WORKING FOR A HEALTHY FUTURE

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Health, socio-economic and environmental aspects of possible amendments to the EU Directive on the protection of workers from the risks related to exposure to carcinogens and mutagens at work

1,2-Dichloroethane

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SUMMARY

1,2-dichloroethane has been classified by the International Agency for Research on Cancer (IARC) as possibly carcinogenic to humans based on limited human epidemiological data and sufficient animal toxicity (IARC category 2b). Under the classification and labelling legislation in Europe it is classified as a Cat 2 carcinogen and is therefore within the scope of the EU Carcinogens Directive. However, there is no occupational exposure limit (OEL) for 1,2-dichloroethane specified in the Directive.

This report considers the likely health, socioeconomic and environmental impacts associated with possible changes to the Carcinogens Directive, in particular the possible introduction of an occupational exposure limit (OEL) of either 1 ppm or 5 ppm.

1,2-dichloroethane is mainly used in the production of vinyl chloride (VCM) for use in the manufacture of PVC (about 95% of the total amount made). There are at least 18 producers in the EU making more than 10 million tonnes per annum. Less than 3,000 people are potentially exposed in Europe, most in the manufacture of VCM with about 500 exposed when 1,2-dichloroethane is used as a solvent in the pharmaceutical industry.

In 2006 the European plastics manufacturers carried out an extensive survey of 1,2-dichloroethane levels. A total of 1,653 eight-hour time-weighted average exposure measurements were taken across different manufacturing sites and job groups. Measured exposures ranged from 0.2 ppm to 10 ppm with an average exposure of 0.48 ppm across all job groups and sites. Based on these data we judge that occupational exposure levels are currently low, with about 11% of manufacturing workers exposed to average levels above 1 ppm and only 0.36% of workers exposed above 5 ppm. Exposures have been decreasing over recent years by about 9% per annum.

Information about the hazard from 1,2-dichloroethane is limited. Animal toxicity studies have shown a range of tumours induced from ingested 1,2-dichloroethane. However, the human epidemiological evidence for occupational exposure causing cancer is weak. There is no basis to identify a suitable risk estimate. We have considered it is not possible to undertake a health impact assessment, but we also do not believe there is any important risk because of the current low exposures and the limited number of people exposed.

The cost of compliance with a limit of 1 ppm, aggregated over the period 2010 to 2069, is judged to be between zero and €43m and for a limit of 5 ppm between zero and €13m. The range of estimates reflects the uncertainties involved the appropriate approach to compliance. There are also no social or macro-economic costs associated with introducing an OEL at either of these levels.

There are no significant environmental impacts foreseen.

1 PROBLEM DEFINITION

1.1 OUTLINE OF THE INVESTIGATION

Exposure to 1,2-dichloroethane in workplace air may be associated with increased risk of cancer, although there is limited evidence as to which type of cancer may be associated with this substance. 1,2-dichloroethane has been classified as a group 2b carcinogen (Possibly carcinogenic to humans) by IARC based on the results of epidemiological and toxicological studies.[1] It is classified as a Cat 2 carcinogen in the EU under the classification and labelling legislation.[2] It is therefore already regulated as a carcinogen throughout the EU. In this assessment we consider the impacts of introducing an OEL for 1,2-dichloroethane within the Directive.

The key objectives of the present study are to identify the technical feasibility and the socioeconomic, health and environmental impacts of introducing a regulatory OEL for 1,2-dichloroethane.

1.2 OELS/EXPOSURE CONTROL

Existing national occupational exposure limits (OELs) in EU member states are presented in Table 1.1. These are expressed as long-term limits, averaged over an 8-hour working day or short-term exposure limits (STELs), i.e. 15 minutes. OELs from some countries outside the EU are also presented for comparison.

Table 1.1 Occupational Exposure Limits in Various Member States and selected countries outside the EU

Country	OEL - TWA ppm	OEL - STEL ppm
Austria	5	20
Belgium	10	-
Denmark	1	2
France	10	-
Hungary	-	2.5
Poland	12.4	-
Spain	5	-
Sweden	1	5
The Netherlands	1.7	-
United Kingdom	5	-
Canada - Quebec	1	2
Japan	10	-
Switzerland	5	-
USA - NIOSH	1	2
USA - OSHA	50	100

Source: http://www.dguv.de/bgia/en/gestis/limit_values/index.jsp

[1] Available at: http://monographs.iarc.fr/ENG/Classification/ClassificationsAlphaOrder.pdf
[2] Available at: http://ecb.jrc.ec.europa.eu/esis/

The long-term OELs from the EU member states and outside jurisdictions range from 1 to 50 ppm, and from 1 to 12.4 ppm within the EU. Austria, Denmark, Hungary and Sweden have STELs ranging from 2 to 20 ppm. For the purposes of this report, 8-hr OELs of 1 or 5 ppm (4 or 20 mg/m^3) are considered typical for the EU.

1.3 DESCRIPTION OF DIFFERENT USES

1,2-dichloroethane is produced either by the direct reaction of chlorine with ethylene (known as direct chlorination) or by the reaction of hydrochloric acid and oxygen on ethylene (known as oxychlorination). Over ninety-five percent of the 1,2-dichloroethane produced is used in the manufacture of vinyl chloride monomer (VCM), which is used almost exclusively in the manufacture of polyvinyl chloride (PVC). VCM is produced by subjecting 1,2-dichloroethane to high pressures and temperatures causing pyrolysis (thermal cracking) of the 1,2-dichloroethane to produce VCM. 1,2-dichloroethane, VCM and PVC manufacturing are often done at the same site.

Small amounts of 1,2-dichloroethane are also used as an intermediate in the production of ethylenediamines, tri-and tetrachloroethylene and other chlorinated solvents and as a solvent in pharmaceutical processing. In the past it has also been used as a fumigant and as a lead scavenging agent in leaded gasoline but it is no longer used in these applications [3,4]. As 1,2-dichloroethane is used primarily in the production of VCM this report will focus on exposures in that industry. The number of workers exposed outside of VCM manufacturing is small and the amounts of 1,2-dichloroethane used are also small, and it is likely to be well controlled as well [3,4,5]. For example, the Finnish 2000 CAREX update estimated 1,2-dichloroethane exposure prevalence below 0.05% for NACE codes 51 (Wholesale trade and commission trade except of motor vehicles), 73 (research and development) and 80 (Education).

1.4 RISKS TO HUMAN HEALTH

1.4.1 Introduction

Animal toxicity studies have mainly focused on administration by gavage[3]. In these experiments a range of tumours were produced. 1,2-dichloroethane increased the incidence of hepatocellular carcinomas in male mice, mammary gland adenocarcinomas and tumours in the uterus in female mice, along with benign tumours (adenomas) in the lung in mice of both sexes. Other gavage studies produced squamous cell tumours in the forestomach, hemangiosarcomas in male rats and mammary gland adenocarcinomas in female rats.

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[3] Report on Carcinogens, Eleventh Edition. (2005) U.S. Department of Health and Human Services, Public Health Service, National Toxicology Program: 1,2-Dichloroethane (Ethylene Dichloride)

[4] OECD SIDS. (2002) 1,2-Dichloroethane. Available at: http://www.inchem.org/documents/sids/sids/DICHLOROETH.pdf

[5] IARC Monographs on the Evaluation of Carcinogenic Risks to Humans (1999). Volume 71: Re-Evaluation of some Organic Chemicals, Hydrazine and Hydrogen Peroxide.

No increase in tumour incidence was found following inhalation exposure in rats or in one experiment in mice, but these studies were considered by IARC to be inadequate.

1.4.2 Summary of the available epidemiological literature on risk

Several studies have examined mortality or cancer incidence among chemical workers potentially exposed to 1,2-dichloroethane. In an ecological study Isacson *et al* (1985) examined the association between cancer incidence and indices of water contamination in the central United States. Cancer incidence rates in towns with populations between 1000 and 10 000 were compared by level of volatile organic compounds and metals in the drinking-water. Among men, significant associations between the level of 1,2-dichloroethane (≥ 0.1 ppm) and colon (p = 0.009) and rectal cancer (p = 0.02) were observed. The authors stated that 1,2-dichloroethane might be an indicator for other types of contamination rather than a causal agent.

Hogstedt *et al* (1979) performed a cohort mortality study of 175 Swedish ethylene oxide production workers followed from 1961 through 1977. The workers had been employed for at least one year and were potentially exposed to 1,2-dichloroethane, ethylene oxide (IARC, 1994), ethylene chlorohydrin and bis(2-chloroethyl) ether. The mean exposure level to 1,2-dichloroethane among the most highly exposed workers was estimated to be 100 mg/m3 during 1941–47 but to have decreased after that due to changes in production methods. There were 37 deaths and 12 cancer deaths among exposed workers. Excesses of stomach cancer were found among full-time exposed workers (Observed deaths 3, expected deaths 0.4, p<0.01) and leukaemia (Observed deaths 2, expected deaths 0.14, p<0.01). It was not possible to link the excesses to any particular chemical exposure.

Austin and Schnatter (1983a) conducted a cohort study of 6588 white male workers employed at a petrochemical plant in the United States between 1941 and 1977. There were 765 deaths (SMR=0.8) and 150 cancer deaths (SMR=0.9) observed. A greater than expected number (based on national rates) of brain cancers (SMR=1.6, 95%CI 0.8–2.8, based on 12 cases) was observed. Austin and Schnatter (1983b) also conducted a nested case–control study to examine the relationship between the risk of primary brain tumours and exposures at the facility. No significant association with 1,2-dichloroethane exposure was observed.

Sweeney *et al* (1986) studied mortality among 2510 male chemical workers in the United States, followed from 1952 to 1977. Potential exposures included tetraethyl lead, ethylene dibromide, 1,2-dichloroethane, inorganic lead and vinyl chloride monomer. There were 156 deaths (SMR=0.7) and 38 cancer deaths (SMR=1.0) observed. There were excesses of cancer of the larynx (SMR= 3.6; 90% CI 0.7–11.5, based on 2 cases) and brain (SMR=2.1 90% CI, 0.7–4.9, based on 4 cases). The SMR for all lymphatic and haematopoietic cancers was 0.9 (90% CI 0.3–1.9, based on 4 cases). Levels of exposure were not reported, but a NIOSH survey in 1980 found levels of exposure to 1,2-dichloroethane to be below the recommended NIOSH standard, while lead exposures were elevated. It was not possible to link mortality to any particular chemical exposure.

Benson and Teta (1993) studied the mortality among 278 chlorohydrin production workers who had ever been employed at a facility in the United States between 1940 and 1967. The follow-up period was from 1940 to 1988. This was a 10-year update of an earlier study conducted by Greenberg *et al* (1990). There were 147 deaths (SMR=1.0) and 40 cancer deaths (SMR=1.3) observed. Excesses of pancreatic cancer (SMR=4.9, 95% CI, 1.6–11.4; 8 cases) and lymphatic and haematopoietic cancers (SMR=2.9, 95% CI, 1.3–5.8; 8 cases), which increased with duration of exposure, were observed. The workers were potentially exposed to 1,2-dichloroethane, ethylene chlorohydrin and bis(2-chloroethyl) ether. It was not possible to link the excesses to any particular chemical exposure and levels of exposure were not reported.

Olsen *et al* (1997) studied mortality among 1361 men employed at two chlorohydrins production facilities in the United States similar to that studied by Benson and Teta (1993). There were 300 deaths (SMR=0.9) and 75 cancer deaths (SMR=0.9) observed. The risks of pancreatic cancer (SMR=0.3, 95%CI 0.01–1.4; 1 case) and lymphatic and haematopoietic cancers (SMR=1.3, 95%CI 0.6–2.4; 10 cases) were less than those observed by Benson and Teta and no other cancers were observed in excess. It was not possible to link mortality to any particular chemical exposure and levels of exposure were not reported.

A nationwide register based case control study on male breast cancer morbidity was established among members of a pension fund, compulsory for all employees (Hansen 2000). Employment histories were reconstructed for each of 230 cases and 12,880 control subjects based on computerized records. When a lag time of at least 10 years was included, the odds ratio for breast cancer among men with over three months of employment in trades with potential exposure to gasoline and combustion products was 2.5 (95%CI 1.3-4.5). Among men younger than 40 years at the time of first employment, the OR was 5.4 (95%CI 2.4-1.9). The authors comment that the main carcinogen in Danish gasoline was benzene at between 5-10% before 1980 and 2.5-5% after that. The concentrations of other carcinogens including 1,2-dicloroethane was less than 0.1%.

1.4.3 Choice of risk estimates to assess health impact

Animal studies have produced benign and malignant tumours of the lung and malignant lymphomas in animals of each sex, hepatocellular carcinomas in males and mammary and uterine adenocarcinomas in females. All the epidemiological cohort studies included workers with potential exposure to multiple agents. It is difficult therefore to estimate the excess risk associated with 1,2-dichloroethane in these studies. In addition, although some excess cancer risks were found the specific cancer sites varied between studies. Excesses from pancreatic cancer and lymphatic cancers occurred twice but were not raised in other studies. As a result of the paucity of human data no risk estimate has been selected and a health impact assessment will not be carried out.

2 BASELINE SCENARIOS

2.1 STRUCTURE OF THE SECTOR

Information on production volume of 1,2-dichloroethane was obtained from the European Council of Vinyl Manufacturers (ECVM). ECVM represents the European PVC resin producing companies and is a division of Plastics*Europe*. Its membership includes the 14 European PVC resin producers which together account for 100% of EU 27 production. Its membership also includes all VCM producers in the EU 27, with the exception of one company.

There are at least 18 producers and importers of 1,2-dichloroethane in the EU. The annual production and import volume is 10,386,000 tonnes. Nearly all of this is used to produce VCM, the production of which is located in the following 14 countries: Belgium, the Czech Republic, France, Germany, Hungary, Italy, the Netherlands, Poland, Romania, Slovakia, Spain, Sweden and the UK. The VCM production capacity in the EU is approximately divided as follows:

- Eastern Europe (Czech Republic, Hungary, Poland, Romania and Slovakia): 15%
- Central and Northern Europe (Germany and Sweden): 38%
- Western Europe (Belgium, Netherlands, France, UK): 35%
- Southern Europe (Italy and Spain): 12%

According to Euro Chlor[6] around 95% of ethylene dichloride (EDC) is used in the production of vinyl chloride monomer (VCM), nearly all of which goes into polyvinyl chloride (PVC). The remaining EDC goes into the manufacture of chlorinated solvents, which is likely to be as an intermediate which should be well controlled in occupational exposure terms.

PVC itself is highly dependent on the construction market, which reflects the ups and downs of the world economies. The global EDC market had been growing at 3.5-4%/year but this changed abruptly in 2008 when PVC demand collapsed due to deteriorating economic conditions and destocking in the vinyls chain. Consumption in 2008 was about the same as that in 2005.

The following pie chart from SRI consulting[7] shows world consumption of EDC (Figure 2.1):

[6] http://www.icis.com/V2/Chemicals/9075696/ethylene-dichloride.html
[7] http://www.sriconsulting.com/CEH/Public/Reports/651.5000/:

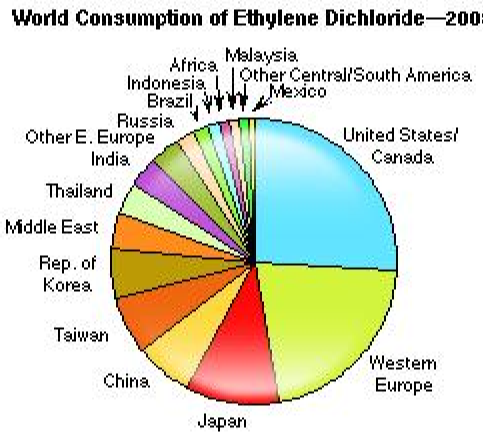

Figure 2.1 World Consumption of Ethylene Dichloride (2008)

2.2 PREVALENCE 1,2-DICHLOROETHANE EXPOSURE IN EU

Communication with industry has indicated that the number of exposed workers at EU 1,2 dichloroethane and VCM manufacturing facilities is 2,264 (based in the year 2009). Based on the estimates of the regional proportions of VCM production capacity it is estimated that the number of workers exposed in different EU regions is as follows:

- Eastern Europe: 340 (15%)
- Central and Northern Europe: 860 (38%)
- Western Europe: 790 (35%)
- Southern Europe: 270 (12%)

An estimated 460 workers are involved in the use of 1,2-dichloroethane as a solvent in pharmaceutical processing.

The majority of 1,2-dichloroethane exposure occurs in the manufacturing industry. The Labour Force Survey available on the Eurostat database includes information on the number of male and female employees in the manufacturing industry (NACE D). When managers, salespeople and office clerks are excluded, 71% of workers in the manufacturing industry in the EU are male and 29% are female. Therefore we estimate that 1930 males and 790 females are exposed to VCM in the EU.[8]

2.3 LEVEL OF EXPOSURE TO 1,2-DICHLOROETHANE

2.3.1 Estimation of exposure levels

In 2006 a survey of exposure to 1,2-dichloroethane in the European plastics manufacturing industry was completed by industry. A total of 1,653 eight-hour time-weighted average exposure measurements were taken across different manufacturing sites and job groups. Measured exposures ranged from 0.2 to 10 ppm with an average exposure of 0.48 ppm across all job groups and sites.[9] The geometric mean (GM) and geometric standard deviation (GSD) were not available. The highest exposures were

[8] Available at: http://epp.eurostat.ec.europa.eu/
[9] Communication with ECVM

seen during decommissioning, product sampling, and loading and unloading during transport. Respirators were used during high exposure tasks at approximately 70% of facilities. The exposure measurements were not corrected for respirator use.

Occupational exposure data are usually lognormally distributed and geometric standard deviations are typically around three. A lognormal distribution and a geometric standard deviation of three were assumed and exposure distributions were simulated with Monte Carlo simulation in @Risk using different geometric means. Ten thousand data points were generated per simulation. A distribution with a GM of 0.26 ppm and a GSD of 3 was found to have an arithmetic mean of 0.48 ppm. This is equivalent to the average of 0.48 ppm found in the 2006 survey therefore 0.26 ppm is a reasonable estimate of the GM exposure level during 1,2-dichloroethane and VCM manufacturing. With a GM of 0.48 ppm and a GSD of 3 an estimated 11% of manufacturing workers would be expected to be exposed to TWAs above 1 ppm and only 0.36% of workers would be exposed above 5 ppm.

No data were available on the levels of exposure of the workers in the pharmaceutical industry who use 1,2-dichloroethane as a solvent. The United States National Toxicology Program 11th Report on Carcinogens has reported that in most cases 1,2-dichloroethane has been replaced by less toxic compounds therefore exposures in the pharmaceutical industry are expected to be intermittent and long term time-weighted average exposures are expected to be low.[10]

2.3.2 Temporal change in exposure

The Organisation for Economic Co-Operation and Development (OECD) Screening Information Data Set (SIDS) for 1,2-dichloroethane[11] reported that 1,2-dichloroethane concentrations ranging from 0.122 to 3.72 ppm were measured during VCM production between 1995 and 1999. The average exposure was 1.12 ppm. If it is assumed that 1.12 ppm is representative of average 1997 exposure levels and 0.48 ppm is representative of exposures in 2006 the temporal trend in exposure to 1,2-dichloroethane can be estimated by fitting an exponential regression equation of the form $y = a.e^{-bx}$ to the values. The regression coefficient can then be used to calculate the average annual change in concentration over the period for which exposure was estimated.

The temporal trends were expressed as the annual change in exposure using the following expression:

$$\% \text{ change per year} = 100 * (\exp[b] - 1)$$

Over the period 1997 to 2006 an annual decline of 9% was calculated.

[10] Substance Profile: 1,2-Dichloroethane. In National Toxicology Program 11th Annual Report on Carcinogens (2005).
[11] OECD SIDS. (2002) 1,2-Dichloroethane. Available at: http://www.inchem.org/documents/sids/sids/DICHLOROETH.pdf

2.4 HEALTH IMPACT FROM CURRENT EXPOSURES

Because of the uncertainty about the carcinogenicity of 1,2-dichloroethane in humans we have not carried out a health impact assessment. It is likely that the number of people exposed to this substance is less than 3,000 and exposure levels are low. This suggests that any health impact will be small.

2.5 POSSIBLE COSTS ASSOCIATED WITH NOT MODIFYING THE DIRECTTIVE

2.5.1 Health impacts – possible costs under the baseline scenario

As it was not possible to estimate a link between exposure to 1,2-dichloroethane and cancer it is not possible to estimate the number of cancer registrations, deaths and life years lost from past and future exposure. Therefore it is not possible to produce monetised health costs of not modifying the directive to include 1,2-dichloroethane.

Since exposure is already well controlled (and has been declining by an estimated average of 9% per year) in the production and use of 1,2-dichloroethane (to make VCM) using closed systems and a highly automated process, it is reasonable to assume that there are not expected to be significant health costs from future exposure without further intervention.

3 POLICY OPTIONS

3.1 DESCRIPTION OF MEASURES

Both 1,2-dichloroethane and VCM are produced in closed systems that are highly automated. Fugitive emissions are minimized through the use of leak-tight connections and seals. Monitoring is conducted to assess the effectiveness of the connections and seals. Transportation within plants or into shipping tankers is done through pipelines. During storage in tanks, inert blanketing substances such as nitrogen are used to prevent venting of 1,2-dichloroethane.[12]

Exposure can occur during decoupling of piping connections during transportation. To reduce emissions during decoupling; the coupling connections are purged before decoupling. Some facilities use closed-loop systems and vapour recovery during coupling and decoupling to reduce emissions. Whenever possible, recovered vapour is recycled to the process. During loading of boats in Sweden, activated carbon is used to absorb 1,2-dichloroethane emissions from the atmosphere.[13]

Exposure can also occur during product sampling and laboratory analysis. In most facilities respiratory protective equipment is used when high exposures are expected.[12]

[12] Communication with the European Council of Vinyl Manufacturers (ECVM)
[13] Integrated Pollution Prevention and Control (IPPC). Reference Document on Best Available Techniques in the Large Volume Organic Chemical Industry. February, 2003. Available at: ftp://ftp.jrc.es/pub/eippcb/doc/lvo_bref_0203.pdf/

4 ANALYSIS OF IMPACTS

4.1 HEALTH IMPACTS FROM CHANGES TO THE EU DIRECTIVE

4.1.1 Health information

It is judged that about 11% of manufacturing workers would be expected to be exposed to average 1,2-dichloroethane exposure levels above 1 ppm and only 0.36% of workers would be exposed above 5 ppm. However, it is very uncertain what health benefits might accrue from exposure being reduced below 1 ppm, although it is considered that these will not be large.

4.1.2 Monetised health benefits

As it was not possible to estimate a link between exposure to 1,2-dichloroethane and cancer it is not possible to estimate the number of cancer registrations, deaths and life years lost from past and future exposure and how this might change with the introduction of an EU-wide OEL. Therefore it is not possible to produce monetised health benefits from the inclusion of 1,2-dichloroethane with OELs at 1ppm and 5ppm.

Since exposure is already well controlled (and has been declining by an estimated 9% per year) in the production and use of 1,2-dichloroethane (to make VCM) using closed systems and a highly automated process, it is reasonable to assume that there are not expected to be significant health benefits from introducing an OEL at 1ppm or 5ppm.

4.2 ECONOMIC IMPACTS

4.2.1 Operating costs and conduct of business

Number of enterprises affected

In section 2.2 it was estimated that 2,264 workers may be exposed (at some level) to 1,2-dichloroethane and from section 2.3 11% of these workers (i.e. 249 workers) may be exposed above an OEL at 1ppm and 0.36% of workers (i.e. 8 workers) exposed above an OEL of 5ppm. These are of course calculated estimates and are subject to uncertainty.

Assuming that the workers affected (249 and 8 workers) are either exposed during the production of 1,2 dichloroethane (assuming 12 in the EU[14]) or VCM[15] (30-40 firms) it is estimated that between 5-10 firms[16] may be affected by an OEL of 1ppm and possibly fewer (0-3[17]) firms may be affected by an OEL of 5ppm.

[14] There are 18 producers and importers and in the absence of better data there is assumed to be 12 firms located in the EU with the remaining 6 being importers located outside the EU.
[15] Over 95% of 1,2 dichloroethane is used to produce VCM, and it is estimated that there are between 30-40 plants producing VCM within the EU and Norway
[16] Based on an average number of employees affected per firm at 44-54 people it is estimated that around 5-6 firms may be affected. Given the uncertainties in the location of workers affected is unknown this is aggregated to 5-10 firms.
[17] The numbers affected was calculated at less than 1 firm but rounded to 0-3 given the uncertainties in the location of workers affected is unknown.

Compliance costs

Consultation responses[18] from the European Council of Vinyl Manufacturers (ECVM) indicate that the main costs of compliance will relate to the procedures required by the Directive (e.g. special medical surveillance) as well as the costs required to comply with a specific occupational exposure limit target. They also note that EDC is used as an intermediate for further chemical reaction (including manufacture of VCM) and that no alternatives could be used.

As consultation was undertaken prior to developing a potential OEL it was difficult for the EVCM to provide an estimate of the costs of an OEL. It was indicated that personal exposure range is between 0.2 and 10 ppm depending on the activity and the plant. The highest levels are observed on specific exposure groups such as those undertaken in decommissioning, sampling, loading and unloading. It was noted that generally personal protective equipment (PPE) (mask with filter) is worn when high exposure is expected.

The ECVM estimated that reductions in the typical exposure range (0.2 and 10 ppm) by a factor 2 or more would lead to significant investment to upgrade exposure control equipment and production equipment, sampling, decommissioning, loading and unloading. The orders of magnitude of costs were suggested to be between €0.5m and €2.5m per plant (this equates to an annualised costs of around €37-184k based on a discount rate of 4% and a lifetime of 20 years).

Alternatively if general PPE (masks with filters or respirators) can be used to control exposure to meet the OELs then there are expected to be relatively low costs for enterprises to implement improved training, enclosure, improved housekeeping and better use PPE. In any case these are considered to be 'best practice'. It is assumed that these costs range between €1,000-2,000 per year per enterprise (including costs of equipment and the cost of time spent on e.g. cleaning and administration).

As it is quite uncertain what action will would be required costs have been estimated on the basis of two scenarios:

- Low cost scenario - requiring just PPE and good practice at an annual cost of €1-2k per enterprise); or
- High cost scenario - More significant investment in upgrading to upgrade exposure control equipment and production equipment at an annualised cost of €36-184k per enterprise.

The total costs of compliance for these scenarios are set out in Table 4.1 and Table 4.2 for the OEL of 1ppm and 5ppm respectively.

[18] Responses received from EDC consortium in November (2nd) 2009

Table 4.1 Estimated costs of compliance with an OEL of 1ppm under two scenarios

Number of enterprises affected		Action required	Annualised average cost per enterprise (2010)		Total annual cost in millions (2010)		Total cost 2010-2070 in millions	
Low	High		Low	High	Low	High	Low	High
5	10	Use of RPE (respirators)	€ 1,000	€ 2,000	€ 0.005	€ 0.02	€ 0.1	€ 0.5
5	10	Upgrade exposure control (derived from ECVM estimates)	€ 36,791	€ 183,954	€ 0.17	€ 1.84	€ 4.0	€ 43.3

Note: These scenarios are alternative scenarios and costs are not cumulative

Table 4.2 Estimated Costs of compliance with an OEL of 5ppm under two scenarios

Number of enterprises affected		Action required	Annualised average cost per enterprise (2010)		Total annual cost in millions (2010)		Total cost 2010-2070 in millions	
Low	High		Low	High	Low	High	Low	High
0	3	Use of RPE (respirators)	€ 1,000	€ 3,000	€ 0	€ 0.01	€ 0	€ 0.1
0	3	Upgrade exposure control (derived from ECVM estimates)	€ 36,791	€ 183,954	€ 0	€ 0.55	€ 0	€ 13

Note: These scenarios are alternative scenarios and costs are not cumulative

The costs of compliance are summarised in Table 4.3 which combines estimates of the low and high scenarios. The total costs of compliance over the period 2010-70 are estimated to be between €0 and €43m for an OEL set at 1ppm and between €0 and €4m for an OEL set at 5ppm.

Table 4.3 Summary of the estimated costs of compliance (€ nearest m)

OEL	Number of firms affected		Total annual costs (€m in 2010)		Total costs 2010-2070 (€m)	
	Low	High	Low	High	Low	High
1ppm	5	10	€ 0	€ 2	€ 0	€ 43
5ppm	0	3	€ 0	€ 1	€ 0	€ 13

Conduct of employers

The introduction of a possible EU-wide OEL might require certain enterprises to reorganise their workplace and work practice to ensure that exposure to EDC is minimised (in terms of the level of exposure and the number of people ever exposed). Additional training and supervision of personnel handling the substance may be required to ensure that employees minimise their exposure by adhering to good practice in order to reduce exposure (e.g. good personal hygiene, wearing protective clothing, improved cleaning procedures and safety instructions). In particular, this relates to improved practices during sampling, decommissioning, loading and unloading of EDC.

Potential for closure of companies

If the cost of compliance per enterprise relate to better use of PPE and improved training (€1-2k), this additional cost is not thought to be prohibitative and therefore there is not expected to be any significant risk of closures.

If more significant upgrading of exposure controls were required this may incur recurrent additional costs (e.g. every 20 years) of between €0.5m and €2.5m. Whilst these costs are much higher, given that the affected industries are manufacturers (of 1,2-dichloroethane or VCM) and not smaller sized firms and that ECVM suggests there are no substitutes to the use 1,2-dichloroethane in VCM production nor a substitute to the use of VCM in PVC production[19], the risks of closure of companies are likely to be small.

Potential impacts for specific types of companies

The annual costs of compliance are not thought to be disproportionately high for medium to large firms (in terms of affordability) and they relate specifically to the production of 1,2-dichloroethane or VCM. No other types of companies are likely to be directly affected, although there may be some indirect impacts in terms of higher final product prices if costs of compliance are passed through.

However, since 1,2-dichloroethane is also imported into the EU, it is possible that EU producers may not necessarily be able to pass through the costs of compliance to end customers (i.e. VCM producers) and therefore, for some affected manufacturers, costs may need to be internalised (i.e. through reduced profit margins and increased operating costs).

Administrative costs to employers and public authorities

The following table (Table 4.4) describes the administrative burden to employers already subject to the Carcinogens Directive but will now incur costs of introducing an EU wide OEL on to Annex III.

[19] It is noted here that this does not necessarily mean there are not any alternatives to PVC for end products or alternatives to those products that contain PVC. In this instance, an analysis of possible alternatives was not deemed necessary given there are estimated to be minimal economic costs to comply with either OEL (relative to the baseline scenario costs). In other words, the information of an EU-wide OEL is unlikely to lead (in itself) to substitution of PVC to alternative materials.

Table 4.4 Administrative burdens to employers

Type of administrative cost	Relevant article(s)	Type of cost	Significance
1. Change in practice to use closed systems when using the substance.	5 – Prevention and reduction of exposure	These costs are already estimated in the cost of compliance section - This will only affect those firms that do not have or use closed systems	Estimated elsewhere
2. Develop/update health and safety and best practice guidance for: o Minimising use and exposure to workers to the substance o Redesign work processes and engineering controls to avoid/minimise release of carcinogens or mutagens o Hygiene measures, in particular regular cleaning of floors, walls and other surfaces o Information for workers o Warnings and safety signs o Drawing up plans to deal with emergencies likely to result in abnormally high exposure	5 – Prevention and reduction of exposure 7 – Unforeseen exposure 8 – Foreseeable exposure 9 – Access to risk areas 10 – Hygiene and individual protection	Firms will already have been required to develop/update health and safety and best practice guidance. The guidance and procedures may be required to be updated as control measures may change in light of a more stringent OEL. Some firms may need to redesign work practices to minimise exposure to workers and the number of workers exposed. The costs of implementing controls on exposure (such as LEV or PPE) are already estimated in the costs of compliance section.	Low
3. Additional costs of training new and existing staff in line with requirements of the Directive 4. Additional costs of making information available to employees 5. Consultation with employees on compliance with the Directive	11 – Information and training of workers 12 – Information for workers 13 – Consultation and participation with workers	Firms will already have been required to ensure training and adequate aware of risks and control measures to reduce/minimise exposure. Largely one-off cost if the revised OEL requires a change in control measures/working practice.	Low

Note: Readers should consult the Directive for the official wording around specific requirements. This table provides only a summary of what are perceived to be the most significant administrative requirements of the Directive. Grading of the significance of impacts is subjective and is based on professional judgement.

The following table (Table 4.5) describes the administrative burden to competent authorities already enforcing the Carcinogens Directive but will now incur costs of introducing an EU wide OEL on to Annex III.

Table 4.5 Administrative burdens to Competent Authorities

Type of administrative cost	Relevant article(s)	Type of cost	Significance
1. Communication with the Commission on provisions in national law to enforce the revised OEL. 2. Time and costs of implementing revised OEL into national law (consultation process)	19 – Notifying the commission 20 – Repeal	Largely one-off cost of transposing the revised OEL into national law	Low - Medium (one-off cost)

Note: Readers should consult the Directive for the official wording around specific requirements. This table provides only a summary of what are perceived to be the most significant administrative requirements of the Directive. Grading of the significance of impacts is subjective and is based on professional judgement.

Third countries

There is not expected to be any significant impact upon third countries such as through redistribution of investment, jobs or sales due to the introduction of either OEL.

4.2.2 Impact on innovation and research

It is likely that firms will adopt readily available known exposure control measures and practices and therefore there is likely to be minimal changes to innovation and research.

4.2.3 Macroeconomic impact

The introduction of an EU-wide OEL is unlikely to lead to plant closures or change the end product. Whilst there would be some compliance costs (€0-43m) if an EU wide OEL is introduced at 1ppm (and €0-13m for an OEL at 5ppm), this is expected to have a negligible macroeconomic impact since costs will be spread all over the EU and over time. These costs are seen as small when compared to for example the total value of goods and services in the manufacturing sector of €5trillion in 2006 alone.

4.3 SOCIAL IMPACTS

4.3.1 Employment and labour markets

There are not expected to be any noticeable changes to the numbers of workers required as a result of introducing an EU-wide OEL. However, job patterns may be altered as it is recognised that in order to meet best practice, behavioural change amongst employees and updating health and safety training will be required.

4.3.2 Changes in end products

There are not expected to be any noticeable changes to the end products since control measures do not change the characteristics of the product and since there is not expected to be any closure of companies, there should not be any change in supply of products relative to the baseline scenario.

4.4 ENVIRONMENTAL IMPACTS

According to the ECVM (EDC consortium), emissions to air from EDC manufacturing plants, as well as plants using EDC to manufacture VCM, are already low, because most of these European plants have to comply with OSPAR Decision 98/4 on Emission and Discharge Limit Values for the Manufacture of Vinyl Chloride Monomer (VCM) including the Manufacture of 1,2-dichloroethane (EDC).

Since the introduction of an OEL is not expected to result in any significant plant closures, or change the end (final) product (predominately PVC) there is unlikely to be any significant change in emissions.

There could be a small increase in energy consumption due to increased intensity of purification and EDC elimination steps. There is no expected change in impacts on waste.

5 COMPARISON OF OPTIONS

The main impacts discussed in more detail in section 4 are summarised in the tables below, which are broken down by the main types of impacts (health, economic, social, macroeconomic and environmental).

Table 5.1 Comparison of health impacts by scenario

<table>
<tr><th colspan="2">Baseline Scenario</th><th colspan="2">Intervention scenario (2) – Assumes full compliance for OEL = 1ppm</th><th colspan="2">Intervention scenario (3) – Assumes full compliance for OEL = 5ppm</th></tr>
<tr><th>Health Costs</th><th>Health Benefits</th><th>Health Costs</th><th>Health Benefits</th><th>Health Costs</th><th>Health Benefits</th></tr>
<tr><td colspan="2">As it was not possible to estimate a link between exposure to 1,2-dichloroethane and cancer it is not possible to estimate the number of cancer registrations, deaths and life years lost from past and future exposure. Therefore it is not possible to produce monetised health costs of not modifying the directive to include 1,2-dichloroethane.

Since exposure is already well controlled (and has been declining by an estimated 9% per year) in the production and use of 1,2-dichloroethane (to make VCM) using closed systems and a highly automated process, it is reasonable to assume that there are not expected to be significant health costs from future exposure without further intervention.</td><td colspan="4">Since exposure is already well controlled (and has been declining by an estimated 9% per year) in the production and use of 1,2-dichloroethane (to make VCM) using closed systems and a highly automated process, it may be reasonable to assume that there are not expected to be significant health benefits from introducing an OEL at 1ppm or 5ppm. However since it is not possible to estimate health benefits this is subject to significant uncertainty.</td></tr>
</table>

Table 5.2 Comparison of economic impacts by scenario (Present Value – 2010 €m prices)

Baseline Scenario		**Intervention scenario (2) – Assumes full compliance for OEL = 1ppm**		**Intervention scenario (3) – Assumes full compliance for OEL = 5ppm**	
Economic Costs	**Economic Benefits**	**Economic Costs**	**Economic Benefits**	**Economic Costs**	**Economic Benefits**
There are expected to be costs for EDC and VCM manufacturers to put into place improved training and use of PPE/RPE to reduce inhalation exposure that would occur regardless of further intervention over the period 2010-2070.	-	There are expected to be economic costs related to changes to workplace practices in order to meet the possible OEL at 1ppm which will affect workers involved in the manufacture of EDC or VCM. It is estimated that few (5-10) enterprises would require some form of additional control measure to meet the possible OEL. The remainder are assumed to already be meeting the possible OEL under the baseline scenario and therefore would require no further action. The total costs over the period 2010-70 are estimated at around €0-43m. There would also be administrative costs of implementing the OEL in national legislation and of demonstrating and verifying compliance.	Having an EU-wide OEL should remove any EU competitive distortions between EU Member States with different limits.	There are expected to be economic costs related to changes to workplace practices in order to meet the possible OEL at 5ppm which will affect some workers involved in the manufacture of EDC or VCM. It is estimated that a few (0-3) enterprises may require some form of additional control measure to meet the possible OEL. The remainder are assumed to already be meeting the possible OEL under the baseline scenario and therefore would require no further action. The total costs over the period 2010-70 are estimated at around €0-13m. There would also be administrative costs of implementing the OEL in national legislation and of demonstrating and verifying compliance.	Having an EU-wide OEL should remove any EU competitive distortions between EU Member States with different limits.

Table 5.3 Comparison of social impacts by scenario

Baseline Scenario		Intervention scenario (2) – Assumes full compliance for OEL = 1ppm		Intervention scenario (3) – Assumes full compliance for OEL = 5ppm	
Social Costs	**Social Benefits**	**Social Costs**	**Social Benefits**	**Social Costs**	**Social Benefits**
There are not expected to be any noticeable social impacts under the baseline scenario at an EU level.		There are not expected to be any noticeable changes to the numbers of workers required as a result of introducing an EU-wide OEL.			

Table 5.4 Comparison of macro-economic impacts by scenario

Baseline Scenario		Intervention scenario (2) – Assumes full compliance for OEL = 1ppm		Intervention scenario (3) – Assumes full compliance for OEL = 5ppm	
Macro-economic Costs	**Macro-economic Benefits**	**Macro-economic Costs**	**Macro-economic Benefits**	**Macro-economic Costs**	**Macro-economic Benefits**
There are not expected to be any noticeable macroeconomic impacts under the baseline scenario.		There are not expected to be any significant macroeconomic impacts relative to the baseline scenario from introducing an EU-wide OEL.			

Table 5.4 Comparison of environmental impacts by scenario

Baseline Scenario		Intervention scenario (2) – Assumes full compliance for OEL = 1ppm		Intervention scenario (3) – Assumes full compliance for OEL = 5ppm	
Environmental Costs	**Environmental Benefits**	**Environmental Costs**	**Environmental Benefits**	**Environmental Costs**	**Environmental Benefits**
There are not expected to be any noticeable environmental impacts under the baseline scenario.		There are not expected to be any significant environmental impacts relative to the baseline scenario from introducing an EU-wide OEL.			

6 CONCLUSIONS

1,2-dichloroethane is mainly used in the manufacture of PVC (95%). There are at least 18 producers in the EU making more than 10 million tonnes per annum. Less than 3,000 people are potentially exposed in Europe. We judge that occupational exposure levels are currently low, with about 11% of manufacturing workers exposed to average levels above 1 ppm and only 0.36% of workers exposed above 5 ppm. Exposures have been decreasing over recent years by about 9% per annum.

Information about the hazard from 1,2-dichloroethane is limited. Animal toxicity studies have shown a range of tumours induced from ingested 1,2-dichloroethane. However, the human epidemiological evidence for occupational exposure causing cancer is weak. There is no basis to identify a suitable risk estimate. We have considered it is not possible to undertake a health impact assessment, but we also do not believe there is any important risk because of the current low exposures and the limited number of people exposed.

There are no predicted health benefits from setting an OEL at either 1ppm or 5ppm. The cost of compliance with a limit of 1 ppm, aggregated over the period 2010 to 2069, is judged to be between zero and €43m and for a limit of 5 ppm between zero and €13m. There are also no social or macro-economic costs associated with introducing an OEL at either of these levels.

There are no significant environmental impacts foreseen.

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