overdose resemble heart failure, there may (or may not) be some under-reporting. The data presented to the Commission by consultants RPA show 3-4 incidents per year in Europe due to the use of DCM-based paint strippers over the last twenty years, of which 1 per year proved fatal. Fatalities were concentrated in France (6), Germany (6) and the UK (5), non fatalities were concentrated in the UK (36), Sweden (12) and France (6).

In the south of Europe, only one incident has been recorded in the period studied by RPA (1930-2007) — an industrial fatality in Spain in 2000. Local climatic conditions and work practices may well be relevant. In warm weather windows are always open, good ventilation is achieved and the risks are negligible; in colder climates, the reverse may be true.

3.8 Fatalities were split equally between industrial and professional users. The bulk of the non-fatal incidents were recorded during use by operators classified as 'professionals'. The causes of the fatalities were recorded as being almost entirely inadequate ventilation and inadequate use of personal protective equipment, especially in the presence of large open tanks.

3.9 A possible fatality reported for a consumer (or a professional) in France in 1993 cannot now be verified and this particular key piece of data has therefore been challenged. The only other death reported for a consumer was in the Netherlands in 1960. Other factors may be relevant.

3.10 Alternatives to DCM-based chemical paint strippers of course exist. These are generally grouped under three headings — 'physical/mechanical stripping' (sanding, scraping, blasting); 'pyrolytic or thermal stripping' (in ovens, over hot fluidised beds or using blow torches or heat guns); and 'chemical stripping' (using high power solvents, including DCM, or corrosive, generally strongly alkaline, liquids or pastes, or formic acid or hydrogen peroxide based mixtures). Each process may work and may be the preferred course under specific circumstances. All pose risks of one sort or another, either due to particle impact, heat, fire, explosion, eye or skin irritation or due to the composition of the coatings being removed, most notably lead from paints applied prior to 1960. With multiple layers dating back 100 years or more in old but still usable or even highly desirable housing stock, or with sensitive surfaces that must not be damaged, more than one approach and some degree of experimentation will be required.

3.11 No data have been presented on the overall market share of these various alternatives under all 3 headings or of the different costs per square metre stripped. DCM is thought to be still the most widely used solvent, in particular in the consumer sector, with caustic soda based applications also popular. Even within the chemicals group, comparative costings are difficult. There is general agreement that DCM-based paint strippers appear cheaper than competing products on a volume basis. This advantage is likely to disappear if the full costs of protective equipment (if used) and waste disposal (if relevant) are taken into account.

3.12 Total costs are also determined by through-put times. Slower acting but more benign products and processes increase the cost of work in progress and reduce profits. Higher boiling solvents allow larger areas to be coated at one time but take

longer to work. For a consumer, short exposures are replaced by longer exposures and potentially greater domestic disruption. (The assumption by RPA that consumers are less time sensitive 'because they usually carry out stripping in their leisure time' should certainly be challenged.) For all users, new methods of working and changes to work flow will become essential. For an industrial user, any switch to water-based products decreases the costs of ventilation but sharply increases the cost of tanks and pipe work to minimise corrosion. Given all these variables, predicting the effect of any restriction on any one route becomes extremely difficult. Consumers are particularly at risk under these circumstances, with little evidence, given conflicting views at government level, that their choices of alternative products or processes will be in their own best interest.

3.13 One of the popular alternatives to DCM as a solvent, methyl-2-pyrrolidone (NMP), has recently been classified as 'toxic to reproduction Category 2' which will eventually lead to a ban on sales of formulations containing it to the general public (but not to professional or industrial users). Other solvents, such as 1,3 dioxolane, are highly flammable.

3.14 Systems based around dibasic esters (DBEs) — mixtures of dimethyl adipate, succinate and glutarate — currently look to be the most promising alternatives, with little to suggest that there are any significant concerns for human health or the environment. Dimethyl sulfoxide (DMSO) and benzyl alcohol also appear to be relatively 'safe'. Whether or not any of these are regarded as cost effective by their users, however, depends on many factors, and their eventual choice as widely used 'safe' alternatives cannot be guaranteed.

3.15 Overall it is clear that there is no single totally acceptable approach — and that inappropriate action may well lead to an increase in the current, relatively low, rate of recorded incidents. The difficulty is to identify a solution which satisfies all the parties, in particular member states with different experiences and, quite reasonably, strongly held positions.

4. Summary of the Commission's proposal

4.1 The Commission's proposal seeks to protect human health and the environment whilst preserving the Internal Market for dichloromethane, in particular when used as a major component of paint strippers for industrial, professional and consumer use.

4.2 The proposal seeks to ban all sales of DCM-based paint strippers to the general public and to professionals, other than to those specially trained and licensed by competent authorities in the member states. Sales to industrial installations would be possible only where a series of protective measures, in particular effective ventilation and the provision and use of the

appropriate personal protective equipment, are in place. All DCM-based formulations should be indelibly marked as being 'reserved for industrial and professional uses' (and then presumably only to those suitably licensed).

4.3 No new DCM-based paint strippers should be placed on the market for supply to the general public or to professionals within 12 months of the entry into force of the Decision. All supplies to these two groups would be banned after a further 12 months.

4.4 The Decision would come into force on the third day following that of its publication in the Official Journal of the EU.

4.5 The proposal is accompanied by an explanatory memorandum and a Commission staff working document (impact assessment report). Further material is available in impact assessments prepared for the Commission by outside consultants (RPA, TNO) or in reports on specific topics (ETVAREAD, on the effectiveness of vapour retardants). These have been in turn reviewed by the appropriate scientific committee (SCHER). There is no formal EU Risk Assessment Report (RAR) as DCM was not defined by any of the stakeholders to be a priority substance despite concerns already being noted.

4.6 Some EU member states (and other major economies and trading partners such as Switzerland and the US) have also conducted studies to support particular — and often strongly conflicting — regulatory and political positions. The concerned industries have generated a wealth of data on the possible risks and comparative benefits of different products and processes; not surprisingly, these too conflict. Comments from other stakeholders were recorded during the European Health and Safety Week 'Building in Safety' in 2004 after a conference of experts hosted by the Danish Painters Union. According to RPA in April 2007, BEUC, EMCEF and the ETUC had not yet expressed formal opinions.

5. General comments

5.1 The EESC recognises the difficulties faced by the Commission in proposing a proportionate and cost effective amendment to Directive 76/769/EEC for DCM usage as a solvent in paint stripping. There have been relatively few incidents reported and verified. There may (or may not) have been under-reporting. Existing legislation has not always been followed — and in respect to labelling, appears inadequate. Alternative products and processes exist but these have not been evaluated and all pose risks. There are good reasons why the views of member states differ. There is no guarantee that the overall outcome will be favourable to any of the groups most likely to be affected.

5.2 The EESC also recognises that, due to obvious time constraints, this is the last opportunity to introduce any

measures under the above Directive. If a common position between the member states and the European Parliament cannot be agreed and the proposed Decision (or any variation to it) adopted and implemented, there will be no further action until DCM is assessed for all its uses under Regulation (EC) No 1907/2006 (REACH).

5.3 The EESC strongly believes that such a delay is unnecessary and undesirable, with respect to protecting the environment and the health of all users in or outside the work place. The EESC would also deeply regret any fracturing of the internal market over this, or any other, issue. The need to find a basis for agreement should be obvious to all concerned. This should seek to manage the risks, not to replace one hazard with another.

5.4 In this respect the EESC notes that DCM can be manufactured, stored, transported and used safely in closed systems. DCM is non-flammable and does not contribute to ground level ozone formation. However, in open systems, for instance in paint stripping, DCM clearly presents problems due to its volatility (it evaporates quickly), the density of the ensuing vapour (it accumulates at the lowest point or where there is inadequate ventilation), and its behaviour as a narcotic (it induces unconsciousness and death). All of these contribute to increased risks for children. DCM is also classified as a category 3 carcinogen and it is this potential risk that dominates the labelling of any product containing DCM.

5.5 RPA and others have all noted that this is both misleading and inadequate to properly protect users in or outside the workplace. There are no R (Risk), S (Safety) phrases or pictograms under existing legislation, or their counterparts under the revised UN Globally Harmonised System of Classification and Labelling, which adequately warn against either narcosis (and a subsequent risk of death) or, more surprisingly, of the serious risk to children (which would of course apply to many products and processes used in domestic situations).

5.6 The focus on the possible but so far unproven cancer risk is also misleading. SCHER, in their Opinion on the ETVAREAD Report on vapour retardants noted that the metabolic mechanism in a mouse for the end-point tested is not the same as in a human and therefore DCM, on the basis of the evidence presented, is unlikely to be a carcinogen. There is little evidence based on actual usage. The results of two major epidemiological studies on cohorts exposed to DCM in the US in other industries are still awaited. Cohorts in the EU may have been exposed to other known carcinogens such as styrene. RPA did not present any evidence of actual risks under this heading from exposures to DCM used in paint stripping. The required R68 phrase ('possible risk of irreversible effects') is not the most useful under the circumstances.

5.7 It should also be noted that the incident statistics presented by RPA for the period 1930-2007 clearly demonstrated the dangers of gross over-exposure to DCM, generally through very poor working practices. The corresponding data for alternative processes and products were not collected. The extent to which these data can be extended to use by either 'professionals' or 'consumers' in a domestic environment is however questionable. Indications of chronic (long term) industrial health effects may (or may not) indicate problems for acute (short term) consumer exposures; accident statistics, which perhaps these are, are harder to pro-rate.

5.8 The studies also highlighted the lack of consistent Occupational Exposure Levels (OELs) for work places across the EU. Limits vary considerably for a single substance (DCM) between member states and between substances (DCM v DBE or DMSO, for example). Manufacturers must recognise their duty of care to their workers; regulators must provide a clear, consistent data-based regulatory framework to achieve this.

5.9 In this respect the EESC took note in particular of the Technical Rules for Hazardous Substances TRGS 612 for alternatives to DCM-based paint strippers produced by the German Federal Ministry of Labour and Social Affairs (BMAS), version dated February 2006. This appears to be a model which others could follow to help ensure work place safety and is considerably more detailed than the current proposal from the Commission.

5.10 The hierarchy of questions to be answered under the above (a) *can you make your process safer by substitution?* (b) *if not, why not?* and (c) *have you taken all appropriate measures to make your work place safe?* should be followed in most cases. The potential risks, as well as benefits, from alternative processes and products should be fully recognised. Above all, there must be some estimate of the likely outcomes of any decision to remove a significant quantity of any material from any market; what actually will users do and will their choice improve their personal safety?

5.11 As an example, taken from a Member State that has already implemented a ban on DCM-based products and applicable to industrial and professional users alike, this is a ban on sales of products containing DCM, not on DCM itself. A powerful paint stripper can still be made by mixing DCM with methanol at the place of use. The resulting product is cheaper but lacks the surfactants and vapour retardants which increase both the effectiveness and the safety of the properly formulated product. This is therefore an undesirable outcome.

5.12 As RPA and the Commission have noted, the distinctions between the different categories of user are hard to justify

or maintain in real life. The only real difference is that single site, high throughput, continuous paint stripping operations require large open tanks of chemical agents into which products are dipped; off-site operations generally do not depend on dipping and therefore do not involve large open tanks. Single sites are covered by other Directives, for instance on solvents emissions and water waste quality which should be strictly enforced; off-site operations depend more on the care and common sense of the individual. Where there is an employer, the duty of care of course rests with him or her to ensure the best possible working environment for any employees involved.

5.13 The 'professional' category should also be split between those engaged permanently in specialty cleaning operations (e.g. graffiti removal, façade restoration, trains and planes) and those having only an occasional need to strip paint (builders, decorators and 'consumers') as a necessary but time-consuming prelude to more profitable activity. The needs, capabilities and vulnerabilities of this last group appear to be identical and they should be treated equally.

5.14 Finally, a proposal to train and license certain operators has been introduced as a possible derogation to enable a compromise between different views. It is however difficult to equate the use of DCM-based paint strippers with, say, asbestos removal or the handling of nuclear waste, for which licenses most certainly are required. Given the high costs of installing and monitoring such a system, it is difficult to see this proposal as likely to meet anyone's needs.

6. Specific comments

6.1 Given the above, the EESC do not believe that the current proposal is either proportionate or, by itself, likely to lead to fewer incidents in or outside the work place. Given the wide actual and political differences between member states, other approaches must be considered and implemented without further delay.

6.2 This would include changes to the packaging and labelling of DCM-based paint strippers to minimise the risk of accident and to highlight the real dangers. Sales to anyone not permanently engaged in paint-stripping, on or off-site, whether regarded as being a 'professional' or a 'consumer' should be limited to a maximum of 1L per container and purchase. The containers should have child-proof seals as defined by the relevant existing or new EU Regulations and Directives and/or EN-ISO standards 8317:2004 and 862:2005. Narrow necks to limit spillage would also be useful, although the consequent need to decant before use with a brush limits their effect. Manufacturers should actively work towards new and safer

delivery systems if they wish to maintain the long term viability of these products. Bulk sales to all other users for 'industrial' or ongoing 'professional' use should be in quantities of not less than 20 L. Manufacturers and suppliers should recognise their duty of care under such circumstances and ensure that sufficient information and training is provided to ensure safe handling and disposal under all conditions of use.

6.3 New pictograms and R and S phrases for narcotics and to warn of the dangers to children should be developed as a matter of urgency to complement those already in use. For DCM-based paint strippers (and other products with similar effects) the appropriate wording for all users would be along the lines of: '*Narcotic: high concentrations lead to unconsciousness and death*'; '*Do not use in the presence of children or vulnerable adults*'; '*Do not use in an enclosed space: heavy vapours asphyxiate*'. These seem to be justified by the evidence and are relevant to actual needs. The phrases should not be lost in an array of less significant warnings. An effective warning and unmistakable pictogram on the need to protect children would be likely to have more effect than many more complicated pieces of advice. The current S2 phrase ('Keep out of the reach of children') is inadequate in this respect.

6.4 There is also a clear need for a standardised and internally consistent set of EU-wide Occupational Exposure Limits (OELs) to further improve work place safety. This should be considered as a useful output of the REACH programme over the coming years.

Brussels, 17 September 2008.

6.5 Good working practice, and the close observance of all existing controls, is obviously key to risk management, in and outside the work place. Manufacturers and retailers share the responsibility of providing good advice and ensuring that recommendations can be followed by members of the general public and others using hazardous materials or processes on an infrequent basis. Safety advice and equipment should be promoted with the same enthusiasm and incentives as the materials for which they are required.

6.6 The approach used in the German TRGS 612 should form the basis of EU-wide controls. Additional technical advice on ventilation or waste treatment can be added as necessary. Best practices should be published and shared.

6.7 Ongoing studies in the US on the effects of long-term exposure to DCM should be completed as quickly as possible and the results presented to SCHER for evaluation. Opportunities should be explored to identify any valid cohorts for study in Europe.

6.8 A systematic evaluation of the risks associated with paint stripping should also be undertaken so that all the products and processes can be evaluated on a comparable basis. This would lead to a better understanding of their relative performance characteristics and risks and eventually the possibility of more informed choices being made by users in and outside the work place. Neither of these proposals should however delay the adoption of the control measures discussed above.

The President
of the European Economic and Social Committee
Dimitris DIMITRIADIS
