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

## Summary report

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# CONTENTS

## REPORTS

The following are hyperlinks to the relevant reports:

01 Hardwood Dust

01A A review of monitoring methods for inhalable hardwood dust

02 Vinyl Chloride Monomer

03 Trichloroethylene

04 Beryllium and beryllium compounds

05 Hexavalent chromium

06 Acrylamide

07 Rubber process fumes and dust

08 Respirable crystalline silica

09 4,4-Methylenedianiline (MDA)

10 4,4'-Methylene bis 2-choloraniline (MbOCA)

11 1,3-Butadiene

12 Ethylene Oxide

13 Diesel engine exhaust emissions

14 Refractory ceramic fibres

15 Hydrazine

16 1,2-Epoxypropane

17 1,2-Dichloroethane

18 1,2-Dibromoethane

19 o-Toluidine

20 Hexachlorobenzene

21 Mineral oils as used engine oils

22 Benzo[a]pyrene

23 2-Nitropropane

24 Bromoethylene

25 1-Chloro-2,3-epoxypropane (epichlorohydrin)

96 Methodology for valuing health impacts on the SHEcan project

97 OELs for carcinogens

98 Review of article 5

99A Summary table spreadsheet

# SUMMARY

This report summarises assessments of the socioeconomic, health and environmental impacts of possible amendments to the European Carcinogens and Mutagens Directive (2004/37/EC) for 25 occupational carcinogenic substances identified by the European Commission (COM). Further details of the work are provided for each substance in separate dossiers.

The work involved collecting available published information about the uses and/or circumstances of exposure for each substance along with additional information provided by stakeholders. These data were used to assess the exposures in the European working population, which in turn provided the basis for assessing the cancer burden from past and future use. Health costs and benefits were evaluated for no intervention and then for the introduction of up to three possible occupational exposure limits (OELs). Compliance costs were separately estimated for the intervention scenarios. OEL values were either suggested by the COM or were identified as being "typical" of values in EU member states.

In undertaking this type of exercise there are always many uncertainties, which may result in over or underestimates in the impacts. We have attempted to minimise such influences as far as possible. However, the presented impacts should not be treated as precise predictions of health impact or costs, but rather as guides to the merits or otherwise of intervening. For some substances the degree of uncertainty was such that it was not possible to undertake a full impact assessment.

Eleven of the substances considered were accepted human carcinogens (IARC category 1), four were probably human carcinogens (IARC 2a) and ten were possible human carcinogens (IARC 2b). For six substances there are probably more than a million workers in the EU currently exposed and for six substances there are less then 10,000 exposed workers. For fourteen of the 44 substance-OEL combinations assessed it was considered there was already full compliance within the EU (<1% exposed above the limit). For eleven substances it was estimated there would be more than 1,000 cancers occurring in the next 60 years if no action is taken; total estimated deaths over this period were in excess of 700,000. There were only seven substances or mixtures where there was a health benefit in terms of avoided cancer cases over the next 60 years from introducing an OEL: giving between 0.2% and 39% reduction in deaths from the baseline estimate. Estimated compliance costs ranged from zero to €115,000m. The financial benefit to cost ratio was less than one, except for respirable crystalline silica (all three potential OEL values).

It is suggested that the strongest cases for introducing an OEL are for: respirable crystalline silica, hexavalent chrome and hardwood dust. Other substances where the evidence supports the introduction of a limit include: diesel engine exhaust emissions, rubber fume, benzo[a]pyrene, trichloroethylene, hydrazine, epichlorohydrin, o-toluidine, mineral oils and used engine oil and MDA.

Brief summaries of two substantive reviews are also included in the report: one related to the procedures for setting OELs using quantitative risk criteria and the second that evaluates the strengths and weaknesses of the aspects of the Carcinogens Directive that relate to the elimination or control of risks form carcinogens at work. Both reports provide suggestions for consideration by the Commission.

# GLOSSARY

| | |
|---|---|
| AF | Attributable Fraction |
| ASL | Angiosarcoma of the Liver |
| B[a]P | Benzo[a]pyrene |
| BMGV | Biological Monitoring Guidance Value |
| CAREX | CARcinogen Exposure |
| CNAMTS | Caisse Nationale d'Assurance Maladie des Travailleurs Salariés |
| DALY | Disability-Adjusted Life Years |
| DEE | Diesel Engine Exhaust |
| EC | Elemental Carbon |
| ECVM | European Council of Vinyl Manufacturers |
| EUROSTAT | Directorate General of European Commission: Statistics |
| EXASRUB | Improved EXposure ASsessment for Prospective Cohort Studies and Exposure Control in the RUBber Manufacturing Industry |
| GM | Geometric Mean |
| GRG | General Rubber Goods |
| GSD | Geometric Standard Deviation |
| HCB | Hexachlorobenzene |
| Health impact Assessment | Procedures, methods and tools that evaluate the potential effects of a policy, plan, programme or project on the health of a population, and identify actions to manage those effects |
| IARC | International Agency for Research on Cancer |
| LEV | Local Exhaust Ventilation, also described a local ventilation |
| LFS | Labour Force Survey |
| MbOCA | 4,4'-methylene bis 2-choroaniline |
| MBS | Methylmethacrylate-butadiene-styrene |
| MDA | 4,4'Methylenedianiline |
| Mesothelioma | A cancer of mesothelial tissue, associated particularly with exposure to asbestos |
| NACE | Statistical classification of economic activities in the European Community |
| NMSC | Non Melanoma Skin Cancer |
| NPC | Nasopharyngeal Cancer |
| NPV | Net Present Value |
| OELs | Occupational Exposure Limits |

| | |
|---|---|
| PAH | Polycyclic Aromatic Hydrocarbon |
| PPE | Personal Protective Equipment |
| PPG | Polyelectrolyte Producers Group |
| PVC | Polyvinyl Chloride |
| RAR | Risk Assessment Report |
| REACH | Registration, Evaluation, Authorisation and Restriction of CHemicals |
| SCOEL | Scientific Committee on Occupational Exposure Limits |
| SED | Solvents Emissions Directive |
| SMEs | Small and Medium Sized Enterprises |
| SNC | Sinonasal Cancer |
| REP | Risk Exposure Period |
| RMM | Risk Management Methods |
| RPE | Respiratory Protective Equipment |
| RR | Relative Risk |
| TCE | Trichloroethylene |
| VCM | Vinyl Chloride Monomer |
| WOODEX | Database on occupational wood dust exposure and health effects |
| WTP | Willingness To Pay |
| YLL | Years of Life Lost |

# 1 INTRODUCTION

## 1.1 BACKGROUND INFORMATION

In 2000 there were more than 1.1 million cancer deaths recorded in the European Union and with the increase in the proportion of the population over the age of 65 it is projected that by 2015 this will increase to between 1.2 and 1.4 million deaths (Ferlay *et al*, 2007). Skin cancers are most commonly diagnosed, but the main causes of premature death are lung cancer (about 20% of all cancer deaths), colorectal cancer (12%) and breast cancer in women (about 17% of all female cancer deaths). For some cancers there are important differences in incidence across Europe. For example, the cumulative lifetime risk of lung cancer in men and women is more than three times higher in Hungary than in Sweden, with this difference being mainly due to differences in tobacco smoking habits. Survival after cancer diagnosis varies depending on many factors, but importantly on the type of cancer. 5-year survival is high for testicular cancer (97%), melanoma (86%) and female breast cancer (79%). However, survival rates are low for stomach cancer (25%), acute myeloid leukaemia (15%) and lung cancer (11%) (Verdecchia *et al*, 2007).

There have been a number of attempts to assess the proportion of cancer cases and deaths due to occupational exposures. Steenland *et al* (2003) estimated the burden of occupational disease in the USA. Their data suggested that occupational exposure, including second-hand cigarette smoke and radon, caused between 6.3% and 13.0% of lung cancers (judged to be approximately 75% of all occupational cancers). More than half of the work-related lung cancers were attributed to asbestos exposure. Rushton *et al* (2010) have carried out a comprehensive assessment of the occupational cancer burden in Great Britain for all IARC definite and probable occupational carcinogens. They showed that about 5.3% of cancer deaths were attributable to occupation (men, 8.2% and women, 2.3%). The cancer judged to have the highest proportion caused by work were: mesothelioma (95%), sinonasal (34%), lung (14.5%), nasopharyngeal (8.2%) and breast (4.6% in women). The main causal agents were asbestos, shift-work, mineral oils, solar radiation, silica, diesel engine exhaust, coal tars and pitches, occupation as a painter or welder, dioxins, environmental tobacco smoke, radon, tetrachloroethylene, arsenic and strong inorganic mists. It seems likely that the overall occupational cancer burden is likely to be of the same order in many European Member States although the exact magnitude of the burden may vary between countries.

In Europe the main legislative instrument to ensure control of occupational carcinogens is Directive 2004/37/EC on the Protection of Workers from the Risks Related to Exposure to Carcinogens or Mutagens at Work (the Carcinogens Directive). The European Commission DG Employment (COM) has sponsored the work described in this report to undertake a socioeconomic, health and environmental analysis of possible changes to the Carcinogens Directive. A consortium of researchers from six organisations has undertaken this project, which is known as SHEcan, i.e. Socioeconomic, Health and Environment and cancer at work.

The main work has involved an assessment of 25 substances identified by the COM and this report summarises the results from these evaluations (Table 1.1).

**Table 1.1** Substances to be evaluated

| SHEcan Reference | Substance or mixture | EU carcinogen | IARC |
|---|---|---|---|
| 1 | Hard wood dust | NA | 1 |
| 2 | Vinyl chloride monomer (VCM) | 1 | 1 |
| 3 | Trichloroethylene | 2 | 2a |
| 4 | Beryllium and beryllium compounds | 2 | 1 |
| 5 | Chrome VI | 2 | 1 |
| 6 | Acrylamide | 2 | 2a |
| 7 | Rubber process fume and dust | NA | 1 |
| 8 | Respirable crystalline silica | NA | 1 |
| 9 | 4, 4'-methylenedianiline | 2 | 2b |
| 10 | 4,4'-methylene bis 2-chloroaniline | 2 | 2a |
| 11 | 1, 3 Butadiene | 1 | 1 |
| 12 | Ethylene oxide | 2 | 1 |
| 13 | Diesel engine exhaust emissions (DEE) | NA | 2a |
| 14 | Refractory ceramic fibres (RCF) | 2 | 2b |
| 15 | Hydrazine | 2 | 2b |
| 16 | 1, 2-Epoxypropane | 2 | 2b |
| 17 | 1, 2-Dichloroethane | 2 | 2b |
| 18 | 1, 2-Dibromoethane | 2 | 2b |
| 19 | o-Toluidine | 2 | 1 |
| 20 | Hexachlorobenzene | 2 | 2b |
| 21 | Mineral oils as used engine oil | NA | 1 |
| 22 | Benzo[a]pyrene | 2 | 1 |
| 23 | 2-Nitropropane | 2 | 2b |
| 24 | Bromoethylene | 2 | 2a |
| 25 | 1-Chloro-2, 3-epoxypropane | 2 | 2a |

The table above shows how each substance has been categorised by the International Agency for Research on Cancer (IARC) and within the EU.

In addition to this summary report, there are separate dossiers for each substance describing in detail the underpinning data and the rationale for the assessment. There is also a separate report describing the methodology used for the socioeconomic assessment (Mistry, 2011) and a report on the sampling methodology for hardwood dust (Sanchez-Jimenez *et al*, 2011).

Finally, the SHEcan project involved additional work packages to assess the options for introducing a system for setting occupational exposure limits based on objective risk criteria and to review the requirement in the Directive for prevention and reduction of exposure (Article 5). Both of these aspects are reported separately, although in this report we provide a brief summary of the work and the main conclusions.

## 1.2 AIMS AND OBJECTIVES

The aim of the SHEcan project was to provide a robust assessment of the health, socioeconomic and environmental impacts associated with a range of policy options concerning possible future amendments to the Carcinogens Directive. The purpose of the assessment was to enable the COM to initiate informed discussions with stakeholders about possible developments.

Specific objectives relating to this report were to evaluate the impact of:

- introducing additional substances or process-generated emissions into the definition of a carcinogen in the Directive (i.e. into Annex I of the Directive);
- revising the OELs for hardwood dust and vinyl chloride monomer listed in Annex III of the Directive;
- introducing OELs for a range of additional substances into Annex III of the Directive, based on limits that are “typical” of those in EU Member States.

In each case the assessment considered the impact in terms of the health of workers and others exposed as a consequence of work, the social and economic consequences of the change and the likely impact on the environment.

The focus of the report is exclusively on occupational cancer and some of the substances considered may also have non-cancer health effects at levels of exposure seen in European workplaces, e.g. respirable crystalline silica may cause silicosis or occupational asthma from exposure to hardwood dust. This report and the underlying substance reports do not consider non-cancer health impacts or the benefits that might arise from reducing the incidence of these diseases. There may be additional benefits from introducing or revising an OEL that are outside the scope of the commissioned work.

# 2 BACKGROUND TO OCCUPATIONAL CANCER IN EUROPE AND THE ASSESSMENT OF THE IMPACT OF CHANGES TO THE CARCINOGENS DIRECTIVE

Cancer describes over 200 different illnesses that result from one of the body's cells beginning to reproduce in an uncontrolled manner because of damage to the cell DNA. There may be several causes for each of these diseases, including exposure in the workplace, and for many cancers the specific causes are still unknown. Although the initial trigger for a cancer tumour is some event or events that damages the genetic material in a cell there are many other processes that must follow before this cell mutation results in a tumour. Cancer is often described as a complex multistage process, which can be simplified into a conceptual two-stage process of *initiation*, followed by *transformation (or promotion)*. Not all mutation events will result in a cancer forming because of the sequence of promoting events that must follow the mutation and the possibility that the cells may die off before the next promoting step occurs. Occupational chemical carcinogens may act as initiators or promoters.

The time between first being exposed to an occupational carcinogen and the diagnosis of the disease is called the latency period. Latency varies by cancer type, but is typically more than 10 years and may be up to 40 or 50 years for some types of tumour. Cancer is sometimes described as a “long-latency disease”. The long time delay between exposure and the manifestation of the disease and the multi-causal nature of cancer generally makes attribution of individual cancer cases to work or other environmental causes problematic. However, when groups of workers are studied in an epidemiological investigation it is possible to identify increased risks associated with a substance or work process.

{Ferlay:2007wu} estimate that in Europe each year there are about three million cancer cases, excluding non-melanoma skin cancer, diagnosed and about 1.7 million cancer deaths. The commonest cancers are breast cancer (13.5% of all cancer cases and 29% of cancer cases in women), colorectal cancers (12.9%) and lung cancer (12.1%). The commonest type of cancer death was lung cancer, with over three hundred thousand deaths (about 20% of the total), followed by colorectal, breast and stomach cancers. There are important differences in overall cancer incidence between countries in Europe, with about a two fold difference for men between the highest (Hungary) and the lowest (Bulgaria), and a slightly smaller inter-country difference in cancer incidence amongst women.

The International Agency for Research on Cancer (IARC) lists 107 agents that have been classified as carcinogenic to humans (Group 1). There are a further 59 agents classified as probably carcinogenic to humans (Group 2a) and 267 classified as possibly carcinogenic to humans (Group 2b). Many of the agents classified by IARC are used or produced in workplaces, for example asbestos, benzene and chromium are all listed as human carcinogens. IARC also classify industrial groups where there is a risk but where the causative agent cannot be clearly identified, and for example employment in the rubber manufacturing industry is classified by IARC in Group 1 as a human carcinogen.

Unfortunately there are no reliable statistics about the number of people in Europe who may be exposed to carcinogenic substances at work or the industries or employment sectors where the main occupational cancer risks may arise. {Kauppinen:2000tz} summarized the best available data from about 20 years ago on the numbers of workers exposed to the then list of IARC Group 1 and 2a agents plus a small number of 2b agents. They estimated that there were 32 million workers in the EU in the period 1990-93 exposed to these carcinogenic substances (23% of those employed). The most prevalent hazardous substance exposures they identified were crystalline silica, diesel exhaust particulate and wood dust. Key industry sectors where most workers were exposed were construction, wholesale, retail and restaurants, and agriculture. Because of the long latency for cancer current and past exposures will continue to be the cause of the current incidence of occupational cancer in Europe, and current and future exposures will be the cause of occupational cancer in the future.

There are also no reliable estimates of the proportion of cancers that are attributable to work (the occupational attributable fraction) and these cancers are clinically indistinguishable from cancers due to other causes. There has been a considerable amount of work on estimating the cancer burden due to work in Britain ({Rushton:2010jr}). In these studies it was estimated that 5.3% of cancer deaths in Great Britain in 2005 were attributable to occupation (in men 8.2% and in women 2.3%) giving over 8000 deaths. The proportion of incident (newly occurring) cases attributed to work was slightly lower (4%) giving over 13500 new cancer registrtaions. The highest attributable fractions were for mesothelioma, sinonasal cancer, lung cancer, cancer of the nasopharynx and breast cancer, but the largest number of attributable deaths was for lung cancer and mesothelioma. Carcinogenic agents that contributed most cases to the occupational cancer burden were asbestos, shift work, mineral oils, solar radiation, silica, diesel engine exhaust plus coal tars and pitches. Industries and occupations with high attributable cancer registrations include construction, metal working, personal and household services and mining. If these attributable proportions from Britain are applicable to the whole of Europe then there could currently be 110,000 cases of cancer and 65,000 cancer deaths amongst Europeans that result from past occupational exposures.

There are two main non-chemical occupational exposures that are known or probable causes of cancer amongst workers, shift working involving night work and solar radiation (UV light). In Britain it is estimated these two exposures contribute a substantial proportion of the incident cancer cases resulting from work. Shift working in particular contributes the highest number of cancer cases in women (breast cancers) and is estimated to be the second highest cause of occupational cancer in Britain.

{Cherrie:2008cg} has noted that thirty years ago the eminent epidemiologists Sir Richard Doll and Richard Peto estimated that about 4% of cancers were probably caused by work, which is similar to that estimated by Rushton and colleagues. In the intervening time the causes of cancer in the workplace have changed but the importance of occupational cancer as a public health priority has remained. All occupational cancers are preventable if we manage exposures appropriately. {Cherrie:2008cg} has argued that if current exposure to a relatively small number of chemical carcinogens is tightly controlled then by 2025 it could be possible to reduce the proportion of occupational cancer deaths to less than 1% of all cancer deaths. He suggests “this would be a major achievement and could … indicate we had ‘eliminated’ occupational cancer as a public health issue.” However, this goal requires all key stakeholders to work together with a common purpose.

The EU Carcinogens Directive is an effective tool to promote control of occupational cancer from exposure to hazardous substances. Setting defined control actions to be taken by employers who are manufacturing or using carcinogenic substances is a necessary requirement. In addition, regulatory “tools” such as the setting of health-based occupational exposure limits (OELs) can be used by employers and regulators to guide appropriate intervention actions and to set policy objectives for specific carcinogens. However, legal instruments are only part of the approach that should be used to tackle the problem of occupational cancer and it is also important to provide convincing information about the benefits to workers and society from intervening and ensure that this information is communicated widely to stakeholders.

Impact assessments are part of the process of evaluating new policy initiatives. They provide evidence for political decision-makers on the advantages and disadvantages of possible policy options, including the potential economic, social and environmental consequences that they may have. However, these assessments are difficult to undertake in the context of chemicals risk management because of the limited amount of data available. For example, there are no reliable European statistics about the number of workers exposed to occupational carcinogens or the range of exposures to carcinogens that occur in European workplaces. We have only limited data on the intensity of exposure in the workplace for a limited number of substances and these data are from a limited number of European countries. It is therefore always necessary to make assumptions about the number of people exposed, the pattern of exposure, intensity, risk etc. In the immediate future it is unlikely that better data will become available and so it is necessary to work with the data that can be collected.

Data are available from a project known as CAREX (the CARcinogen Exposure Database), which was funded by the European Union in the 1990s {Kauppinen:2000tz}. The CAREX database was compiled by an international research team using national statistics, particularly data from Finland, and expert judgement to adapt the data to reflect national experience. CAREX has information about the prevalence of exposure to carcinogens by industry (NACE code). In addition there are comparable national data sources for Spain and Italy that are available. For wood dust there is a more extensive European database on exposure prevalence and exposure level by industry sector that was collected as part of the EU Wood-Risk project ({Kauppinen:2006uq}). Information on the number of employees in each industry may be obtained from the structural business statistics and the labour force survey data available on the Eurostat database, although these are often not sufficiently detailed to accurately estimate the number and extent of use, exposure and control of carcinogens. Other information may be obtained from the published scientific literature or on request from appropriate industry stakeholders.

These data have been used in the present project to define the current and future cancer burden, and the health, socioeconomic and environmental impact of introducing new occupational exposure limits into the Carcinogens Directive for 25 substances. The results provide an impact assessment based on the best available data.

Action should be taken within the European Union to improve the data available for future impact assessments, e.g. updating CAREX and providing additional data on the intensity of exposure in key industries for a small number of key chemical carcinogens. It is important to target important knowledge gaps to reduce the uncertainties in future impact assessments. Some important knowledge gaps also exist for potential risks from specific carcinogenic chemicals widely used in industry. Information on the current levels of workplace exposure controls is also often limited, meaning that various assumptions were needed in the current study.

In the present project, we have attempted to assign an economic cost to the disability and deaths caused by occupational carcinogens and thus to the benefits of further reducing exposure levels. Whilst this is beneficial in allowing impacts to be quantified, the estimates used are subject to significant uncertainty and are by no means universally accepted as being accurate. Such valuation is likely to remain subject to significant uncertainty for the foreseeable future.

One important observation concerning occupational exposures to carcinogens and other hazardous substances is that in general conditions in workplaces are improving and average exposures are decreasing by between 5% and 15% per year ({Creely:2007cj}). These trends have been apparent for at least the last thirty years and the pattern of change looks likely to continue. Reduced exposure must be due to improved control measures in the workplace and better technological processes. The implication of this is that the occupational cancer burden that will arise from current exposures should be much less than at present, at least from our current knowledge base. These are important benefits in terms of reduced life-years lost by workers across the whole of Europe. These trends make the goal of "elimination" of occupational cancer more realistically achievable, provided our interventions are appropriately focused.

There is a significant cost to society from dealing with cancer (in terms of the financial costs associated with disease, and the pain and suffering of those affected by these diseases). In the future cancer will likely become a relatively more important cause of morbidity and mortality in European society, because as people live longer there will be more time for these long-latency diseases to appear. Primary prevention of occupational cancer is an important contribution to reducing part of this burden, a part that is entirely preventable with appropriate action.

# 3 SUMMARY OF THE METHODOLOGY

## 3.1 EXPOSURE ESTIMATION

The occupational exposure assessment has provided input into the evaluation of the impact on health of the workers following the introduction of the various agents into the Carcinogens Directive. In addition, estimation of current exposure levels was needed for estimating of the socioeconomic impact of changes implemented by industry as a consequence of any modifications to the Directive, i.e. these data have provided the baseline to judge what extent of changes would be necessary to comply with the suggested OEL.

The following occupational exposure information was required for each substance for estimating the health impact of any changes in exposure:

- prevalence of exposure by industry (current);
- classification of industries into high, medium, low and background exposure, or a subset of these categories;
- distribution of exposure (the geometric mean = GM and geometric standard deviation = GSD), ideally by country, across industries; and
- temporal change in exposure (% change per year) arising from general improvements in European workplaces and work processes, not taking into account the impact of changes to the Carcinogens Directive.

Figure 3.1 provides a graphic overview of the general procedure for estimating the prevalence of exposure.

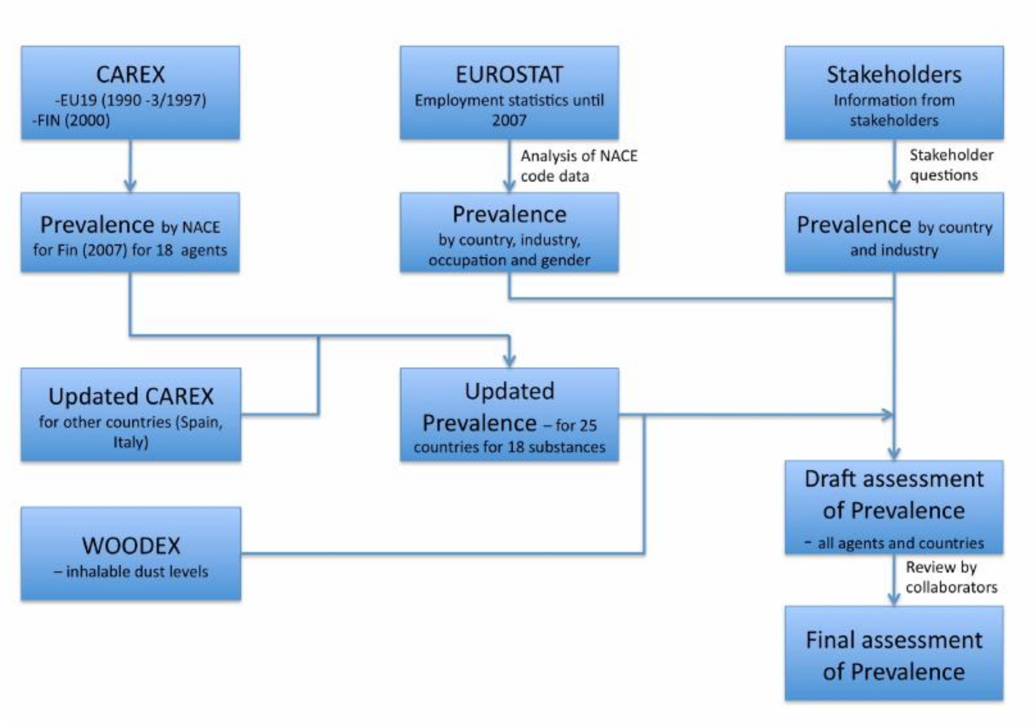


**Figure 3.1** Flow-chart demonstrating the procedures for estimating prevalence of exposure

The main sources of information to estimate prevalence of exposure were:

- Labour Force Survey and structural business statistics (EUROSTAT website[1]);
- CAREX for 15 EU countries (1993), updated in Finland for 2000 and 2007, in Spain for 2004 and in Italy for the period 2000 – 2003;
- WOODEX – database with estimates of prevalence and levels of wood dust exposure for 25 EU countries by industry; and
- information from stakeholders such as trade associations.

Micro data from the EU Labour Force Surveys (LFS) were requested and obtained from EUROSTAT. Unfortunately, for reasons of confidentiality the occupational and industry information is only available coded to 1 digit ISCO and 1 digit NACE code. Subsequently, EU wide structural business statistics data were accessed from the EUROSTAT website. Structural Business Statistics (SBS) describe the structure, conduct and performance of economic activities, down to the most detailed activity level (several hundred sectors), including the number of employees by 4-digit NACE code. SBS covers the "business economy", which includes industry, construction and services (NACE Sections C to K). These data are available from 1995 to 2007, for all 25 EU countries (although some gaps exist and reliability of the information varies).

Exposure prevalence data are available from CAREX for 19 of 25 agents under study. The six agents that are not included are: rubber fumes, mineral oils as used engine oils, 1,2-epoxypropane, 1-chloro-2,3-epoxypropane, 2-nitropropane and 4,4'-methylenedianiline and exposure prevalence for these were estimated based on information from other available sources. Exposure prevalence for rubber fumes and dust exposure was estimated from the SBS data. Exposure prevalence for the remaining agents has come from information collected from trade associations and other stakeholders.

For wood dust exposure, information on the prevalence (and level) of exposure was available for 25 countries following a EU project estimating the risk of exposure to wood dust (Kauppinen *et al*, 2005). Data on rubber dust and fume levels was similarly available from the Exasrub project database (de Vocht, 2005).

The information from CAREX and other sources, were combined with data from EUROSTAT to obtain estimates of exposure prevalence.

The level or intensity of exposure was assessed using:

- published scientific literature;
- information from European Risk Assessment Reports compiled in relation to the Existing Substances Regulations;
- the Woodex database (hardwood dust);
- the Exasrub database (rubber dust);
- information provided by industry stakeholders.

The overall weighted geometric mean (GM) and geometric standard deviation (GSD) exposure level for each substance was estimated across all "medium" and "high" exposure industries across the EU using @Risk© (Palisade Corporation, New York).

[1] http://epp.eurostat.ec.europa.eu/portal/page/portal/statistics/themes

Where possible, exposures were simulated using the GM and GSD for each country. The number of values each industry contributed was weighted according to the number of workers exposed in that industry.

Temporal changes in exposure were determined from information from the literature, which was ideally specific to the substance being considered but in situations where this was not available and it was our view that there was a decline in exposure levels over time we relied on the results of a systematic review of the literature (Creely *et al*, 2007).

## 3.2 HEALTH IMPACT

### 3.2.1 Introduction

The aim of the health impact assessment was to provide current estimates of occupational cancers in the EU associated with the relevant substances and the trends expected to occur in the future under different scenarios of change of exposure. This has been expressed in terms of attributable fractions (see below), numbers of deaths and cancer registrations, Disability Adjusted Life Years (DALYs) and Years of Life Lost (YLL). These data provide the input into the socioeconomic assessment. The health impact assessment builds on work to quantify the burden of cancer due to occupation in Great Britain (Rushton *et al*, 2010). The methods are briefly described below.

### 3.2.2 Methodology for estimation of current burden

The primary measure of the burden of cancer used in this project is the attributable fraction (AF) i.e. the proportion of cases that would not occur in the absence of exposure; this was then used to estimate the attributable numbers. There are several methods for estimating the AF but all depend on knowledge of the risk of the disease due to the exposure of interest and the proportion of the target population exposed (data described in the previous section on exposure assessment).

The period during which exposure occurred that was relevant to the development of a cancer in a target year e.g. 2010 is defined as the risk exposure period (REP). For solid tumours a latency of 10-50 years is assumed giving a REP for 2010 of 1961-2000 for haematopoietic neoplasms 0-20 year's latency is assumed giving a REP of 1991-2010. The proportion of the population ever exposed to each carcinogenic agent or occupation in the REP was obtained from the ratio of the numbers ever exposed to the carcinogens of interest in each relevant industry/occupation over the total number of people ever employed. National data were used to obtain these (see section 2.1). Estimates of employment turnover for grouped main industry sectors and of life expectancy were used to estimate the exposed population, and adjustment factors were applied to the exposure prevalence data to take account of the change in numbers employed in the industry sector groups.

The attributable fraction (AF) for each cancer/occupational carcinogen was estimated using Levin's method (Levin, 1953). The AFs are applied to total numbers of cancer specific deaths and cancer registrations in the target year for ages that could have been exposed during the REP to give attributable numbers. Where AFs were only available for mortality these were used for estimation of attributable registrations and *vice versa*. Similarly if separate AFs for women could not be estimated those for men or for men and women combined were used.

### 3.2.3 Review of the epidemiological literature

The relative risk (RR)[2] for the cancer(s) in question for the relevant agent or work environments, were derived from a review of the published epidemiological literature.

Risk estimates were obtained from key studies, meta-analyses or pooled studies, taking into account quality, relevance to the EU, large sample size, effective control for confounders, adequate exposure assessment, and clear case definition. Exposure-response risk estimates are generally not available in the epidemiological literature nor are proportions of those exposed at different levels of exposure over time available for the working population. Where possible risk estimates were obtained for two or more levels of exposure to the agents of concern, e.g. "lower" and "higher". We also attempted to ensure consistency in the risk estimates with the occupational cancer burden studies being carried out in Britain (Rushton *et al*, 2010).

In cases where the epidemiological literature was judged inadequate, i.e. mostly those substances classified as IARC 2b substances, we attempted to identify an analogous substance for which risk information was available. If it was possible to identify a suitable RR then the assessment of occupational cancer burden proceeded. However, where it was not possible to identify suitable epidemiological data to define the risk from exposure then we have not undertaken any health impact assessment.

### 3.2.4 Predicting future burden

For predicting future burden, the risk exposure windows were projected forward in time, and estimation was carried out for a series of forecast target years (FTYs) that stretch far enough into the future to account for the latency of cancers currently being initiated (i.e. the decade starting 2060). Estimates were made for alternative scenarios of changes in exposure levels and proportions exposed, for example assuming the introduction of new or reduced exposure limits, which were assumed introduced in 2010. In addition, we assume that there will be "full compliance" with the OEL from the date it is introduced, i.e. that more than 99% of exposures are less than the limit value. Where a substance has been banned or usage has been restricted in the past then these changes were reflected in the exposure prevalence data used for estimation of future burden.

To predict future attributable cancer numbers based on the pattern of past and current exposure either a "static" baseline, where no change in exposed numbers or exposure levels is expected beyond 2010, or a "dynamic" baseline was used, where current trends are forecast to continue until 2030.

Projected changes in exposed numbers were based on estimates of numbers employed from the EU LFS, in grouped main industry sectors. Projections of cancer deaths and registrations for the forecast target years were based on current rates (2006 for deaths[3], generally 2002 for registrations[4]) applied to EU country specific population projections by age.

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[2] A relative risk is a ratio of the probability of a specific type of cancer incidence or mortality in the exposed group divided by the corresponding probability in a non-exposed group

[3] Eurostat, Causes of death by age and sex, 2006. Date of extraction: 15 Dec 09

[4] GLOBOCAN, 2002

Results from projections in the future based on the pattern of past and current exposure and intervention scenarios are compared with the appropriate baseline scenario to assess relative impact on reducing attributable numbers of cancers. We calculated the number of avoided cases as a consequence of introducing the proposed OELs.

### 3.3 SOCIOECONOMIC ASSESSMENT

We have assessed the economic impacts of exposure in terms of the cost of disability and death based on the estimated cancer burden, which acts as the "do nothing" baseline for assessing the impacts and benefits of the proposed amendments to the Directive. We then estimated the value of disability and deaths avoided by imposition of the proposed amendments - based on the assessment of cancer burden under the reduced workplace exposure level.

We have reviewed possible approaches for analysing the costs and benefits of health impacts, which has resulted in the development of an approach that has been applied in this study. This methodology is presented as a separate methods paper (Mistry, 2011).

A spreadsheet tool was developed to allow calculation of the costs of disability and deaths from cancers that allows a range of valuations to be considered and includes consideration of the discount rate for future impacts - by Member State, if and where possible.

We considered the compliance costs of meeting the proposed amendments to the Directive, particularly the introduction of a limit value. To do this we identified the main uses leading to exposures that are a risk to human health and the industry sectors in which those uses take place (e.g. metal degreasing is the primary focus for the trichloroethylene assessment). Minor uses were considered but not assessed in detail

Consideration was given to the possible risk management measures (RMM) that may be applied in order to meet the investigated OEL and whether these RMM may have already been applied – in some countries or all EU countries. Background information on all agents in the project were obtained from published literature and stakeholder contacts to identify:

- the uses and activities that lead to workplace exposure risks to human health;
- the structure of the sectors in which exposure occurs: (e.g. numbers employed; demographics of employees and geographical distribution of firms in the EU);
- exposure control measures currently in place, available and required to meet the proposed OEL; and
- the possible costs of exposure control measures.

In order to understand the economic impacts on sectors in which specific uses cause a risk to the health of workers we have used publicly available data from Eurostat to define the number enterprises operating in different sectors, the number of workers employed in those enterprises, the distribution of enterprises in the EU, and financial measures such as turnover, personnel costs and research and development expenditure.

Estimates were made of:

- the number of firms needing to apply RMMs and the cost of the RMMs over the same time period as health benefits (2010-69);
- the cost of the administrative burden of implementing the OEL (e.g. the cost of monitoring and audit);
- the potential effect on the market for the substance by the imposition of the OEL - i.e. the change in the market for the substance as a result of increase cost of control - leading to adoption of substitutes and possible change in price of the substance itself.

The end analysis comprises a comparison of the costs and benefits of the "do nothing" or "business as usual" situation with the scenario in which the possible OEL is added to the Directive.

## 3.4 ENVIRONMENTAL ASSESSMENT

This assessment includes an analysis, where possible, of the extent to which the proposed amendments could imply the release of these substances to the environment and what impact this could have on ecosystems, i.e. air, soil and water quality as well as on plants and animals.

In practice, we review relevant environmental risk reduction strategies (where available), consider any risk assessments and the hazardous properties of the substance in relation to environmental effects, e.g. based on classification and labelling. We then determine whether there is any information to suggest that there is a risk/concern for the environment. We then determine whether the amendments would lead to any changes in release to the environment and what implications this might have for environmental impacts. This has been done qualitatively - and at a relatively high level - for all substances.

No quantitative assessment has been made of the impact of possible changes to the Directive on human health from environmental exposure.

## 3.5 UNCERTAINTIES IN THE EVALUATIONS

### 3.5.1 Uncertainties in the health impact assessments

The methodology that we have developed for the health impact assessment has many advantages over alternative approaches in explicitly linking exposure estimates to the estimation of the number of cancer registrations and deaths. It is based on an approach developed for estimating the cancer burden in Great Britain (Rushton *et al*, 2010), which was extensively reviewed by international experts in occupational cancer epidemiology before being finalised. However, as with all health impact assessments the reliability of the final output is determined to a large extent by the accuracy of the underlying data.

In our assessments we have relied on the CAREX data as the basis for estimating the number of people potentially exposed at work, which has the advantage that the data are representative of past conditions and so are relevant for estimating the current cancer burden. However, there may be uncertainties in the CAREX data because it relied heavily on information from Finland with a more limited review input from scientists elsewhere in Europe.

CAREX tends to provide a sensitive measure of the number of workers exposed in each industry, i.e. it seems to have a low threshold of exposure level for an industry to be included (Cherrie *et al*, 2007). Where we had data from other sources, for example from industry, we have incorporated this into the assessment but in many cases only CAREX data was available. A further limitation of CAREX is that it does not cover all of the substances included in our projects (mainly data are missing for IARC 2b substances) and here we have had to rely completely on either published data or information from industry. Inevitably the quality of these data is variable and the data are generally incomplete.

Based on the CAREX information assigned to the relevant NACE codes we have devised a categorical assessment of exposure to link with the epidemiological information; generally “high”, “low” and / or ”background”). These assignments were based on expert judgment and in many instances this is clearly supported by objective information, such as from exposure monitoring. However, for a large proportion of these low or background exposure categories there is very limited information to substantiate our decision. It is possible that some industries were assigned to the wrong exposure category and this may have increased or decreased the estimated health impacts.

To estimate future cancer impact we have used an estimate of the geometric mean (GM) and geometric standard deviation (GSD) of exposures for the whole of the exposed population in Europe. This has generally been based on data from the peer-reviewed literature, although occasionally data has been available from industry. All of these data generally tend to focus on situations where exposure levels were higher. We have therefore not had data to estimate the levels for most background and low exposure groups. In this situation we have chosen to assume these groups may be represented by the available data. We consider this will generally have overestimated the GM level and may underestimate the GSD. The net effect would, in most cases, result in an overestimate of exposure and risk.

We have relied upon the published epidemiological literature to identify appropriate levels of risk for the calculation of health impact and we have attempted to ensure these are selected after consideration of the categorical assessment of exposure. However, it is possible that our choice of risk estimates was inappropriate and such errors may have either increased or decreased our estimated impacts. In addition there may be a mismatch between the selected risk estimates and some or all of the exposure groups where we identified these would be appropriate, for example the epidemiological study selected may not be relevant to the “high” exposure groups for which it was selected. In most cases we have assigned low/background exposures a relative risk of 1, mainly because of limited information about the risks at low exposures and the actual levels of people in these groups. In our opinion this may result in some relatively small underestimate of risk.

Possible human carcinogens (IARC 2b) necessarily have limited epidemiological data available and this has made the assessment of risk in these cases more problematic. We have reviewed the data, taking account the toxicity data and information from other substances that may have analogous toxicity. However, considering the limited information about the hazard and the generally limited information about exposure to these agents the assessment of health impacts for these substances is much more uncertain than for substances where there is greater certainty about their carcinogenicity (i.e. IARC 1 and 2a).

We have attempted to summarise the potential effects of these and other uncertainties on the health impacts in the following table (Table 3.1). In addition, we discuss some of these issues further in the paper describing the methodology as used in the British cancer burden study (Rushton *et al*, 2008).

**Table 3.1** Uncertainties in the health impact assessments

| Source of uncertainty | Potential impact on cancer burden |
|---|---|
| CAREX data may not correctly identify the numbers exposed in specific industries throughout Europe | Uncertain |
| No CAREX data (IARC 2b carcinogens) | High |
| Assignment of high/medium/low/background to industry groups in error | Uncertain |
| Inadequate data on exposure low/background groups | Uncertain |
| Limited quantitative exposure data | Low |
| No exposure data for low/background exposed groups | Low but may overestimate impact |
| Risk estimates inappropriate for the assigned groups | Uncertain |
| Source of risk estimates from a group of high exposed workers applied to low exposed groups | Low but may overestimate impact |
| Risk estimates from the epidemiological literature biased by the 'Healthy Worker' effect | Low but may underestimate impact |
| Use of a relative risk of 1 for low/background exposed groups | Low but may underestimate impact |
| In accurate risk-exposure period, i.e. wrong assumption about the latency of the cancer | Uncertain |
| Effect of unknown/unmeasured confounders | Uncertain |

The estimated exposures and risks are subject to a range of potential uncertainties arising from the data; some may increase the health impact and other decrease the impact. However, we believe that our estimates are reasonably reliable and probably represent the best that can be achieved given the limited nature of the underlying data.

### 3.5.2 Uncertainties in the socioeconomic assessments

There are similar uncertainties associated with the socioeconomic assessments. The key areas of uncertainty are summarised in Table 3.2. Note that all of these assessments are based on the professional judgement of the authors.

**Table 3.2** Uncertainties in the socioeconomic impact assessments

| Area of uncertainty | Methodological approach | Potential impact on socioeconomic assessment |
|---|---|---|
| Valuing health impacts | There was insufficient data to factor in the age of when affected workers are expected to be diagnosed with cancer. Assumptions were made based on average EU life expectancy in order to work out the years of life lost.<br><br>Willingness to pay (WTP) estimates to avoid getting cancer that were used in this study do not factor in the exact age of the person being diagnosed with cancer (although a distinction is made between children and those of working age) or their gender. Given a lack of WTP estimates it is therefore not clear if the valuation of WTP to avoid getting cancer used is an over or under estimate. | Unknown |
| Number of firms affected | The study has been reliant on Eurostat data for information about the number and size (based on employee numbers) of firms. Where available this is supplemented with data gathered through stakeholder consultation. This information is then used in conjunction with estimates of the proportion of workers affected (%) to estimate the number of enterprises affected.<br><br>It is recognised there are limitations to this approach, as it assumes that affected workers are distributed across the NACE code sector in the same way as the average distribution for the NACE code as a whole.<br><br>Given the uncertainties present, for a number of substances, a range in the number of firms affected by the introduction of a possible OEL is provided. | High |
| Method of compliance | For most substances, assumptions were made based on exposure data and existing literature concerning exposure control measures to determine how firms affected might comply, when there are multiple options available in order to comply with the possible OEL. In practice, the allocated split between each approach to compliance may differ. However, where data were available from industry or other sources on likely compliance techniques, these were assumed to be the means of achieving compliance. | Medium |
| Cost of compliance per firm | The assessments considered relatively generic types of control measures for many of the substance-specific analyses. Where possible, these estimates were based on stakeholder consultation and available literature. For example, the cost implications of introducing specified workplace controls (e.g. use of personal protective equipment and local exhaust ventilation systems) were assumed to be equal (per size of company) for each substance that these control measures were relevant for. In the absence of better data, this was deemed a proportionate approach | High |

| Area of uncertainty | Methodological approach | Potential impact on socioeconomic assessment |
|---|---|---|
| Marco-economic impacts | No macro-economic modelling has been undertaken. Instead, conclusions regarding possible macro-economic effects have been based largely on expert judgement and sector-level economic impacts. | Low |
| Presentation of costs | Results have mainly been generated at an EU level, with relatively little consideration of distributional effects for some parameters, although health benefits have generally been estimated for each member state. Given the large number of substances assessed, the potential for detailed consultation with industry and other stakeholders on the impacts of the possible OELs has been limited, meaning that there is a lack of sector-specific data in some cases. | Low/Medium |
| Substitution | For some substances, it has been possible to identify alternative substances or processes that are being used to deliver the same (or similar) final consumer product. There are however limited instances where it has been possible to estimate the impacts of substitution as a method of compliance. | Unknown |

# 4 REPORTS FOR PROCESS-GENERATED SUBSTANCES

## 4.1 RESPIRABLE CRYSTALLINE SILICA

Crystalline silica, inhaled in the form of quartz or cristobalite from occupational sources has been classified as a group 1 carcinogen (Carcinogenic to humans) by the International Agency for Research on Cancer (IARC). It is not currently included within the scope of the Carcinogens Directive. The key objectives of the present study are to identify the technical feasibility and the socioeconomic, health and environmental impacts of setting an OEL for respirable crystalline silica of 0.05, 0.1 or 0.2 mg/m$^3$.

Crystalline silica is abundant in rocks, sands and soils and exposure to respirable crystalline silica (RCS) occurs in many industries. Common exposure scenarios include earth moving (eg. mining, quarrying, tunnelling), crushing or grinding of silica containing material such as concrete, aggregate or mortar, the manufacture of glass and other non-metallic mineral products and use of sand as moulding media in foundries. We estimate that approximately 5 300 000 employees in the EU were potentially exposed to RCS in 2006. Over 4 million of these workers are in the construction industry.

The estimated overall weighted geometric mean exposure across all countries and industries is 0.07 mg/m$^3$ with a GSD of 5.2. The sectors with the highest estimated mean exposure (0.09 mg/m$^3$) are construction and the electricity, gas, steam and hot water supply industries. The percentages of workers currently exposed to concentrations greater than 0.05, 0.1 and 0.2 mg/m$^3$ in the construction sector are estimated as 63%, 48% and 32%, respectively. Mean exposure concentrations in most other sectors are less than 0.03 mg/m$^3$ with the exception of non-metallic mineral products (0.045 mg/m$^3$). The findings of an earlier IOM study indicate that exposure concentrations have fallen by about 7% per year over the past 20 – 30 years.

We estimate that in 2010 in the EU there will be about 6,870 deaths from lung cancer and 7,645 registrations that might be attributable to past exposure to RCS, which corresponds to about 2.45% of all lung cancer deaths amongst the exposed workers. If no specific actions are taken to reduce exposure to RCS, based on the assumption that current trends in employment and exposure are maintained until 2030 and remain steady thereafter, the predicted numbers of lung cancer deaths in 2060 attributable to RCS would be 5,685 with a predicted 72,091 years loss of life expectancy (YLLs) or 73,394 DALYS and 5,824 registrations. The lung cancers that might be attributable to RCS would have reduced to 1.265% of all lung cancer deaths in the exposed population.

The introduction of an OEL of 0.05 mg/m$^3$ would lead to reductions in the number of predicted lung cancer deaths and registrations in 2060 to 337 and 345 respectively corresponding to 4,151 YLLs or 4,347 DALYS. The introduction of an OEL of 0.1 mg/m$^3$ would lead to reductions in the number of predicted lung cancer deaths and registrations in 2060 to 818 and 838 respectively corresponding to 10,089 YLLs or 10,565 DALYS. The introduction of an OEL of 0.2 mg/m$^3$ would lead to reductions in the number of predicted lung cancer deaths and registrations in 2060 to 1,721 and 1,763 respectively corresponding to 21,217 YLLs or 22,217 DALYS. The number of "avoided" cancers associated with the introduction of an OEL of 0.05, 0.1 or 0.2 mg/m$^3$ would be 5,479, 4,985 and 4,061 respectively.

The total net health benefits accrued by 2069 from setting an OEL at 0.05 mg/m$^3$ are estimated to be between €27,858m and €74,096. The benefits associated with an OEL of 0.1 mg/m$^3$ are estimated to be between €25,522m and €67,921m and the benefits associated with an OEL of 0.2 mg/m$^3$ are estimated to be between €21,171m and €56,393m. As most of the benefits are not realised until after 2040, the level of discounting has a substantial impact on estimated benefits. The biggest benefits arise in the construction sector.

The estimated costs of compliance are thought to be lower or within the range of the estimated benefits, indicating that the benefits of introducing an OEL may outweigh the costs of compliance. The total costs of compliance over the period 2010-2069 with an OEL of 0.05mg/m$^3$ are estimated to be €34bn over the period 2010-2069. The greatest costs are predicted to fall on the construction sector (€17bn) given the the number of enterprises thought to be affected (around 485,000). The compliance costs for an OEL of 0.1mg/ m$^3$ are estimated to be substantially lower at €19bn over the same period. The greatest costs, €13 bn, would fall on the construction sector because of the large number of affected enterprises (around 370,000). The estimated costs of compliance with an OEL of 0.2 mg/m$^3$ are estimated to be €10bn with €8n falling on the construction sector (around 250,000 entreprises affected).

The majority of the companies that would be affected by the imposition of an OEL are small and the costs of meeting an OEL of 0.05 or 0.1 mg/m$^3$ may be very expensive for a large proportion of the affected sectors. This may lead to some company closures and, for industries for which relocation is possible, some relocation of activities to outside of the EU. The imposition of an OEL of 0.2 mg/m$^3$ would not be expected to have such a significant adverse impact on small businesses.

No significant environmental impacts would be anticipated following any increase in emissions of silica to ambient air as a result of improved workplace controls. The increased use of local exhaust ventilation (LEV), however, in order to achieve an OEL could lead to increased fossil fuel consumption and greenhouse emissions.

The main identified impacts of introducing an OEL at 0.2mg/m$^3$, 0.1mg/m$^3$ and 0.05mg/m$^3$ are summarised in the tables below, which are broken down by the main types of impacts (health, economic, social, macroeconomic and environmental).

**Table 4.1** Comparison of health impacts by scenario (Present Value – 2010 €m prices)

| Type of impact | Baseline Scenario: Costs | Baseline Scenario: Benefits | Introduce OEL=0.05mg/m$^3$: Costs | Introduce OEL=0.05mg/m$^3$: Benefits | Introduce OEL=0.1mg/m$^3$: Costs | Introduce OEL=0.1mg/m$^3$: Benefits | Introduce OEL=0.2mg/m$^3$: Costs | Introduce OEL=0.2mg/m$^3$: Benefits |
|---|---|---|---|---|---|---|---|---|
| Health | As set out in section 2.5, the health costs of cancer (lung) over the period 2010-70 are estimated to be:<br>- Females: €7bn to €13bn<br>- Males: €185bn to €481bn<br>- Total: €192bn to €493bn<br>This range takes into consideration tangible costs (e.g. lost income, lost output from reduced productivity, medical costs, life years lost) and intangible costs (e.g. emotional and physical suffering from having cancer). | It is assumed that exposures fall by 7% per year in the future continuing the historical trend in reduced exposure. Therefore there are expected to be some reduction in health costs going forward in the absence of further regulatory intervention. | None relative to the baseline scenario - there is expected to be a cost saving from avoided health care and reduced cost of illness due to reductions in cancer registrations. This has been estimated as a benefit. | Health benefits of the proposed OELs have been analysed at the Member State and industrial sector level. The results showed that the benefits of introducing an OEL in 2010 are most apparent to the construction sector from 2040 onwards. It was also found that the monetised benefits are likely to affect men more than women. The monetised benefits were estimated at €28-74bn over the period 2010-2070. | None - there is expected to be a cost saving from avoided health care and reduced cost of illness due to reductions in cancer registrations. This has been estimated as a benefit. | The monetised benefits were estimated at €26-68bn over the period 2010-2070. | None - there is expected to be a cost saving from avoided health care and reduced cost of illness due to reductions in cancer registrations. This has been estimated as a benefit. | The monetised benefits were estimated at €21-56bn over the period 2010-2070. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 4.2** Comparison of economic impacts by scenario (Present Value – 2010 €m prices)

| Type of impact | Baseline Scenario Costs | Baseline Scenario Benefits | Introduce OEL=0.05mg/m$^3$ Costs | Introduce OEL=0.05mg/m$^3$ Benefits | Introduce OEL=0.1mg/m$^3$ Costs | Introduce OEL=0.1mg/m$^3$ Benefits | Introduce OEL=0.2mg/m$^3$ Costs | Introduce OEL=0.2mg/m$^3$ Benefits |
|---|---|---|---|---|---|---|---|---|
| Economic | Exposure is estimated to decline by 7% per year and therefore firms will already be incurring costs for exposure control measures without intervention. However these costs may be incurred later over time without further intervention. | Ventilation system and RPE manufacturers and suppliers should benefit from increased demand over time for exposure control measures. | The expected costs of compliance are estimated to be around €34bn over the period 2010-2070. The greatest costs are predicted to fall on the construction sector (€17bn) given the number of enterprises thought to be affected (around 485,000). | Similar benefits to the baseline scenario | OEL 0.1mg/m$^3$ - The expected costs of compliance are estimated to be €19bn over the period 2010-2070. The greatest costs are predicted to fall on the construction sector (around €13bn) given the number of enterprises thought to be affected (around 370,000). | Similar benefits to the baseline scenario | The expected costs of compliance are estimated to be €10bn over the period 2010-2070. The greatest costs are predicted to fall on the construction sector (around €8bn) given the number of enterprises thought to be affected (around 250,000). | Similar benefits to the baseline scenario |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 4.3** Comparison of social impacts by scenario

| | Baseline Scenario | | Introduce OEL=0.05mg/m³ | | Introduce OEL=0.1mg/m³ | | Introduce OEL=0.2mg/m³ | |
|---|---|---|---|---|---|---|---|---|
| **Type of impact** | **Costs** | **Benefits** | **Costs** | **Benefits** | **Costs** | **Benefits** | **Costs** | **Benefits** |
| Social | Under the baseline there is estimated to be a greater number of firms installing and using closed systems and using RPE, PPE and wet cleaning rather than dry cleaning, These should not affect the skills required by workers and training costs are expected to be small. | Since the control measures such as closed system reduce risks of human exposure in a way that should not inhibit production, there should also be improvements in working conditions. The use of wet cleaning and RPE should also reduce risks of human exposure, although their use may potentially slow down operations or be perceived to do so. | Introducing an EU wide OEL of 0.05 is likely to have a much more significant impact on SMEs and there is a genuine risk that the costs of compliance could lead to firms closing down if the costs can not be passed through to consumer prices. . | | Introducing an EU wide OEL of $0.1 mg/m^3$ is likely to have a much more significant impact on SMEs and there is a genuine risk that the costs of compliance could lead to firms closing down if the costs can not be passed through to consumer prices. | | There are not expected to be significant change relative to the baseline scenario, although there is a possible risk that the costs of compliance could lead to SMEs closing down if the costs can not be passed through to consumer prices | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 4.4** Comparison of macro-economic impacts by scenario (Present Value – 2010 €m prices)

<table>
<tr><th rowspan="2">Type of impact</th><th colspan="2">Baseline Scenario</th><th colspan="2">Introduce OEL=0.05mg/m$^3$</th><th colspan="2">Introduce OEL=0.1mg/m$^3$</th><th colspan="2">Introduce OEL=0.2mg/m$^3$</th></tr>
<tr><th>Costs</th><th>Benefits</th><th>Costs</th><th>Benefits</th><th>Costs</th><th>Benefits</th><th>Costs</th><th>Benefits</th></tr>
<tr><td>Marco-economic</td><td colspan="2">There are not expected to be any noticeable macroeconomic impacts under the baseline scenario.</td><td colspan="2">Given the costs of compliance of around €34bn pounds over the period 2010-2070 there could possibly be a small macroeconomic impact over time. However this should be compared to the total value of goods and services in the manufacturing sector along which was €5trillion in 2006.</td><td colspan="4">Short term spending on risk management measures may be good for the economy as equipment manufacturers (e.g. ventilation systems, booths, bag balers), installers and others will benefit with money flowing through the economy, if the alternative is that profits are retained (by shareholders or the company and not spent e.g. on R&D, meaning the wider economy would not benefit from increased spending).<br>With fewer life years lost and cancer registrations, there should be a benefit to the economy through avoided loss of output and consumption in the future (post 2040), for example due to greater productivity from fewer sick days as well as greater consumption due to fewer premature deaths and greater taxes raised.<br>However this is not expected to have a significant macroeconomic impact given the costs of compliance (€8-13bn) are small compared to the total value of goods and services in the manufacturing sector along which was €5trillion in 2006.</td></tr>
</table>

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 4.5** Comparison of environmental impacts by scenario

| Type of impact | Baseline Scenario Costs | Baseline Scenario Benefits | Introduce OEL=0.05mg/m$^3$ Costs | Introduce OEL=0.05mg/m$^3$ Benefits | Introduce OEL=0.1mg/m$^3$ Costs | Introduce OEL=0.1mg/m$^3$ Benefits | Introduce OEL=0.2mg/m$^3$ Costs | Introduce OEL=0.2mg/m$^3$ Benefits |
|---|---|---|---|---|---|---|---|---|
| Environmental | Very little information is available regarding the ecotoxicitiy of respirable crystalline silica. No significant environmental effects are expected due to the chemical inertness and slow solubility of the substance. Crystalline silica is resistant to decomposition by weathering, biological activity and further oxidation. | | The achievement of the OEL via the measures described in this report may lead to more direct emissions of respirable crystalline silica to the environment (through ventilation), but probably not to an increased overall environmental burden and therefore would not increase the level of environmental harm. Having said this, a quantitative assessment of the amounts of respirable crystalline silica releases into the environment as a result of the measures that would be put in place to achieve the OEL has not been done for the purposes of this study.<br>The increased used of LEV may lead to additional demand for electricity. This, in turn, may result in additional GHG emissions. A quantitative assessment of the additional energy use has not been undertaken for the purposes of this study. | | | | | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

## 4.2 RUBBER PROCESS FUME AND DUST

Working in the rubber manufacturing industry has been classified as a group 1 carcinogen (Carcinogenic to humans) by the International Agency for Research on Cancer (IARC). Airborne rubber dust and fume comprise complex mixtures of chemicals and in the absence of a clear understanding of the specific chemicals that may increase the risk of cancer these measures have been used as pragmatic markers of exposure as part of a strategy to control occupational cancer risks in the industry. Rubber dust and fume are not classified under the EU classification and labelling legislation and are therefore not currently within the scope of the EU Carcinogens Directive. There are no occupational exposure limits (OELs) for rubber dust and fume 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 OELs of 6 mg/m$^3$ for rubber process dust and 0.6 mg/m$^3$ for rubber fume.

The use of rubber is widespread. Tyres and tubes are the largest consumers of rubber (56%) and the remaining 44% is taken up by the general rubber goods (GRG) sector. There are more about 8,000 companies involved in the European rubber industry, employing approximately 370,000 individuals. The turnover of these companies is more than €49 billion with exports of more than €6 billion. GRG companies are mostly SMEs whilst tyre companies tend to be large in size. There are only eleven companies that produce tyres in the EU and in 2006 around 240 million units of tyres were produced, which represents 22% of world production. Seventy-five percent of the goods produced in the GRG industry are used in the automobile sector.

From data provide by the industry we have assumed that workers in mixing, component preparation and curing may be exposed to rubber fume (23 – 47% of employees). Exposure to rubber process dust occurs during mixing, but not during component preparation or curing, and we have assumed that 9% – 16 % of employees are exposed to rubber dust. However, in calculating the health impact we have selected the upper figures, i.e. 56,800 workers exposed to rubber dust and 172,300 to rubber fume.

We estimate the geometric mean (GM) exposure to rubber process dust across all countries is 1.14 mg/m$^3$ with a geometric standard deviation (GSD) of 4.7. It is estimated that 14% of exposed workers are currently exposed to dust levels above 6 mg/m$^3$. The estimated GM exposure to rubber fume is 0.37 mg/m$^3$ with a GSD of 4.00. Thirty seven percent of exposed workers are estimated to be currently exposed above 0.6 mg/m$^3$. Exposure levels were estimated to have declined by between 0.7% and 7.4% per annum for process dust, depending on the country where the plants were located. For rubber fume an average decline of 3% per annum was estimated for the GRG sector and 0.9% per annum in tyre production.

Workers in the rubber industry have an increased risk from leukaemia and cancers of the larynx, lung and stomach. The risk from bladder cancer due to aromatic amines identified in workers before the 1950’s, has essentially disappeared due to the elimination of the relevant substances from the process. There is a large amount of epidemiological literature for this industry, and for the health impact we have chosen to use data from a meta-analysis carried out in 2006 involving 36 published studies of 31 different cohort groups. Separate risk estimates have been used for workers producing tyres and for GRG, the latter being the overall cancer site-specific risk estimates. For tyre manufacture the relative risks (RRs) were: leukaemia 1.03; cancer of the larynx 1.01; lung cancer 1; stomach cancer 1. The identified risk estimates for all other rubber workers were: leukaemia 1.70; cancer of the larynx 1.19; lung cancer 1.05; stomach cancer 1. As the risk estimates for stomach cancer were both judged to be 1 this cancer site has been excluded from the assessment.

Health and economic impacts were estimated separately for rubber dust and rubber fume, but these data cannot be added together since the exposures are not independent and to do so may result in an overstatement of any benefits arising from the interventions. Deaths and registrations attributable to rubber process dust slowly decrease for all three types of cancer; for lung from 7 registrations in 2010 to 2 in 2060; from 3 registrations to 1 for larynx and from 7 to 4 registrations for leukaemia. The decrease is a consequence of the assumed decline in exposure up to 2020. The attributable fraction in 2010, i.e. the proportion of all cancers of that type in the exposed workers that has been attributed to the exposure, ranges from 0.0093% for laryngeal cancer to 0.012% for leukaemia; in 2060 the corresponding figures are 0.00244% to 0.005%. In 2010 the estimated DALYs were highest for laryngeal cancer (380 years) and lowest for leukaemia (68 years). By 2060 these estimates range form 131 DALYs for laryngeal cancer to 26 years for lung cancer.

The attributable cancer deaths and registrations for rubber fume are higher than for rubber process dust, although as we noted above it is not possible to add these health impacts since the exposures are not independent. In 2010 the estimated number of registrations and deaths from lung cancer were 20 and 18, for larynx cancer 10 and 2 and for leukaemia 31 and 19. The corresponding data for the decade starting 2060 are 16 registrations and 16 deaths per annum, 8 and 2 per annum and 31 and 25 per annum, for lung, larynx and leukaemia, respectively. Estimated DALYs in 2010 were highest for cancer of the larynx (1,152 years) and lowest for leukaemia (292 years). By the decade starting 2060 the annual DALYs ranged from 866 years for larynx to 211 years for lung cancer.

Total estimated health costs associated with inaction for the period up to 2069 range from €721m to €859m for rubber process dust and from €2,961m to €3,930m for rubber fume. Note these estimates are not additive.

Further reduction in exposure to rubber dust and fume could be achieved by a combination of engineering, technical and operational control measures, coupled with appropriate training and instruction for workers.

Introducing an OEL of 6 mg/m$^3$ for rubber process dust has a small health impact; by 2060 there is only one cancer that is estimated to be avoided with this measure. The effect of introducing a limit of 0.6 mg/m$^3$ for rubber fume is larger with 47 cancers being avoided each year (15 lung, 6 larynx and 26 leukaemia). The total number of attributable cancer registrations and deaths estimated to occur in 2060 with an OEL for rubber fume are: one registration and one death from lung cancer, two registrations and no deaths from laryngeal cancer and six registrations and five deaths from leukaemia. The monetised health benefits from introducing an OEL for rubber process dust is between €24m and €46m and between €579m and 1,207m for an OEL for rubber fume. Note these estimates are not additive.

Total compliance costs for the period from 2010 to 2069 are estimated to range from €55m to €275m for the rubber process dust OEL and from €466m to €3,212m for the rubber fume OEL. There are no significant social or macro-economic costs associated with introducing an OEL for rubber dust given that only 9-16% of the firms are thought to require any further compliance measures. It is estimated that a significant proportion of enterprises (54-100%) would require further action to comply with an EU-wide OEL of 0.6mg/m$^3$ for rubber fumes. Of the affected firms, 70% are thought to require ventilation systems. Given the upfront costs of ventilation systems, the affordability of ventilation systems may affect the long term viability of some SMEs in the market.

There are no significant environmental impacts foreseen from the introduction of an OEL for either rubber process dust or rubber fume.

The rubber manufacturing industry has an active programme to identify carcinogenic compounds in rubber dust and fume and to reduce or eliminate their presence in the mix. This was an effective approach to eliminate bladder carcinogens and it has continued to be applied. It has been difficult to judge whether introducing an OEL for rubber dust or fume would divert resource away from such activities, although this is a possibility.

The main identified impacts of introducing an OEL of 6 mg/m$^3$ for rubber process dust and 0.6 mg/m$^3$ rubber fume are summarised in the tables below, which are broken down by the main types of impacts (health, economic, social, macroeconomic and environmental).

**Table 4.6** Comparison of health impacts by scenario (Present Value – 2010 €m prices)

| Baseline Scenario | | Intervention scenario | |
|---|---|---|---|
| **Health Costs** | **Health Benefits** | **Health Costs** | **Health Benefits** |
| **Rubber Dust** | | Assumes full compliance for OEL = 6 mg/mg[3] | |
| As set out in section 2.5, the health costs of cancer (leukaemia and cancers of the larynx and lung in relation to rubber dust) over the period 2010-70 are estimated to be:<br>- Females: €129m to €129m<br>- Males: €592m to €729m<br>- Total: €721m to €857m<br>This range takes into consideration tangible costs (e.g. lost income, lost output from reduced productivity, medical costs, life years lost) and intangible costs (e.g. emotional and physical suffering from having cancer). | It is estimated that exposures to rubber dust decline by between 0.7% and 7.4% per annum.<br>Therefore there is expected to be some reduction in health costs going forward in the absence of further regulatory intervention. | There is expected to be a cost saving from avoided health care and reduced cost of illness due to reductions in cancer registrations. This has been estimated as a benefit. | Health benefits of the possible OEL have been analysed at the Member State and industrial sector level. The results showed that the benefits of introducing an OEL in 2010 are most apparent to the manufacture of other rubber products sector. It was also found that the monetised benefits are likely to affect men more than women.<br>The monetised benefits over 2010-2070 were estimated as:<br>- Females: €4m to €9m<br>- Males: €20m to €38m<br>- Totals: €24m to €46m |
| **Rubber Fumes** | | Assumes full compliance for OEL = 0.6 mg/mg[3] | |
| As set out in section 2.5, the health costs of cancer (leukaemia and cancers of the larynx and lung in relation to rubber fumes) over the period 2010-70 are estimated to be:<br>- Females: €553m to €675m<br>- Males: €2.4bn to €3.3bn<br>- Total: €3bn to €3.9bn<br>This range takes into consideration tangible costs (e.g. lost income, lost output from reduced productivity, medical costs, life years lost) and intangible costs (e.g. emotional and physical suffering from having cancer). | It is assumed that exposures to rubber fumes will fall by 3% per year in the future in the GRG sector and 0.9% per annum in tyre production.<br>Therefore there is expected to be some reduction in health costs going forward in the absence of further regulatory intervention. | There is expected to be a cost saving from avoided health care and reduced cost of illness due to reductions in cancer registrations. This has been estimated as a benefit. | Health benefits of the possible OEL have been analysed at the Member State and industrial sector level. The results showed that the benefits of introducing an OEL in 2010 are most apparent to the manufacture of other products sector. It was also found that the monetised benefits are likely to affect men more than women.<br>The monetised benefits over 2010-2070 were estimated as:<br>- Females: €119m to 251m<br>- Males: €460m to 956m<br>- Totals: €579m to 1.2bn |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 4.7** Comparison of economic impacts by scenario (Present Value – 2010 €m prices)

| Baseline Scenario | | Intervention scenario | |
|---|---|---|---|
| **Economic Costs** | **Economic Benefits** | **Economic Costs** | **Economic Benefits** |
| **Rubber Dust** | | Assumes full compliance for OEL = 6 mg/mg$^3$ | |
| There are expected to be costs to firms exposed to rubber dust to put into place improved training and cleaning measures 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 for the manufacture of rubber products industry.<br>It is estimated that between 600 and 1,100 enterprises could require some form of additional control measure to meet the possible OEL. The remainder of enterprise are assumed to already be meeting the possible OEL under the baseline scenario and therefore would require no further action.<br>It is assumed that the majority of those enterprises that do not currently comply would need to implement relatively low-cost measures to reduce exposure levels to meet this OEL. These costs (€0.5-2k per enterprise) are not considered to be significant. The remainder (20% of affected firms) may need to invest in new ventilation systems. The up-front capital cost of a ventilation system is estimated to be in the region of €42k - 252k per enterprise.<br>The total costs of compliance over the period 2010-2069 (NPV) are estimated at between €55m to €275 m.<br>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 OEL limits. |

| Baseline Scenario | | Intervention scenario | |
|---|---|---|---|
| **Economic Costs** | **Economic Benefits** | **Economic Costs** | **Economic Benefits** |
| **Rubber Fumes** | | Assumes full compliance for OEL = 0.6 mg/mg$^3$ | |
| There are expected to be costs to firms exposed to rubber fumes to put into place improved training and cleaning measures 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 for the manufacture of rubber products industry.<br>It is estimated that between 3,800 and 7,000 enterprises would require some form of additional control measure to meet the possible OEL. The remainder of enterprises are assumed to already be meeting the possible OEL under the baseline scenario and therefore would require no further action.<br>It is assumed that the majority of those enterprises that do not currently (~70%) comply would need to invest in new ventilation systems. The up-front capital cost of a ventilation system is estimated to be in the region of €42k - 252k per enterprise.<br>The total costs of compliance over the period 2010-2069 (NPV) are estimated at between €470m to €3.2bn.<br>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 OEL limits. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 4.8** Comparison of social impacts by scenario

| Baseline Scenario | | Intervention scenario | |
|---|---|---|---|
| Social Costs | Social Benefits | Social Costs | Social Benefits |
| **Rubber Dust** | | Assumes full compliance for OEL = 6 mg/mg$^3$ | |
| There are not expected to be any significant social impacts under the baseline scenario at an EU level. | | It is estimated that only 9-16% of the firms might be affected by the introduction of an OEL at 6mg/m$^3$ and therefore the majority of the sector will not require further exposure control measures to meet the OEL. Therefore there is not expected to be any significant social and labour market impacts. | |
| **Rubber Fumes** | | Assumes full compliance for OEL = 0.6 mg/mg$^3$ | |
| There are not expected to be any significant social impacts under the baseline scenario at an EU level. | | It is estimated that a significant proportion of enterprises (54-100%) would require further action to comply with an EU-wide OEL of 0.6mg/m$^3$. Of the affected firms, 70% are thought to require ventilation systems. Given the upfront costs of ventilation systems, the affordability of ventilation systems may affect the long term viability of some SMEs in the market. | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 4.9** Comparison of macro-economic impacts by scenario

| Baseline Scenario | | Intervention scenario | |
|---|---|---|---|
| Macro-economic Costs | Macro-economic Benefits | Macro-economic Costs | Macro-economic Benefits |
| **Rubber Dust** | | Assumes full compliance for OEL = 6 mg/mg$^3$ | |
| There are not expected to be any significant 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. | |
| **Rubber Fumes** | | Assumes full compliance for OEL = 0.6 mg/mg$^3$ | |
| There are not expected to be any significant 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. | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 4.10** Comparison of environmental impacts by scenario

| Baseline Scenario | | Intervention scenario | |
|---|---|---|---|
| **Environmental Costs** | **Environmental Benefits** | **Environmental Costs** | **Environmental Benefits** |
| **Rubber Dust** | | Assumes full compliance for OEL = 6 mg/mg$^3$ | |
| There are not expected to be any significant changes in environmental impacts. | | Minimal – it is expected that the imposition of measures would not cause additional environmental impacts. | It is not expected that the measures for human health would lead to any additional environmental benefit. |
| **Rubber Fumes** | | Assumes full compliance for OEL = 0.6 mg/mg$^3$ | |
| There are not expected to be any significant macroeconomic impacts under the baseline scenario. | | Minimal – it is expected that the imposition of measures would not cause additional environmental impacts. | It is not expected that the measures for human health would lead to any additional environmental benefit. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

## 4.3 DIESEL ENGINE EXHAUST EMISSIONS

Diesel engine exhaust (DEE) has been classified by the International Agency for Research on Cancer (IARC) as probably carcinogenic to humans based on animal toxicity and epidemiological data (IARC category 2a). The two cancers most clearly linked to DEE exposure are lung and bladder cancer. There is no occupational exposure limit (OEL) for DEE specified in the Directive. DEE is not classified under the EU classification and labelling legislation and it is therefore not currently within the scope of the EU Carcinogens 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 100 $\mu g/m^3$ for DEE measured as elemental carbon (EC).

DEE arises from the combustion of diesel fuel in compression ignition engines. The sources of occupational exposure to DEE include motor vehicles, locomotives and diesel powered heavy equipment such as tractors and forklifts. Workers may either be exposed because they operate equipment that has a diesel engine or because their work takes them into environments where diesel engines are operating. DEE makes up an important part of the particulate air pollution found in European cities and towns.

Emissions from diesel engines are a complex mixture of gasses, liquids and solids. IARC identified that the carcinogenic components of DEE are probably associated with the particulate emissions and it is common to use EC, which makes up a significant fraction of these emissions, as a marker of exposure.

It is estimated that there are 3.6 million workers in the EU potentially exposed to DEE above background levels. The overall distribution of exposure levels across all industries in the EU gave an estimated geometric mean of 13 $\mu g/m^3$ with a geometric standard deviation of 2.7. The percentage of workers who may be exposed above the typical OEL (100 $\mu g/m^3$) was estimated to be between 0.1% and 3% in sectors other than mining, and between 10% and 54% in underground mining.

Over about the last 20 years EU legislation has required engine manufacturers to reduce emissions from vehicles and, for example, the permitted particulate emissions from trucks and lorries will decreased by a factor of more than 50 times between 1992 and 2013. Despite the increase in the proportion of diesel vehicles in the EU the exposure to DEE has probably been decreasing (we assume 7.4% decline per annum).

From a review of the epidemiological literature carried out in 2001 a relative risk (RR) of 1.24 was identified for bladder cancer incidence amongst high exposed work groups and 1.03 for low exposed workers. A pooled RR estimate for lung cancer was identified for high exposed workers from a review where the data were adjusted for smoking habits (RR=1.47) and for low exposed workers of 1.09. The RR for background-exposed workers was set to 1.

The number of people in the EU that are estimated to ever be occupationally exposed to DEE is projected to increase from about 12 million in 2010 to almost 20 million in 2060. This trend, in addition to the increased number of cancers that are expected to occur in the general population because of increasing life expectancy tends to reduce the health impact of reductions in the level of exposure. In 2010 it is estimated that in the EU there will be 4,698 incident cases of lung cancer (4,242 deaths) and 1,031 cases of bladder cancer (314 deaths) from past exposure to DEE. Over the following fifty years the annual number of attributable cases of lung cancer is estimated to decrease to 2,643 (2,594 deaths) and bladder cancer to 415 cases (168 deaths). Annual DALYs for lung cancer decrease from 67,064 to 33,766 years and from 4,704 to 2,023 years for bladder cancer over the period to 2060. Total estimated health costs associated with inaction for the period up to 2069 range from €99,084m to €258,000m.

Current exposures in the EU are judged to be mostly below 100 µg/m$^3$ and so there are no predicted health benefits and no important costs associated with compliance with the suggested OEL (between €25m and €249m). There are also no social or macro-economic costs associated with introducing an OEL at this level.

To have an effect on the expected number of lung and bladder cancers the OEL would need to be much lower than is typically set in the EU (i.e. less than 100 µg/m$^3$) and the approach to controlling exposures more extensive. It would probably be necessary to make greater use of air-conditioned cabs in vehicles or ventilation in workplaces, and to consider the use of personal respiratory protection where other means of control were impracticable or uneconomic.

It is likely that there would be a positive health impact from introducing an OEL of 100 µg/m$^3$ in the mining sector, although it has not been possible of us to quantify the effect from the present analysis.

There are no significant environmental impacts foreseen from introducing an OEL at 100 µg/m$^3$.

The main identified impacts of introducing an OEL of 100 $\mu$g/m$^3$ for DEE are summarised in the tables below, which are broken down by the main types of impacts (health, economic, social, macroeconomic and environmental).

**Table 4.11** Comparison of health impacts by scenario (Present Value – 2010 €m prices)

| Baseline Scenario | | Introduce OEL = 100 µg/m$^3$ | |
|---|---|---|---|
| **Health Costs** | **Health Benefits** | **Health Costs** | **Health Benefits** |
| As set out in section 2.5, the health costs of cancer (bladder and lung) over the period 2010-70 are estimated to be:<br>- Females: €7bn to €14bn<br>- Males: €91bn to €244bn<br>- Total: €99bn to €258bn<br>This range takes into consideration tangible costs (e.g. lost income, lost output from reduced productivity, medical costs, life years lost) and intangible costs (e.g. emotional and physical suffering from having cancer). | It is assumed that exposures fall by 7.9% per year in the future, continuing the historical trend in reduced exposure. Therefore there is expected to be some reduction in health costs going forward in the absence of further regulatory intervention | None<br><br>There are not expected to be any costs in addition to those being incurred under the baseline scenario | None<br><br>Only 2% of workers exposed to DEE (to some level) are estimated to be exposed above the most commonly adopted OEL of 100 µg/m$^3$. Factoring in a declining exposure under the baseline, there is not expected to be any further reduction in cancer registrations or life years lost and therefore no cost saving e.g. from avoided health care and reduced cost of illness. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 4.12** Comparison of economic impacts by scenario (Present Value – 2010 €m prices)

| Baseline Scenario | | Introduction OEL = 100 µg/m³ | |
|---|---|---|---|
| **Economic Costs** | **Economic Benefits** | **Economic Costs** | **Economic Benefits** |
| There are expected to be costs to sectors exposed to DEE due to expected further spending on control measures to reduce exposure.<br>These costs might relate to improving working practice or installation and use of engineering control measures (e.g. filters, closed systems, improved ventilation). | - | It is estimated that around 10,600 enterprises could be affected by the introduction of an EU-wide OEL of 100 µg/m³. This might mean these enterprises requiring some form of control measures earlier than planned for without intervention.<br>If compliance with the OEL can be achieved for just improving existing work practices, then the annual cost of compliance per enterprise (€100-1000) is not thought to be prohibitive. This is approximately €11-249m for all enterprises over the period 2010-2070.<br>However, if specific engineering control measures are required then the cost of compliance is likely to be higher which may be of more concern to SMEs. However it is not known to what extent these costs can be passed on to customers through the service they provide. | Having an EU-wide OEL would avoid any EU competitive distortions between EU Member States if they adopted different national limits in the future. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 4.13** Comparison of social impacts by scenario

| Baseline Scenario | | Introduction OEL = 100 µg/m³ | |
|---|---|---|---|
| **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. 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. | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 4.14** Comparison of macro-economic impacts by scenario

| Baseline Scenario | | Introduction OEL = 100 µg/m$^3$ | |
|---|---|---|---|
| **Marco-economic Costs** | **Marco-economic Benefits** | **Marco-economic Costs** | **Marco-economic Benefits** |
| There are not expected to be any noticeable macroeconomic impacts under the baseline scenario. | | Since there are not expected to be any significant economic or health impacts, there is not expected to be any significant change in macroeconomic impacts relative to the baseline scenario from introducing an EU-wide OEL. | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 4.15** Comparison of environmental impacts by scenario

| Baseline Scenario | | Introduction OEL = 100 µg/m$^3$ | |
|---|---|---|---|
| **Environmental Costs** | **Environmental Benefits** | **Environmental Costs** | **Environmental Benefits** |
| Only 2% of workers exposed to DEE (to some level) are estimated to be exposed above the most commonly adopted OEL of 100 µg/m$^3$ and therefore most workplaces are unlikely to be affected/require further changes to their existing working practice. Therefore there are not estimated to be any significant changes in environmental impacts. | | Where there is a need to reduce exposure to DEE earlier than otherwise might have been planned, this may have environmental benefits.<br>Improvements to engines and proper maintenance and use of diesel particulate filters will have environmental benefits through reductions in emissions of PM in particular. Additionally, improvements in working practices (e.g. reduced exposure to the general public through not having engines running when not in use) should also lead to reduced emissions to the environment (air). | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

## 4.4 MINERAL OILS AS USED ENGINE OIL

Untreated or mildly treated mineral oils are classified by the International Agency for Research on Cancer as carcinogenic to humans (IARC category 1). Mineral oils as used engine oils are not specifically classified, although there is evidence that they, like untreated oils, can cause non-melanoma skin cancer, probably as a result of contamination with PAHs. Used engine oils are not classified in Europe under the classification and labelling regulations and so they are not currently within the scope of the Directive.

The main potential hazardous exposure arises from skin contact and so it is inappropriate to consider setting an inhalation Occupational Exposure Limit. A biological monitoring limit value is also considered impractical and inappropriate. We therefore consider that the best approach to control the risk from used engine oils would be through the application of best practice in preventative work practices and personal protective equipment.

Non-melanoma skin cancer is the commonest malignancy in Europe with perhaps half a million cases occurring each year, although reliable statistics are not available. Incidence is increasing, partly because of the ageing population and partly because of changing exposure to sunlight, which is the main environmental cause. Treatment is relatively straightforward and there is a very high survival rate (about 99%). The health costs are therefore lower than for other types of cancer.

We judge that exposure is most likely amongst people employed in motor vehicle maintenance and recycling of non-metal scrap, although we do not have reliable information about the prevalence of exposure. It is estimated that at most there could be 1 million people exposed to used engine oil in the EU.  There is no information about the magnitude of exposure or about how this may have changed in recent years.

The predicted number of deaths in 2010 from past occupational exposure to used engine oil is 7, which is based on about 916 incident cases. There are judged to be an associated 93 DALYs and 71 YLLs. Over the period until 2060 the annual incidence is expected to rise to about 3,554 cases and 36 deaths as a consequence of demographic changes and increased employment in the relevant industry sectors. DALYs and YLLs increase correspondingly. These data are likely to overestimate the health impact because we have had to used data on employment within the relevant sectors rather than exposure to used engine oil and because we have been unable to take account of improvements in controls in recent years.

The health costs over the next 60 years, if no action is taken, are estimated to be between about €445m and €2,815m. Possible policy interventions focus on ensuring best practice techniques are used in handling used engine oil. In our view the appropriate changes to the Directive would need to focus on suitable protective clothing and protective gloves, training and supervision to ensure exposure was minimised, encouragement of good personal hygiene and appropriate health surveillance to ensure early detection of NMSC.  In our analysis we assumed that between 10% and 40% of employees are currently being exposed to used engine oil in a way that does not conform with best practice; involving between about 20,000 and 78,000 enterprises in Europe. The total estimated cost of introducing best practice over the next 60 years is judged to be between about €46m and €920m.

It are not expected that there will be any important social, macro-economic or environmental impacts.

We consider that it would be prudent to undertake measurements of dermal exposure to used engine oil to assess the extent of exposure, both in situations that are poorly controlled and perhaps representative of historic exposure, and in situations where good practice is in place.  These data would help inform any regulatory action.

The main identified impacts control measures for ‘best practice’ for mineral oils used as engine oil are summarised in the tables below, which are broken down by the main types of impacts (health, economic, social, macroeconomic and environmental).

**Table 4.16** Comparison of health impacts by scenario (Present Value – 2010 €m prices)

| Baseline Scenario | | Introduce 'best practice' control measures | |
|---|---|---|---|
| **Health Costs** | **Health Benefits** | **Health Costs** | **Health Benefits** |
| As set out in section 2.5, the health costs of cancer (NMSC) over the period 2010-70 are estimated to be:<br>- Females: €140m to €900m<br>- Males: €300m to €2bn<br>- Total: €450m to €3bn<br>This range takes into consideration tangible costs (e.g. lost income, lost output from reduced productivity, medical costs, life years lost) and intangible costs (e.g. emotional and physical suffering from having cancer). | There are note expected to be any health benefits over time as it is assumed that the number of cancer registrations increase over time. | None - there is expected to be a cost saving from avoided health care and reduced cost of illness due to reductions in cancer registrations.<br><br>This has been estimated as a benefit. | Whilst full compliance with best practice is unlikely to significantly alter health costs under the baseline due to past exposure (e.g. costs up to 2030-2040), compliance with good practice could avoid the health costs associated with future exposure.<br><br>Therefore a tentative and broad estimate of health benefits could be the total avoided costs associated with getting cancer post 2040 (i.e. avoided future exposure), which is estimated to be around €0.3-1.6bn. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 4.17** Comparison of economic impacts by scenario (Present Value – 2010 €m prices)

| Baseline Scenario | | Introduce 'best practice' control measures | |
|---|---|---|---|
| **Economic Costs** | **Economic Benefits** | **Economic Costs** | **Economic Benefits** |
| In the analysis presented, a static baseline is assumed. Therefore, no firms will incur costs to reduce exposure under the baseline scenario. | - | It is estimated that between 20,000 and 80,000 enterprises could be affected.<br>There are expected to be relatively low costs for enterprises to implement improved training, housekeeping, PPE , measures that are already considered to be 'best practice'.<br>There may be some initial costs associated with familiarisation with the new requirements but in general it is assumed that costs will range between €100-500 per year per enterprise (including costs of equipment and the cost of time spent on e.g. additional cleaning and administration).<br>The total compliance cost over the assessment period is estimated to be between €2 and €40 million per year which is estimated to be around €50 to €900m in total over the period 2010-70 (in 2010 prices and discounted using a 4% discount rate). | Having more consistent EU-wide controls should remove any EU competitive distortions between EU Member States with different limits. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 4.18** Comparison of social impacts by scenario

| Baseline Scenario | | Introduce 'best practice' control measures | |
|---|---|---|---|
| **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. | | Impacts are expected to be similar to the baseline. It is estimated that between 20,000 and 80,000 enterprises would need to make changes to workplace best practice. | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 4.19** Comparison of macro-economic impacts by scenario

| Baseline Scenario | | Introduce 'best practice' control measures | |
|---|---|---|---|
| **Marco-economic Costs** | **Marco-economic Benefits** | **Marco-economic Costs** | **Marco-economic Benefits** |
| There are not expected to be any noticeable macroeconomic impacts under the baseline scenario. | | Negligible - since no additional engineering controls are expected to be required, there are not expected to be any significant macroeconomic impacts relative to the baseline scenario from introducing EU-wide controls to comply with the Directive. | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 4.20** Comparison of environmental impacts by scenario

| **Baseline Scenario** | | **Introduce 'best practice' control measures** | |
|---|---|---|---|
| **Environmental Costs** | **Environmental Benefits** | **Environmental Costs** | **Environmental Benefits** |
| No significant change expected. | | However, since the proposed control measures to limit worker exposure do not generally also target releases to the environment, there is not expected to be any *significant* change in environmental impacts relative to the baseline scenario. | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

# 5 REPORTS FOR SUBSTANCES ALREADY INCLUDED IN ANNEX III OF THE DIRECTIVE

## 5.1 HARDWOOD DUST

Hardwood dust can cause sinonasal cancer (SNC) and probably also causes nasopharyngeal cancer (NPC). These are relatively rare cancers that may also be caused by factors other than inhaling wood dust. In addition, hardwood dust may cause non-malignant respiratory health problems, including occupational asthma.

Hardwood dust is specifically included within the EU Carcinogens Directive (2004/37/EC) as an occupational carcinogen with an Occupational Exposure Limit (OEL) of 5 mg/m$^3$. Exposure to hardwood dust has been classified as group 1 (Carcinogenic to humans) and the activity of carpentry and joinery as group 2B (Possibly carcinogenic to humans) according to the IARC monographs.

This report considers the likely health, socioeconomic and environmental impacts associated with possible changes to the EU Carcinogens Directive, in particular the possible introduction of a lower occupational exposure limit (OEL) of either 3 mg/m$^3$ or 1 mg/m$^3$.

In the EU there are over 3 million people working with hardwood in over 340,000 companies, mainly small and medium sized enterprises (SMEs). Total production value is around €230 billion per annum. While all EU countries have people working with hardwood, more than half of people exposed work in Germany, Italy, France, Spain and Poland. In the past a substantial part of exposures were above 5 mg/m$^3$, which is the current OEL in the Carcinogens Directive, but we judge that average levels have been falling steadily at about 8% per annum. Currently, average exposure in each EU country is less than 1 mg/m$^3$ with about 90% or more of exposures generally below 3 mg/m$^3$. The highest estimated geometric mean exposure levels were for building and repairing of ships and boats.

We estimate that in the EU in 2010 there will be about 90 deaths from nasopharyngeal cancer and 73 deaths for sinonasal cancer that could be attributed to past exposure to hardwood dust. If no action is taken then by 2060 there will be about 6 cancer deaths from hardwood dust exposure, which is a consequence of the decrease in hardwood dust exposure over the last 40 or so years. The health costs associated with no action up to 2069 are between €3.6bn and €16bn, which fall mainly on Germany, France, Italy, Spain and the United Kingdom.

It is considered that EU industry is already compliant with an exposure limit of 3 mg/m$^3$. In 2060 it is estimated there will be eight deaths from NPC and SNC if an OEL of 3 mg/m$^3$ was introduced and two deaths if a 1mg/m$^3$ OEL was introduced.

Total net health benefits of an OEL at 3mg/m$^3$ are estimated at €9m - €44m, with no significant change to social, economic, macro-economic and environmental impacts. Introducing an OEL of 1mg/m$^3$ would incur compliance costs between €3.8bn and €8.6bn, which is much greater than the avoided future costs to the health system and cancer sufferers (€51m - €252m). We consider that the imposition of this lower OEL would disproportionately affect SMEs and may either force these organisations to use other materials or force them out of business.

The main identified impacts of introducing an OEL of 3 mg/m$^3$ and 1 mg/m$^3$ for hardwood dust are summarised in Tables 5.1 to 5.5, which are broken down by the main types of impacts (health, economic, social, macroeconomic and environmental).

## 5.2 VINYL CHLORIDE

Workplace exposure to vinyl chloride monomer (VCM) is associated with increased risks of the usually rare form of liver cancer, angiosarcoma (ASL) and possible increased risks of hepatocellular carcinomas (HCC). VCM has been classified as a group 1 carcinogen (Carcinogenic to humans) carcinogen by IARC and as Cat 1 carcinogens in the EU under the classification and labelling legislation. This report considers the likely health, socioeconomic and environmental impacts associated with possible changes to the Carcinogens Directive, in particular, replacing the existing 3 ppm EU-wide OEL for VCM with a more stringent OEL of 1 ppm or 2 ppm.

The main use of VCM is in the manufacture of PVC and most production plants are co-located with PVC batch polymerisation plants. In 2007, 7.2 million tons of VCM were produced in the EU and Norway and used to manufacture 7.2 million tons of PVC in batch polymerisation plants. There was an increase in PVC production (and therefore also VCM production) at a rate of approximately 1% per year from 2000-2007. This trend faltered during the 2008 – 2009 financial crisis but is expected to resume as the EU economy recovers.

We estimate that in 2006 about 19,000 workers in the EU were exposed to VCM with most exposed workers being involved in chemicals manufacture and a smaller proportion of exposed workers being involved in the production of plastic and rubber goods. The estimated geometric mean of current exposure levels is 0.14 mg/m$^3$ (0.05 ppm) and it is believed that exposures have fallen substantially since the 1970s when reported concentrations frequently exceeded 50 mg/m$^3$ (19.6 ppm). At the estimated current exposure levels approximately 5% of workers in the EU are exposed above 3 ppm.

We estimate that in 2010 in the EU there will be about 14 deaths from liver cancer and a similar number of registrations that might be attributable to past exposure to VCM, which corresponds to about 0.03% of all liver cancer deaths amongst the exposed workers. If no specific actions are taken to reduce exposure to VCM, based on the assumption that current employment and exposure levels are maintained, the predicted numbers of liver cancer deaths in 2060 attributable to VCM would be 0 with a predicted 3 years loss of life expectancy (YLLs/DALYs). The introduction of an OEL of I or 2 ppm would lead to reductions in the YLLs/DALYs to 0 or 2 respectively. There is no net health benefit estimated to occur from setting an OEL at 2 ppm. The benefits associated with an OEL of 1 ppm are estimated between €1m and €3m.

There is already an EU-wide OEL in place for VCM of 3 ppm and a number of Member States have set national OELs at 1 or 2 ppm. The 90th percentile of exposure in most plants is already below 2ppm, whereas the 90th percentile of exposure is only below 1 ppm in about a quarter of plants for which data are available. Consultation with the industry association (ECVM) indicated that plants located in countries that have recently joined the EU would require the most adaptation in order to comply with an OEL of 1 ppm. The main additional risk management measures required are upgrades to manufacturing equipment and increased maintenance in order to reduce leaks. The main costs associated with these measures arise from lost production time.

It is judged that under the baseline scenario, firms are already moving towards complying with the 1 ppm OEL. The cost of compliance with an OEL of 2ppm may be in the region of €15m to €30m over the period 2010-69 if there are annual production shutdowns for several days for maintenance. If it is assumed that there are no additional shutdowns, the costs could be lower at around €3m to €5m over the period 2010-69.

It is assumed that the impact of introducing an EU wide OEL of 1ppm is that reductions in exposure would be achieved sooner than would otherwise occur (i.e. investment would be made earlier than planned). It is estimated that the cost of compliance may be in the region of €90m to €185m over the period 2010-69 if there are annual production shutdowns for several days for maintenance. If it is assumed at there are no additional shutdowns, the costs could be lower at around €40 to €65m over the period 2010-69.

There is a ready market for VCM and no plant closures are expected to result from the implementation of a more stringent OEL.

There are no significant environmental impacts foreseen.

The main identified impacts of introducing an OEL of 1ppm and 2ppm for VCM are summarised in Tables 5.6 to 5.10, 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 (Present Value – 2010 €m prices)

| Type of Impact | Baseline Scenario<br>Health Costs | <br>Health Benefits | Introduce OEL=3 mg/m$^3$<br>Health Costs | <br>Health Benefits | Introduce OEL=1 mg/m$^3$<br>Health Costs | <br>Health Benefits |
|---|---|---|---|---|---|---|
| Health | As set out in section 2.5, the health costs of cancer (sinonasal and nasopharynegal) over the period 2010-70 are estimated to be €3.6bn to €16bn This range takes into consideration tangible costs (e.g. lost income, lost output from reduced productivity, medical costs, life years lost) and intangible costs (e.g. emotional and physical suffering from having cancer). | It is assumed that exposures will fall by 8% per year in the future. Therefore there is expected to be some reduction in health costs going forward in the absence of further regulatory intervention | None - There is expected to be a cost saving from avoided health related costs due to reductions in cancer registrations – This is estimated as a benefit (in the box to the right) | Net health benefits of the OEL:<br>Females: €2-8m<br>Males: €8-36m<br>Totals: €9-44m | None- There is expected to be a cost saving from avoided health care due to reductions in cancer registrations – This is estimated as a benefit (in the box to the right) | Net health benefits of the OEL:<br>Females: €7-38m<br>Males - €44-214m<br>Totals - €51-252m<br>There are also avoided health costs post 2070 which are not quantified in this study |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

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

| | Baseline Scenario | | Introduce OEL=3 mg/m$^3$ | | Introduce OEL=1 mg/m$^3$ | |
|---|---|---|---|---|---|---|
| Type of Impact | Economic Costs | Economic Benefits | Economic Costs | Economic Benefits | Economic Costs | Economic Benefits |
| Economic | It is assumed that exposures will fall by 8% per year in the future. Therefore, there are expected to be some costs to firms where hardwood exposure requires firms to put into place ventilation measures to reduce inhalation exposure. These would occur regardless of further intervention over the period 2010-2070. | - | There are not expected to be significant costs relative to the baseline since geometric mean exposures across affected sectors are already lower than 2mg/m$^3$. | Having an EU OEL level will remove any EU competitive distortions between EU Member States with different OELs. | €3,800-8,600m to install ventilation systems (mobile and stationary). This is expected to be an excessive cost for industry to finance and absorb. It is not clear if these costs may be passed through the supply chain or whether grants / subsidies will be required similar to the approach used in France. | Having an EU OEL level will remove any EU competitive distortions between EU Member States with different OELs. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 5.3** Comparison of social impacts by scenario

| Type of Impact | Baseline Scenario: Social Costs | Baseline Scenario: Social Benefits | Introduce OEL =3 mg/m$^3$: Social Costs | Introduce OEL =3 mg/m$^3$: Social Benefits | Introduce OEL=1 mg/m$^3$: Social Costs | Introduce OEL=1 mg/m$^3$: Social Benefits |
|---|---|---|---|---|---|---|
| Social | It is assumed that exposures will fall by 8% per year in the future. Therefore, there are expected to be some costs to firms where hardwood dust exposure requires firms to put into place ventilation measures. These are likely to be firms who can afford ventilation systems which minimises the risks of plant closures under the baseline scenario. | | Minimal since an OEL of 5mg/m$^3$ is already in force and compliance costs are not expected to be significant to meet an OEL set at 3mg/m$^3$. | | There is a genuine risk that firms will not be able to afford ventilation systems unless they can pass through the costs of the systems (both capital and operational costs, e.g. maintenance and electricity consumed). The impacts on employment would be more severe if the OEL were to be applied to all wood dust rather than just hardwood dust. | Mechanical ventilation may be better for workers than natural ventilation as air change rates and flow can be controlled. If the mechanical ventilation includes a heat exchanger with high efficiency this might typically reduce the ventilation heat loss. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 5.4** Comparison of macro-economic impacts by scenario (Present Value – 2010 €m prices)

| Type of Impact | Baseline Scenario: Macro-economic Costs | Baseline Scenario: Macro-economic Benefits | Introduce OEL=3 mg/m$^3$: Macro-economic Costs | Introduce OEL=3 mg/m$^3$: Macro-economic Benefits | Introduce OEL=1 mg/m$^3$: Macro-economic Costs | Introduce OEL=1 mg/m$^3$: Macro-economic Benefits |
|---|---|---|---|---|---|---|
| Macro-economic | According to the CEI-Bois, the woodworking and furniture industries are an important player in the overall economy, with a production value is around €230 billion per year. They estimate the woodworking industry (EU-25) annually imports wood based products worth €20.8 billion and up to €19 billion of wood based products are exported outside the EU-25 each year. More recent estimates from CEI-Bois at an EU-27 level indicate turnover has increased to €269 billion. Based on Eurostat data the three sector groups spent approximately €244 billion in 2006 on goods and services within the EU economy. This compares to the total GDP in the EU of €12,305 billion in 2007. | | Since compliance with an OEL would not involve changing the current manufacturing process there is unlikely to be any significant change to macro-economic impacts. | | Unless, the majority of the companies affected decide to shut down, there is not anticipated to be a significant negative macro-economic impact, since many companies could opt to not use hardwood rather than spend money to comply with the lower OEL.<br>A lower OEL on wood dust however may have a more profound negative impact. This would affect the majority of companies within these sectors, who are mostly SMEs and may not be able to afford ventilation equipment to achieve a 1 mg/m$^3$ OEL for wood dust. | Short term spending on RMMs may also be good for the economy.<br>With fewer life years lost and cancer registrations, there should be a net benefit in output and consumption in the future (post 2040) |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 5.5** Comparison of environmental impacts by scenario

| Type of Impact | Baseline Scenario: Environmental Costs | Baseline Scenario: Environmental Benefits | Introduce OEL=3 mg/m$^3$: Environmental Costs | Introduce OEL=3 mg/m$^3$: Environmental Benefits | Introduce OEL=1 mg/m$^3$: Environmental Costs | Introduce OEL=1 mg/m$^3$: Environmental Benefits |
|---|---|---|---|---|---|---|
| Environmental | None | | Since compliance with an OEL would not involve changing the current manufacturing process there is unlikely to be any significant change to environmental impacts. | | The use of ventilation systems will consume more electricity which would result in greater GHG emissions | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 5.6** Comparison of health impacts by scenario (Present Value – 2010 €m prices)

| Type of impact | Introduce OEL=2ppm Costs | Introduce OEL=2ppm Benefits | Introduce OEL=1ppm Costs | Introduce OEL=1ppm Benefits |
|---|---|---|---|---|
| Health | None - There is expected to be a cost saving from avoided health care and reduced cost of illness due to reductions in cancer registrations.<br>This has been estimated as a benefit. | Health benefits of the proposed OEL have been analysed at the Member State and industrial sector level. The results showed that the benefits of introducing an OEL in 2010 are most apparent from 2040 onwards. It was also found that the monetised benefits are likely to affect men more than women given the VCM and PVC manufacturers employ more men.<br>The monetised benefits were estimated as:<br>○ Females: < €1m<br>○ Males: < €1m<br>○ Totals: < €1m<br>The impacts of introducing an OEL at 2ppm are estimated to have limited benefits as there is already estimated to be a reduction towards 1ppm under the baseline scenario.<br>There is also avoided health costs post-2070, which is not quantified in this study, but again this is expected to be small. | None - There is expected to be a cost saving from avoided health care and reduced cost of illness due to reductions in cancer registrations.<br>This has been estimated as a benefit. | The monetised benefits were estimated as:<br>○ Females: < €1m<br>○ Males: €1-2m<br>○ Totals: €1-3m<br>The impacts of introducing an OEL at 1ppm again are estimated to have limited benefits as there is already estimated to be a reduction towards 1ppm under the baseline scenario.<br>There is also avoided health costs post-2070, which is not quantified in this study, but again this is expected to be small. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 5.7** Comparison of economic impacts by scenario (Present Value – 2010 €m prices)

| | Introduce OEL=2ppm | | Introduce OEL=1ppm | |
|---|---|---|---|---|
| **Type of impact** | **Costs** | **Benefits** | **Costs** | **Benefits** |
| Economic | It is estimated that under the baseline scenario, firms are already moving towards complying with the 1ppm OEL. It is estimated that the cost of compliance with an OEL of 2ppm may be in the region of €15m to €30m over the period 2010-69 if there are annual shutdowns. If it is assumed that there are no additional shutdowns, the costs could be lower at around €3 to €5m over the period 2010-69. | Having an EU-wide OEL level should remove any EU competitive distortions between EU Member States with different OELs. | The impact of introducing an EU wide OEL of 1ppm is that reductions in exposure will be achieved sooner than planned (i.e. investment will be made earlier than planned). It is estimated that the cost of compliance may be in the region of €90m to €185m over the period 2010-69 if there are annual shutdowns. If it is assumed that there are no additional shutdowns, the costs could be lower at around €40 to €65m over the period 2010-69. | Having an EU-wide OEL level should remove any EU competitive distortions between EU Member States with different OELs. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 5.8** Comparison of social impacts by scenario

| | Introduce OEL=2ppm | | Introduce OEL=1ppm | |
|---|---|---|---|---|
| **Type of impact** | **Social Costs** | **Social Benefits** | **Social Costs** | **Social Benefits** |
| Social | Based on consultation with ECVM, there are not expected to be any noticeable changes to jobs skills, patterns or the numbers of workers required as a result of equipment modifications for the proposed OEL of 2ppm. | | Based on consultation with ECVM, there are not expected to be any noticeable changes to jobs skills, patterns or the numbers of workers required as a result of equipment modifications for the proposed OEL of 1ppm. | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 5.9** Comparison of macro-economic impacts by scenario

| Type of impact | Introduce OEL=2ppm Marco-economic Costs | Introduce OEL=2ppm Marco-economic Benefits | Introduce OEL=1ppm Marco-economic Costs | Introduce OEL=1ppm Marco-economic Benefits |
|---|---|---|---|---|
| Macro-economic | Since investment in risk management measures would occur under the baseline, there is not expected to be any macroeconomic impacts relative to the baseline scenario from introducing an EU-wide OEL of 2ppm. With fewer life years lost and cancer registrations, there might be an economic benefit (for VCM and PVC manufacturers and employees) through avoided loss of output and consumption in the future (post-2040), for example due to greater productivity from fewer sick days as well as greater consumption due to fewer premature deaths and greater taxes raised. However, at a macroeconomic level any benefit would be negligible for the proposed OEL of 2ppm. | | Since investment in risk management measures would occur under the baseline, there is not expected to be any macroeconomic impacts relative to the baseline scenario from introducing an EU-wide OEL of 1ppm. With fewer life years lost and cancer registrations, there might be an economic benefit (for VCM and PVC manufacturers and employees) through avoided loss of output and consumption in the future (post-2040), for example due to greater productivity from fewer sick days as well as greater consumption due to fewer premature deaths and greater taxes raised. However, at a macroeconomic level any benefit would be negligible for the proposed OEL of 1ppm. | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 5.10** Comparison of environmental impacts by scenario

| Type of impact | Introduce OEL=2ppm Environmental Costs | Introduce OEL=2ppm Environmental Benefits | Introduce OEL=1ppm Environmental Costs | Introduce OEL=1ppm Environmental Benefits |
|---|---|---|---|---|
| Environmental | None – it is expected that the imposition of measures would not cause additional environmental impacts. | It is not expected that the measures for human health would lead to any additional environmental benefit. | None – it is expected that the imposition of measures would not cause additional environmental impacts. | It is not expected that the measures for human health would lead to any additional environmental benefit. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

# 6 REPORTS WHERE THE EUROPEAN COMMISSION SUGGESTED THE OEL VALUES

## 6.1 CHROME VI

Workplace exposure to hexavalent chromium is associated with increased risks of lung cancer and sinonasal cancers. 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) for hexavalent chromium of 0.1, 0.05 or 0.025 mg/m$^3$

Hexavalent chromium compounds are no longer manufactured in Europe and the use of imported hexavalent chromium is reducing. The main use of hexavalent compounds is in wood preservatives, metal coatings, chromium production and catalyst manufacture. Other uses include Montan wax manufacture, vitamin K manufacture and use as a mordent in wool dying. We estimate that in 2006 about 917,000 workers in the EU were exposed to hexavalent chromium across a wide range of industries. There were estimated to be about 552,000 workers with relatively high levels of exposure who were employed in chemicals manufacture, basic metals production, manufacture or machinery and equipment, manufacture of other transport equipment and the manufacture of furniture. Since 2006, the manufacture of hexavalent chromium compounds and the use of copper chrome arsenate wood preservatives has ceased in the EU, hexavalent chromium has been banned in new vehicles or electronic/electrical equipment and plating processes are increasingly replacing hexavalent chromium with trivalent chromium or chrome-free substances. The number of workers in sectors with relatively high levels of exposure is likely to have declined substantially since 2006.

We estimate that in 2010 in the EU there will be about 336 deaths from lung cancer and a similar number of registrations that might be attributable to past exposure to hexavalent chromium, which corresponds to about 0.12% of all lung cancer deaths amongst the exposed workers. We estimate that there will also be about 39 deaths from sinonasal cancers (118 registrations) that might be attributable to past exposure to hexavalent chromium, which corresponds to about 3.3% of all sinonasal cancer deaths in the group of workers exposed. If no specific actions are taken to reduce exposure to hexavalent chromium, based on the assumption that current trends in employment and exposure continue until 2030, the predicted numbers of cancer deaths in 2060 would be 105 and 95, for lung and sinonasal cancer respectively. The increased number of sinonasal cancer deaths reflects the increasing prevalence of this type of cancer in the general population. The introduction of an OEL of 0.025, 0.05 or 0.1 mg/m$^3$ would lead to reductions in the number of lung cancer registrations in 2060 of 80, 57 or 20 respectively and reductions in the number of sinonasal cancer registrations of 8, 6 and 2 respectively.

The total net health benefits from setting an OEL at 0.1 mg/m$^3$ are estimated to be between €157m and €445m, compared with benefits of between €339m and €966m associated with an OEL of 0.05 mg/m$^3$ or benefits of between €453m and €1,294m associated with an OEL of 0.025 mg/m$^3$.

Most EU countries already have an OEL in place for hexavalent chromium and we estimate that nearly 90% of exposed workers already have exposures that are below the most stringent proposed EU-wide OEL. The majority of these workers are employed in larger organisations. Only 4% of workers are believed to have current exposures that exceed this level. The main additional risk management measures required are local ventilation systems in companies that do not already have adequate systems. It is estimated that the proportion of enterprises that will require additional control measure to meet the proposed OELs of 0.1, 0.05 and 0.025 mg/m$^3$ is 9%, 16% and 27% respectively. Total compliance costs over the period 2010-2069 (Net Present Value) are estimated to be € 7bn to € 37 bn, € 18bn to € 67 bn and € 30 bn to € 115 bn respectively.

We consider that the costs of compliance with the OEL will disproportionately affect small firms employing less than 20 people, particularly in the manufacture of fabricated metal products where 91% of businesses fall into this category. It is possible that some could either close or cease to use hexavalent chromium containing components.

There are no significant environmental impacts foreseen.

The main identified impacts of introducing an OEL of 0.1 mg/m$^3$, 0.05 mg/m$^3$ and 0.025 mg/m$^3$ for hexavalent chromium are summarised in Table 6.1 to 6.5, which are broken down by the main types of impacts (health, economic, social, macroeconomic and environmental).

### 6.2 1, 3 BUTADIENE

1,3-butadiene is classified as a human carcinogen by IARC (Group 1) and is a Cat 1 carcinogen in the EU. It is associated with an increased risk of lymphohaematopoietic cancer. We have considered the impacts of introducing an OEL of 0.5, 1 or 5 ppm, averaged over an 8-hour working day.

1,3-butadine is a very flammable, colourless gas. Most 1,3-butadiene produced is polymerized at a relatively small number of sites in Europe to form synthetic rubber. It is also used as a chemical intermediate in the production of neoprene, in the production of methylmethacrylate-butadiene-styrene (MBS) polymer and for producing adiponitrile, a nylon precursor. The production capacity in 2006 in the EU was estimated to be 2.9 million tonnes.

We estimated that about 27,600 workers in the EU are potentially exposed to 1,3-butadiene. About 4.3% of workers in the high exposure industries are exposed above 5 ppm, 27.8% above 1 ppm and 45.8% above 0.5 ppm. In the low exposure industries levels are probably below 0.5 ppm. Exposure levels in the industries where 1,3-butadiene is used are judged to be decreasing by 7% per annum over recent years.

We estimate that in 2010 in the EU there will be about one death from lymphohaematopoietic cancer, based on two incident cases, that might be attributable to past exposure to 1,3-butadiene, which corresponds to about 0.0014% of all LH cancer deaths amongst the exposed workers. If no specific actions are taken to reduce exposure to 1,3-butadiene the predicted numbers of liver cancer deaths increases slightly so that in 2060 there would be two attributable LH deaths. DALYs and YLL also increase; from 24 to 32 years and 19 to 25 years, respectively. Total estimated health costs associated with inaction range from €41m to €167m, which mostly fall on Germany, UK, France and Spain.

**Table 6.1** Comparison of health impacts by scenario (Present Value – 2010 €m prices)

| | **Baseline scenario** | | **Introduce OEL=0.1 mg/m$^3$** | | **Introduce OEL=0.05 mg/m$^3$** | | **Introduce OEL=0.025 mg/m$^3$** | |
|---|---|---|---|---|---|---|---|---|
| **Type of impact** | **Costs** | **Benefits** | **Costs** | **Benefits** | **Costs** | **Benefits** | **Costs** | **Benefits** |
| Health | The health costs of cancer (l lung cancer and sino-nasal cancers) over the period 2010-70 are estimated to be:<br>• Females:€1.6 – 4.7bn<br>• Males: €7 – 22bn<br>• Total: €8.6-27bn<br>This range takes into consideration tangible costs (e.g. lost income, lost output from reduced productivity, medical costs, life years lost) and intangible costs (e.g. emotional and physical suffering from having cancer). A large proportion of costs occurs prior to 2030 and is the result of past exposure. This is unlikely to change significantly with further invention. | It is assumed that exposures fall by 7% per year in the future, continuing the historical trend in reduced exposure. Therefore there is expected to be a significant reduction in health costs going forward in the absence of further regulatory intervention. | None - There is expected to be a cost saving from avoided health care and reduced cost of illness due to reductions in cancer registrations. This has been estimated as a benefit. | The benefits of introducing an OEL in 2010 are most apparent from 2040 onwards. It was also found that the monetised benefits are likely to affect men more than women given the industrial sectors most exposed to hexavalent chromium.<br>The monetised benefits were estimated as:<br>• Females: €25-57m<br>• Males - €132-388m<br>• Totals - €157-445m<br>The impacts of introducing an OEL at 0.1 mg/m$^3$ are estimated to have limited benefits as there is already estimated to be a reduction towards 0.1 mg/m$^3$ and below under the baseline scenario. | None - There is expected to be a cost saving from avoided health care and reduced cost of illness due to reductions in cancer registrations.<br>This has been estimated as a benefit. | The benefits of introducing an OEL in 2010 are most apparent from 2040 onwards. It was also found that the monetised benefits are likely to affect men more than women given the industrial sectors most exposed to hexavalent chromium.<br>The monetised benefits were estimated as:<br>• Females: €53-123m<br>• Males - €286-843m<br>• Totals - €339-966m | None - There is expected to be a cost saving from avoided health care and reduced cost of illness due to reductions in cancer registrations. This has been estimated as a benefit. | The benefits of introducing an OEL in 2010 are most apparent from 2040 onwards. It was also found that the monetised benefits are likely to affect men more than women given the industrial sectors most exposed to hexavalent chromium.<br>The monetised benefits were estimated as:<br>• Females: €71-165m<br>• Males - €382-1,129m<br>• Totals - €453-1,294m<br>These results show that introducing an OEL at 0.025 mg/m$^3$ would result in the greatest health benefits of all three proposed EU-wide OELs. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 6.2** Comparison of economic impacts by scenario (Present Value – 2010 €m prices)

| Type of impact | Baseline scenario Costs | Baseline scenario Benefits | Introduce OEL=0.1 mg/m$^3$ Costs | Introduce OEL=0.1 mg/m$^3$ Benefits | Introduce OEL=0.05 mg/m$^3$ Costs | Introduce OEL=0.05 mg/m$^3$ Benefits | Introduce OEL=0.025 mg/m$^3$ Costs | Introduce OEL=0.025 mg/m$^3$ Benefits |
|---|---|---|---|---|---|---|---|---|
| Economic | It is assumed that exposures will fall by 7% per year in the future. Therefore, there are expected to be some costs to firms where hexavalent chromium exposure requires firms to put into place ventilation measures to reduce inhalation exposure. These would occur regardless of further intervention over the period 2010-2070. | - | It is estimated that 9% of enterprises will require some form of control measure to meet the proposed OEL. The remainder are assumed to already be meeting the proposed OEL and therefore will require no further action. It is assumed that the majority of those that cannot comply will require ventilation systems to reduce exposure levels to meet the OEL. Cost per enterprise over the period 2010-2069 (NPV) is estimated at:<br>• No additional action: €0<br>• New ventilation system: €126-483k<br>The total costs over the period 2010-2069 (NPV) is estimated at between €9-37bn. | Having an EU-wide OEL should remove any EU competitive distortions between EU Member States with different OELs. | It is estimated that 16% of enterprises will require some form of control measure to meet the proposed OEL. The remainder are assumed to already be meeting the proposed OEL and therefore will require no further action. It is assumed that the majority of those that cannot comply will require ventilation systems to reduce exposure levels to meet the OEL. Cost per enterprise over the period 2010-2069 (NPV) is estimated at:<br>• No additional action: €0<br>• New ventilation system: €126-483k<br>The total costs over the period 2010-2069 (NPV) is estimated at between €18-67bn. | Having an EU-wide OEL should remove any EU competitive distortions between EU Member States with different OELs. | It is estimated that 27% of enterprises will require some form of control measure to meet the proposed OEL. The remainder are assumed to already be meeting the proposed OEL and therefore will require no further action. It is assumed that the majority of those that cannot comply will require ventilation systems to reduce exposure levels to meet the OEL. Cost per enterprise over the period 2010-2069 (NPV) is estimated at:<br>• No additional action: €0<br>• New ventilation system: €126-483k<br>The total costs over the period 2010-2069 (NPV) is estimated at between €30-115bn. | Having an EU-wide OEL should remove any EU competitive distortions between EU Member States with different OELs. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 6.3** Comparison of social impacts by scenario (Present Value – 2010 €m prices)

| Type of impact | Baseline scenario | | Introduce OEL=0.1 mg/m$^3$ | | Introduce OEL=0.05 mg/m$^3$ | | Introduce OEL=0.025 mg/m$^3$ | |
|---|---|---|---|---|---|---|---|---|
| | **Costs** | **Benefits** | **Costs** | **Benefits** | **Costs** | **Benefits** | **Costs** | **Benefits** |
| Social | It is assumed that exposures will fall by 7% per year in the future. Therefore, there are expected to be some costs to firms where hexavalent chromium exposure requires firms to put into place ventilation measures. These are likely to be firms who can afford ventilation systems which minimises the risks of plant closures under the baseline scenario. | In terms of working conditions, the use of mechanical local ventilation may be better for workers than natural ventilation as air change rates and flow can be controlled, and thermal environmental conditions maintained at more acceptable levels. | It is estimated that an EU-wide OEL of 0.1mg/m$^3$ would affect only 9% of all enterprises in affected industries (~76,500 enterprises). However, there appears to be a disproportionate burden on SMEs - according to the ratio of costs to operating surplus the fitting of the equipment in order to achieve the OEL is not financially feasible. The up-front capital cost of a ventilation system is estimated to be in the region of €42k - 252k. This is likely to be a significant cost, which may potentially result in those companies stopping their use of chromium or forcing the closure of some companies, if they are dependent upon the use of hexavalent chromium. | In terms of working conditions, the use of mechanical local ventilation may be better for workers than natural ventilation as air change rates and flow can be controlled, and thermal environmental conditions maintained at more acceptable levels. | It is estimated that an EU-wide OEL of 0.05mg/m3 would affect 16% of all enterprises in affected industries (~139,000 enterprises). however there appears to be a disproportionate burden on SMEs - according to the ratio of costs to operating surplus the fitting of the equipment in order to achieve the OEL is not financially feasible. The up-front capital cost of a ventilation system is estimated to be in the region of €42k - 252k. This is likely to be a significant cost, which may potentially result in those companies stopping their use of chromium or forcing the closure of some companies, if they are dependent upon the use of hexavalent chromium. | In terms of working conditions, the use of mechanical local ventilation may be better for workers than natural ventilation as air change rates and flow can be controlled, and thermal environmental conditions maintained at more acceptable levels. | It is estimated that an EU-wide OEL of 0.025mg/m3 would affect nearly one quarter of all enterprises in affected industries (~238,000 enterprises). However, there appears to be a disproportionate burden on SMEs - according to the ratio of costs to operating surplus the fitting of the equipment in order to achieve the OEL is not financially feasible. The up-front capital cost of a ventilation system is estimated to be in the region of €42k - 252k. This is likely to be a significant cost, which may potentially result in those companies stopping their use of chromium or forcing the closure of some companies, if they are dependent upon the use of hexavalent chromium. | In terms of working conditions, the use of mechanical local ventilation may be better for workers than natural ventilation as air change rates and flow can be controlled, and thermal environmental conditions maintained at more acceptable levels. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 6.4** Comparison of macro-economic impacts by scenario (Present Value – 2010 €m prices)

| | Baseline scenario | | Introduce OEL=0.1 mg/m$^3$ | | Introduce OEL=0.05 mg/m$^3$ | | Introduce OEL=0.025 mg/m$^3$ | |
|---|---|---|---|---|---|---|---|---|
| **Type of impact** | **Costs** | **Benefits** | **Costs** | **Benefits** | **Costs** | **Benefits** | **Costs** | **Benefits** |
| Macro-economic | Based on Eurostat data the five sector groups spent approximately €146bn in 2007 on goods and services within the EU economy. This compares to the total GDP in the EU of €12,305 billion in 2007 and so is considered to be a significant contribution to the EU economy. | | Since compliance with an OEL would not involve changing the current manufacturing process there is unlikely to be any significant change to macro-economic impacts. | | | | | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 6.5** Comparison of environmental impacts by scenario

| | Baseline scenario | | Introduce OEL=0.1 mg/m$^3$ | | Introduce OEL=0.05 mg/m$^3$ | | Introduce OEL=0.025 mg/m$^3$ | |
|---|---|---|---|---|---|---|---|---|
| **Type of impact** | **Costs** | **Benefits** | **Costs** | **Benefits** | **Costs** | **Benefits** | **Costs** | **Benefits** |
| Environmental | It is considered that the controls in place to control environmental emissions are sufficient to control the potential risk to the environment. | | Any additional releases of hexavalent chromium as a result of additional controls on workplace exposure should not lead to increased risk for the environment. | | | | | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

The introduction of an OEL is predicted to have little impact on risk of LH, regardless of the level it is set at. This is because we assume that exposures will continue to drop steadily so that most workers in the high exposed jobs will by 2030 be in the low exposure category (90% of the high exposed jobs < 0.6 ppm). However, we were unable to identify a level at which there was no risk for LH cancer and the low exposed workers still have associated elevated relative risk of 1.05. There are therefore no net health benefits from setting an OEL.

Potential improvements in handling 1,3-butadiene to ensure compliance with an OEL include, technical measures such as improved equipment for loading/unloading and leak detection, organisational measures, such as regular inspection of equipment, and greater use of personal respiratory protection.

The total compliance costs aggregated over the period 2010 to 2069 range from between €2m to €7m for an OEL of 5 ppm to €27 to €100m for an OEL of 0.5 ppm. In part the range of costs for each option depends on the relative use of engineering controls or personal protective equipment to control exposure to episodic releases. The sectors that experience the highest impact and thus cost are those that would experience the largest benefits from the control of exposure and meeting the OEL (i.e. NACE 25.1 and 23). No plant closures are foreseen as a consequence of introducing and OEL. There is unlikely to be any significant change to macro-economic impacts.

The main identified impacts of introducing an OEL of 0.5 ppm, 1 ppm and 5 ppm for 1,3 Butadiene are summarised in Tables 6.6 to 6.10, which are broken down by the main types of impacts (health, economic, social, macroeconomic and environmental).

**Table 6.6** Comparison of health impacts by scenario (Present Value – 2010 €m prices)

| | Baseline Scenario | | Introduce OEL = 0.5 ppm | | Introduce OEL = 1 ppm | | Introduce OEL = 5 ppm | |
|---|---|---|---|---|---|---|---|---|
| **Type of Impact** | **Health Costs** | **Health Benefits** | **Health Costs** | **Health Benefits** | **Health Costs** | **Health Benefits** | **Health Costs** | **Health Benefits** |
| Health | The health costs of cancer (LH) over the period 2010-70 are estimated to be:<br>Females: €13 – 47m<br>Males: €29 – 120 m<br>Total: €41 – 167 m<br>This range takes into consideration tangible costs (e.g. lost income, lost output from reduced productivity, medical costs, life years lost) and intangible costs (e.g. emotional and physical suffering from having cancer). | It is assumed that exposures fall by 7% per year in the future, continuing the historical trend in reduced exposure.<br>Therefore there is expected to be some reduction in health costs going forward in the absence of further regulatory intervention | None - There is expected to be a cost saving from avoided health care and reduced cost of illness due to reductions in cancer registrations.<br>This has been estimated as a benefit. | Health benefits of the proposed OEL have been analysed at the Member State and industrial sector level. The results showed that the benefits of introducing an OEL in 2010 are most apparent in the period 2030-2039 onwards. It was also found that the monetised benefits are likely to affect men more than women given the industrial sectors most exposed to 1,3-butadiene.<br>The monetised benefits were estimated as:<br>Females: €0 -0.1 m<br>Males - €0.1- 0.4 m<br>Totals - €0.1 – 0.6 m<br>There are also avoided health costs post-2070, which are not quantified in this study. | None - There is expected to be a cost saving from avoided health care and reduced cost of illness due to reductions in cancer registrations.<br>This has been estimated as a benefit. | Health benefits of the proposed OEL have been analysed at the Member State and industrial sector level. The results showed that the benefits of introducing an OEL in 2010 are most apparent in the period 2030-2039 onwards. It was also found that the monetised benefits are likely to affect men more than women given the industrial sectors most exposed to 1,3-butadiene.<br>The monetised benefits were estimated as:<br>Females: €0 -0.1 m<br>Males - €0.1- 0.4 m<br>Totals - €0.1 – 0.5 m<br>There are also avoided health costs post-2070, which are not quantified in this study. | None - There is expected to be a cost saving from avoided health care and reduced cost of illness due to reductions in cancer registrations.<br>This has been estimated as a benefit. | Health benefits of the proposed OEL have been analysed at the Member State and industrial sector level. The results showed that the benefits of introducing an OEL in 2010 are most apparent in the period 2030-2039 onwards. It was also found that the monetised benefits are likely to affect men more than women given the industrial sectors most exposed to 1,3-butadiene.<br>The monetised benefits were estimated as:<br>Females: €0 - 0 m<br>Males - €0 - 0.1 m<br>Totals - €0 – 0.1 m<br>There are also avoided health costs post-2070, which are not quantified in this study. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 6.7** Comparison of economic impacts by scenario (Present Value – 2010 €m prices)

| | Baseline Scenario | | Introduce OEL of 0.5 ppm | | Introduce OEL of 1 ppm | | Introduce OEL of 5 ppm | |
|---|---|---|---|---|---|---|---|---|
| **Type of Impact** | **Economic Costs** | **Economic Benefits** | **Economic Costs** | **Economic Benefits** | **Economic Costs** | **Economic Benefits** | **Economic Costs** | **Economic Benefits** |
| Economic | There are expected to be costs to sectors exposed to 1,3-butadiene due to expected further spending on control measures to reduce exposure.<br>These costs might relate to improving working practice or installation and use of engineering control measures (e.g. improved ventilation, improved loading/ unloading equipment). | - | There are expected to be economic costs related to the installation of control measures in order to meet the OEL for certain industrial sectors.<br>It is estimated that 4% of enterprises (251 enterprises) will require some form of control measure to meet the proposed OEL. The remainder are assumed to already be meeting the proposed OEL and therefore will require no further action. It is assumed that the majority of those that cannot comply will require ventilation systems, with the rest able to implement 'best practice' low-cost measures to reduce exposure levels to meet the OEL. Whilst some enterprises may already own ventilation systems, others will have to purchase a new ventilation system. Cost per enterprise over the | Having an EU-wide OEL level will remove any EU competitive distortions between EU Member States with different OELs. | There are expected to be economic costs related to the installation of control measures in order to meet the OEL for certain industrial sectors.<br>It is estimated that between 2% of enterprises (159 enterprises) will require some form of control measure to meet the proposed OEL. The remainder are assumed to already be meeting the proposed OEL and therefore will require no further action. It is assumed that the majority of those that cannot currently comply will require ventilation systems, with the rest able to implement 'best practice' low-cost measures to reduce exposure levels to meet the OEL. Whilst some enterprises may already own ventilation systems, others will | Having an EU-wide OEL level will remove any EU competitive distortions between EU Member States with different OELs. | There are expected to be economic costs related to the installation of control measures in order to meet the OEL for certain industrial sectors.<br>It is estimated that <0.3% of enterprises (19 enterprises) will require some form of control measure to meet the proposed OEL. The remainder are assumed to already be meeting the proposed OEL and therefore will require no further action. It is assumed that the majority of those that cannot comply will require ventilation systems, with the rest able to implement 'best practice' low-cost measures to reduce exposure levels to meet the OEL. Whilst some enterprises may already own ventilation systems, others will have to purchase a new ventilation system. Cost per enterprise over the period 2010-2069 (NPV) is estimated at:<br>• RPE: €0.5-2k | Having an EU-wide OEL level will remove any EU competitive distortions between EU Member States with different OELs. |

| Type of Impact | Baseline Scenario | | Introduce OEL of 0.5 ppm | | Introduce OEL of 1 ppm | | Introduce OEL of 5 ppm | |
|---|---|---|---|---|---|---|---|---|
| | Economic Costs | Economic Benefits | Economic Costs | Economic Benefits | Economic Costs | Economic Benefits | Economic Costs | Economic Benefits |
| | | | period 2010-2069 (NPV) is estimated at:<br>• RPE: €0.5-2k<br>• RPE + proper use of existing LEV: €3-7k<br>• RPE + new LEV: €6-25k<br>The total costs over the period 2010-2069 (NPV) are estimated at between €1– 89m | | have to purchase a new ventilation system. Cost per enterprise over the period 2010-2069 (NPV) is estimated at:<br>• RPE: €0.5-2k<br>• RPE + proper use of existing LEV: €3-7k<br>• RPE + new LEV: €6-25k<br>The total costs over the period 2010-2069 (NPV) are estimated at between €0 – 56 m. | | • RPE + proper use of existing LEV: €3-7k<br>• RPE + new LEV: €6-25k<br>The total costs over the period 2010-2069 (NPV) are estimated at between €0 – 7m. | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 6.8** Comparison of social impacts by scenario

| Type of Impact | Baseline Scenario Social Costs | Baseline Scenario Social Benefits | Introduce OEL = 0.5 ppm Social Costs | Introduce OEL = 0.5 ppm Social Benefits | Introduce OEL = 1 ppm Social Costs | Introduce OEL = 1 ppm Social Benefits | Introduce OEL = 5 ppm Social Costs | Introduce OEL = 5 ppm Social Benefits |
|---|---|---|---|---|---|---|---|---|
| Social | There are not expected to be any noticeable social impacts under the baseline scenario at an EU level. At an installation level, some personnel may change their working practices (e.g. wearing RPE) to reduce risks of inhalation exposure regardless of further intervention over the period 2010-2070. | | 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 the OEL, behavioural change amongst employees and updating health and safety training will be required. | Mechanical ventilation may be better for workers than natural ventilation as air change rates and flow can be controlled. If the mechanical ventilation includes a heat exchanger with high efficiency this might typically reduce the ventilation heat loss. The sectors (NACE 25.1 and 23) that experience the highest impact and thus cost are those that would experience the largest benefits from the control of exposure and meeting the OEL. | 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 the OEL, behavioural change amongst employees and updating health and safety training will be required. | Mechanical ventilation may be better for workers than natural ventilation as air change rates and flow can be controlled. If the mechanical ventilation includes a heat exchanger with high efficiency this might typically reduce the ventilation heat loss. The sectors (NACE 25.1 and 23) that experience the highest impact and thus cost are those that would experience the largest benefits from the control of exposure and meeting the OEL. | 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 the OEL, behavioural change amongst employees and updating health and safety training will be required. | Mechanical ventilation may be better for workers than natural ventilation as air change rates and flow can be controlled. If the mechanical ventilation includes a heat exchanger with high efficiency this might typically reduce the ventilation heat loss. The sectors (NACE 25.1 and 23) that experience the highest impact and thus cost are those that would experience the largest benefits from the control of exposure and meeting the OEL. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 6.9** Comparison of macro-economic impacts by scenario

| | Baseline Scenario | | Introduce OEL = 0.5 ppm | | Introduce OEL = 1 ppm | | Introduce OEL = 5 ppm | |
|---|---|---|---|---|---|---|---|---|
| **Type of Impact** | **Macro-economic Costs** | **Macro-economic Benefits** | **Macro-economic Costs** | **Macro-economic Benefits** | **Macro-economic Costs** | **Macro-economic Benefits** | **Macro-economic Costs** | **Macro-economic Benefits** |
| Macro-economic | There are not expected to be any noticeable macroeconomic impacts under the baseline scenario. | | Since compliance with an OEL would not involve changing the current manufacturing process there is unlikely to be any significant change to macro-economic impacts. | | | | | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 6.10** Comparison of environmental impacts by scenario

| | Baseline Scenario | | Introduce OEL = 0.5 ppm | | Introduce OEL = 1 ppm | | Introduce OEL = 5 ppm | |
|---|---|---|---|---|---|---|---|---|
| **Type of Impact** | **Environmental Costs** | **Environmental Benefits** | **Environmental Costs** | **Environmental Benefits** | **Environmental Costs** | **Environmental Benefits** | **Environmental Costs** | **Environmental Benefits** |
| Environmental | Not estimated | | The achievement of the OEL via the measures described in this report may lead to more direct emissions 1,3- butadiene to the environment (through ventilation), but probably not to an increased overall environmental burden and therefore would not increase the level of environmental risk. | | | | | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

# 7 REPORTS WHERE THE SUGGESTED OEL VALUES ARE TYPICAL OF VALUES IN EU MEMBER STATES

## 7.1 TRICHLOROETHYLENE

Workplace exposure to trichloroethylene (TCE) is associated with increased risks of Kidney cancer, liver and biliary cancer and non-Hodgkin's Lymphoma (NHL). TCE has been classified as a group 2a carcinogen (Probably carcinogenic to humans) carcinogen by IARC and as a Category 2 carcinogen in the EU under the classification and labelling legislation. This report considers the likely health, socioeconomic and environmental impacts associated with possible changes to the Carcinogens Directive, in particular, the establishment of an EU-wide OEL for TCE of 10 ppm or 50 ppm (50 or 273 mg/m$^3$).

The main use of TCE is as an intermediate for the synthesis of CFC substitutes (75%), in metal cleaning and in the adhesives industry. Its use in metal cleaning has declined sharply and its use in the adhesives industry is very small. TCE consumption in solvent applications is expected be about a quarter of 1996 levels by the end of 2010. This is largely due to implementation of the Solvents Emissions Directive. The annual production of TCE in the EU is well under 100,000 ktonnes.

We estimate that in 2006 approximately 74,000 workers in the EU were potentially exposed to TCE with most exposed workers being involved in the manufacture of fabricated metal products including machinery and transport equipment or the manufacture of furniture. In these industries, about 28% of workers are exposed to more than 10 ppm and about 2% are exposed are to more than 50 ppm. The estimated overall weighted geometric mean (GM) exposure across all countries and industries is 4.6 ppm with a GSD of 3.7.

We estimate that in 2010 in the EU there will be about 34 deaths from liver cancer and a similar number of registrations that might be attributable to past exposure to TCE, which corresponds to about 0.071% of all liver cancer deaths amongst the exposed workers. There will also be about 13 deaths from kidney cancer and about 31 registrations, accounting for 0.046% of all kidney cancer deaths amongst the exposed workers. There will be about 12 deaths from NHL and 28 registrations accounting for 0.054% of all NHL deaths amongst exposed workers. If no specific actions are taken to reduce exposure to TCE, based on the assumption that current employment and exposure levels are maintained, the predicted numbers of cancer deaths in 2060 attributable to TCE would be 21, 15 and 7 for cancers of the liver and kidney and NHL respectively. The corresponding numbers of registrations are 18, 29 and 15. The relative reduction in incidence differs for each of the cancers because of differences in the trends of background incidence (the incidence of kidney cancer is increasing as is the incidence of liver cancer to a lesser degree) and also to differences in the period of latency between exposure and the onset of disease. The predicted Years of Life Lost (YLLs) and Disability Adjusted Life Years (DALYs) are expected to decrease for all three cancers from a combined 866 YLLs and 904 DALYs in 2010 falling to 515 YLLs and 544 DALYs in 2060.

The introduction of an OEL of 50 ppm is not predicted to lead to any significant health benefit relative to the baseline scenario. The impact would be to reduce the number of liver cancer deaths and registrations in 2060 attributable to TCE from current levels to 25 and 22 respectively, the number of kidney cancer deaths and registrations to 15 and

30 respectively and the number of NHL deaths and registrations to 10 and 20 respectively. The predicted loss of life expectancy attributable to these cancers in 2060 would be 603 YLLs and 636 DALYs.

The introduction of an OEL of 10 ppm is predicted to reduce the number of liver cancer deaths and registrations in 2060 attributable to TCE from current levels to 10 and 9 respectively, the number of kidney cancer deaths and registrations to 14 and 27 respectively and the number of NHL deaths and registrations to 4 and 8 respectively. The predicted loss of life expectancy attributable to these cancers in 2060 would be 328 YLLs and 353 DALYs.

The total net health benefits from setting an OEL at 10 ppm are estimated to be between €1,118m and €430m for the period of 2010-2069, whereas there would be no significant health benefit in setting an OEL of 50 ppm.

Given that the current GM exposure to TCE is 4.6 ppm, it is anticipated that the majority of employers will be able to comply with an OEL of 50ppm (with around 4% of workers potentially affected above this OEL). There may be more workers affected with an OEL of 10 ppm (with around 28% of workers potentially affected above this OEL).

However, since under the Solvents Emissions Directive (SED) those firms using solvents that are covered by the SED (i.e. not just TCE) above 1 tonne per year are required to install and use a closed system. This is also reinforced by a voluntary industry agreement (Charter for the safe use of Trichloroethylene in metal cleaning) whereby TCE will not be sold to those without an installed closed system. Therefore it is possible that the main costs of compliance with an OEL (i.e. the use of closed systems) may already have been incurred by industries affected.

Given the interactions with the SED, it is difficult to provide a good estimate of the number of firms affected, but it is possible to examine costs per firm affected. The capital cost of installing closed systems (estimated to be between €58k-135k per enterprise, which is appropriately €6k per year).

Therefore the cost to comply with an OEL of 10 ppm (or 50ppm) is unlikely to be significant for large businesses but for SMEs, the majority of affected enterprises, it could represent a substantial proportion of their operating surplus, which could potentially lead to some business closures. Many businesses, however, may be able to switch to use of an alternative substance or pass on the additional costs by charging more for their products. The macroeconomic, social and environmental impacts of introducing an OEL of 10 ppm are not predicted to be significant (relative to the baseline scenario).

The main identified impacts of introducing an OEL of 10 ppm and 50 ppm for TCE are summarised in the tables below, which are broken down by the main types of impacts (health, economic, social, macroeconomic and environmental).

**Table 7.1** Comparison of health impacts by option (Present Value – 2010 €m prices)

| Type of Impact | Baseline scenario – National OELs<br>Health costs | <br>Health benefits | Introduce OEL=50ppm<br>Health costs | <br>Health benefits | Introduce OEL=10ppm<br>Health costs | <br>Health benefits |
|---|---|---|---|---|---|---|
| Health | As set out in section 2.5, the costs of cancer (kidney, liver and NHL) over the period 2010-70 is estimated to be:<br>- Females: €105m to €1,287m<br>- Males: €1,210 m to €4,370m<br>- Total: €1,582m to €5,657m<br>This range takes into consideration tangible costs (e.g. lost income, lost output from reduced productivity, medical costs, life years lost) and intangible costs (e.g. emotional and physical suffering from having cancer). | It is assumed that exposures fall by 7% per year in the future continuing the historical trend in reduced exposure.<br>Therefore there is expected to be avoided health costs going forward in the absence of further regulatory intervention. | There is not expected to be a reduction in health costs relative to the baseline scenario. | There are not expected to be any health benefits since the estimated geometric mean exposure is already 5.5ppm at an EU level and taking into consideration there is already declining exposure assumed under the baseline scenario. | There is expected to be a reduction in health costs relative to the baseline scenario. This is shown as a benefit (see right). | There is expected to be more significant health benefits of introducing an OEL at 10ppm, which is also the SCOEL recommended TWA, than at 50ppm due to the additional reduction in exposure.<br>The total health benefit is estimated to be between €118-430m (male and female) over the whole period of 2010-2070.<br>Health benefits post 2070 is not included in the estimate. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.2** Comparison of economic impacts by option (Present Value – 2010 €m prices)

| Type of Impact | Baseline scenario: Economic costs | Baseline scenario: Economic benefits | Introduce OEL=50ppm: Economic costs | Introduce OEL=50ppm: Economic benefits | Introduce OEL=10ppm: Economic costs | Introduce OEL=10ppm: Economic benefits |
|---|---|---|---|---|---|---|
| Economic | Industries affected (e.g. in particular the metal degreasing sectors) are estimated to incur costs of installing and using closed systems to achieve national OELs, the solvent emissions directive (SED) if use is above 1tpa and the voluntary industry agreement (Charter for the safe use of Trichloroethylene in metal cleaning) meaning any firms using trichloroethylene above 1tpa should already have closed systems in place. | Closed systems manufacturers should benefit from increased demand over time for closed systems. | There are not expected to be any significant costs relative to those already being incurred under the baseline scenario as firms are already investing in closed systems which will help to control exposure to below 50ppm. | There are not expected to be any significant benefits relative to those already being incurred under the baseline scenario as firms are already investing in closed systems which will help sales for closed systems manufacturers. | The GM exposure of 5.5ppm under the baseline means that the majority of the sector will comply with an OEL of 10ppm.<br>There is insufficient data to estimate the number of firms that will require closed systems in order to meet an OEL of 10ppm. It is estimated that the cost of a small unit (when <1tpa is used) is €58-135k (annualised as €6k per year). For large sized firms this is not estimated to be a significant cost but for SMEs this could be more difficult to finance as it can represent a significant proportion of their operating surplus (see table 5.4), potentially leading to business closures.<br>However it may be possible for firms to use an alternative substance to avoid the cost of a closed system or instead to pass through costs in terms of higher final good prices. Since the OEL will be applied at an EU level, there will be less competitive distortions within the EU if prices were increased. | Closed systems manufacturers should benefit from increased demand over time for closed systems.<br>There may also be a sales redistribution benefit to manufacturers of alternative substances. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.3** Comparison of social impacts by option

| Type of Impact | Baseline scenario: Social costs | Baseline scenario: Social benefits | Introduce EU wide OEL=50ppm: Social costs | Introduce EU wide OEL=50ppm: Social benefits | Introduce EU wide OEL=10ppm: Social costs | Introduce EU wide OEL=10ppm: Social benefits |
|---|---|---|---|---|---|---|
| Social | Under the baseline there is estimated to a greater number of firms installing and using closed systems for metal degreasing.<br>The use of closed vapour degreasing systems should not affect the skills required by metal degreasing workers. Training costs are expected to be minimal. | Since the closed system reduces risks of human exposure in a way that should not inhibit production, there should also be improvements in working conditions.<br>There should not be any changes in end products since would still be possible to use trichloroethylene and comply with the EU-wide OEL by using a closed system. | There are not expected to be any significant changes relative to the baseline scenario. | | There are not expected to be any significant changes relative to the baseline scenario.<br>Table 5.4 showed that smaller firms were most vulnerable to the capital cost of a closed system and may opt to close down or switch to an alternative substance or process (if technically feasible to do so). If they do decide to close down there is potential for some unemployment in Italy, Germany, Poland and the UK (in particular), who have the most employers with numbers of employees between 1 and 9. | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.4** Comparison of macroeconomic impacts by option (Present Value – 2010 €m prices)

| Type of Impact | Baseline scenario: Macroeconomic costs | Baseline scenario: Macroeconomic benefits | Introduce OEL=50ppm: Macroeconomic costs | Introduce OEL=50ppm: Macroeconomic benefits | Introduce OEL=10ppm: Macroeconomic costs | Introduce OEL=10ppm: Macroeconomic benefits |
|---|---|---|---|---|---|---|
| Macro-economic | There is not expected to be any noticeable macroeconomic impacts under any scenario. | | There is not expected to be any noticeable macroeconomic impacts under any scenario. | | There is not expected to be any noticeable macroeconomic impacts under any scenario. | |
| | The treatment and coatings of metals sector spent approximately €63bn in 2006 on goods and services within the EU economy. This is not significant considering the total value of goods and services in the manufacturing sector was €5trillion in 2006 and that users of trichloroethylene above 1tpa per year should already be using a closed system and therefore largely unaffected, (especially if they already have to comply with monitoring, reporting and verification requirements for national OELs). Therefore, while much of the sector may (or may not) be using less than 1tpa, it is very unlikely that the costs would be high enough collectively to cause significant macroeconomic impacts. It is also possible that some firms will substitute trichloroethylene or use an alternative process for metal degreasing. Therefore, there may only be a small redistribution of goods and services bought (i.e. to those firms producing the alternative substance rather than trichloroethylene) rather than any significant change in overall gross output. | | | | | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.5** Comparison of environmental impacts by option

<table>
<tr><th rowspan="2">Type of Impact</th><th colspan="2">Baseline scenario</th><th colspan="2">Introduce OEL=50ppm</th><th colspan="2">Introduce OEL=10ppm</th></tr>
<tr><th>Environmental costs</th><th>Environmental benefits</th><th>Environmental costs</th><th>Environmental benefits</th><th>Environmental costs</th><th>Environmental benefits</th></tr>
<tr><td rowspan="2">Environmental</td><td colspan="2">There is not expected to be any noticeable change in environmental impacts</td><td colspan="2">There is not expected to be any noticeable change in environmental impacts</td><td colspan="2">There is not expected to be any noticeable change in environmental impacts</td></tr>
<tr><td colspan="6">The EU risk assessment for trichloroethylene concluded that there was a need to limit the risks to the environment associated with use of the substance in metal cleaning. However, as detailed in the environmental risk reduction strategy, once the implications of the Solvent Emissions Directive are taken into account (as of 2007), it was concluded that there would be no need for further limiting the environmental risks in this area. Nonetheless, if certain companies are required to install closed systems when using trichloroethylene (i.e. a certain proportion of generally smaller consumers of the substance), there could be a reduction in overall emissions of trichloroethylene to the environment.</td></tr>
</table>

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

## 7.2 BERYLLIUM AND BERYLLIUM COMPOUNDS

Beryllium and beryllium compounds have been reviewed by the International Agency for Research on Cancer (IARC) and classified as carcinogenic to humans based on human epidemiological data and other evidence that they may cause lung tumours. Under the classification and labelling legislation in Europe, these substances are classified as Cat 2 carcinogens and they are therefore within the scope of the EU Carcinogens Directive. However, there is no occupational exposure limit (OEL) for beryllium or beryllium compounds 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 OEL for beryllium and beryllium compounds of 0.002 mg/m$^3$ (2 μg/m$^3$).

Beryllium metal is not manufactured in Europe, but is imported for use in scientific, defence and medical applications. The largest use of beryllium is as an alloying element in non-ferrous metals, typically copper-beryllium alloys contain less than 2% beryllium. There are less than 3,000 people in Europe employed in foundry or other similar processes likely to generate the highest exposure levels, mostly in Italy, France, Germany, UK, Switzerland and Hungary. In total there are probably about 65,000 people in the EU who may be exposed to beryllium or its compounds. Average exposure levels amongst foundry workers (NACE code 27) are probably about 0.5 μg/m$^3$, with less than 10% of exposures in all sectors exceeding 2 μg/m$^3$. It is likely that average beryllium exposures have been decreasing by about 4% per annum because of improving risk management measures.

We estimate that in 2010 in the EU there will be about 6 deaths from lung cancer that might be attributable to past exposure to beryllium, which corresponds to about 0.002% of all lung cancer deaths in this group. If no actions are taken it is unlikely that this annual attributable mortality will change importantly. Cancer incidence rates are similar to there mortality rate. The main costs associated with inaction occur in the period 2010-2040, and these are predominately the result of past exposure. It is estimated that in total over the next 60 years there will be between €203m and €529m of health costs if no OEL is introduced, with the highest costs falling on France, Germany and Italy.

It is considered that the majority of EU industry already complies with an OEL of 2 μg/m$^3$. However, introducing this limit would see a slight reduction in the attributable cancer deaths from 2030 onwards so that by 2060 there will be about 4 lung cancer deaths per annum in the EU attributable to beryllium exposure.

The total net health benefits from setting an OEL at 2 μg/m$^3$ are estimated to be between €11m and €30m, with France, Germany, Italy and Poland predicted to particularly benefit from compliance with the limit. The main additional risk management measures required are local ventilation systems in companies that do not already have adequate systems. It is estimated that between 6-12% of enterprises will require some form of additional control measure to meet the proposed OEL. Total costs over the period 2010-2069 (Net Present Value) is estimated to be between €5bn and €34bn.

We consider that the costs of compliance with the OEL will disproportionately affect SMEs and it is possible that some could either close or cease to use beryllium-containing components. There are no significant environmental impacts foreseen.

The main identified impacts of introducing an OEL of 0.002 mg/m$^3$ (2 μg/m$^3$) for beryllium and beryllium compounds are summarised in the tables below, which are broken down by the main types of impacts (health, economic, social, macroeconomic and environmental).

**Table 7.6** Comparison of health impacts by option (Present Value – 2010 €m prices)

| | Introduce OEL=2 μg/m$^3$ | |
|---|---|---|
| **Type of impact** | **Health Costs** | **Health Benefits** |
| Health | None - There is expected to be a cost saving from avoided health care and reduced cost of illness due to reductions in cancer registrations. This has been estimated as a benefit. | Health benefits of the proposed OEL have been analysed at the Member State and industrial sector level. The results showed that the benefits of introducing an OEL in 2010 are most noticeable from 2040 onwards. It was also found that the monetised benefits are likely to affect men more than women given the industrial sectors most exposed to beryllium and beryllium compounds.<br>The monetised benefits were estimated as:<br>Females: €0-0m<br>Males - €11-30m<br>Totals - €11-30m<br>There are also avoided health costs post-2070, which are not quantified in this study. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.7** Comparison of economic impacts by option (Present Value – 2010 €m prices)

| | Introduce OEL=2 µg/m$^3$ | |
|---|---|---|
| **Type of impact** | **Economic Costs** | **Economic Benefits** |
| Economic | There are expected to be economic costs related to the installation of control measures in order to meet the OEL for certain industrial sectors.<br>It is estimated that between 6-12% of enterprises will require some form of control measure to meet the proposed OEL. The remainder are assumed to already be meeting the proposed OEL and therefore will require no further action. It is assumed that the majority of those that cannot comply will require ventilation systems, with the rest able to implement 'best practice' low-cost measures to reduce exposure levels to meet the OEL. Whilst some enterprises may already own ventilation systems, others will have to purchase a new ventilation system. Cost per enterprise over the period 2010-2069 (NPV) is estimated at:<br>No additional action: €0<br>Best practice measures: €23-47k<br>New ventilation system: €126-483k<br>Ventilation system usage: €58-69k<br>The total costs over the period 2010-2069 (NPV) is estimated at between €5 – 34 bn. | Having an EU-wide OEL level will remove any EU competitive distortions between EU Member States with different OELs. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.8** Comparison of social impacts by option (Present Value – 2010 €m prices)

| | Introduce OEL=2 μg/m³ | |
|---|---|---|
| **Type of impact** | **Social Costs** | **Social Benefits** |
| Social | There appears to be a disproportionate burden on SMEs - according to the ratio of costs to operating surplus the fitting of equipment in order to achieve the OEL is not financially feasible. The up-front capital cost of a ventilation system is estimated to be in the region of €42k - 252k. This is likely to be a significant cost, which may potentially result in those companies discontinuing their use of beryllium or forcing the closure of some companies, if they are dependent upon beryllium.<br>The sector that experiences the highest health costs is manufacturing of machinery and equipment. According to Eurostat data this sector is 74% composed of firms with between 1 and 9 employees. In this sector there is estimated to be between 94 to 156% capital cost to operating surplus, meaning that the cost of measures would take all or more of the profit that these firms make in a year, which would constitute a burden on the firm in this sector. There are smaller impacts on the manufacturing of fabricated metal and medicinal, precision and optical instruments sectors with 87 and 84% of firms with 1-9 employees, and capital costs/operating surplus % of 512- 3075 and 123 -742, respectively | Mechanical ventilation may be better for workers than natural ventilation as air change rates and flow can be controlled. If the mechanical ventilation includes a heat exchanger with high efficiency this might typically reduce the ventilation heat loss.<br><br>The sectors that experience the highest impact and thus costs are those that would experience the largest benefits from the control of exposure and meeting the OEL. While the majority of exposure is controlled the industry sectors that stand to gain the most benefits (e.g. manufacturing of machinery and equipment , up to €20m (high benefits scenario)) are those that can least afford to apply the necessary measures to capture those benefits. This is because those sectors are largely composed of small firms. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.9** Comparison of macroeconomic impacts by option

| | Introduce OEL=2 μg/m³ | |
|---|---|---|
| **Type of impact** | **Macro-economic Costs** | **Macro-economic Benefits** |
| Marco-economic | Since compliance with an OEL would not involve changing the current manufacturing process there is unlikely to be any significant change to macro-economic impacts. | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.10** Comparison of environmental impacts by option

| | Introduce OEL=2 μg/m³ | |
|---|---|---|
| **Type of impact** | **Environmental Costs** | **Environmental Benefits** |
| Environmental | The achievement of the OEL via the measures described in this report may lead to more direct emissions of beryllium and beryllium compounds to the environment (through ventilation), but probably not to an increased overall environmental burden and therefore would not increase the level of environmental risk. | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

## 7.3 ACRYLAMIDE

Acrylamide is classified as a group 2a (probably carcinogenic to humans) carcinogen by the IARC because of evidence that it may cause pancreatic cancer. It is on the Candidate List of Substances of Very High Concern for authorisation within the REACH Regulations and is classified as a Category 2 occupational carcinogen by the EU. Acrylamide is therefore already regulated as a carcinogen under the Carcinogens Directive. In this report we consider the likely health, socioeconomic and environmental impacts associated with introducing an OEL for acrylamide of 0.03 mg/m$^3$, which is considered typical of OELs currently in place in EU countries.

Up to 99.9% of acrylamide in the EU is used in the production of polyacrylamide (which, once produced, contains less than 0.1% acrylamide). Acrylamide monomer may also be sold for a small number of other uses. The three largest uses of polyacrylamide are in wastewater treatment, paper and pulp processing and mineral processing - estimated by Industry to be 80% of the market. Three companies are reported as producing acrylamide within the EU (in UK, Germany and the Netherlands) while a further two companies are involved in the import of acrylamide into the EU. The total plant capacity within the EU is estimated at between 80,000-150,000 tonnes per annum.

Approximately 53,000 workers in the EU are potentially exposed to acrylamide, based on 2006 employment data. We estimate that from this total about 12,000 are employed in the sector manufacturing chemicals and chemical products workers in (NACE Group 24), and of these about 1,220 are exposed during acrylamide manufacturing.

Measurement data from 1992 – 1995 and 2005 suggests that exposure in the manufacture of acrylamide and polyacrylamide have been decreasing by 10.5% per annum. Assuming this trend has continued as we have estimated, then our best estimate for the geometric (GM) exposure in 2010 is 0.008 mg/m$^3$, with 90% of exposures less than 0.038 mg/m$^3$. Steps continue to be taken to reduce exposures in the industry in relation to the requirements of the REACH Regulations and it is expected that by 2012 90% of all exposures will be less than 0.03 mg/m$^3$. Exposures in other sectors are considered already compliant with the suggested OEL.

It is not possible to calculate the temporal trend in dermal exposure based on the available data, although we consider that given the range of likely interventions to reduce inhalation exposure the corresponding dermal exposure will have also decreased and our best estimate is that the rate of decline is probably similar to that for inhalation exposure.

Given that exposures are either in compliance or are likely to become compliant in the near future we predicted that the health impacts are the same for the baseline and intervention (i.e. OEL introduction) scenarios. In 2010 it is estimated that there were seven deaths (six registrations) in the EU from pancreatic cancer that could be attributed to past acrylamide exposure. Over the coming years the number of attributable cancer deaths and registrations are predicted to decrease to about 3 or 4 per annum and remain at this figure from about 2030. Years of Life Lost (YLL) and Disability Adjusted Life Years (DALYs) per annum are predicted to be between about 40 and 50 from 2030 onwards.

Total health costs (2010 to 2069) for the baseline scenario are estimated to range from €156m to €326m. These costs will affect Member States differently depending upon the overall number of workers affected within industry groups, existing control measures and the proportion of males and females within these groups. We judge that the Czech Republic, France, Germany and the UK will have relatively high health costs. The only industrial sector affected is the manufacture of chemicals and chemical products (NACE Code 24).

We judge that there are no expected additional health benefits from introducing an OEL of 0.03 mg/m$^3$ and only minimal economic costs given that the industry has generally already invested to control exposure in connection with the REACH Regulations.

We do not envisage any social, macroeconomic or environmental impacts with introducing an OEL for acrylamide.

The main identified impacts of introducing an OEL of 0.03 mg/m$^3$ for acrylamide are summarised in the tables below, which are broken down by the main types of impacts (health, economic, social, macroeconomic and environmental).

**Table 7.11** Comparison of health impacts by option

| | Introduce OEL=0.03 mg/m$^3$ | |
|---|---|---|
| **Type of impact** | **Health Costs** | **Health Benefits** |
| Health | There are not expected to any additional health costs relative to the baseline scenarios. | There are not expected to any additional health benefits relative to the baseline scenarios, since manufacturers of acrylamide and polyacrylamide are expected to already comply with the proposed 0.03mg/m$^3$ OEL. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.12** Comparison of economic impacts by option

| | Introduce OEL=0.03 mg/m$^3$ | |
|---|---|---|
| **Type of impact** | **Economic Costs** | **Economic Benefits** |
| Economic | Based on consultation with the Polyelectrolyte Producers Group (PPG) the vast majority of investment required to control exposure associated with the manufacture of acrylamide and polyacrylamide has already occurred in the last 20 years. | Having an EU-wide OEL level will remove any competitive distortions between EU Member States with different OELs. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.13** Comparison of social impacts by option

| | Introduce OEL=0.03 mg/m$^3$ | |
|---|---|---|
| **Type of impact** | **Social Costs** | **Social Benefits** |
| Social | Since there are not expected to be any significant economic costs to manufacturers of acrylamide and polyacrylamide from the introduction of an EU-wide OEL, there is unlikely to be any significant change in employment. | Under the baseline scenario, production is expected to increase over time, which may indicate that employment should at least be relatively stable or may increase. This is not expected to change with the introduction of an EU-wide OEL. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.14** Comparison of macroeconomic impacts by option

| | Introduce OEL=0.03 mg/m³ | |
|---|---|---|
| **Type of impact** | **Marco-economic Costs** | **Macro-economic Benefits** |
| Marco-economic | **No change -** Since there are not expected to be any significant economic or health impacts, there is not expected to be any significant change in macroeconomic impacts relative the baseline scenario from introducing an EU-wide OEL. | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.15** Comparison of environmental impacts by option

| | Introduce OEL=0.03 mg/m³ | |
|---|---|---|
| **Type of impact** | **Environmental Costs** | **Environmental Benefits** |
| Environmental | **No change -** Since the vast majority of manufacturers of acrylamide and polyacrylamide already comply with the proposed OEL and those that do not currently, are expected to comply without further intervention, there are not expected to be any significant change in environmental impacts from the introduction of an EU-wide OEL. | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

## 7.4 4, 4'-METHYLENEDIANILINE

4,4’-Methylenedianiline (MDA) has been classified by the International Agency for Research on Cancer (IARC) as possibly carcinogenic to humans based on sufficient animal toxicity (IARC category 2b). MDA is structurally similar to other chemicals that are known or suspected of causing bladder cancer and it is assumed it may have a similar mode of action. 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 MDA specified in the Directive. MDA is identified as a candidate “substance of very high concern” under the REACH regulations.

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 0.8 mg/m$^3$ (0.1 ppm) or 0.08 mg/m$^3$ (0.01 ppm). MDA may be taken up into the body by inhalation and skin exposure and it is generally assigned a skin notation along with the numeric limit value.

MDA is an aromatic diamine used is used in the production of polyurethane foams and this accounts for 99% of the total quantity produced in the EU. In 2008, about 1.4 million tonnes of MDA was produced in the EU. MDA is also used as a hardener in epoxy resins and other adhesives, although these uses have been decreasing over time as alternative substances have been introduced.

It is estimated that there are between 70 and 140 people exposed to MDA in the EU chemical industry, primarily in the manufacture of polyurethane foam. The number of people potentially exposed in construction and other manufacturing is unknown, but could be between about 390,000 and 3.9 million people. MDA inhalation exposures are judged to be low. Exposure in 2010 was estimated to be at most 0.14 mg/m$^3$ during manufacture in the chemical industry and 0.07 mg/m$^3$ in other industrial sectors.

There is more uncertainty about potential dermal exposure and there is very little quantitative information available to inform the assessment of exposure. However, it is likely that in the chemical industry dermal exposures are low and in other sectors exposure may be higher.

Information about the hazard from MDA is limited. It is carcinogenic in animal toxicity studies but there is no human epidemiological evidence that occupational exposure causes cancer. By analogy with other aromatic amines it is presumed that MDA may cause bladder cancer. However, we were unable to identify a suitable risk estimate. We have not undertaken a health impact assessment because of the uncertainties surrounding the hazard in humans and the exposures in construction and sectors other than chemical manufacturing.

We have not been able to assess the health benefits that might arise from setting an OEL, although we believe the impact of setting a limit at 0.8 or 0.08 $mg/m^3$ would be relatively small because of the low current estimated inhalation exposures. We judge that there would be no significant economic costs associated with complying with an airborne OEL. The cost of reducing dermal exposures, aggregated over the period 2010 to 2069, might range between about €1,400m and €29,000m. These high costs arise from the potentially large number of workplaces that might be affected (between about 60,000 to 600,000). There are also no social or macro-economic costs associated with introducing an OEL or of introducing measures to reduce dermal exposure to MDA. There are no significant environmental impacts foreseen.

There are considerable uncertainties concerning estimates of skin exposure to MDA, although it seems this is probably the predominant route of exposure in most industry sectors. Given the potentially large number of people exposed in the EU it would be prudent to collect further MDA exposure data using biological and personal exposure monitoring.

The main identified impacts of control measures to reduce dermal exposure to MDA are summarised in the tables below, which are broken down by the main types of impacts (health, economic, social, macroeconomic and environmental). Since a specific EU wide biological monitoring value has not been proposed (due to a lack of data) impacts are based on the general costs and benefits associated with improved training, enclosure, housekeeping, personal protective equipment (PPE), which in any case would be considered to be ‘best practice’, but are not necessarily standard practice.

**Table 7.16** Comparison of health impacts by scenario

| Type of Impact | Baseline Scenario Health Costs | Baseline Scenario Health Benefits | Introduce 'best practice' control measures Health Costs | Introduce 'best practice' control measures Health Benefits |
|---|---|---|---|---|
| Health | The predominant route of exposure for MDA is most likely to be from skin contact rather than inhalation. Currently 4 million workers are estimated to be potentially exposed to MDA.<br>Due to insufficient exposure data it has not been possible undertaken a health assessment. | There is expected to be health benefits without further intervention as it is assumed that levels will continue to decrease by 7% per year based on a general review of historical changes in exposure level. | There is expected to be any decline in health costs from the introduction of best practice measures to reduce dermal exposure | Due to insufficient exposure data it has not been possible undertaken assess the benefits of introducing best practice measures to reduce dermal exposure. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.17** Comparison of economic impacts by scenario (Present Value – 2010 €m prices)

| Type of Impact | Baseline Scenario Economic Costs | Baseline Scenario Economic Benefits | Introduce 'best practice' control measures Economic Costs | Introduce 'best practice' control measures Economic Benefits |
|---|---|---|---|---|
| Economic | There is expected to be a 7% decline in exposure per year with some firms incurring costs on control dermal exposure (improved training, enclosure, housekeeping and use of PPE) which in any case would be considered to be 'best practice'.<br>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). | - | It is estimated that between 61,659 to 616,585 enterprises could be affected. This is highly uncertain given a lack of exposure data.<br>The total compliance cost over the assessment period for firms introducing measures earlier than maybe planned, is estimated to be around €62 to €1.2 billion per year which is estimated to be €1.4-29 billion in total over the period 2010-70.<br>Some of these costs will have been incurred under the baseline but perhaps much later than with the introduction of 'best practice' control measures. | Having more consistent EU-wide controls should remove any EU competitive distortions between EU Member States with different limits. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.18** Comparison of social impacts by scenario

| Type of Impact | Baseline Scenario: Social Costs | Baseline Scenario: Social Benefits | Introduce 'best practice' control measures: Social Costs | Introduce 'best practice' control measures: Social Benefits |
|---|---|---|---|---|
| Social | There are not expected to be any noticeable social impacts under the baseline scenario at an EU level.<br>At an installation level, some personnel may change their working practices (e.g. wearing PPE) to reduce risks of dermal exposure regardless of further intervention over the period 2010-2070. | | There are not expected to be any noticeable changes to the numbers of workers required as a result of introducing an EU-wide biological monitoring value. 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. | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.19** Comparison of macro-economic impacts by scenario

| Type of Impact | Baseline Scenario: Marco-economic Costs | Baseline Scenario: Marco-economic Benefits | Introduce 'best practice' control measures: Marco-economic Costs | Introduce 'best practice' control measures: Marco-economic Benefits |
|---|---|---|---|---|
| Macro-economic | There are not expected to be any noticeable macroeconomic impacts under the baseline scenario. | | Since compliance with an OEL would not involve changing the current manufacturing or agricultural process there is unlikely to be any significant change to macro-economic impacts. | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.20** Comparison of environmental impacts by scenario

| Type of Impact | Baseline Scenario: Environmental Costs | Baseline Scenario: Environmental Benefits | Introduce 'best practice' control measures: Environmental Costs | Introduce 'best practice' control measures: Environmental Benefits |
|---|---|---|---|---|
| Environmental | As set out in the EU RAR (EC, 2001) there are not expected to be any significant releases to air, water and aquatic environment. | | Since the proposed control measures should not affect end-uses or production quantity, there is not expected to be any significant change in environmental impacts relative to the baseline scenario. | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

## 7.5 4,4'-METHYLENE BIS 2-CHLOROANILINE

4,4'-methylene bis 2-chloroaniline (MbOCA) been classified by the International Agency for Research on Cancer (IARC) as carcinogenic to humans based on limited human epidemiological data and other evidence that it may cause bladder tumours. Under the classification and labelling legislation in Europe it is classified as a Cat 2 carcinogen and they are therefore within the scope of the EU Carcinogens Directive. However, there is no occupational exposure limit (OEL) for MbOCA specified in the Directive.

Exposure to MbOCA is primarily by skin uptake and so in this report we focus on biological monitoring data rather than inhalation exposure. This report considers the likely health, socioeconomic and environmental impacts associated with possible changes to the Carcinogens Directive, in particular the possible introduction of a limit value equivalent to a biological monitoring guidance value (BMGV) of either 5 and 15 μmol/mol.

MbOCA is an aromatic amine used as a curing agent in epoxy resins and mixed with isocyanate based resins to produce polyurethanes and elastomers. It is widely used in the rubber and plastic industries. It is not manufactured in the European Union (EU) countries and is supplied as pellets, granules or liquid form. It is estimated that approximately 2,500 workers in the EU are potentially exposed to MbOCA, of which about 1,400 are estimated to be potentially exposed in high exposure industries (manufacture of rubber and plastic products). Average exposure levels are probably about 2.3 μmol/mol with a geometric standard deviation of 5. This implies that currently about 16% of exposures are above 5 μmol/mol and about 5% above 15 μmol/mol. It is likely that average MbOCA exposures have been decreasing by about 7.9% per annum.

We estimate that in 2010 in the EU there will be about 3 deaths (eight registrations) from bladder cancer that might be attributable to past exposure to MbOCA, which corresponds to about 0.006% of all bladder cancer deaths and a loss of 39 Disability-Adjusted Life Years (DALYs). In the absence of any intervention the health burden is predicted to drop steadily over the next 50 years.

The main costs associated with inaction occur in the period 2010-2040, and these are predominately the result of past exposure. It is estimated that in total over the next 60 years there will be between €45m and €353m of health costs if no limit value is introduced, with the highest costs falling on Germany, France, Italy, the UK and Poland.

It is judged that compliance with a BMGV of 15 μmol/mol could be achieved with no important cost implications through improved training and supervision. By 2060 it is predicted the attributable cancer deaths with this limit would be less than one per annum (based on <1 registration). It is estimated there will be two DALYs vs four DALYs for the baseline scenario. Compliance with a limit of 5 μmol/mol would result in less than one attributable cancer registration and death by 2060 (zero DALYs by 2060). The health benefits over the period 2010 to 2069 are expected to be between €1m and €7m for the 15 μmol/mol limit and between €1m and €11m for the 5 μmol/mol limit. Corresponding cost of compliance over the same period are estimated as between €564m and €1,129m for the higher limit and between €1,482m and €2,964m for the lower limit.

It are not expected that there will be any important social, macro-economic or environmental impacts.

The main identified impacts of introducing a biological monitoring guidance value (BMGV) of either 5 and 15 μmol/mol for MbOCA are summarised in the tables below, which are broken down by the main types of impacts (health, economic, social, macroeconomic and environmental).

**Table 7.21** Comparison of health impacts by scenario (Present Value – 2010 €m prices)

| | **Baseline Scenario** | | **Introduce BMGV=5 µmol/ mol** | | **Introduce BMGV=15 µmol/ mol** | |
|---|---|---|---|---|---|---|
| **Type of impact** | **Health Costs** | **Health Benefits** | **Health Costs** | **Health Benefits** | **Health Costs** | **Health Benefits** |
| Health | As set out in section 2.5, the health costs of cancer (bladder) over the period 2010-70 are estimated to be:<br>• Females: €3m to €41<br>• Males: €38 m to €313m<br>• Total: €45m to €353m<br>This range takes into consideration tangible costs (e.g. lost income, lost output from reduced productivity, medical costs, life years lost) and intangible costs (e.g. emotional and physical suffering from having cancer). | It is assumed that exposures fall by 7.9% per year in the future continuing the historical trend in reduced exposure.<br>Therefore there are expected to be some reduction in health costs going forward in the absence of further regulatory intervention. | None - there is expected to be a cost saving from avoided health care and reduced cost of illness due to reductions in cancer registrations.<br>This has been estimated as a benefit. | Health benefits of the proposed BMGV have been analysed at the Member State and industrial sector level. The results showed that the benefits of introducing a BMGV in 2010 are most apparent to the manufacture of rubber and plastics products sector from 2040 onwards. It was also found that the monetised benefits are likely to affect men more than women.<br>The monetised benefits were estimated as:<br>Females: €0-1m<br>Males: €1-9m<br>Totals: €1-11m | None - there is expected to be a cost saving from avoided health care and reduced cost of illness due to reductions in cancer registrations.<br>This has been estimated as a benefit. | The monetised benefits were estimated as:<br>• Females: €0-1m<br>• Males: €1-7m<br>• Totals: €1-7m<br>The impacts of introducing an EU-wide BMGV at 15µmol/ mol are estimated to have more limited health benefits as there is already estimated to be a reduction towards 15µmol/ mol under the baseline scenario. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.22** Comparison of economic impacts by scenario (Present Value – 2010 €m prices)

| | Baseline Scenario | | Introduce BMGV=5 µmol/ mol | | Introduce BMGV=15 µmol/ mol | |
|---|---|---|---|---|---|---|
| **Type of impact** | **Economic Costs** | **Benefits** | **Economic Costs** | **Economic Benefits** | **Economic Costs** | **Economic Benefits** |
| Economic | There are expected to be costs to some rubber and plastics manufacturing firms to put into place improved training and cleaning measures to reduce dermal exposure by 7.9% per year. | | There are expected to be economic costs related to changes to workplace practices in order to meet the possible BMGV for the manufacture of rubber and plastic products sector.<br>It is estimated that ~31% of enterprises would require some form of additional control measure to meet the proposed limit. The remainder are assumed to already be meeting the possible BMGV under the baseline scenario and therefore would require no further action. It is assumed that the majority of those that do not currently comply would need to implement relatively low-cost measures to reduce exposure levels to meet the BMGV. These costs (€1-2k) are not considered to be significant in comparison to gross operating surplus.<br>There would be administrative costs of implementing the BMGV in national legislation and of demonstrating and verifying compliance. | Having an EU-wide BMGV 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 BMGV for the manufacture of rubber and plastic products sector.<br>It is estimated that ~12% of enterprises will require some form of control measure to meet the proposed OEL. The remainder are assumed to already be meeting the proposed BMGV under the baseline scenario and therefore will require no further action. It is assumed that the majority of those that cannot comply will need to implement 'best practice' low-cost measures to reduce exposure levels to meet the BMGV. These costs (€1-2k) are not considered to be significant in comparison to gross operating surplus.<br>There would be administrative costs of implementing the BMGV in national legislation and of demonstrating and verifying compliance. | Having an EU-wide BMGV should remove any EU competitive distortions between EU Member States with different BMGV limits. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.23** Comparison of social impacts by scenario

| Type of impact | Baseline Scenario Social Costs | Baseline Scenario Social Benefits | Introduce BMGV=5 µmol/ mol Social Costs | Introduce BMGV=5 µmol/ mol Social Benefits | Introduce BMGV=15 µmol/ mol Social Costs | Introduce BMGV=15 µmol/ mol Social Benefits |
|---|---|---|---|---|---|---|
| Social | There are not expected to be any noticeable social impacts under the baseline scenario at an EU level. At an installation level, employees will need to change their working practice (e.g. hygiene and cleaning) to reduce risks of dermal exposure. | | Impacts are expected to be similar to the baseline. Some firms (63) will require changes to workplace best practice. | | Impacts are expected to be similar to the baseline. Some firms (24) will require changes to workplace best practice. | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.24** Comparison of macro-economic impacts by scenario

| Type of impact | Baseline Scenario Macro-economic Costs | Baseline Scenario Macro-economic Benefits | Introduce BMGV=5 µmol/ mol Macro-economic Costs | Introduce BMGV=5 µmol/ mol Macro-economic Benefits | Introduce BMGV=15 µmol/ mol Macro-economic Costs | Introduce BMGV=15 µmol/ mol Macro-economic Benefits |
|---|---|---|---|---|---|---|
| Marco-economic | There are not expected to be any noticeable macroeconomic impacts under the baseline scenario. | | None - since no additional engineering controls are expected to be required, there are not expected to be any significant macroeconomic impacts relative to the baseline scenario from introducing an EU-wide BMGV. | | | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.25** Comparison of environmental impacts by scenario

| Type of impact | Baseline Scenario Environmental Costs | Baseline Scenario Environmental Benefits | Introduce BMGV=5 µmol/ mol Environmental Costs | Introduce BMGV=5 µmol/ mol Environmental Benefits | Introduce BMGV=15 µmol/ mol Environmental Costs | Introduce BMGV=15 µmol/ mol Environmental Benefits |
|---|---|---|---|---|---|---|
| Environmental | None | | None – controls on MbOCA in the workplace that would be needed to meet this BMGV relate to improvements in training and supervision of employees rather than implementation of additional engineering controls. Therefore it is not expected that achievement of the BMGV would lead to changes in environmental impacts. | | None – it is assumed that controls on MbOCA in the workplace that would be needed to meet this BMGV have already been implemented. Therefore it is not expected that achievement of the BMGV would lead to changes in environmental impacts. | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

## 7.6 ETHYLENE OXIDE

Ethylene oxide been classified by the International Agency for Research on Cancer (IARC) as carcinogenic to humans based on limited human epidemiological data and other evidence that it may cause leukaemia (IARC category 1). Under the classification and labelling legislation in Europe it is classified as a Cat 2 carcinogen and it is therefore within the scope of the EU Carcinogens Directive. However, there is no occupational exposure limit (OEL) for ethylene oxide 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 1 ppm (1.8 mg/m$^3$).

About 3.8 million tonnes of ethylene oxide are produced in Europe each year. The majority is used in the manufacture of ethylene oxide derivatives such as ethylene glycols, which are used in the production of consumer goods. Other uses include surface active agents, for example non-ionic alkylphenol ethoxylates, and other minor uses. About 0.05% of ethylene oxide produced is used in its gaseous form as a sterilizing agent for heat sensitive equipment. It is estimated that approximately 15,600 workers in the EU are potentially exposed to ethylene oxide. Average exposure levels in the 1980s were probably between about 1 ppm and 5 ppm, although since the 1980s exposures are judged to have been below 1 ppm.

We estimate that in the period 2000-2010 in the EU there were about 5 deaths or less per year from leukaemia that were attributable to exposure to ethylene oxide before the early 1980s, which corresponded to about 0.01% of all deaths from leukaemia and a loss of 82 Disability-Adjusted Life Years (DALYs) each year. It is judged that employers in the EU are probably already fully compliant with the suggested OEL of 1 ppm (1.8 mg/m$^3$), and have been so for more than 20 years. Leukaemia caused by ethylene oxide exposure is assumed to have a relatively short latency (20 years) and so there are no attributable registrations or deaths from 2010 onwards.

We judge that there will be no additional costs to comply with an OEL of 1 ppm and no health benefits because employers are already in full compliance with this limit.

It is not expected that there will be any important social, macro-economic or environmental impacts from introducing an OEL at 1 ppm.

The main identified impacts of introducing an OEL of 1 ppm for ethylene oxide are summarised in the tables below, which are broken down by the main types of impacts (health, economic, social, macroeconomic and environmental).

**Table 7.26** Comparison of health impacts by option

| Type of impact | Baseline Scenario | | Introduce OEL=1ppm | |
|---|---|---|---|---|
| | **Health Costs** | **Health Benefits** | **Health Costs** | **Health Benefits** |
| Health | Large-scale implementation of control measures during the 1980s and 1990s means that exposure is maintained well below the proposed EU-wide OEL of 1ppm in the baseline scenario. Therefore there is not estimated to be a cancer risk from worker exposure ethylene oxide under current conditions. | No health benefits are expected as exposure is already estimated to be controlled to below 1ppm under the baseline scenario. | None | The impacts of introducing an EU-wide OEL at 1ppm is estimated to have no health benefits as exposure is already estimated to be controlled to below 1ppm under the baseline scenario. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.27** Comparison of economic impacts by option

| | Baseline Scenario | | Introduce OEL=1ppm | |
|---|---|---|---|---|
| **Type of impact** | **Economic Costs** | **Economic Benefits** | **Economic Costs** | **Economic Benefits** |
| Economic | It is assumed that industries affected have already incurred costs of installing control measures to reduce ethylene oxide emissions. | Hospitals may replace EO sterilisation units with non-EO alternatives which are associated with fewer health hazards. The development of feasible alternatives may benefit research and development in exposure controls. | Controls on EO in the workplace needed to meet the possible OEL of 1ppm have largely been installed, therefore it is assumed there is not expected to be any significant additional compliance cost in meeting an OEL of 1ppm relative to the baseline scenario. There would be administrative costs of implementing the OEL in national legislation and of demonstrating and verifying compliance. | Having an EU-wide OEL level should remove any EU competitive distortions between EU Member States with different OELs. However, there are unlikely to be significant practical differences in compliance costs based on data from the exposure assessment. Hospitals may replace EO sterilisation units with non-EO alternatives which are associated with fewer health hazards. The development of feasible alternatives may benefit research and development in exposure controls. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.28** Comparison of social impacts by option

| | Baseline Scenario | | Introduce OEL=1ppm | |
|---|---|---|---|---|
| **Type of impact** | **Social Costs** | **Social Benefits** | **Social Costs** | **Social Benefits** |
| Social | There is not expected to be any noticeable social impacts under the baseline scenario. | | None - there are not expected to be any social impacts relative to the baseline scenario from introducing an EU-wide OEL | None – there are not expected to be any social impacts relative to the baseline scenario from introducing an EU-wide OEL |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.29** Comparison of macroeconomic impacts by option

| | Baseline Scenario | | Introduce OEL=1ppm | |
|---|---|---|---|---|
| **Type of impact** | **Macro-economic Costs** | **Macro-economic Benefits** | **Macro-economic Costs** | **Macro-economic Benefits** |
| Marco-economic | There is not expected to be any noticeable macroeconomic impacts under the baseline scenario. | | None - since no additional controls are expected to be required, there are not expected to be any macroeconomic impacts relative to the baseline scenario from introducing an EU-wide OEL. | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.30** Comparison of environmental impacts by option

| | Baseline Scenario | | Introduce OEL=1ppm | |
|---|---|---|---|---|
| **Type of impact** | **Environmental Costs** | **Environmental Benefits** | **Environmental Costs** | **Environmental Benefits** |
| Environmental | None - controls on EO in the workplace needed have already been implemented. | | None - controls on EO in the workplace that would be needed to meet the possible OEL have already been implemented. Therefore it is not expected that achievement of the OEL would lead to additional environmental impact. | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

## 7.7 REFRACTORY CERAMIC FIBRES

Based on animal toxicity data, exposure to refractory ceramic fibres (RCF) may cause lung cancer. However, there is no human epidemiological data to enable us to estimate the risks. To enable us to make a health impact assessment we have assumed that exposure to RCF is no worse than chrysotile (white) asbestos in its ability to cause lung cancer, which we consider is a “worst-case” assessment.

The International Agency for Research on Cancer (IARC) considers RCF is a possible human carcinogen (category 2b) and it is classified as a category 2 carcinogen in Europe under the classification and labelling regulations. RCF has also been identified as a Substance of Very High Concern under the REACH Regulation, although we understand that the substance definitions may be amended. This report considers the likely health, socioeconomic and environmental impacts associated with possible changes to the EU Carcinogens Directive, in particular the possible introduction of an occupational exposure limit (OEL) of either 0.1 fibres/ml or 1 fibres/ml. Note, in October 2010, SCOEL recommended a limit of 0.3 fibres/ml.

Lung cancer is the commonest cancer amongst men in Europe that is generally diagnosed on people over 40 years of age, and incidence rises steadily thereafter. Cigarette smoking most commonly causes lung cancer, although there are several occupational agents that are also known to cause this disease. Most people with lung cancer die within 5 years of diagnosis.

RCF are synthetic vitreous fibres or man-made mineral fibres used in industry for their properties of heat resistance, tensile strength and durability. European Union Directive 97/69/EC defined RCFs as “Man-made vitreous (silicate) fibres with random orientation with alkaline oxide and alkaline earth oxide content less than 18% by weight.” There are about 730 workers employed in RCF production plants in Germany, France and the UK. There are about 9,270 people employed in the downstream user industry. Geometric mean exposures in the industry are less than 0.2 fibres/ml and it is estimated that about 7% of workers in manufacturing facilities and 12% of workers at downstream user facilities have been exposed above 1 fibres/ml. More than half of workers are exposed above 0.1 fibres/ml. It is assumed that exposure levels have been decreasing by about 7% per annum since the late 1990s.

The predicted number of deaths from past occupational exposure to RCF using our worst-case assumptions about potential risks is low (in 2010, no attributable deaths in manufacturing and two deaths in downstream users). The predicted number of deaths decreases in the future so that by 2050 there are no predicted deaths occurring as a result of RCF exposure at work. The number of incident lung cancers is similar to the estimated number of deaths. Introducing a OEL of either 0.1 or 1 fibres/ml has no important effect on the predicted cancer deaths or registrations from RCF. For both potential OELs the estimated DALYs decrease from 29 years in 2010 to zero years by 2060; with no intervention there are two DALYs predicted in 2060.

We have not estimated risks of mesothelioma because we do not believe the human epidemiological data substantiates such a risk. However, if this assumption is in error then a worst case assumption might be that RCF exposure could cause three times as many cancers as we have currently estimated. While this would increase the health impact we do not believe this importantly changes our conclusions.

It is likely that an EU-wide OEL of 1.0 fibres/ml could be met through greater uptake of currently applied techniques within the industry. The associated costs are likely to be relatively low. There is calculated to be a small health benefit associated with such an OEL, valued at up to €1-2 million in total over the period 2010-2069. The value is relatively low because of the low level of assumed cancer incidence under the baseline and the existing controls in place. It is not expected that there would be any important social, macro-economic or environmental impacts with an OEL at 1.0 fibres/ml.

The other OEL investigated in detail, 0.1 fibres/ml, could have much more significant impacts upon the industry. To achieve exposure at this level would require a degree of automation and enclosure that is unlikely to be feasible, especially for certain downstream users. The compliance costs associated with an OEL of 0.1 fibres/ml are estimated at:

- Around €60 to €140 million over the period 2010 to 2069 associated with controlling exposure. This includes controls at manufacturing sites as well as downstream users, although the controls adopted at downstream users are unlikely to allow the possible OEL to be achieved in practice.

- If achieving the OEL is technically or economically infeasible, companies may decide to substitute RCF with alternatives such as AES and PCW. The associated costs could be of the order of €2.5 billion over the same period.

These costs, coupled with the technical feasibility issues, could lead to some relocation of activities to outside the EU, with associated loss of employment.

The health benefits of achieving an OEL of 0.1 fibres/ml are likely to be minimal, and have been valued at up to €1-2 million in total over the period 2010-2069. Again, the value is relatively low because of the low level of assumed cancer incidence under the baseline and the existing controls in place.

The SCOEL has recently recommended an OEL of 0.3 fibres/ml. Whilst this recommendation was issued after the OELs for analysis in the study (1.0 and 0.1 fibres/ml) were agreed, some indicative estimates have been derived for the costs of compliance, including: €6 to €20 million for an OEL at 0.2 fibres/ml and €4 to €17 million for an OEL at 0.3 fibres/ml. The latter OEL could be more technically feasible than 0.1 fibres/ml, meaning that the costs of substitution with alternatives would not be incurred.

The main identified impacts of introducing an OEL of 0.1 fibres/ml or 1 fibres/ml for refractory ceramic fibres are summarised in the tables below, which are broken down by the main types of impacts (health, economic, social, macroeconomic and environmental).

**Table 7.31** Comparison of health impacts by scenario (Present Value – 2010 €m prices)

| Type of Impact | Baseline Scenario<br>Health Costs | <br>Health Benefits | Introduce OEL = 1 fibres/ml<br>Health Costs | <br>Health Benefits | Introduce OEL = 0.1 fibres/ml<br>Health Costs | <br>Health Benefits |
|---|---|---|---|---|---|---|
| Health | As set out in section 2.5, the health costs of cancer (lung) over the period 2010-70 are estimated to be €33m to €83m.<br>This range takes into consideration tangible costs (e.g. lost income, lost output from reduced productivity, medical costs, life years lost) and intangible costs (e.g. emotional and physical suffering from having cancer).<br>These costs are themselves be an upper bound given the difficulties in attributing lung cancer to exposure of RCF/ASW. | It is assumed that exposures will fall by 7% per year in the future.<br>Therefore there is expected to be some reduction in health costs going forward in the absence of further regulatory intervention | There is expected to be a small cost saving from avoided health care and reduced cost of illness due to reductions in cancer registrations.<br>This has been estimated as a benefit. | Health benefits of the possible OEL have been analysed at the Member State and industrial occupational level.<br>The benefits of introducing an OEL in 2010 are likely to be most apparent during the installation of RCF/ASW.<br>It was also found that the monetised benefits are likely to predominantly affect men.<br>The monetised benefits over 2010-2070 were estimated at €1-2m. | There is expected to be a small cost saving from avoided health care and reduced cost of illness due to reductions in cancer registrations.<br>This has been estimated as a benefit. | Health benefits of the possible OEL have been analysed at the Member State and industrial occupational level.<br>The benefits of introducing an OEL in 2010 are likely to be most apparent during the installation of RCF/ASW.<br>It was also found that the monetised benefits are likely to predominantly affect men.<br>The monetised benefits over 2010-2070 were estimated at €1-3m. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.32** Comparison of economic impacts by scenario (Present Value – 2010 €m prices)

| Type of Impact | Baseline Scenario: Economic Costs | Baseline Scenario: Economic Benefits | Introduce OEL = 1 fibres/ml: Economic Costs | Introduce OEL = 1 fibres/ml: Economic Benefits | Introduce OEL = 0.1 fibres/ml: Economic Costs | Introduce OEL = 0.1 fibres/ml: Economic Benefits |
|---|---|---|---|---|---|---|
| Economic | There are expected to be costs to RCF/ASW related firms to put into place improved training and cleaning measures (e.g. the CARE programme) to reduce exposure that would occur regardless of further intervention over the period 2010-2070. | - | Consultation with ECFIA suggested that there would be limited costs of meeting an OEL of 1 fibres/ml as average exposure is already below 1fibres/ml but there may be some job occupations across the EU that may require action to meet a 1 fibres/ml. Therefore it is assumed that there would not be significant costs of compliance with an OEL of 1 fibres/ml. | Having an EU-wide OEL should remove competitive distortions between EU Member States with different limits. | The total costs of compliance through exposure control measures are estimated to be between €60m and €139m over the period 2010-69. The extra cost if all RCF/ASW (~20kt per year) was replaced with AES could be around £566million over the period 2010-69 with costs mainly as result of reduced durability. The premium if all RCF/ASW (~20kt per year) was replaced with PCW could be around €13-20billion over the period 2010-69; with the upper estimate assuming a 2% increase in annual prices over time for inflation. As it is not technically feasible to substitute all ASW/RCF with AES, perhaps a more realistic scenario would be substitution of around 15% with PCW and 85% with AES, at an estimated cost of €95m over the period 2010-69. | Having an EU-wide OEL should remove competitive distortions between EU Member States with different limits. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.33** Comparison of social impacts by scenario

| Type of Impact | Baseline Scenario Social Costs | Baseline Scenario Social Benefits | Introduce OEL = 1 fibres/ml Social Costs | Introduce OEL = 1 fibres/ml Social Benefits | Introduce OEL = 0.1 fibres/ml Social Costs | Introduce OEL = 0.1 fibres/ml Social Benefits |
|---|---|---|---|---|---|---|
| Social | There are not expected to be any noticeable social impacts under the baseline scenario at an EU level. | | **No change** - There are not expected to be any noticeable changes to the numbers of workers required as a result of introducing an EU-wide at 1 fibres/ml. 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. | | There is a risk that production of RCF/ASW (and possibly AES and PCW) may be relocated outside of the EU at an OEL of 0.1 fibres/ml as costs of abatement and/or substitution are likely to be prohibitive in some cases, although some of the costs may be passed on e.g. to furnace operators.<br>The price premium from using PCW in particular will mean that EU firms may be more susceptible to imports of PCW into the EU, as shipping costs will account for a smaller proportion of the total cost to end consumers relative to RCF. Therefore an OEL set at 0.1 fibres/ml could lead to greater demand from non-EU countries. | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.34** Comparison of macro-economic impacts by scenario

| Type of Impact | Baseline Scenario Macro-economic Costs | Baseline Scenario Macro-economic Benefits | Introduce OEL = 1 fibres/ml Macro-economic Costs | Introduce OEL = 1 fibres/ml Macro-economic Benefits | Introduce OEL = 0.1 fibres/ml Macro-economic Costs | Introduce OEL = 0.1 fibres/ml Macro-economic Benefits |
|---|---|---|---|---|---|---|
| Macro-economic | 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. | | | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.35** Comparison of environmental impacts by scenario

| Type of Impact | Baseline Scenario: Environmental Costs | Baseline Scenario: Environmental Benefits | Introduce OEL = 1 fibres/ml: Environmental Costs | Introduce OEL = 1 fibres/ml: Environmental Benefits | Introduce OEL = 0.1 fibres/ml: Environmental Costs | Introduce OEL = 0.1 fibres/ml: Environmental Benefits |
|---|---|---|---|---|---|---|
| Environmental | The use of RCF/ASW as a furnace insulation material has environmental benefits, including improved energy efficiency of furnaces through reducing heat loss for optimum furnace temperatures and through reduced $CO_2$ emissions from reduced energy consumption. | | **No change -** It is thought to be unlikely that furnace operators would move to older-type brick insulation or go without insulation given the environmental (and cost) benefits. The use of general exposure controls therefore should not affect these environmental benefits or lead to significant increased environmental impacts. | | A potentially negative aspect of using AES as an alternative is that as it is currently not as durable as RCF/ASW, this is likely to lead to an overall increase in resource consumption and lifecycle emissions (e.g. increased production, distribution, repairs and disposable). These impacts are not expected to occur with PCW, although it is a much more expensive alternative (20 times) relative to RCF/ASW.<br>Both the production of AES and PCW are more energy intensive than RCF/ASW and therefore there will be a small increase in emissions from production and use of electricity. | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

## 7.8 HYDRAZINE

Exposure to hydrazine may cause lung and colorectal cancer. Hydrazine has been classified as a group 2b carcinogen (Possibly carcinogenic to humans) by the International Agency for Research on Cancer and as a Cat 2 carcinogens in the EU under the classification and labelling legislation, and it is therefore within the scope of the EU Carcinogens Directive. This report considers the likely health, socioeconomic and environmental impacts associated with possible changes to the EU Carcinogens Directive, in particular the possible introduction of an occupational exposure limit (OEL) of either 0.013 mg/m$^3$ (0.01 ppm) or 0.13 mg/m$^3$ (0.1 ppm).

Both lung and colorectal cancer are relatively common and they are generally diagnosed on people over 60 years of age. In the EU, these cancers make up about 25% of all cancer incidence. About half of all people diagnosed with colorectal cancer will die from their disease within 5-years and about 90% of lung cancer patients die in the same timeframe.

The main uses of hydrazine include chemical blowing agents, agricultural pesticides, and water treatment. In the EU the largest producers are located in Germany and France. There are probably about 23 thousand tonnes of hydrazine produced in Europe each year. We estimated that in 2006, a total of 2.1 million individuals are exposed to low levels of hydrazine, about 15,000 to medium levels and around 800 to high levels.

There is very little information available on current hydrazine exposure levels in industry. However based on the available data we estimate that the upper estimate of exposure in the high group industries is probably about 0.7 mg/m$^3$ and the corresponding levels in the medium and low groups are 0.1 and 0.06 mg/m$^3$, respectively. Overall, we consider there are about 75% of workers exposed above 0.013 mg/m$^3$ and about 8% above 0.13 mg/m$^3$. Exposures were assumed to be decreasing by about 7% per annum.

We estimate that in 2010 there will be 18 cases of lung cancer (16 deaths) from past exposure to hydrazine and 131 cases of colorectal cancer (27 deaths). Over the next 40 years the incidence of cancers attributable to hydrazine decreases to zero for both types of cancer. The corresponding DALYs for lung cancer decrease from 267 in 2010 to zero in 2050 and beyond, and from 698 to zero over the same time period for colorectal cancer. Health costs associated with these cancers are between about €500m and €3,000m, aggregated over the period 2010 to 2069. These costs fall mainly on France, Germany, Italy, Poland, Romania, Spain and the UK.

There are no important health benefits from introducing a limit at either 0.013 or 0.13 mg/m$^3$, mainly because exposures are predicted to continue to decrease over the next 20 years and the additional impact of any limit is judged to be negligible. The monetised health benefits are very small (<€0.02m). Costs of compliance with the higher suggested OEL range from €15m to €47m and for the lower OEL from €62 to €196m.  It is not expected that there will be any important social, macro-economic or environmental impacts.

The main identified impacts of introducing an OEL of 0.013 mg/m$^3$ (0.01 ppm) and 0.13 mg/m$^3$ (0.1 ppm) for hydrazine are summarised in the tables below, which are broken down by the main types of impacts (health, economic, social, macroeconomic and environmental).

**Table 7.36** Comparison of health impacts by scenario (Present Value – 2010 €m prices)

| Type of Impact | Baseline Scenario: Health Costs | Baseline Scenario: Health Benefits | Introduce OEL = 0.013mg/m$^3$: Health Costs | Introduce OEL = 0.013mg/m$^3$: Health Benefits | Introduce OEL = 0.13mg/m$^3$: Health Costs | Introduce OEL = 0.13mg/m$^3$: Health Benefits |
|---|---|---|---|---|---|---|
| Health | The health costs of cancer (lung and colorectal) over the period 2010-70 are estimated to be:<br>• Females:€165 – 1,234m<br>• Males: €330 – 1,722m<br>• Total: €495 – 2,956m<br>However over 95% of costs occur prior to 2030 and are the result of past exposure. Health costs of future exposure are estimated to be limited. This range takes into consideration tangible costs (e.g. lost income, lost output from reduced productivity, medical costs, life years lost) and intangible costs (e.g. emotional and physical suffering from having cancer). | It is assumed that exposures fall by 7% per year in the future, continuing the historical trend in reduced exposure. Therefore there is expected to be a significant reduction in health costs going forward in the absence of further regulatory intervention. | None | There is estimated to be little to no benefit to introducing an EU wide OEL.<br><br>The impacts of introducing an OEL are estimated to have no/limited benefits as there is already estimated to be a reduction towards 0.013mg/m$^3$ and below under the baseline scenario. Even without discounting health benefits over time the benefits are estimated to be limited. | None | There is estimated to be little to no benefit to introducing an EU wide OEL.<br><br>The impacts of introducing an OEL are estimated to have no/limited benefits as there is already estimated to be a reduction towards 0.013mg/m3 and below under the baseline scenario. Even without discounting health benefits over time the benefits are estimated to be limited. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.37** Comparison of economic impacts by scenario (Present Value – 2010 €m prices)

| | **Baseline Scenario** | | **Introduce OEL = 0.013mg/m$^3$** | | **Introduce OEL = 0.13mg/m$^3$** | |
|---|---|---|---|---|---|---|
| **Type of Impact** | **Economic Costs** | **Economic Benefits** | **Economic Costs** | **Economic Benefits** | **Economic Costs** | **Economic Benefits** |
| Economic | There are expected to be costs to sectors exposed to hydrazine due to expected further spending on control measures to reduce exposure.<br>These costs might relate to improving working practice (PPE) or installation and use of engineering control measures (e.g. improved ventilation, improved loading/ unloading equipment). | - | The largest industry sectors where workers are exposed to hydrazine are those involved with its manufacture (NACE 24) and those who use it as a herbicide in the agricultural sector (NACE 1).<br>It is estimated that around 2,126 firms may be affected by an OEL at 0.013mg/m$^3$ with 2,024 from NACE 1 and 103 from NACE 24. These represent a very small proportion of the sector (<1%).<br>Annual costs of RPE and compliance with the carcinogens Directive per enterprise in NACE code 1 over the period 2010-2069 (NPV) is estimated at €1-3k.<br>Annual costs of use/installation of local exhaust ventilation (LEVs) and compliance with the carcinogens Directive per enterprise in NACE code 24 over the period 2010-2069 (NPV) is estimated at €3-7k p.a for those who have existing LEVs but not being properly used/maintained. The costs are around €6-25k p.a. for those that need to install an LEV.<br>The total costs over the period 2010-2069 (NPV) are estimated at between €62– 196m. However these costs are subject to high uncertainty as many of the costs set out above *may* also be occurred under the baseline in the future without further intervention. | Having an EU-wide OEL level will remove any EU competitive distortions between EU Member States with different OELs. | The largest industry sectors where workers are exposed to hydrazine are those involved with its manufacture (NACE 24) and those who use it as a herbicide in the agricultural sector (NACE 1).<br>It is estimated that around 426 firms may be affected by an OEL at 0.13mg/m$^3$ with 388 from NACE 1 and 38 from NACE 24. These represent a very small proportion of the sector (<1%).<br>Annual costs of RPE and compliance with the carcinogens Directive per enterprise in NACE code 1 over the period 2010-2069 (NPV) is estimated at €1-3k.<br>Annual costs of use/installation of local exhaust ventilation (LEVs) and compliance with the carcinogens Directive per enterprise in NACE code 24 over the period 2010-2069 (NPV) is estimated at €3-7k p.a for those who have existing LEVs but not being properly used/maintained. The costs are around €6-25k p.a. for those that need to install an LEV.<br>The total costs over the period 2010-2069 (NPV) are estimated at between €15– 47m. However these costs are subject to high uncertainty as many of the costs set out above *may* also be occurred under the baseline in the future without further intervention. | Having an EU-wide OEL level will remove any EU competitive distortions between EU Member States with different OELs. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.38** Comparison of social impacts by scenario

| Type of Impact | Baseline Scenario Social Costs | Baseline Scenario Social Benefits | Itnroduce OEL = 0.013mg/m$^3$ Social Costs | Itnroduce OEL = 0.013mg/m$^3$ Social Benefits | Introduce OEL = 0.13mg/m$^3$ Social Costs | Introduce OEL = 0.13mg/m$^3$ Social Benefits |
|---|---|---|---|---|---|---|
| Social | There are not expected to be any noticeable social impacts under the baseline scenario at an EU level. At an installation level, some personnel may change their working practices (e.g. wearing PPE or using LEVs) to reduce risks of inhalation exposure regardless of further intervention over the period 2010-2070. | | 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 the OEL, behavioural change amongst employees and updating health and safety training will be required. | Mechanical ventilation may be better for workers than natural ventilation as air change rates and flow can be controlled. If the mechanical ventilation includes a heat exchanger with high efficiency this might typically reduce the ventilation heat loss. The sectors (NACE 24 and 1) that experience the highest impact and thus cost are those that would experience the largest benefits from the control of exposure and meeting the OEL. | 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 the OEL, behavioural change amongst employees and updating health and safety training will be required. | Mechanical ventilation may be better for workers than natural ventilation as air change rates and flow can be controlled. If the mechanical ventilation includes a heat exchanger with high efficiency this might typically reduce the ventilation heat loss. The sectors (NACE 24 and 1) that experience the highest impact and thus cost are those that would experience the largest benefits from the control of exposure and meeting the OEL. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.39** Comparison of macro-economic impacts by scenario

| Type of Impact | Baseline Scenario: Macro-economic Costs | Baseline Scenario: Macro-economic Benefits | Introduce OEL = 0.013mg/m$^3$: Macro-economic Costs | Introduce OEL = 0.013mg/m$^3$: Macro-economic Benefits | Introduce OEL = 0.13mg/m$^3$: Macro-economic Costs | Introduce OEL = 0.13mg/m$^3$: Macro-economic Benefits |
|---|---|---|---|---|---|---|
| Macro-economic | There are not expected to be any noticeable macroeconomic impacts under the baseline scenario. | | Since compliance with an OEL would not involve changing the current manufacturing or agricultural process there is unlikely to be any significant change to macro-economic impacts. | | | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.40** Comparison of environmental impacts by scenario

| Type of Impact | Baseline Scenario: Environmental Costs | Baseline Scenario: Environmental Benefits | Introduce OEL = 0.013mg/m$^3$: Environmental Costs | Introduce OEL = 0.013mg/m$^3$: Environmental Benefits | Introduce OEL = 0.13mg/m$^3$: Environmental Costs | Introduce OEL = 0.13mg/m$^3$: Environmental Benefits |
|---|---|---|---|---|---|---|
| Environmental | Not estimated | | The increased use of LEVs will mean more hydrazine will be sent to air although this is not expected to have a significant environmental impact as hydrazine is degraded rapidly in air. The use of PPE and best practice when using hydrazine as a herbicide may reduce risks to soil (e.g. over spraying, exposure to soil from storage transfer) but overall there is not expected to be a significant environmental impact relative to the baseline. | | | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

## 7.9 1, 2-EPOXYPROPANE

1,2-epoxypropane (or propylene oxide) 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-epoxypropane 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 2 ppm or 5 ppm. The SCOEL committee have recently recommended a long-term OEL of 1ppm.

The production capacity for 1,2-epoxypropane within the EU is 2.75 million tonnes per year and it is produced in eight member states. The major use of 1,2-epoxypropane is to make 1,2-epoxypropane polymers called polyether polyols that are used in the manufacture of polyurethane foams. The second most important use is in the production of propylene glycol, which is made by high pressure and temperature hydrolysis of 1,2-epoxypropane. About 5% of all 1,2-epoxypropane production is used in a diverse range of applications such as the manufacture of surfactants and as a stabiliser for dichloromethane. It is estimated that there are 35 to 70 workers across the EU exposed to 1,2-epoxypropane during its manufacture (total 450 to 1,500 workers exposed in the chemical industry).

There are limited data available about current exposure levels within the chemical industry. We estimate the geometric mean level in the mid 1990s was 0.08 ppm and about 0.17% of manufacturing workers would have been exposed to average levels above 2 ppm and only 0.01% of workers would have been exposed above 5 ppm. If, as we assume, exposure control has improved since 1996 it is possible that no workers are currently exposed above 2 ppm. A more recent biological monitoring study (2005) amongst manufacturing workers suggested that none of the workers were exposed to average 1,2-epoxypropane concentrations above 0.1 ppm.

Information about the human health hazard from 1,2-epoxypropane is limited. Animal toxicity studies have shown a risk for cancer in the nasal epithelium. However, the human epidemiological evidence suggests a risk for lymphopoietic and haematopoietic cancer, and we have assumed for the purposes of this impact assessment that there may be a leukaemia risk.

We estimate that in 2010 in the EU there will be less than one incident case or death from leukaemia that might be attributable to past exposure to 1,2-epoxypropane. This corresponds to about 0.0002% of all leukaemia cases amongst the exposed workers. If no specific actions are taken to reduce exposure to 1,2-epoxypropane then the predicted numbers of cancer cases continues to be less than one per year up to 2069. DALYs and YLL both increase from 1 to 2 years per annum over the period to 2069. Total estimated health costs associated with inaction range from €2.5m to €11m. Because of the limited epidemiological data we recognise that there is uncertainty in our health impact assessment, but even with this uncertainty we are reasonably confident that the annual number of cancer cases from occupational exposure to 1,2-epoxypropane is small.

Current exposures in the EU are judged to be well below 2ppm and so there are no important costs associated with compliance with the suggested OELs. There are also no social or macro-economic costs associated with introducing an OEL at either of these levels.

Although we have no explicitly assessed the impact of introducing an OEL of 1ppm, as recently suggested by SCOEL, we believe that our conclusions would apply equally to that value.

There are no significant environmental impacts foreseen.

The main identified impacts of introducing an OEL of 2 ppm and 5 ppm for 1,2 epoxypropane are summarised in the tables below, which are broken down by the main types of impacts (health, economic, social, macroeconomic and environmental).

**Table 7.41** Comparison of health impacts by scenario (Present Value – 2010 €m prices)

| Type of impact | Baseline Scenario | | Introduce OEL=2 ppm | | Introduce OEL=5 ppm | |
|---|---|---|---|---|---|---|
| | Costs | Benefits | Costs | Benefits | Costs | Benefits |
| Health | As set out in section 2.5, the health costs of cancer (leukaemia) over the period 2010-70 are estimated to be:<br>- Females: €0m<br>- Males: €1 m to €3m<br>- Total: €1m to €3m<br>This range takes into consideration tangible costs (e.g. lost income, lost output from reduced productivity, medical costs, life years lost) and intangible costs (e.g. emotional and physical suffering from having cancer). | | There is expected to be a small cost saving (e.g. a few €k) from avoided health care and reduced cost of illness due to reductions in cancer registrations.<br><br>This has been estimated as a benefit. | Monetised health benefits have not been quantified. However, the benefits of introducing an OEL in 2010 are expected to be most apparent to the downstream use sector. | **No change -** There are not expected to be any additional health costs relative to the baseline scenarios. | **No change** – There are expected to be negligible additional health benefits relative to the baseline scenario, as exposure is already expected to be largely/wholly below 5ppm.. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.42** Comparison of economic impacts by scenario (Present Value – 2010 €m prices)

| Type of impact | Baseline Scenario Costs | Baseline Scenario Benefits | Introduce OEL=2 ppm Costs | Introduce OEL=2 ppm Benefits | Introduce OEL=5 ppm Costs | Introduce OEL=5 ppm Benefits |
|---|---|---|---|---|---|---|
| Economic | - | | There are expected to be economic costs related to changes to workplace practices in order to meet the possible OEL for the downstream use sector.<br>It is estimated that few if any enterprises would require some form of additional control measure to meet the possible OEL (the calculated value was one single enterprise). The remainder are assumed to already be meeting the possible OEL under the baseline scenario and therefore would require no further action. It is assumed that any enterprises that do not currently comply would need to implement relatively low-cost measures to reduce exposure levels to meet this OEL. These costs (€1-2k) are not considered to be significant.<br>There would 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. | **Minimal** - The vast majority of investment required to control exposure associated with the manufacture of PO has already occurred in the last 20 years. | **Minimal** - Having an EU-wide OEL level would remove any competitive distortions between EU Member States with different limits. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.43** Comparison of social impacts by scenario

| Type of impact | Baseline Scenario: Costs | Baseline Scenario: Benefits | Introduce OEL=2 ppm: Costs | Introduce OEL=2 ppm: Benefits | Introduce OEL=5 ppm: Costs | Introduce OEL=5 ppm: Benefits |
|---|---|---|---|---|---|---|
| Social | There are not expected to be any noticeable social impacts under the baseline scenario at an EU level. At an installation level employees may need to change their working practice (e.g. hygiene and cleaning) to reduce risks of exposure. | | Impacts are expected to be similar to the baseline. A very small number of firms may require changes to workplace best practice. | | **No change -** Since there are not expected to be any significant economic costs to manufacturers of PO from the introduction of an EU-wide OEL, there is unlikely to be any significant change in employment. | **No change** - Under the baseline scenario, production is expected to increase over time, which may indicate that employment should at least be relatively stable or may increase. This is not expected to change with the introduction of an EU-wide OEL. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.44** Comparison of macro-economic impacts by scenario

| Type of impact | Baseline Scenario: Costs | Baseline Scenario: Benefits | Introduce OEL=2 ppm: Costs | Introduce OEL=2 ppm: Benefits | Introduce OEL=5 ppm: Costs | Introduce OEL=5 ppm: Benefits |
|---|---|---|---|---|---|---|
| Marco-economic | There are not expected to be any noticeable macroeconomic impacts under the baseline scenario. | | **No change -** Since there are not expected to be any significant economic or health impacts, there is not expected to be any significant change in macroeconomic impacts relative the baseline scenario from introducing an EU-wide OEL. | | | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.45** Comparison of environmental impacts by scenario

| Type of impact | Baseline Scenario Costs | Baseline Scenario Benefits | Introduce OEL=2 ppm Costs | Introduce OEL=2 ppm Benefits | Introduce OEL=5 ppm Costs | Introduce OEL=5 ppm Benefits |
|---|---|---|---|---|---|---|
| Environmental | There may be some environmental impacts under the baseline scenario, but these are expected to relate to humans exposed via the wider environment, rather than costs associated with damage to e.g. ecosystems.. | | None – controls on PO in the workplace that would be needed to meet this OEL relate to improvements in training and supervision of employees rather than implementation of additional engineering controls. Therefore it is not expected that achievement of the OEL would lead to changes in environmental impacts. | | None – it is assumed that controls on PO in the workplace that would be needed to meet this OEL have already been implemented. Therefore it is not expected that achievement of the OEL would lead to changes in environmental impacts. | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

## 7.10 1, 2-DICHLOROETHANE

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.

The main identified impacts of introducing an OEL of 1 ppm and 5 ppm for 1,2-dichloroethane are summarised in the tables below, which are broken down by the main types of impacts (health, economic, social, macroeconomic and environmental).

**Table 7.46** Comparison of health impacts by scenario

| Type of Impact | Baseline Scenario Health Costs | Baseline Scenario Health Benefits | Introduce OEL = 1ppm Health Costs | Introduce OEL = 1ppm Health Benefits | Introduce OEL = 5ppm Health Costs | Introduce OEL = 5ppm Health Benefits |
|---|---|---|---|---|---|---|
| Health | 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. | | 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. | | | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.47** Comparison of economic impacts by scenario (Present Value – 2010 €m prices)

| | Baseline Scenario | | Introduce OEL = 1ppm | | Introduce OEL = 5ppm | |
|---|---|---|---|---|---|---|
| **Type of Impact** | **Economic Costs** | **Economic Benefits** | **Economic Costs** | **Economic Benefits** | **Economic Costs** | **Economic Benefits** |
| Economic | 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.<br>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.<br>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.<br>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.<br>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. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.48** Comparison of social impacts by scenario

| Type of Impact | Baseline Scenario Social Costs | Baseline Scenario Social Benefits | Introduce OEL = 1ppm Social Costs | Introduce OEL = 1ppm Social Benefits | Introduce OEL = 5ppm Social Costs | Introduce OEL = 5ppm Social Benefits |
|---|---|---|---|---|---|---|
| Social | 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. | | | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.49** Comparison of macro-economic impacts by scenario

| Type of Impact | Baseline Scenario Macro-economic Costs | Baseline Scenario Macro-economic Benefits | Introduce OEL = 1ppm Macro-economic Costs | Introduce OEL = 1ppm Macro-economic Benefits | Introduce OEL = 5ppm Macro-economic Costs | Introduce OEL = 5ppm Macro-economic Benefits |
|---|---|---|---|---|---|---|
| Macro-economic | 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. | | | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.50** Comparison of environmental impacts by scenario

| Type of Impact | Baseline Scenario Environmental Costs | Baseline Scenario Environmental Benefits | Introduce OEL = 1ppm Environmental Costs | Introduce OEL = 1ppm Environmental Benefits | Introduce OEL = 5ppm Environmental Costs | Introduce OEL = 5ppm Environmental Benefits |
|---|---|---|---|---|---|---|
| Environmental | 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. | | | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

### 7.11 1, 2-DIBROMOETHANE

1,2-dibromoroethane 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-dibromoethane 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 0.1 ppm. Current OELs in the EU range from 0.00025 ppm to 0.5 ppm.

1,2-dibromoethane has been used as a scavenger for lead in gasoline, as a soil fumigant, as a pesticide for grain and tree crops, as a solvent for resins, in waterproofing preparations, and in organic synthesis. Production has declined considerably since the 1970s and some uses, e.g. as a pesticide, are now banned. It is still used in aviation and racing fuels and as intermediate for the production of some organic chemicals as a source of bromine. There is one manufacturer in the EU and up to 19 other suppliers.

Less than 8,000 people are potentially exposed in Europe, but only about 100 employed in chemical manufacturing. There are few measurement data for 1,2-dibromoethane, and that which is available dates from the 1970s and 80s. We judge that occupational exposure levels are currently low, with about 8% of workers in chemical manufacturing exposed to average levels above 0.1 ppm and workers in other sectors exposed to less than 0.1 ppm. Exposures are assumed to have been decreasing over recent years by about 7% per annum.

Information about the hazard from 1,2-dibromoethane is limited. Animal toxicity studies have shown a range of tumours induced, but 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, although we believe the impact of setting a limit at 0.1 ppm would be relatively small because of the relatively low current exposures and the small number of people likely to be exposed above the proposed OEL. The cost of compliance with a limit of 0.1 ppm, aggregated over the period 2010 to 2069, is judged to be between €0.086m and €0.29m. There are also no social or macro-economic costs associated with introducing an OEL.

There are no significant environmental impacts foreseen.

The main identified impacts of introducing an OEL of 0.1 ppm for 1,2-dibromoethane are summarised in the tables below, which are broken down by the main types of impacts (economic, social, macroeconomic and environmental).

**Table 7.51** Comparison of health impacts by scenario (Present Value – 2010 €m prices)

| Baseline Scenario | | Intervention scenario (2) – Assumes full compliance for OEL = 0.1ppm | |
|---|---|---|---|
| **Health Costs** | **Health Benefits** | **Health Costs** | **Health Benefits** |
| Insufficient data to estimate possible costs of health impacts. | It is assumed that exposures fall by 7% per year in the future. Therefore there is expected to be some reduction in health costs going forward in the absence of further regulatory intervention | None - There is expected to be a cost saving from avoided health care and reduced cost of illness due to reductions in cancer registrations. This has been estimated as a benefit. | Whilst it has not been possible to produce monetised health benefits it is thought that given (a) the relatively low percentage of workers are assumed to be above the possible OEL and (b) the overall relatively low number of people exposed (100), the overall benefit of an OEL is likely to be low. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.52** Comparison of economic impacts by scenario

| | Baseline Scenario | | Introduce OEL = 0.1ppm | |
|---|---|---|---|---|
| **Type of Impacts** | **Economic Costs** | **Economic Benefits** | **Economic Costs** | **Economic Benefits** |
| Economic | It is estimated that under the baseline scenario, firms are already moving towards complying with the 0.1ppm OEL. Therefore there is assumed there will not be a significant cost to achieve the 0.1ppm OEL. | Having an EU-wide OEL level should remove any EU competitive distortions between EU Member States with different OELs. | The impact of introducing an EU wide OEL of 0.1ppm is that reductions in exposure will be achieved sooner than planned (i.e. investment will be made earlier than planned). Therefore it is assumed there is not expected to be any significant additional costs of meeting an OEL of 0.1ppm relative to the baseline scenario.<br>The only issue may relate to getting access for necessary finance earlier than potentially planned for. | Having an EU-wide OEL level should remove any EU competitive distortions between EU Member States with different OELs. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.53** Comparison of social impacts by scenario

| Type of Impact | Baseline Scenario: Social Costs | Baseline Scenario: Social Benefits | Introduce OEL = 0.1ppm: Social Costs | Introduce OEL = 0.1ppm: Social Benefits |
|---|---|---|---|---|
| Social | 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. | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.54** Comparison of macro-economic impacts by scenario

| Type of Impact | Baseline Scenario: Marco-economic Costs | Baseline Scenario: Marco-economic Benefits | Introduce OEL = 0.1ppm: Marco-economic Costs | Introduce OEL = 0.1ppm: Marco-economic Benefits |
|---|---|---|---|---|
| Macro-economic | There are not expected to be any noticeable macroeconomic impacts under the baseline scenario. | | Since there are not expected to be any significant economic impacts, there is not expected to be any significant change in macroeconomic impacts relative to the baseline scenario from introducing an EU-wide OEL. | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.55** Comparison of environmental impacts by scenario

| Type of Impact | Baseline Scenario: Environmental Costs | Baseline Scenario: Environmental Benefits | Introduce OEL = 0.1ppm: Environmental Costs | Introduce OEL = 0.1ppm: Environmental Benefits |
|---|---|---|---|---|
| Environmental | Only 8% of workers exposed to EDB are estimated to be exposed above the most commonly adopted OEL of 0.1ppm and therefore most workplaces are unlikely to be affected/require further changes to their existing working practice. Therefore there are not estimated to be any significant changes in environmental impacts. | | None – it is expected that the imposition of measures would not cause additional environmental impacts. | It is not expected that the measures for human health would lead to any additional environmental benefit. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

## 7.12 O-TOLUIDINE

3,3'-Dimethylbenzidine or ortho-toluidine (o-toluidine) may cause bladder cancer. Exposure to o-toluidine has been classified as a group 2b carcinogen (Possibly carcinogenic to humans) by the International Agency for Research on Cancer (IARC) and as Cat 2 carcinogens in the EU under the classification and labelling legislation and it is therefore within the scope of the EU Carcinogens Directive. However, there is no occupational exposure limit (OEL) for o-toluidine 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 a limit value of either 0.1 ppm or 1 ppm, with an associated skin notation to reflect the potential uptake of o-toluidine through the skin.

Ortho-toluidine is a synthetic aromatic amine, which is used primarily as feedstock in chemical synthesis. As recently as 2000 the major use of o-toluidine was in the production of dyes and pigments, although in Europe this use is decreased because of regulatory restrictions. It is estimated that approximately 5,500 workers in the EU are potentially exposed to o-toluidine, of which about 2,900 are in manufacture of chemicals, chemical products and man-made fibres (NACE 24) or manufacture of rubber products (NACE 251). It was judged that 98% of exposures in these groups were less than 0.1 ppm, which corresponds to a geometric mean concentration of 0.01 ppm (assumed geometric standard deviation of 3). In recent years exposure levels have been decreasing by about 8.8% per annum.

We estimate that in 2010 in the EU there will be about 7 deaths from bladder cancer (22 incident cases) that might be attributable to past exposure to o-toluidine, which corresponds to about 0.017% of all bladder cancer deaths and a loss of 120 Disability-Adjusted Life Years (DALYs). In the absence of any intervention the health burden is predicted to drop steadily over the next 50 years. In 2060 it is predicted that there will be no deaths and possibly one bladder cancer registration that could be attributed to o-toluidine exposure at work (4 DALYs).

The main costs associated with inaction occur in the period 2010-2040, and these are predominately the result of past exposure. It is estimated that in total over the next 60 years there will be between €86m and €696m of health costs if no limit value is introduced, with the highest costs falling on Germany, France, Italy and the UK.

It is judged that compliance with an OEL of 1 ppm could be achieved with no cost implications and that introducing a limit of 0.1 ppm would incur limited costs (between €0.03m and €0.09m). However, neither limit is predicted to give rise to any important reduction in bladder cancer deaths or registrations over the baseline assumptions, primarily because exposures are already very low. There are no monetised health benefits from introducing a limit at 1 ppm and between €1m and €7.6m for the 0.1 ppm limit.

It are not expected that there will be any important social, macro-economic or environmental impacts.

The main identified impacts of introducing an OEL of 0.1 ppm and 1 ppm for o-toluidine are summarised in the tables below, which are broken down by the main types of impacts (health, economic, social, macroeconomic and environmental).

**Table 7.56** Comparison of health impacts by scenario (Present Value – 2010 €m prices)

| Type of Impact | Baseline Scenario: Health Costs | Baseline Scenario: Health Benefits | Introduce OEL = 0.1ppm: Health Costs | Introduce OEL = 0.1ppm: Health Benefits | Introduce OEL = 1ppm: Health Costs | Introduce OEL = 1ppm: Health Benefits |
|---|---|---|---|---|---|---|
| Health | As set out in section 2.5, the health costs of cancer (bladder) over the period 2010-70 are estimated to be:<br>1) Females: €16m to €107m<br>2) Males: €70m to €590m<br>3) Total: €86m to €696m<br>This range takes into consideration tangible costs (e.g. lost income, lost output from reduced productivity, medical costs, life years lost) and intangible costs (e.g. emotional and physical suffering from having cancer). | It is assumed that exposures will fall by 8.8% per year in the future.<br>Therefore there is expected to be some reduction in health costs going forward in the absence of further regulatory intervention | There is expected to be a small cost saving (e.g. a few €k) from avoided health care and reduced cost of illness due to reductions in cancer registrations.<br>This has been estimated as a benefit. | Health benefits of the possible OEL have been analysed at the Member State and industrial sector level. The results showed that the benefits of introducing an OEL in 2010 are most apparent to the manufacture of chemical products and manufacture of rubber products sector. It was also found that the monetised benefits are likely to affect men more than women.<br>The monetised benefits over 2010-2070 were estimated as:<br>Females: €0.2m to 1.2m<br>Males: €0.8m to 6.5m<br>Totals: €1m to 7.6m | **No change -** There are not expected to be any additional health costs relative to the baseline scenarios. | **No change** – There are expected to be negligible additional health benefits relative to the baseline scenario, as exposure is already expected to be largely/wholly below 1ppm. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.57** Comparison of economic impacts by scenario (Present Value – 2010 €m prices)

| Type of Impact | Baseline Scenario: Economic Costs | Baseline Scenario: Economic Benefits | Introduce OEL = 0.1ppm: Economic Costs | Introduce OEL = 0.1ppm: Economic Benefits | Introduce OEL = 1ppm: Economic Costs | Introduce OEL = 1ppm: Economic Benefits |
|---|---|---|---|---|---|---|
| Economic | There are expected to be costs to o-toluidine related firms to put into place improved training and cleaning measures to reduce inhalation and dermal 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 for the manufacture of chemical products and manufacture of rubber products industries.<br>It is estimated that few (less than 10) enterprises would require some form of additional control measure to meet the possible OEL (the calculated value was eight enterprises). The remainder are assumed to already be meeting the possible OEL under the baseline scenario and therefore would require no further action.<br>It is assumed that the majority of those enterprises that do not currently comply would need to implement relatively low-cost measures to reduce exposure levels to meet this OEL. These costs (€0.5-2k) are not considered to be significant. The remainder may need to invest in new ventilation systems. The up-front capital cost of a ventilation system is estimated to be in the region of €42k - 252k.<br>There would be administrative costs of implementing the OEL in national legislation and of demonstrating and verifying compliance. | Having an EU-wide BMGV should remove any EU competitive distortions between EU Member States with different limits. | **Minimal** - The vast majority of investment required to control exposure associated with the manufacture of o-toluidine has already occurred in the last 20 years. | Having an EU-wide OEL should remove any EU competitive distortions between EU Member States with different limits. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.58** Comparison of social impacts by scenario

| Type of Impact | Baseline Scenario | | Introduce OEL = 0.1ppm | | Introduce OEL = 1ppm | |
|---|---|---|---|---|---|---|
| | Social Costs | Social Benefits | Social Costs | Social Benefits | Social Costs | Social Benefits |
| Social | There are not expected to be any noticeable social impacts under the baseline scenario at an EU level. | | **No change -** There are not expected to be any noticeable changes to the numbers of workers required as a result of introducing an EU-wide OEL. | | | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.59** Comparison of macro-economic impacts by scenario

| Type of Impact | Baseline Scenario | | Introduce OEL = 0.1ppm | | Introduce OEL = 1ppm | |
|---|---|---|---|---|---|---|
| | Macro-economic Costs | Macro-economic Benefits | Macro-economic Costs | Macro-economic Benefits | Macro-economic Costs | Macro-economic Benefits |
| Macro-economic | 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. | | | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.60** Comparison of environmental impacts by scenario

| Type of Impact | Baseline Scenario | | Introduce OEL = 0.1ppm | | Introduce OEL = 1ppm | |
|---|---|---|---|---|---|---|
| | Environmental Costs | Environmental Benefits | Environmental Costs | Environmental Benefits | Environmental Costs | Environmental Benefits |
| Environmental | Only 2% of workers exposed to o-toluidine are estimated to be exposed above 0.1ppm and therefore most workplaces are unlikely to be affected/require further changes to their existing working practices. Therefore there are not estimated to be any significant changes in environmental impacts. | | Minimal – it is expected that the imposition of measures would not cause significant additional environmental impacts. | It is not expected that the measures for human health would lead to any significant additional environmental benefit above the baseline. | None - it is assumed that controls on o-toluidine in the workplace that would be needed to meet this OEL have already been implemented. Therefore it is not expected that achievement of the OEL would lead to changes in environmental impacts. | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

## 7.13 HEXACHLOROBENZENE

Hexachlorobenzene 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 hexachlorobenzene 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 0.002 mg/m$^3$ or 0.025 mg/m$^3$.

Hexachlorobenzene is a chlorinated aromatic hydrocarbon, which was previously used as a fungicide and in some industrial processes. However, it is now banned and the only occupational sources are in a small number of processes where it may be produced as an unwanted by-product. The exact quantity of hexachlorobenzene emitted into workplaces is unknown and the number of workers who may be exposed is also unknown.

Animal toxicological studies have shown that hexachlorobenzene can cause liver and other tumours, but the information from epidemiological studies is inadequate to identify whether there is any risk of cancer in humans. We were unable to identify suitable risk estimates to undertake a health impact assessment.

Few measurements of occupational exposure to hexachlorobenzene are available, but the available evidence suggests that exposure levels are very low and probably not much higher than found in the general population (i.e. <0.0001 mg/m$^3$). We judge that it is unlikely that there are any workers in the EU exposed to hexachlorobenzene above the typical OELs of 0.002 and 0.025 mg/m$^3$.

We judge that there will be no additional costs in compliance with an OEL of either 0.002 or 0.025 mg/m$^3$ and no health benefits because employers are probably already in full compliance with these limits. However, it would be prudent for industry to undertake further occupational exposure measurements to confirm that this is the case.

It is not expected that there will be any important social, macro-economic or environmental impacts.

The main identified impacts of introducing an OEL of 0.002 mg/m$^3$ and 0.025 mg/m$^3$ for hexachlorobenzene are summarised in the tables below, which are broken down by the main types of impacts (health, economic, social, macroeconomic and environmental).

**Table 7.61** Comparison of health impacts by scenario

| Type of Impact | Baseline Scenario: Health Costs | Baseline Scenario: Health Benefits | Introduce OEL = 0.002 mg/m$^3$: Health Costs | Introduce OEL = 0.002 mg/m$^3$: Health Benefits | Introduce OEL = to 0.025 mg/m$^3$: Health Costs | Introduce OEL = to 0.025 mg/m$^3$: Health Benefits |
|---|---|---|---|---|---|---|
| Health | Health impacts are expected from past exposure which would occur regardless of any future intervention. These impacts have not been quantified but they are likely to be small given that evidence for carcinogenicity in humans is extremely weak with very few positive associations. | Marketing and use of HCB has now been banned in the EU. Therefore whilst health impacts are expected from past exposure, there is expected to be some reduction in health costs going forward in the absence of further regulatory intervention. | None | In the absence of available data it has not been possible to assess the health impacts of introducing new exposure limits. It has therefore not been possible to produce monetised health benefits. Given that it is unlikely that there are any workers in the EU exposed to HCB above the typical OEL, the overall benefit of an OEL is likely to be low. | None | In the absence of available data it has not been possible to assess the health impacts of introducing new exposure limits. It has therefore not been possible to produce monetised health benefits. Given that it is unlikely that there are any workers in the EU exposed to HCB above the typical OEL, the overall benefit of an OEL is likely to be low. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.62** Comparison of economic impacts by scenario

| Type of Impact | Baseline Scenario Economic Costs | Baseline Scenario Economic Benefits | Introduce OEL = 0.002 mg/m$^3$ Economic Costs | Introduce OEL = 0.002 mg/m$^3$ Economic Benefits | Introduce OEL = to 0.025 mg/m$^3$ Economic Costs | Introduce OEL = to 0.025 mg/m$^3$ Economic Benefits |
|---|---|---|---|---|---|---|
| Economic | It is estimated that under the baseline scenario, firms are already achieving exposures less than 0.002 mg/m$^3$.<br><br>Therefore there is assumed there will not be a significant cost to achieve a possible 0.002 mg/m$^3$ OEL. | - | It is unlikely that there are any workers in the EU exposed above 0.002 mg/m$^3$. Therefore there are not expected to be any significant additional costs of meeting an OEL of 0.002 mg/m$^3$ relative to the baseline scenario. | Having an EU-wide OEL level should remove any EU competitive distortions between EU Member States with different OELs. | It is unlikely that there are any workers in the EU exposed above 0.002 mg/m$^3$. Therefore there are not expected to be any significant additional costs of meeting an OEL of 0.025 mg/m$^3$ relative to the baseline scenario. | Having an EU-wide OEL level should remove any EU competitive distortions between EU Member States with different OELs. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.63** Comparison of social impacts by scenario

| Type of Impact | Baseline Scenario Social Costs | Baseline Scenario Social Benefits | Introduce OEL = 0.002 mg/m$^3$ Social Costs | Introduce OEL = 0.002 mg/m$^3$ Social Benefits | Introduce OEL = to 0.025 mg/m$^3$ Social Costs | Introduce OEL = to 0.025 mg/m$^3$ Social Benefits |
|---|---|---|---|---|---|---|
| Social | 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. | | | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.64** Comparison of macro-economic impacts by scenario

| Type of Impact | Baseline Scenario<br>Marco-economic Costs | <br>Marco-economic Benefits | Introduce OEL = 0.002 mg/m$^3$<br>Marco-economic Costs | <br>Marco-economic Benefits | Introduce OEL = to 0.025 mg/m$^3$<br>Marco-economic Costs | <br>Marco-economic Benefits |
|---|---|---|---|---|---|---|
| Macro-economic | There are not expected to be any noticeable macroeconomic impacts under the baseline scenario. | | Since there are not expected to be any significant economic impacts, there are not expected to be any significant change in macroeconomic impacts relative to the baseline scenario from introducing an EU-wide OEL. | | | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.65** Comparison of environmental impacts by scenario

| Type of Impact | Baseline Scenario<br>Environmental Costs | <br>Environmental Benefits | Introduce OEL = 0.002 mg/m$^3$<br>Environmental Costs | <br>Environmental Benefits | Introduce OEL = to 0.025 mg/m$^3$<br>Environmental Costs | <br>Environmental Benefits |
|---|---|---|---|---|---|---|
| Environmental | It is considered unlikely that there are any workers exposed to HCB above the typical OELs of 0.002 and 0.025mg/m$^3$ and therefore most workplaces are unlikely to be affected/ require further changes to their existing working practice. Therefore there are not estimated to be any significant changes in environmental impacts. | | None – it is expected that the imposition of measures would not cause additional environmental impacts. | | | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

## 7.14 BENZO[A]PYRENE

Benzo[a]pyrene (B[a]P) has been classified by the International Agency for Research on Cancer (IARC) as carcinogenic to humans based on animal toxicity and other supporting information (IARC category 1). 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 benzo[a]pyrene specified in the Directive.

Benzo[a]pyrene is a polycyclic aromatic hydrocarbon (PAH), which is generally only found as part of a complex mixture in emissions from combustion or other similar sources. It is often used as a marker of exposure to the PAH mixture and it is in this way that we have evaluated it in this report. 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 0.002 mg/m$^3$ for benzo[a]pyrene (2 µg/m$^3$).

There is potential exposure to benzo[a]pyrene in aluminium, iron and steel production plants, foundries, waste incineration, mining or oil refining, coke and tar production plants, coal gasification sites, bitumen and asphalt production plants, road and roof tarring operations, and other facilities that burn carbonaceous materials. While benzo[a]pyrene may be found in diesel engine exhaust emissions we have excluded this source as we have considered these emissions in a separate report (P937/13).

We estimated that in 2006 in the EU there were 234,000 workers who were potentially exposed to high levels of benzo[a]pyrene and about 7 million to low levels. The overall geometric mean exposure level was 0.000023 mg/m$^3$ with a geometric standard deviation of 6.29. According to these data exposure concentrations are below the suggested OEL in all EU countries and it is unlikely that many workers are exposed above the potential OEL of 0.002 mg/m$^3$. We assume exposure levels have been decreasing by about 6% per annum and that this reduction will continue for at least the next 20-years.

Exposure to PAH may cause lung and bladder cancer and skin contact with tar or pitch containing PAH may cause non-melanoma skin cancer (NMSC). For bladder cancer we identified a relative risk of 1.44 for high exposed work groups and 1.0 for low exposed groups. In the case of lung cancer we have identified four risk categories as shown in the following table.

| **Exposure category (µg/m$^3$)** | **<0.01** | **0.01 - <0.75** | **0.75 - <2.0** | **2.0+** |
|---|---|---|---|---|
| RR estimate | 1.00 | 1.02 | 1.08 | 1.25 |

The low exposed were assumed to have a RR=1.0 for lung cancer, corresponding to <0.00001 mg/m$^3$ (i.e. 0.01µg/m$^3$) B[a]P 8-h average. The main risk from NMSC appears to be from dermal contact with coal tars and pitches in road workers and roofers. The combined risk estimate of 1.74 was selected for groups where such exposure was likely.

We estimate that in 2010 in the EU there will be about 151 incident cases of bladder cancer and 466 cases of lung cancer that might be attributable to past exposure to PAH mixtures containing benzo[a]pyrene (corresponding to 0.114% of all bladder cancer cases and 0.153% of lung cancers amongst the exposed workers). There are estimated to be 47 bladder and 430 lung cancer deaths in the same year attributable to past PAH exposure. Future attributable incidence and mortality are expected to decreases from the identified decline in exposures. By the decade starting 2060 it is judged there will be three bladder cancer registrations per year and five lung cancer registrations per year that are attributable to exposure to PAH containing benzo[a]pyrene. DALYs decrease from 6,978 to 64 per year and 703 to 17 each year for lung and bladder cancer, respectively.

For NMSC there are 254 incident cases in 2010 attributed to past exposure to PAH containing benzo[a]pyrene with two deaths and 24 DALYs. The number of NMSC each year from PAH exposure is estimated to rise slowly so that by the decade starting 2060 there are 299 incident cases, three deaths and 29 DALYs, per year. The main cause of the increase is the increase in survival amongst the population as a consequence of improving general health and our assumption of continued exposure to benzo[a]pyrene in remediation of roads and roofs containing tar or pitch. Total estimated health costs over the period up to 2069 that are associated with inaction range from €6,292m to €19,438m.

The impacts of NMSC are relatively limited compared to the total health costs (€6-19bn), with total NMSC health costs over the period 2010-69 being between €45m and €453m. The rest of the health costs relate to bladder and lung cancer.

Current exposures in the EU are judged to be well below 0.002 mg/m$^3$ and so there are no predicted health benefits and no important costs associated with compliance with the suggested OEL. There are also no social or macro-economic costs associated with introducing an OEL at the suggested level.

There are no significant environmental impacts foreseen.

The main identified impacts of introducing an OEL of 0.002 mg/m$^3$ (2 µg/m$^3$) for benzo[a]pyrene are summarised in the tables below, which are broken down by the main types of impacts (health, economic, social, macroeconomic and environmental).

**Table 7.66** Comparison of health impacts by scenario (Present Value – 2010 €m prices)

| Type of Impact | Baseline Scenario: Health Costs | Baseline Scenario: Health Benefits | Introduce OEL = 0.002 mg/m$^3$: Health Costs | Introduce OEL = 0.002 mg/m$^3$: Health Benefits |
|---|---|---|---|---|
| Health | As set out in section 2.5, the health costs of cancer (bladder, lung and NMSC) over the period 2010-70 are estimated to be:<br>- Females: €1.4bn to €3.1bn<br>- Males: €4.8bn to €16bn<br>- Total: €6.2bn to €194bn<br>This range takes into consideration tangible costs (e.g. lost income, lost output from reduced productivity, medical costs, life years lost) and intangible costs (e.g. emotional and physical suffering from having cancer). | It is assumed that exposures fall by 6% per year in the future continuing the historical trend in reduced exposure.<br>Therefore there is expected to be some reduction in health costs going forward in the absence of further regulatory intervention. | None. | None – exposure is already estimated to be below the possible OEL. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.67** Comparison of economic impacts by scenario

| Type of Impact | Baseline Scenario<br>Economic Costs | Baseline Scenario<br>Economic Benefits | Introduce OEL = 0.002 $mg/m^3$<br>Economic Costs | Introduce OEL = 0.002 $mg/m^3$<br>Economic Benefits |
|---|---|---|---|---|
| Economic | It is assumed that exposures will fall by 6% per year in the future. Therefore, there are expected to be some costs to firms where b[a]p exposure occurs to put into place employee training, PPE and ventilation measures to reduce inhalation and dermal exposure. These would occur regardless of further intervention over the period 2010-2070. | - | It is estimated that, under the baseline scenario, firms are already achieving exposures less than 0.002 $mg/m^3$. Therefore there are not expected to be any significant additional costs of meeting an OEL of 0.002 $mg/m^3$ relative to the baseline scenario. | Having an EU-wide OEL should remove any EU competitive distortions between EU Member States with different OELs. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.68** Comparison of social impacts by scenario

| Type of Impact | Baseline Scenario<br>Social Costs | Baseline Scenario<br>Social Benefits | Introduce OEL = 0.002 $mg/m^3$<br>Social Costs | Introduce OEL = 0.002 $mg/m^3$<br>Social Benefits |
|---|---|---|---|---|
| Social | 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. | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.69** Comparison of macro-economic impacts by scenario

| Type of Impact | Baseline Scenario: Marco-economic Costs | Baseline Scenario: Marco-economic Benefits | Introduce OEL = 0.002 mg/$m^3$: Marco-economic Costs | Introduce OEL = 0.002 mg/$m^3$: Marco-economic Benefits |
|---|---|---|---|---|
| Macro-economic | There are not expected to be any noticeable macroeconomic impacts under the baseline scenario. | | Since there are not expected to be any significant economic impacts, there are not expected to be any significant changes in macroeconomic impacts relative to the baseline scenario from introducing an EU-wide OEL. | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.70** Comparison of environmental impacts by scenario

| Type of Impact | Baseline Scenario: Environmental Costs | Baseline Scenario: Environmental Benefits | Introduce OEL = 0.002 mg/$m^3$: Environmental Costs | Introduce OEL = 0.002 mg/$m^3$: Environmental Benefits |
|---|---|---|---|---|
| Environmental | There are not expected to be any noticeable environmental impacts under the baseline scenario. | | No workers exposed to b[a]p are estimated to be exposed above the possible EU-wide OEL value of 0.002 mg/$m^3$ and therefore most workplaces are unlikely to be affected/require further changes to their existing working practice. Therefore there are not estimated to be any significant changes in environmental impacts. | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

## 7.15 2-NITROPROPANE

2-nitropropane has been classified by the International Agency for Research on Cancer (IARC) as possibly carcinogenic to humans based on 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 2-nitropropane 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 8-hour occupational exposure limit (OEL) of 19 mg/m$^3$ (5 ppm). Current OELs in the EU range from 3.6 mg/m$^3$ (1 ppm) to 37 mg/m$^3$ (10 ppm).

2-nitropropane is produced in relatively low volumes and occupational exposures occur primarily in its production and use as a solvent in inks, adhesives, paints and coatings. It is assumed that these uses have been decreasing over time as employers have eliminated 2-nitropropane from solvent mixtures they used. There is only one supplier of 2-nitropropane in the EU.

It is difficult to provide a good estimate of the number of people exposed. We have relied upon Labour Force Survey data in identifying likely industrial uses, but we accept that these data are likely to provide an overestimate of the numbers exposed. Currently we estimate that less than about 50,000 individuals exposed, although in the past there could have been more than ten times this number exposed. There are very little data on the level of exposure to 2-nitropropane in industry. However, based on the available data we consider it is likely that none would be exposed in excess of the typical OEL of 19 mg/m$^3$ (our worst-case estimate suggests levels are below 6 mg/m$^3$) in manufacturing. Exposures are assumed to have been decreasing over recent years by about 7% per annum.

Information about the hazard from 2-nitropropane is limited. Animal toxicity studies have shown that liver tumours may be produced from inhalation exposure, but the human epidemiological evidence is negative. There is no basis to identify a suitable risk estimate and we have considered that it is not possible to undertake a health impact assessment. However, given the low exposures and the probably small and decreasing number of people exposed, we believe that the health impact is unlikely to be large.

There are no predicted health benefits from setting an OEL. It is assumed there will be no additional costs to comply with an OEL of 19 mg/m$^3$. There are also no social or macro-economic costs associated with introducing an OEL.

There are no significant environmental impacts foreseen.

The main identified impacts of introducing an OEL of 19 mg/m$^3$ for 2-nitropropane are summarised in the tables below, which are broken down by the main types of impacts (health, economic, social, macroeconomic and environmental).

**Table 7.71** Comparison of health impacts by scenario

| Type of Impact | Baseline Scenario Health Costs | Baseline Scenario Health Benefits | Introduce OEL = 19 mg/m$^3$ Health Costs | Introduce OEL = 19 mg/m$^3$ Health Benefits |
|---|---|---|---|---|
| Health | There is no evidence for an increased risk in humans so no health impacts are expected under the baseline. | It is assumed that exposures fall by 7% per year in the future. | None. | None – exposure is already estimated to be below the possible OEL. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.72** Comparison of economic impacts by scenario

| Type of Impact | Baseline Scenario Economic Costs | Baseline Scenario Economic Benefits | Introduce OEL = 19 mg/m$^3$ Economic Costs | Introduce OEL = 19 mg/m$^3$ Economic Benefits |
|---|---|---|---|---|
| Economic | It is assumed that exposures will fall by 7% per year in the future. Therefore, there are expected to be some costs to 2-nitropropane related firms for putting into place employee training, PPE and ventilation measures to reduce inhalation and dermal exposure that would occur regardless of further intervention over the period 2010-2070. | - | It is estimated that, under the baseline scenario, firms are already achieving exposures less than 19 mg/m$^3$. Therefore there are not expected to be any significant additional costs of meeting an OEL of 19 mg/m$^3$ relative to the baseline scenario. | Having an EU-wide OEL level should remove any EU competitive distortions between EU Member States with different OELs. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.73** Comparison of social impacts by scenario

| Type of Impact | Baseline Scenario: Social Costs | Baseline Scenario: Social Benefits | Introduce OEL = 19 mg/m$^3$: Social Costs | Introduce OEL = 19 mg/m$^3$: Social Benefits |
|---|---|---|---|---|
| Social | 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. | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.74** Comparison of macro-economic impacts by scenario

| Type of Impact | Baseline Scenario: Marco-economic Costs | Baseline Scenario: Marco-economic Benefits | Introduce OEL = 19 mg/m$^3$: Marco-economic Costs | Introduce OEL = 19 mg/m$^3$: Marco-economic Benefits |
|---|---|---|---|---|
| Macro-economic | There are not expected to be any noticeable macroeconomic impacts under the baseline scenario. | | Since there are not expected to be any significant economic impacts, there are not expected to be any significant changes in macroeconomic impacts relative to the baseline scenario from introducing an EU-wide OEL. | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.75** Comparison of environmental impacts by scenario

| Type of Impact | Baseline Scenario: Environmental Costs | Baseline Scenario: Environmental Benefits | Introduce OEL = 19 mg/m$^3$: Environmental Costs | Introduce OEL = 19 mg/m$^3$: Environmental Benefits |
|---|---|---|---|---|
| Environmental | No workers exposed to 2-nitropropane are estimated to be exposed above the possible EU-wide OEL value of 19 mg/m$^3$ and therefore most workplaces are unlikely to be affected/require further changes to their existing working practice. Therefore there are not estimated to be any significant changes in environmental impacts. | | Minimal – it is expected that the imposition of measures would not cause additional environmental impacts. | It is not expected that the measures for human health would lead to any additional significant environmental benefit above the baseline. |

Note: Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

## 7.16 BROMOETHYLENE

Bromoethylene (vinyl bromide) has been classified by the International Agency for Research on Cancer (IARC) as probably carcinogenic to humans, based on sufficient animal toxicity and mechanistic data (IARC category 2a). 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) specified in the Directive for bromoethylene.

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 OEL for bromoethylene of 22 mg/m$^3$ (5 ppm). Current OELs in the EU range from 0.012 to 22 mg/m$^3$, with the lowest OEL in the Netherlands.

Bromoethylene is mostly used as a flame retardant in the production of acrylic fibres for carpet backing materials. Other uses include children's sleepwear and home furnishings. It has been available commercially since 1968.

The number of people potentially exposed in Europe is likely to be small, i.e. less than a few hundred, but we have no information to assess the actual extent of exposure. There are few measurement data for bromoethylene, and that which is available dates from the 1980s. It has been assumed that exposure levels have been decreasing over recent years by about 7% per annum. Based on the available measurements and the annual reduction in exposure we judge that occupational exposure levels are currently low, with the highest exposures probably about 3 mg/m$^3$.

There is clear evidence for the carcinogenicity of bromoethylene in experimental animals, and on mechanistic grounds it is assumed that it may act similarly to vinyl chloride causing liver cancer in humans. Based on this analogy we have identified the relative risk associated with high exposure should be 2.86 and for low exposure 1.89. Given the uncertainties around the number of exposed workers we have considered it is not possible to undertake a health impact assessment. However, if as we assume the current exposure levels are low and there are a limited number of people in Europe who are exposed then there is unlikely to be any important cancer risk for this substance. There are no estimates of health costs of inaction for this substance.

There are no predicted health benefits from setting an OEL at 22 mg/m$^3$, although we believe the impact would be relatively small because current exposures are estimated to be much lower than the proposed OEL. There are no additional costs associated with compliance with a limit of 22 mg/m$^3$. There are also no social or macro-economic costs associated with introducing an OEL. There are no significant environmental impacts foreseen.

The main identified impacts of introducing an OEL of 22 mg/m$^3$ for bromoethylene are summarised in the tables below, which are broken down by the main types of impacts (health, economic, social, macroeconomic and environmental).

**Table 7.76** Comparison of health impacts by scenario

| Type of Impact | Baseline Scenario Health Costs | Health Benefits | Introduce OEL = 22 mg/m$^3$ Health Costs | Health Benefits |
|---|---|---|---|---|
| Health | There is insufficient information to calculate the health impacts expected under the baseline. | It is assumed that exposures fall by 7% per year in the future. | None. | None – exposure is already estimated to be below the possible OEL. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.77** Comparison of economic impacts by scenario

| Type of Impact | Baseline Scenario Economic Costs | Economic Benefits | Introduce OEL = 22 mg/m$^3$ Economic Costs | Economic Benefits |
|---|---|---|---|---|
| Economic | It is assumed that exposures will fall by 7% per year in the future. Therefore, there are expected to be some costs to firms where bromoethylene exposure occurs to put into place employee training, PPE and ventilation measures to reduce inhalation and dermal exposure that would occur regardless of further intervention over the period 2010-2070. | - | It is estimated that, under the baseline scenario, firms are already achieving exposures less than 22 mg/m$^3$. Therefore there are not expected to be any significant additional costs of meeting an OEL of 22 mg/m$^3$ relative to the baseline scenario. | Having an EU-wide OEL level should remove any EU competitive distortions between EU Member States with different OELs. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.78** Comparison of social impacts by scenario

| Type of Impact | Baseline Scenario Social Costs | Social Benefits | Introduce OEL = 22 mg/m$^3$ Social Costs | Social Benefits |
|---|---|---|---|---|
| Social | 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. | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.79** Comparison of macro-economic impacts by scenario

| Type of Impact | Baseline Scenario Marco-economic Costs | Baseline Scenario Marco-economic Benefits | Introduce OEL = 22 mg/m$^3$ Marco-economic Costs | Introduce OEL = 22 mg/m$^3$ Marco-economic Benefits |
|---|---|---|---|---|
| Macro-economic | There are not expected to be any noticeable macroeconomic impacts under the baseline scenario. | | Since there are not expected to be any significant economic impacts, there are not expected to be any significant changes in macroeconomic impacts relative to the baseline scenario from introducing an EU-wide OEL. | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.80** Comparison of environmental impacts by scenario

| Type of Impact | Baseline Scenario Environmental Costs | Baseline Scenario Environmental Benefits | Introduce OEL = 22 mg/m$^3$ Environmental Costs | Introduce OEL = 22 mg/m$^3$ Environmental Benefits |
|---|---|---|---|---|
| Environmental | There are not expected to be any noticeable environmental impacts under the baseline scenario. | | No workers exposed to bromoethylene are estimated to be exposed above the possible EU-wide OEL value of 22 mg/m$^3$ and therefore most workplaces are unlikely to be affected/require further changes to their existing working practice. Therefore there are not estimated to be any significant changes in environmental impacts. | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

## 7.17 1-CHLORO-2, 3-EPOXYPROPANE

1-chloro-2,3-epoxypropane (epichlorohydrin) has been classified by the International Agency for Research on Cancer (IARC) as probably carcinogenic to humans based on animal toxicity and other supporting information (IARC category 2a). 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-chloro-2,3-epoxypropane 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 1.9 mg/m$^3$ (0.5 ppm).

There are fifteen high volume producers or importers of 1-chloro-2,3-epoxypropane within the EU in eight member states: Germany, Netherlands, United Kingdom, Italy, Sweden, Finland, Austria and Belgium. The total amount produced in the EU is estimated to be about 360,000 tonnes. 1-chloro-2,3-epoxypropane is used as a feedstock in the manufacture of a wide range of products, including epoxy resins, paper manufacture, ink and paint manufacture, processing of wool and cotton, and in rubber and pharmaceutical processes. The total estimated number of exposed workers in the EU is about 44,000, although this figure may include a number of workers who are exposed to very low levels.

We estimate that current overall geometric mean exposure level amongst EU workers is 0.085 mg/m$^3$, with an estimated geometric standard deviation of about 2.5. With this exposure distribution it is unlikely that anyone is exposed to levels above the typical OEL of 1.9 mg/m$^3$. We have no information about temporal trends, although exposures are lower than they were in the 1950s, which is the earliest data we have identified. However, we have assumed that there has been no change in exposure levels over more recent years.

Experimental inhalation toxicology studies have produced cancers in the nasal cavity in male rats. However, the limited human epidemiological studies suggest that 1-chloro-2,3-epoxypropane may cause lung and central nervous system (CNS) cancers, likely mostly brain cancers. Based on these studies we have identified a relative risk for "medium" exposure industry groups (i.e. manufacture starch products, preparation of cotton and wool and rubber processes) as 1.7 for lung cancer and 4.2 CNS cancers. A risk estimate of 1.0 has been chosen for the "low" exposure groups.

We estimate that in 2010 in the EU there will be about 22 incident cases or deaths from lung cancer that might be attributable to past exposure to 1-chloro-2,3-epoxypropane. This corresponds to about 0.0073% of all lung cancer cases amongst the exposed workers. The corresponding number of incident CNS cancers is about 12, with a similar number of deaths. If no specific actions are taken to reduce exposure to 1-chloro-2,3-epoxypropane then the predicted numbers of cancer cases increases to 34 cases of lung cancer and 15 cases of brain cancer by 2060. The main cause of the increase is the increase in survival amongst the population as a consequence of improving general health. Estimated Disability Adjusted Life Years (DALYs) increase over the period up to 2060 from 331 to 446 years per annum for lung cancer and from 332 to 395 years per annum for brain cancer. Total estimated health costs associated with inaction range from €1,362m to €2,752m.

Current exposures in the EU are judged to be well below 1.9 mg/m$^3$ and so there are no predicted health benefits and no important costs associated with compliance with the suggested OEL. 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.

The main identified impacts of introducing an OEL of 1.9 mg/m$^3$ for epichlorohydrin are summarised in the tables below, which are broken down by the main types of impacts (health, economic, social, macroeconomic and environmental).

**Table 7.81** Comparison of health impacts by scenario (Present Value – 2010 €m prices)

| Type of Impact | Baseline Scenario: Health Costs | Baseline Scenario: Health Benefits | Introduce OEL = 1.9 mg/m$^3$: Health Costs | Introduce OEL = 1.9 mg/m$^3$: Health Benefits |
|---|---|---|---|---|
| Health | As set out in section 2.5, the health costs of cancer (lung and CNS) over the period 2010-70 are estimated to be:<br>- Females: €81m to €542m<br>- Males: €1009 m to €2210m<br>- Total: €1362m to €2752m<br>This range takes into consideration tangible costs (e.g. lost income, lost output from reduced productivity, medical costs, life years lost) and intangible costs (e.g. emotional and physical suffering from having cancer). | As a static baseline has been assumed due to historical exposure being fairly constant, there are not expected to be health benefits from reduced exposure over time. | None. | None – exposure is already estimated to be below the possible OEL. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.82** Comparison of economic impacts by scenario

| Type of Impact | Baseline Scenario: Economic Costs | Baseline Scenario: Economic Benefits | Introduce OEL = 1.9 mg/m$^3$: Economic Costs | Introduce OEL = 1.9 mg/m$^3$: Economic Benefits |
|---|---|---|---|---|
| Economic | In the analysis presented, a static baseline is assumed. Therefore, no firms will incur costs to reduce exposure under the baseline scenario | - | It is estimated that, under the baseline scenario, firms are already achieving exposures less than 1.9 mg/m$^3$. Therefore there are not expected to be any significant additional costs of meeting an OEL of 1.9 mg/m$^3$ relative to the baseline scenario other than administrative costs. | Having an EU-wide OEL level should remove any EU competitive distortions between EU Member States with different OELs. |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.83** Comparison of social impacts by scenario

| Type of Impact | Baseline Scenario Social Costs | Baseline Scenario Social Benefits | Introduce OEL = 1.9 mg/m$^3$ Social Costs | Introduce OEL = 1.9 mg/m$^3$ Social Benefits |
|---|---|---|---|---|
| Social | 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. | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.84** Comparison of macro-economic impacts by scenario

| Type of Impact | Baseline Scenario Marco-economic Costs | Baseline Scenario Marco-economic Benefits | Introduce OEL = 1.9 mg/m$^3$ Marco-economic Costs | Introduce OEL = 1.9 mg/m$^3$ Marco-economic Benefits |
|---|---|---|---|---|
| Macro-economic | There are not expected to be any noticeable macroeconomic impacts under the baseline scenario. | | Since there are not expected to be any significant economic impacts, there are not expected to be any significant changes in macroeconomic impacts relative to the baseline scenario from introducing an EU-wide OEL. | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

**Table 7.85** Comparison of environmental impacts by scenario

| Type of Impact | Baseline Scenario Environmental Costs | Baseline Scenario Environmental Benefits | Introduce OEL = 1.9 mg/m$^3$ Environmental Costs | Introduce OEL = 1.9 mg/m$^3$ Environmental Benefits |
|---|---|---|---|---|
| Environmental | There are not expected to be any noticeable environmental impacts under the baseline scenario. | | No workers exposed to 1-chloro-2,3-epoxypropane are estimated to be exposed above the possible EU-wide OEL value of 1.9 mg/m$^3$ and therefore most workplaces are unlikely to be affected/require further changes to their existing working practice. Therefore there are not estimated to be any significant changes in environmental impacts. | |

**Note:** Costs and benefits under the intervention options are relative to the baseline scenario (i.e. are not absolute impacts but differences)

# 8 DISCUSSION OF THE IMPACT ASSESSMENTS

## 8.1 OVERALL SUMMARY OF EVALUATIONS

Table 8.1 summarises all of the evaluations that were carried out and these information are discussed in the following sections in terms of the weight of evidence supporting the introduction or otherwise of an OEL.

The cells in the table are colour-coded as follows:

Green = this information tends to support the introduction of the suggested OEL

Orange = there is uncertainty in this information and/or uncertainty about how well it supports the introduction of the OEL

Red = this information indicates that it may not be appropriate to introduce the suggested OEL.

Note, the assessments in the table are those of the research team and we recognise that ultimately it is for the COM to decide whether to support or otherwise the introduction of an OEL.

Six of the substances have been identified as Substances of very High Concern (SVHC) under the REACH Regulation.

One substance (hexachlorobenzene) has been banned in the EU.

Five substances have SCOEL recommendations for OELs, the latest for 1,2-epoxypropance and refractory ceramic fibres, were published in 2010 after we had begun this research. For 1,2-epoxypropane the selected “typical” EU OELs are higher than the SCOEL value (12 and 4.8 mg/m$^3$ rather than 2.4 mg/m$^3$), but we do not consider that this difference would have an important impact on our conclusions for this substance. For RCF the SCOEL recommendation (0.3 fibres/ml) is between the two values evaluated in this report (0.1 and 1 fibre/ml).

**Table 8.1** Summary of the impact assessments

| Report number | Substance or mixture | Soutce of suggested OEL | OEL values evaluated | SCOEL recommendation | Cancer Types | Relative Risk estimates (RRs) >2 | RRs statistically significant | Dynamic/ Static baseline | Number of workers exposed ('000) | % exposures more than suggested OEL | Strength of evidence for occupational cancer (IARC) | EU carcinogenicty category | Baseline health impact (incident cancers 2010) | Baseline health impact (incident cancers 2010 - 2069) | Baseline health impact (deaths 2010) | Baseline health impact (deaths 2010 - 2069) | Extent of decrease in health risks (avoided cases) | Impact on SMEs | Baseline health costs (€m) | Health benefits from introducing OEL (€m) | Compliance costs (€m) | Benefit to cost ratio | Comments |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 8 | Respirable crystalline silica | COM | 0.2 mg/m3 | <0.05 mg/m3 | Lung | No | Yes | Dynamic | 720 | 14% | 1 | NA | 7,600 | 470,000 | 6,900 | 440,000 | 80,000 | Minimal | €190,000,000 - €490,000,000 | €21,000 - €56,000 | € 10,000 | 3.800 | |
| | | | 0.1 mg/m3 | | | | | | | 26% | | | | | | | 99,000 | Yes | | €26,000 - €68,000 | € 19,000 | 2.500 | |
| | | | 0.05 mg/m3 | | | | | | | 41% | | | | | | | 110,000 | Yes | | €28,000 - €74,000 | € 34,000 | 1.500 | |
| 7 | Rubber process fume and dust | Typical | 6mg/m3 (dust) | - | Lung, Larynx and Leukaemia | No | Only leukaemia | Dynamic | 57 | 14% | 1 | NA | 17 | 710 | 11 | 490 | 20 | Minimal | €720 - €860 | €24 - €46 | €55 - €280 | 0.200 | |
| | | Typical | 0.6 mg/m3 (fume) | - | | | | | 172 | 37% | | NA | 61 | 3,600 | 39 | 2,500 | 1,400 | Minimal | €2,961 - €3,930 | €580 - €1,200 | €470 - €3,200 | 0.490 | |
| 13 | Diesel engine exhaust emissions | Typical | 0.1 mg/m3 | - | Lung and Bladder | No | Yes | Dynamic | 3,600 | 1% | 2A | NA | 5,700 | 270,000 | 4,600 | 230,000 | 0 | Minimal | €99,000 - €260,000 | € 0 | €25 - €250 | 0 | |
| 21 | Mineral oils as used engine oil | Typical | NA | - | Non-melanoma skin cancer | No | No | Dynamic | 1,000 | NA | 1 | NA | 900 | 130,000 | 7 | 1,200 | Not assessed | Minimal | €450 - €2,800 | Not assessed | €46 - €920 | | Health impact assumes incresing numbers of people exposed over time, but no change in dermal exposure<br>Recommend measure dermal exposure |
| 1 | Hard wood dust | COM | 3 mg/m3 | 1 mg/m3 | Sinonasal and Nasopharyngeal | Yes | Yes | Dynamic | 3,000 | 1% | 1 | NA | 450 | 14,000 | 200 | 6,300 | 500 | Minimal | €3,900 - €17,000 | €11 - €51 | € 0 | | |
| | | | 1mg/m3 | | | | | | | 8% | | | | | | | 3,900 | Yes | | €61 - €297 | €3,800 - €8,600 | 0.029 | |
| 2 | Vinyl chloride monomer | COM | 7.67 mg/m3 | - | Liver | Yes | Yes | Static | 19 | 1% | 1 | 1 | 14 | 300 | 14 | 300 | 0 | Minimal | €190 - €470 | € 0 | € 0 | | |
| | | | 5.11 mg/m3 | | | | | | | 2% | | | | | | | 0 | | | € 0 | €3 - €30 | 0 | |
| | | | 2.56 mg/m3 | | | | | | | 4% | | | | | | | 0 | | | €1 - €3 | €40 - €185 | 0.018 | |
| 5 | Chrome VI | COM | 0.1 mg/m3 | - | Lung and Sinonasal | Not lung | Yes | Dynamic | 920 | 2% | 1 | 2 | 490 | 24,000 | 380 | 17,000 | 600 | Possible | €9,000 - €29,000 | €159 - €456 | €9,000 - €37,000 | 0.001 | Anumber of substances containing hexavalent chrome have been identified as SVHC |
| | | | 0.05 mg/m3 | | | | | | | 4% | | | | | | | 1,400 | Possible | | €340 - €991 | €18,000 - €67,000 | 0.016 | |
| | | | 0.025 mg/m3 | | | | | | | 8% | | | | | | | 1,800 | Possible | | €461 - €1,327 | €30,000 - €115,000 | 0.012 | |
| 11 | 1, 3 Butadiene | COM | 11.4 mg/m3 | - | Lympho-haematopoietic | Yes | Yes | Dynamic | 28 | 4% | 1 | 1 | 2 | 160 | 1 | 100 | 0 | Minimal | €41 - €167 | € 0 | €2 - €7 | 0 | |
| | | | 2.28 mg/m3 | | | | | | | 28% | | | | | | | 0 | Minimal | | € 0 | €17 - €63 | 0 | |

| Report number | Substance or mixture | Soutce of suggested OEL | OEL values evaluated | SCOEL recommendation | Cancer Types | Relative Risk estimates (RRs) >2 | RRs statistically significant | Dynamic/ Static baseline | Number of workers exposed ('000) | % exposures more than suggested OEL | Strength of evidence for occupational cancer (IARC) | EU carcinogenicty category | Baseline health impact (incident cancers 2010) | Baseline health impact (incident cancers 2010 - 2069) | Baseline health impact (deaths 2010) | Baseline health impact (deaths 2010 - 2069) | Extent of decrease in health risks (avoided cases) | Impact on SMEs | Baseline health costs (€m) | Health benefits from introducing OEL (€m) | Compliance costs (€m) | Benefit to cost ratio | Comments |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | 1.14 mg/m3 | | | | | | | 46% | | | | | | | 0 | Minimal | | € 0 | €27 - €100 | 0 | |
| 3 | Trichloroethylene | Typical | 273 mg/m3 | 54.7 mg/m3 | Liver, Kidney and Non-Hodgkin's Lymphoma | No | Most | Dynamic | 74 | 2% | 2A | 2 | 93 | 4,800 | 59 | 3,300 | 10 | Minimal | €1,600 - €5,700 | € 0 | € 61 | 0 | Identified as SVHC |
| | | | 50 mg/m3 | | | | | | | 28% | | | | | | | 580 | Possible | | €120 - €430 | € 428 | 0.64 | Compliance cost assessment influenced by requirements fo the Solvent Directive |
| 4 | Beryllium and beryllium compounds | Typical | 0.002 mg/m3 | - | Lung | No | No | Dynamic | 65 | 10% | 1 | 2 | 7 | 430 | 6 | 390 | 50 | Yes | €200 - €530 | €11 - €30 | €18,000 - €34,000 | 0.011 | |
| 6 | Acrylamide | Typical | 0.03 mg/m3 | - | Pancreatic | No | No | Dynamic | 53 | 10% | 2A | 2 | 7 | 250 | 6 | 230 | 0 | Minimal | €160 - €330 | € 0 | € 0 | | Identified as SVHC |
| 9 | 4, 4' methylenedianiline (MDA) | Typical | 0.8 mg/m3 | - | Bladder | None identified | | | between 390 and 3,900 | Not known | 2B | 2 | | Not assessed | | Not assessed | | Minimal | Not assessed | Not assessed | €1,400 - €29,000 | | Identified as SVHC |
| | | | 0.08 mg/m3 | | | | | | | | | | | | | | | Minimal | | Not assessed | €1,400 - €29,000 | | Recommended measure exposure |
| 10 | 4,4'-Methylene bis 2-chloroaniline (MbOCA) | Typical | 15µmol/mol | - | Bladder | Yes | No | Dynamic | 2.5 | 5% | 2A | 2 | 8 | 280 | 3 | 100 | 0 | Minimal | €45 - €350 | €1 - €7 | €560 - €1,100 | 0.005 | |
| | | | 5µmol/mol | | | | | | | 16% | | | | | | | 20 | Minimal | | €1 - €11 | €1,500 - €3,000 | 0.003 | |
| 12 | Ethylene oxide | Typical | 1.8 mg/m3 | - | Leukaemia | Yes | No | Dynamic | 16 | 0% | 1 | 2 | 0 | 0 | 0 | 0 | 0 | Minimal | € 0 | € 0 | € 0 | | |
| 14 | Refractory ceramic fibres | Typical | 1 f/ml | 0.3 f/ml | Lung | Analogy | NA | Dynamic | 10 | 10% | 2B | 2 | 2 | 60 | 2 | 50 | 0 | Possible | €33 - €83 | €1 - €2 | € 0 | | Identified as SVHC |
| | | | 0.1 f/ml | | | | | | | 50% | | | | | | | 0 | Possible | | €1 - €2 | €60 - €2,500 | 0.001 | SCOEL recommendation made 2010 |
| 15 | Hydrazine | Typical | 0.13 mg/m3 | - | Lung and Colorectal | Yes | Yes | Dynamic | 2,100 | 8% | 2B | 2 | 149 | 2,500 | 43 | 710 | 0 | Minimal | €500 - €3,000 | € 0 | €15 - €47 | 0 | |
| | | | 0.013 mg/m3 | | | | | | | 75% | | | | | | | 0 | Minimal | | € 0 | €62 - €200 | 0 | |
| 16 | 1, 2-Epoxypropane | Typical | 12 mg/m3 | 2.4 mg/m3 | Leukaemia | No | No | Static | <1.2 | <1% | 2B | 2 | 0 | 0 | 0 | 0 | 0 | Minimal | €2.5 - €11 | € 0 | € 0 | | SCOEL recommendation made 2010 |
| | | | 4.8 mg/m3 | | | | | | | <1% | | | | | | | 0 | Minimal | | € 0 | € 0 | | |

| Report number | Substance or mixture | Soutce of suggested OEL | OEL values evaluated | SCOEL recommendation | Cancer Types | Relative Risk estimates (RRs) >2 | RRs statistically significant | Dynamic/ Static baseline | Number of workers exposed ('000) | % exposures more than suggested OEL | Strength of evidence for occupational cancer (IARC) | EU carcinogenicty category | Baseline health impact (incident cancers 2010) | Baseline health impact (incident 2010 - 2069) cancers | Baseline health impact (deaths 2010) | Baseline health impact (deaths 2010 - 2069) | Extent of decrease in health risks (avoided cases) | Impact on SMEs | Baseline health costs (€m) | Health benefits from introducing OEL (€m) | Compliance costs (€m) | Benefit to cost ratio | Comments |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 17 | 1, 2-Dichloroethane | Typical | 20 mg/m3 | - | Uncertain | None identified | | | <3 | <1% | 2B | 2 | | Not assessed | | Not assessed | | Minimal | Not assessed | Not assessed | €0 - €13 | | |
| | | | 4 mg/m3 | | | | | | | 13% | | | | | | | | Minimal | | Not assessed | €0 - €43 | | |
| 18 | 1, 2-Dibromoethane | Typical | 0.8 mg/m3 | - | Uncertain | None identified | | | <8 | 8% | 2B | 2 | | Not assessed | | Not assessed | | Minimal | Not assessed | Not assessed | € 0 | | |
| 19 | o-Toluidine | Typical | 4.4 mg/m3 | - | Bladder | Yes | Yes | Static | 5.5 | 0% | 1 | 2 | 22 | 490 | 7 | 150 | 0 | Minimal | €86 - €700 | € 0 | € 0 | | |
| | | | 0.4 mg/m3 | | | | | | | 2% | | | | | | | 0 | Minimal | | € 0 | € 0 | | |
| 20 | Hexachlorobenzene | Typical | 0.002 mg/m3 | - | Uncertain | None identified | | | Unknown | 0% | 2B | 2 | | Not assessed | | Not assessed | | Minimal | Not assessed | Not assessed | € 0 | | Substance banned |
| | | | 0.025 mg/m3 | | | | | | | 0% | | | | | | | | Minimal | | Not assessed | € 0 | | Recommend measure exposure |
| 22 | Benzo[a]pyrene | Typical | 0.002 mg/m3 | - | Lung and Bladder | No | Yes | Dynamic | 7,000 | 0% | 1 | 2 | 600 | 13,000 | 480 | 10,000 | 0 | Minimal | €6,300 - €19,000 | € 0 | € 0 | | Pitch and anthracene oil identified as a SVHC |
| | | | | | Non-melanoma skin cancer | No | Yes | | | NA | | | 250 | 18,000 | 2 | 160 | 0 | Minimal | €45 - €450 | € 0 | € 0 | | |
| 23 | 2-Nitropropane | Typical | 19 mg/m3 | - | Uncertain | None identified | | | 50 | 0% | 2B | 2 | | Not assessed | | Not assessed | | Minimal | Not assessed | € 0 | € 0 | | |
| 24 | Bromoethylene | Typical | 22 mg/m3 | - | Assumed to be Liver | Analogy | NA | | <1 | 0% | 2A | 2 | 0 | 0 | 0 | 0 | 0 | Minimal | € 0 | € 0 | € 0 | | |
| 25 | 1-Chloro-2, 3-epoxypropane | Typical | 1.9 mg/m3 | - | Lung and CNS | only CNS | No | Static | 44 | 0% | 2A | 2 | 34 | 2,600 | 31 | 2,400 | 0 | Minimal | €1,400 - €2,800 | € 0 | € 0 | | |

The following provides a brief glossary for the table (for each column A to X). The detailed content of the table is discussed in the remainder of this report.

| | Descriptor | Explanation |
|---|---|---|
| A | Report number | The number of the detailed report. |
| B | Substance or mixture name | |
| C | Source of suggested OEL | COM = European Commission, Typical = value(s) selected by the authors as being "typical" of values in EU Member States. |
| D | OEL values evaluated | Note there may be between one and three limits evaluated. Later in the table the data may refer specifically to each of these limits, e.g. % exposures above the suggested OEL, but the majority of table entries refer to the substance rather than the limit values. |
| E | SCOEL recommendation | Listed where there is a SCOEL recommendation. |
| F | Cancer types | Cancers that are considered causally associated with exposure to the substance and evaluated in this report. |
| G | Relative risk estimates (RR>2) | An assessment of whether there is a strong association between risk and exposure (as assessed by the relative risk from the epidemiological studies). |
| H | RRs statistically significant | An assessment of the strength of the evidence for an association (assessed by the statistical significance of the RR estimates). |
| I | Dynamic/Static baseline | A technical aspect of the health impact as to whether account is taken of any temporal trends in exposure (Dynamic) or whether exposure is assumed to remain unchanged (Static). |
| J | Number of workers exposed | For the whole of the EU, expressed as thousands ('000) |
| K | % exposures more than the suggested OEL | Estimated percentage of workers exposed above the suggested limit value – note there is a figure for each limit assessed. |
| L | Strength of evidence for occupational cancer | IARC categorisation of carcinogenicity: 1 = human carcinogen, 2a = probably human carcinogen, 2b = possible human carcinogen. |
| M | EU carcinogenicity category | Category 1 or 2. For process-generated substances this is not applicable (NA). |
| N | Baseline health impact (incident cases 2010) | Estimated number of cancers in the EU (all types identified in Column F combined) occurring in 2010 that are attributed to past exposure to the substance. |
| O | Baseline health impact (incident cases 2010 – 2069) | Cumulative number of cancer cases over the period attributed to exposure to the substance. |
| P | Baseline health impact (deaths 2010) | Estimated number of cancer deaths in the EU (all types identified in Column F) occurring in 2010 that are attributed to past exposure. |
| Q | Baseline health impact (deaths 2010 – 2069) | Cumulative number of cancer deaths over the period attributed to exposure to the substance. |
| R | Extent of decrease in health risks (avoided cases) | The number of avoided cancer cases from introducing an OEL at the values specified – note there are figures for each OEL assessed. |
| S | Impact on SMEs | An assessment of whether the specified OEL would have an important financial impact on SMEs. |
| T | Baseline health costs | Estimated baseline health costs (million Euros), expressed as a range to reflect the uncertainties of the assessment. |
| U | Health benefits from introducing and OEL | Estimated health benefits (million Euros) of introducing an OEL – note there are figures for each OEL value assessed. |
| V | Compliance costs | Estimated costs of complying with a limit value (million Euros) |
| W | Benefit to cost ratio | The ratio of the mid point of the range of values for the benefits to the mid point of the range for the compliance costs. Values greater than one suggest the benefits outweigh the costs. |

| | Descriptor | Explanation |
|---|---|---|
| X | Comments | Additional comments for some substances. |

#### 8.1.1 Evidence about the occupational cancer hazards

There were eleven of the 25 substances that have been categorised by the IARC as human carcinogens; two are EU cat 1 substances and the remainder are classified as cat 2 (Table 8.2). Four substances are classified as IARC 2a, probable human carcinogens and ten as IARC 2b, possible human carcinogens.

**Table 8.2** Summary of evidence on occupational cancer hazards

| IARC category 1 | | IARC category 2a | | IARC category 2b | |
|---|---|---|---|---|---|
| Hard wood dust | S, N | Trichloroethylene | H, K and NHL | 4, 4' methylenedianiline (MDA) | B |
| Vinyl chloride monomer | H | Acrylamide | P | Refractory ceramic fibres | L |
| Beryllium and beryllium compounds | L | 4,4'-Methylene bis 2-chloroaniline (MbOCA) | B | Hydrazine | L, C |
| Chrome VI | L, S | Diesel engine exhaust emissions | L, B | 1, 2-Epoxypropane | Leuk |
| Rubber process fume and dust | L, Lar, Leuk | | | 1, 2-Dichloroethane | Uncertain |
| Respirable crystalline silica | L | | | 1, 2-Dibromoethane | Uncertain |
| 1, 3 Butadiene | Lymph | | | Hexachlorobenzene | Uncertain |
| Ethylene oxide | Leuk | | | 2-Nitropropane | Uncertain |
| Mineral oils as used engine oil | NMSC | | | Bromoethylene | H |
| Benzo[a]pyrene | L, B, NMSC | | | 1-Chloro-2,3-epoxypropance | L, CNS |
| o-Toluidine | B | | | | |

S = sinonasal N = nasopharyngeal H = liver L = lung Lar = larynx Leuk = leukaemia
Lymph = lympho-haematopoietic NMSC = non-melanoma skin cancer B = bladder
K = kidney NHL = non-Hodgkin's lymphoma P = pancreatic C = colorectal CNS = central nervous system

In general the evidence to support setting an OEL is weaker for the IARC 2b substances and in four of these cases there is uncertainty about which human organ system may be at risk.

For seven of the substances categorised as IARC category 1 the epidemiological evidence used for the health impact assessment provide statistically significantly raised risk estimates with a relative risk (RR) more than 2 – hardwood dust, vinyl chloride monomer, chrome VI, respirable crystalline silica, 1,3-butadiene, o-toluidine and benzo[a]pyrene. For hexavalent chromium the RR that was used was statistically significantly above 2 for nasopharyngeal cancer but not lung cancer.

For five of the IARC 2b compounds it was not possible to identify a suitable RR for use in the health impact assessment (the four substances where there was uncertainty about the type of cancer produced along with MDA where it was judged the main route of exposure was by skin contact and it was not practicable to identify a suitable epidemiological study on which to base the health impact assessment).

In two cases we relied on analogous epidemiological data to derive a RR for the health impact – refractory ceramic fibres and bromoethylene. These assumptions may have increase the uncertainty of the estimates for these substances, although for RCF the effect is most likely to overestimate the health impact from exposure.

### 8.1.2 Numbers exposed and the estimated level of exposure in relation to the proposed OEL

For six substances there was more than a million people estimated to be currently exposed in the EU and for 16 there were less than 100,000 workers potentially exposed (Table 8.3). For substances where there are large numbers of people exposed the impact of introducing an OEL on overall cancer burden is likely to be greater than for substances where few people are exposed at work.

**Table 8.3** Estimated number of people exposed in the EU

| Substance or mixture | Estimated number exposed |
|---|---:|
| Benzo[a]pyrene | 7,000,000 |
| Diesel engine exhaust emissions | 3,600,000 |
| Hard wood dust | 3,000,000 |
| Hydrazine | 2,100,000 |
| Mineral oils as used engine oil | 1,000,000 |
| 4, 4' methylenedianiline (MDA) | 390,000 - 3,900,000 |
| Chrome VI | 920,000 |
| Respirable crystalline silica | 720,000 |
| | 172,000 |
| Trichloroethylene | 74,000 |
| Beryllium and beryllium compounds | 65,000 |
| Rubber process fume and dust | 57,000 |
| Acrylamide | 53,000 |
| 2-Nitropropane | 50,000 |
| 1-Chloro-2, 3-epoxypropane | 44,000 |
| 1, 3 Butadiene | 28,000 |
| Vinyl chloride monomer | 19,000 |
| Ethylene oxide | 16,000 |
| Refractory ceramic fibres | 10,000 |
| o-Toluidine | 5,500 |
| 1, 2-Dibromoethane | <8,000 |
| 4,4'-Methylene bis 2-chloroaniline (MbOCA) | 2,500 |
| 1, 2-Dichloroethane | <3,000 |
| 1, 2-Epoxypropane | <1,200 |
| Bromoethylene | <1,000 |
| Hexachlorobenzene | Unknown |

For the 24 substances, we identified a total of 43 OELs for which we carried out our assessments; between one and three OELs per substance. For five substances the limits were specified by the COM in the original specification for this work and for the remainder we selected values that were considered typical of existing OELs in EU Member States, in accordance with the terms of reference for the project (Table 8.4).

**Table 8.4** OEL values tested and the estimated percentage of workers using the substance that are judged to be exposed above the suggested OEL

| Substance or mixture | Basis for the limit | OEL | Percentage >OEL |
|---|---|---|---|
| Hydrazine | Typical | 0.13 mg/m$^3$ | 8% |
| | | 0.013 mg/m$^3$ | 75% |
| Refractory ceramic fibres | Typical | 1 f/ml | 10% |
| | | 0.1 f/ml | 50% |
| 1, 3 Butadiene | EC | 11.4 mg/m$^3$ | 4% |
| | | 2.28 mg/m$^3$ | 28% |
| | | 1.14 mg/m$^3$ | 46% |
| Respirable crystalline silica | EC | 0.2 mg/m$^3$ | 14% |
| | | 0.1 mg/m$^3$ | 26% |
| | | 0.05 mg/m$^3$ | 41% |
| Rubber process fume and dust | Typical | 6mg/m$^3$ (dust) | 14% |
| | Typical | 0.6 mg/m$^3$ (fume) | 37% |
| Trichloroethylene | Typical | 273 mg/m$^3$ | 2% |
| | | 50 mg/m$^3$ | 28% |
| 4,4'-Methylene bis 2-chloroaniline | Typical | 15μmol/mol | 5% |
| (MbOCA) | | 5μmol/mol | 16% |
| 1, 2-Dichloroethane | Typical | 20 mg/m$^3$ | <1% |
| | | 4 mg/m$^3$ | 13% |
| Acrylamide | Typical | 0.03 mg/m$^3$ | 10% |
| Beryllium and beryllium compounds | Typical | 0.002 mg/m$^3$ | 10% |
| Hard wood dust | EC | 3 mg/m$^3$ | 1% |
| | | 1 mg/m$^3$ | 8% |
| Chrome VI | EC | 0.1 mg/m$^3$ | 2% |
| | | 0.05 mg/m$^3$ | 4% |
| | | 0.025 mg/m$^3$ | 8% |
| 1, 2-Dibromoethane | Typical | 0.8 mg/m$^3$ | 8% |
| Vinyl chloride monomer | EC | 7.67 mg/m$^3$ | 1% |
| | | 5.11 mg/m$^3$ | 2% |
| | | 2.56 mg/m$^3$ | 4% |
| o-Toluidine | Typical | 4.4 mg/m$^3$ | 0% |
| | | 0.4 mg/m$^3$ | 2% |
| Diesel engine exhaust emissions | Typical | 0.1 mg/m$^3$ | 1% |

| Substance or mixture | Basis for the limit | OEL | Percentage >OEL |
|---|---|---|---|
| 1, 2-Epoxypropane | Typical | 12 mg/m$^3$ | <1% |
| | | 4.8 mg/m$^3$ | <1% |
| Ethylene oxide | Typical | 1.8 mg/m$^3$ | 0% |
| Hexachlorobenzene | Typical | 0.002 mg/m$^3$ | 0% |
| | | 0.025 mg/m$^3$ | 0% |
| Benzo[a]pyrene | Typical | 0.002 mg/m$^3$ | 0% |
| 2-Nitropropane | Typical | 19 mg/m$^3$ | 0% |
| Bromoethylene | Typical | 22 mg/m$^3$ | 0% |
| 1-Chloro-2, 3-epoxypropane | Typical | 1.9 mg/m$^3$ | 0% |
| 4, 4' methylenedianiline (MDA) | Typical | 0.8 mg/m$^3$ | NK |
| | | 0.08 mg/m$^3$ | NK |
| Mineral oils as used engine oil | Typical | NA | NA |

In the table, “NK” = not known, and “NA” = an inhalation or biomonitoring OEL considered not applicable

For all substances assessed there was at least one of the suggested OEL values where there was less than 14% of the EU working population using that substance exposed above the suggested limit. However, for some OEL values there is a relatively large proportion of workers exposed above the OEL, e.g. 75% of workers using hydrazine are judged to be exposed above the suggested limit of 0.013 mg/m$^3$. For 14 substance-OEL combinations there is less than 1% of workers exposed above the suggested limit value, which we would consider represents current full compliance with the OEL being considered. In those situations where there is a high proportion of people already exposed below the suggested OEL then there is likely to be little additional health benefit from introducing an OEL at that value.

### 8.1.3 Baseline health impact assessment

The estimated baseline number of incident cancer cases and deaths, both for the year 2010 and for the whole period from 2010 to 2069 are summarised in Table 5.5. These data are sorted by the cumulative number of deaths, with the greatest impact being due to exposure to respirable crystalline silica and diesel engine exhaust emissions. There are ten substances for which the cumulative number of deaths over the next 60 years is less than 1,000, which equates to on average less than 17 deaths per year in the EU attributed to these exposures. Clearly much of the attributable health impact from the baseline scenario is due to past exposure.

The potential impact of introducing an OEL will clearly be much greater in situations where the baseline health burden is large compared to those substances where relatively small numbers of cancers may be attributed to occupational exposure. Note, substances where there is estimated to be no health impact are excluded from this table.

**Table 8.5** Baseline health impact assessment: estimated numbers of incident cancers and deaths from inaction

| Substance or mixture | Incident cancers 2010 | Incident cancers 2010 - 2069 | Deaths 2010 | Deaths 2010 - 2069 |
|---|---|---|---|---|
| Respirable crystalline silica | 7,600 | 470,000 | 6,900 | 440,000 |
| Diesel engine exhaust emissions | 5,700 | 270,000 | 4,600 | 230,000 |
| Chrome VI | 490 | 24,000 | 380 | 17,000 |
| Benzo[a]pyrene (excluding NMSC) | 600 | 13,000 | 480 | 10,000 |
| Hard wood dust | 450 | 14,000 | 200 | 6,300 |
| Trichloroethylene | 93 | 4,800 | 59 | 3,300 |
| Rubber process fume | 61 | 3,600 | 39 | 2,500 |
| 1-Chloro-2, 3-epoxypropane | 34 | 2,600 | 31 | 2,400 |
| Mineral oils as used engine oil | 900 | 130,000 | 7 | 1,200 |
| Hydrazine | 149 | 2,500 | 43 | 710 |
| Rubber process dust | 17 | 710 | 11 | 490 |
| Beryllium and beryllium compounds | 6 | 390 | 6 | 390 |
| Vinyl chloride monomer | 14 | 300 | 14 | 300 |
| Acrylamide | 7 | 250 | 6 | 230 |
| Benzo[a]pyrene (NMSC) | 250 | 18,000 | 2 | 160 |
| o-Toluidine | 22 | 490 | 7 | 150 |
| 4,4'-Methylene bis 2-chloroaniline (MbOCA) | 8 | 280 | 3 | 100 |
| 1,3-butadiene | 2 | 160 | 1 | 100 |
| RCF | 2 | 60 | 2 | 50 |

For two substances (1,2-epoxypropane and bromoethylene) there were no deaths predicted from past or future exposures.

No baseline health impact was made for five substances (4, 4' methylenedianiline – MDA, 1,2-dichloroethane, 1,2-dibromoethane, hexachlorobenzene and 2-nitropropane) because there was insufficient epidemiological evidence to sustain these assessments.

Note, rubber process dust and rubber fume are shown separately in this table.

### 8.1.4 Estimated numbers of avoided cancer cases avoided by introducing an OEL

There are only seven substances or mixtures where the data suggests a clear health benefit in terms of avoided cancer cases over the next 60 years from introducing an OEL (Table 8.6). The largest benefits arise from the introduction of OELs for respirable crystalline silica, hardwood dust, hexavalent chrome and rubber fume. The highest percentage reduction in incident cases was for the OEL for rubber fume (39%), followed by hardwood dust at 1 mg/m$^3$ (28%) and respirable crystalline silica at 0.05 mg/m$^3$ (23%).

**Table 8.6** Estimated number of cancer cases prevented by introducing an OEL at the specified value

| Substance or mixture | OEL value | Extent of decrease in health risks (avoided cases 2010 to 2069) | % decrease in health risk |
|---|---|---|---|
| Respirable crystalline silica | 0.2 mg/m$^3$ | 80,000 | 17% |
| | 0.1 mg/m$^3$ | 99,000 | 21% |
| | 0.05 mg/m$^3$ | 110,000 | 23% |
| Hard wood dust | 3 mg/m$^3$ | 500 | 3.6% |
| | 1mg/m$^3$ | 3,900 | 28% |
| Chrome VI | 0.1 mg/m$^3$ | 600 | 2.5% |
| | 0.05 mg/m$^3$ | 1,400 | 5.8% |
| | 0.025 mg/m$^3$ | 1,800 | 7.5% |
| Rubber process fume | 0.6 mg/m$^3$ | 1,400 | 39% |
| Trichloroethylene | 273 mg/m$^3$ | 10 | 0.2% |
| | 50 mg/m$^3$ | 580 | 12% |
| Beryllium and beryllium compounds | 0.002 mg/m$^3$ | 50 | 13% |
| Rubber process dust | 6 mg/m$^3$ | 20 | 2.8% |
| 4,4'-Methylene bis 2-chloroaniline (MbOCA) | 5 µmol/mol | 20 | 7.1% |

Note, that for the substance and OEL combinations not shown in the table there is no significant health benefit from introducing the specific OEL evaluated.

### 8.1.5 Compliance costs and benefit to cost ratio

Details of the estimated compliance costs are shown in Table 8.7 for each substance OEL combination.

**Table 8.7** Estimated compliance costs for each substance and OEL, with benefit to cost ratio

| Substance or mixture | OEL | Total compliance costs (€m) | Benefit to cost ratio |
|---|---|---|---|
| Chrome VI | 0.1 mg/m$^3$ | €9,000 - €37,000 | 0.001 |
| | 0.05 mg/m$^3$ | €18,000 - €67,000 | 0.016 |
| | 0.025 mg/m$^3$ | €30,000 - €115,000 | 0.012 |
| Respirable crystalline silica | 0.2 mg/m$^3$ | € 10,000 | 3.8 |
| | 0.1 mg/m$^3$ | € 19,000 | 2.5 |
| | 0.05 mg/m$^3$ | € 34,000 | 1.5 |
| Beryllium and beryllium compounds | 0.002 mg/m$^3$ | €18,000 - €34,000 | 0.011 |
| 4,4'methylenedianiline (MDA) | 0.8 mg/m$^3$ | €1,400 - €29,000 | - |
| | 0.08 mg/m$^3$ | €1,400 - €29,000 | - |
| Hard wood dust | 3 mg/m$^3$ | € 0 | |
| | 1 mg/m$^3$ | €3,800 - €8,600 | 0.029 |
| Rubber process fume and dust | 6mg/m$^3$ (dust) | €55 - €280 | 0.2 |
| | 0.6 mg/m$^3$ (fume) | €470 - €3,200 | 0.49 |
| 4,4'-Methylene bis 2-chloroaniline (MbOCA) | 15µmol/mol | €560 - €1,100 | 0.005 |
| | 5µmol/mol | €1,500 - €3,000 | 0.003 |
| Refractory ceramic fibres | 1 f/ml | € 0 | - |
| | 0.1 f/ml | €60 - €2,500 | 0.001 |
| Mineral oils as used engine oil | NA | €46 - €920 | - |
| Trichloroethylene | 273 mg/m$^3$ | €61 | 0 |
| | 50 mg/m$^3$ | €428 | 0.64 |
| Diesel engine exhaust emissions | 0.1 mg/m$^3$ | €25 - €250 | 0 |
| Hydrazine | 0.13 mg/m$^3$ | €15 - €47 | 0 |
| | 0.013 mg/m$^3$ | €62 - €200 | 0 |
| Vinyl chloride monomer | 7.67 mg/m$^3$ | € 0 | - |
| | 5.11 mg/m$^3$ | €3-€30 | 0 |
| | 2.56 mg/m$^3$ | €40 - €185 | 0.018 |
| 1, 3 Butadiene | 11.4 mg/m$^3$ | €2 - €7 | 0 |
| | 2.28 mg/m$^3$ | €17 - €63 | 0 |
| | 1.14 mg/m$^3$ | €27 - €100 | 0 |

| Substance or mixture | OEL | Total compliance costs (€m) | Benefit to cost ratio |
|---|---|---|---|
| 1, 2-Dichloroethane | 20 $mg/m^3$ | €0 - €13 | - |
| | 4 $mg/m^3$ | €0 - €43 | - |
| Acrylamide | 0.03 $mg/m^3$ | € 0 | - |
| Ethylene oxide | 1.8 $mg/m^3$ | € 0 | - |
| 1, 2-Epoxypropane | 12 $mg/m^3$ | € 0 | - |
| | 4.8 $mg/m^3$ | € 0 | - |
| 1, 2-Dibromoethane | 0.8 $mg/m^3$ | € 0 | - |
| o-Toluidine | 4.4 $mg/m^3$ | € 0 | - |
| | 0.4 $mg/m^3$ | € 0 | - |
| Hexachlorobenzene | 0.002 $mg/m^3$ | € 0 | - |
| | 0.025 $mg/m^3$ | € 0 | - |
| Benzo[a]pyrene | 0.002 $mg/m^3$ | € 0 | - |
| 2-Nitropropane | 19 $mg/m^3$ | € 0 | - |
| Bromoethylene | 22 $mg/m^3$ | € 0 | - |
| 1-Chloro-2, 3-epoxypropane | 1.9 $mg/m^3$ | € 0 | - |

Compliance costs aggregated over the next 60 years were highest for chrome VI for an OEL of 0.025 $mg/m^3$ at €30,000m - €115,000m. Estimated compliance costs were more than €1,000m for: respirable crystalline silica (all OEL values assessed), beryllium, MDA, hardwood dust (1 $mg/m^3$), rubber fume, MbOCA (both values assessed) and RCF.

Compliance costs were judged to be zero (or not significant) for 16 of the substance OEL combinations, i.e. EU industry is already assumed to be fully compliant with these proposed values.

There were only three proposed OEL values that produced a benefit to cost ratio greater than one, i.e. for respirable crystalline silica. For the eleven other substance-OEL combinations where we were able to calculate a benefit to cost ratio the values ranged from 0.001 (chrome VI at 0.1 $mg/m^3$ and RCF at 0.1 fibres/ml) to 0.64 (trichloroethylene at 50 $mg/m^3$).

In nine substance-OEL combinations assessed it was judged that introducing the limit value could have a disproportionate detrimental financial impact on SMEs. These were for hardwood dust at 1 $mg/m^3$, trichloroethylene at 50 $mg/m^3$, beryllium and beryllium compounds, chrome VI (all OEL values), respirable crystalline silica (0.1 and 0.05 $mg/m^3$) and refractory ceramic fibres (0.1 fibre/ml).

There may be other sectors where some detrimental effect on SMEs might occur but these were not explicitly identified as significant using the method applied.

## 8.2 DISCUSSION OF THE STRENGTH OF EVIDENCE FOR EACH SUGGESTED OEL

### 8.2.1 Respirable crystalline silica

In relative terms perhaps the strongest case for introducing an OEL exists for respirable crystalline silica. In summary:

- Statistically significant relative risk estimates were identified for lung cancer
- It is an IARC category 1 carcinogen
- A large number of workers in the EU are exposed (720,000)
- Exposure to respirable crystalline silica occurs in mining, construction, manufacturing products incorporating minerals and other industrial sectors
- A relatively high proportion of workers are judged to be exposed above the suggested OELs (14% above 0.2 mg/m$^3$, 26% above 0.1 mg/m$^3$ and 41% above 0.05 mg/m$^3$)
- A large number of cancers are projected to occur if no action is taken (440,000 deaths and a similar number of incident cases over the next 60 years)
- Introducing an OEL is thought to result in considerable number of avoided cancers (80,000 to 110,000 cases, depending on the OEL selected)
- There are estimated to be very large health costs (€) of inaction and potentially large health benefits (€) from implementing an OEL
- Introducing an OEL is thought to have a negative financial effect on small and medium size companies and compliance may be particularly problematic for some SMEs
- And, finally, there is a benefit to cost ratio greater than 1 for all three possible OELs, i.e. estimated compliance costs are less than the monetised health benefits.

### 8.2.2 Chrome VI

There is also a strong case for introducing an OEL for hexavalent chrome compounds. In this case:

- There are statistically significant relative risks estimates identified for lung and sinonasal cancer
- It is an IARC category 1 carcinogen
- A large number of workers in the EU are exposed (920,000)
- Exposure to chrome VI occurs in various manufacturing processes, in some welding processes and in some foundries
- Some workers are judged to be exposed above the suggested OELs (2% above 0.1 mg/m$^3$, 4% above 0.05 mg/m$^3$ and 8% above 0.025 mg/m$^3$)
- A large number of cases are projected to occur if no action is taken (24,000 cases and 17,000 deaths over the next 60 years)
- An OEL would result in avoided cancers (600 to 1,800, depending on the OEL selected)
- There are large health costs (€) of inaction and potentially large health benefits (€) from implementing an OEL

- However, the benefit to cost ratio is much less than 1 for all OELs investigated, i.e. estimated compliance costs are much greater than the monetised health benefits
- Introducing an OEL could have a negative financial impact on small and medium size companies.

### 8.2.3 Hardwood dust

There is a strong case for introducing an OEL for hardwood dust, measured as inhalable dust. In this case:

- There are statistically significant relative risks estimates identified for sinonasal and nasopharyngeal cancer
- It is an IARC category 1 carcinogen
- A very large number of workers in the EU are potentially exposed (3,000,000)
- Exposure to hardwood dust mainly occurs in the wood working industry and the furniture manufacture sectors
- Some workers are judged to be exposed above the suggested OELs (1% above 3 mg/m$^3$, 8% above 1 mg/m$^3$)
- A large number of cancers are projected to occur if no action is taken (14,000 cases and 6,300 deaths over the next 60 years)
- An OEL would result in avoided cancers (500 to 3,900, depending on the OEL selected)
- There are large health costs (€) of inaction and potentially large health benefits (€) from implementing an OEL
- However, the benefit to cost ratio is much less than 1 for all OELs investigated, i.e. estimated compliance costs are much greater than the monetised health benefits
- A limit of 1 mg/m$^3$ would have a negative financial effect on small and medium size companies.

### 8.2.4 Diesel engine exhaust emissions

There is a case for introducing an OEL for diesel engine exhaust particulate, but the OEL would need to be much lower than the typical European OEL that we tested (0.1 mg/m$^3$, as elemental carbon). In this case:

- There are statistically significant relative risks estimates identified for lung and bladder cancer
- It is an IARC category 2a carcinogen
- A very large number of workers in the EU are potentially exposed (3,600,000)
- Exposure to diesel engine exhaust emissions occurs in transportation and other industries where diesel engines are used
- We judged that most EU industries are already in compliance with the OEL tested, with the exception of underground mining where between 10% and 54% of exposures may exceed 0.1 mg/m$^3$.
- A very large number of cancers are projected to occur if no action is taken (270,000 cases and 230,000 deaths over the next 60 years)

- The typical EU OEL investigated would not result in any avoided cancers in non-underground mining. To have an impact the OEL would need to be much lower than the typical values in the EU today
- It is likely that there would be a positive health impact from introducing an OEL of 0.1 mg/m$^3$ in the mining sector, although it has not been possible for us to quantify the effect from the present analysis.
- There are very large health costs (€) of inaction and no identified health benefits (€) from implementing an OEL at the current 'typical' OEL level
- Compliance costs for the investigated OEL are relatively small.

It should be noted that diesel engine exhaust particulate is a complex mixture and it is uncertain exactly which components of the mixture cause a risk of cancer. Consideration should also be given to encouraging the development of technologies that result in less hazardous emissions and not just lower particulate emissions.

#### 8.2.5 Rubber fume

Rubber dust and fumes are discussed separately since the exposed populations and exposure levels differ. There is a case for introducing an OEL for rubber fume within the tyre and general rubber goods manufacturing sectors.

- There are statistically significant relative risks estimates identified for leukaemia, but not for lung or laryngeal cancer
- Working in the rubber manufacturing industry is classified as an IARC category 1 carcinogen
- A large number of workers in the EU are potentially exposed to rubber fume (172,000)
- Exposure to rubber fume occurs in mixing of rubber compounds, component preparation (i.e. extruding, calendaring etc.) and product curing in rubber tyre and general rubber goods manufacturing
- A relatively high proportion of workers are judged to be exposed above the suggested OEL of 0.6 mg/m$^3$ (37%)
- A large number of cancers are projected to occur if no action is taken (3,600 cases and 2,500 deaths over the next 60 years)
- Introducing the OEL would result in a large number of avoided cancers (1,400 over the next 60 years)
- There are large health costs (€) of inaction and potentially large health benefits (€) from implementing an OEL
- The benefit to cost ratio is just less than 1, i.e. estimated compliance costs are a little less than the monetised health benefits
- Introducing an OEL could have a financial impact on small and medium size companies.

It should be noted that rubber fume is a complex mixture and it is uncertain exactly which components of the mixture cause a risk of cancer. Consideration should also be given to encouraging the development of technologies that result in less hazardous emissions and not just lower fume levels in the workplace.

### 8.2.6 Benzo[a]pyrene

Benzo[a]pyrene is considered as a marker compound for the complex mixture of polycyclic aromatic hydrocarbons (PAH) that arise in the combustion of organic material. In this assessment we exclude exposure to benzo[a]pryrene in diesel engine exhaust as the risk is dealt with separately (see above). There is a case for introducing an OEL for benzo[a]pyrene.

- There are statistically significant relative risks estimates identified for lung, bladder and non-melanoma skin cancer (NMSC)
- Various industries where PAH exposure occurs and complex mixtures containing PAHs are classified as IARC category 1 carcinogens. Benzo[a]pyrene is also classified as an IARC category 1 carcinogen
- A very large number of workers in the EU are exposed (7,000,000)
- Exposure to benzo[a]pyrene occurs in aluminium, iron and steel production plants, foundries, waste incineration, mining or oil refining, coke and tar production plants, coal gasification sites, bitumen and asphalt production plants, road and roof tarring operations, and other facilities that burn carbonaceous materials
- No workers are judged to be exposed above the typical EU exposure limit considered in this report (0.002 mg/m$^3$)
- Dermal exposure to pitch or tar containing benzo[a]pyrene may occur
- A large number of cancers are projected to occur if no action is taken (13,000 cases and 10,000 deaths from lung and bladder cancer and 18,000 cases and 160 deaths from NMSC, over the next 60 years)
- An EU OEL at the 'typical' level would result in no avoided cancers; to have any impact on the cancer burden the exposure limit would need to be much lower than the typical EU OEL
- There are large health costs (€) of inaction and no identified health benefits (€) from implementing the OEL considered
- There would be no additional compliance costs associated with the OEL evaluated, although there would be some administrative costs.

### 8.2.7 Trichloroethylene

There is a case for introducing an OEL for trichloroethylene. In summary:

- Statistically significant relative risk estimates were identified for most of the cancers associated with trichloroethylene exposure (liver, kidney and non-Hodgkin's lymphoma)
- It is an IARC category 2a carcinogen
- A fairly large number of workers in the EU are exposed (74,000)
- Exposure to trichloroethylene occurs in production of the substance, during use in metal degreasing, in adhesive use, and other diverse situations
- A relatively high proportion of workers are judged to be exposed above the 50 mg/m$^3$ typical OEL (28%) although most are exposed below 273 mg/m$^3$ (only 2% above this value)
- A large number of cancers are projected to occur if no action is taken (4,800 cases and 3,300 deaths over the next 60 years)

- An OEL of 50 mg/m$^3$ would result in about 580 avoided cancers
- There are large health costs (€) of inaction and smaller health benefits (€) from implementing an OEL of 50 mg/m$^3$ (no benefits with the higher limit assessed)
- There is a benefit to cost ratio of 0.64 for the 50 mg/m$^3$ OEL value, i.e. estimated compliance costs are more than the monetised health benefits.
- Introducing an OEL at 50 mg/m$^3$ would possibly have a negative financial effect on small and medium size companies.

### 8.2.8 Hydrazine

There is a limited case for introducing an OEL for hydrazine, primarily because exposure has been decreasing consistently over time and this trend is considered likely to continue. In summary:

- There are statistically significant relative risks estimates identified for lung and colorectal cancer
- It is an IARC category 2b carcinogen, although there have been further epidemiological studies carried out since the IARC evaluation (1999)
- A large number of workers in the EU are potentially exposed (2,100,000)
- Hydrazine is used as a chemical blowing agents, in agricultural pesticides, water treatment and other minor uses
- Some workers are judged to be exposed above the suggested OEL of 0.13 mg/m$^3$ (8%) and most workers are exposed above the proposed limit of 0.013 mg/m$^3$ (75%)
- If no action is taken 2,500 cancers and 710 cancer deaths are projected to occur over the next 60 years
- There are no important health benefits from introducing an OEL at either 0.013 or 0.13 mg/m$^3$, mainly because exposures are predicted to continue to decrease over the next 20 years and the additional impact of any limit is judged to be negligible.
- There are large health costs (€) of inaction and no health benefits (€) from implementing an OEL
- Depending on the choice of OEL, the cumulative compliance costs are likely to range between €15m and €200m over the next 60 years.

### 8.2.9 1-Chloro-2, 3-epoxypropane (epichlorohydrin)

There is a limited case for introducing an OEL for 1-Chloro-2,3-epoxypropane, primarily because exposure has been decreasing consistently over time and this trend is considered likely to continue. In summary:

- There are statistically significant relative risks estimates identified for CNS cancer but not for lung cancer
- It is an IARC category 2a carcinogen
- A relatively small number of workers in the EU are potentially exposed (44,000)
- 1-Chloro-2,3-epoxypropane is used in the manufacture of epoxy resins, in paper and board manufacture, in textiles and the manufacture of synthetic rubber products and other manufacturing

- No workers are judged to be exposed above the typical EU OEL value of 1.9 $mg/m^3$
- If no action is taken 2,600 cancers are projected to occur over the next 60 years (2,400 deaths), although there is some uncertainty about the prediction because we were unable to allow for any change in the level of exposure over time
- There are no important health benefits from introducing an OEL at 1.9 $mg/m^3$, mainly because exposures are predicted to already be below this limit
- There are large health costs (€) of inaction and no health benefits (€) from implementing an OEL
- There are no compliance costs for this OEL.

### 8.2.10 o-Toluidine

There is a limited case for introducing an OEL for o-toluidine, mainly because exposure is judged to be already mostly below the limit values assessed, and the predicted number of cancer cases attributed to exposure is relatively small. In summary:

- There are statistically significant relative risks estimates identified for bladder cancer
- It is an IARC category 1 carcinogen
- A relatively small number of workers in the EU are potentially exposed (5,500)
- o-toluidine is mainly used in the chemical industry as a feedstock
- Some workers are judged to be exposed above the suggested OEL of 0.4 $mg/m^3$ (2%), but none are exposed above the suggested OEL of 4.4 $mg/m^3$
- If no action is taken 490 cancers and 150 cancer deaths are projected to occur over the next 60 years
- There are no health benefits from introducing an OEL at the proposed levels because exposures are generally below the chosen values.
- There are relatively large health costs (€) of inaction and no health benefits (€) from implementing an OEL
- There are no compliance costs associated with the introduction of an OEL.

### 8.2.11 Mineral oils as used engine oil

There is a limited case for introducing some regulatory action to manage the risks from mineral oils as used engine oils, but it is probably inappropriate to introduce an inhalation OEL because the main route of exposure is by skin contact and the main risk is NMSC from PAHs.

- It was not possible to identify a statistically significant relative risks estimate for NMSC
- It is an IARC category 1 carcinogen
- A large number of workers in the EU are potentially exposed (1,000,000)
- Exposure to mineral oils as used engine oil occurs in motor vehicle maintenance and repair, and other similar situations
- It is estimated there may be 130,000 incident cases and 1,200 deaths from NMSC over the next 60 years attributable to exposure to used engine oil

- Improvements have been made in work practices to reduce skin exposure to used engine oil, but there is no information to judge how effective these measures have been
- There are large health costs (€) of inaction
- It was impracticable to assess the health benefits from introducing best practice for handling used engine oils
- Compliance costs were not assessed for this substance.

Because of the uncertainties it would be appropriate to obtain further information about the exposure to used engine oil and the effectiveness of exposure controls before deciding on any regulatory action.

#### 8.2.12 4, 4' methylenedianiline (MDA)

There is considerable uncertainty around the potential occupational cancer hazard from exposure to MDA. However, because there are so many people in the EU potentially exposed we consider there is a limited case for introducing some regulatory action.

- It was not possible to identify a statistically significant relative risks estimate for bladder cancer
- It is an IARC category 2b carcinogen
- A very large number of workers potentially exposed to MDA in the EU (between 390,000 and 3,900,000)
- Exposure to MDA may occur during the production of polyurethane foams and in a diverse range of industry sectors as a hardener in epoxy resins and adhesives
- Because of the uncertainties surrounding the cancer hazard we were unable to estimate the occupational cancer burden arising from MDA exposure
- Because of uncertainties about the level of exposure we were unable to estimate the proportion of people who may be exposed above the typical EU exposure limits we considered
- We could not assess the health costs (€) of inaction or the health benefits from introducing at OEL or other regulatory action
- There were very high estimated compliance costs associated with the introduction of an OEL.

Because of the uncertainties it would be appropriate to obtain further information about the exposure to MDA before deciding on any regulatory action.

#### 8.2.13 Other substances with little or no baseline health impact

There are several substances that have been evaluated where there is little evidence for any important health impact from current and relatively recent past exposures in the EU. The projected number of cancer cases that might be attributed to these occupational exposures was less than about 10 per year across the whole EU (2010 – 2069) for the following:

- Vinyl chloride monomer
- Beryllium and beryllium compounds
- Acrylamide

- Rubber process dust
- 4,4'-Methylene bis 2-chloroaniline (MbOCA)
- 1,3-butadiene
- Ethylene oxide
- Refractory ceramic fibres
- 1,2-epoxypropane
- Bromoethylene

The health benefit (€) from introducing OELs for these substances ranged from zero to at most €46m (over the next 60 years); the two highest figures were for rubber process dust and beryllium. Across all of these substances, introducing the most stringent limit in each case would result in 90 lives saved over the next 60 years. Compliance costs range from zero (Bromoethylene, 1,2-epoxypropane, acrylamide) to €34,000m for beryllium and beryllium compounds.

We do not consider there is a strong case for introducing limits for these substances.

### 8.2.14 Other substances where there is uncertainty about the occupational cancer hazard and risk

There are four substances for which there was considerable uncertainty about the cancer hazard associated with workplace exposure. These are:

- 1, 2-Dichloroethane
- 1, 2-Dibromoethane
- Hexachlorobenzene
- 2-nitropropane

In addition hexachlorobenzene is banned in the EU.

No health impact was carried out for these substances and in our opinion there is insufficient justification for introducing an OEL for any of them.

## 8.3 OTHER ISSUES ARISING FROM OUR ASSESSMENTS

As we have indicated there are several uncertainties that have affected our evaluations and for some substances such as with MDA, these have limited the assessment possible. The main problems have been the limited amount of data that are available about the prevalence and intensity of exposure in European industry and the risks arising from these exposures. Further information on some of the chemicals considered may become available through the REACH registration process, particularly in relation to prevalence and intensity of exposure. However, we consider that it would be prudent for the future to more proactively collect information about occupational carcinogens, which could be achieved by repeating the CAREX project. Priority should be given to collect better information about MDA and mineral oil as used engine oil.

For some substances we noted that there may be a disproportionate financial impact on SMEs, for example hardwood dust and respirable crystalline silica. In some countries there is assistance for SMEs in such circumstances. For example, consultation with the

French Caisse Nationale d'Assurance Maladie des Travailleurs Salariés (CNAMTS) provided some details of initiatives to encourage SMEs act on the prevention of risks.

# 9 A REVIEW OF THE REQUIREMENTS IN THE CARCINOGENS DIRECTIVE FOR PREVENTION AND REDUCTION OF EXPOSURE TO HAZARDOUS SUBSTANCES

This chapter summarises a review of the strengths and weaknesses of the requirements in Article 5 to minimise the exposure of workers and the role of occupational exposure limits (OEL) values. The work comprises two main strands, a review of the published scientific literature and engagement with knowledgeable stakeholders through a series of workshops and a questionnaire survey. The full report is available as IOM report P937/98.

An analysis of the factors that influence the reduction in exposure through workplace interventions, within the framework of the Theory of Planned Behaviour (TPB), suggests that the attitudes and beliefs of key managers in companies play a key role. Of particular importance are their beliefs and perceptions of the ease of implementing controls, the perceived social pressures to act to reduce exposures, and their beliefs about the consequences of their actions or inactions. Managers who believe it is straightforward to introduce new control measures, who believe that labour unions, regulators and competitors all favour better exposure controls and who have concern for the health of their workforce are more likely to repeatedly act to reduce exposure than those who do not hold such beliefs.

Other factors that influence decisions to change processes that may result in reduced exposures include improvements in process efficiency and hence the profitability of the process; for example, introducing more automation or new process equipment. It may be only incidental that such changes result in reduced exposure.

For most of the options specified in Article 5 there is no scientific information to determine how effective the approach is at reducing exposure levels, i.e. the magnitude of the reduction that might be expected. The main approaches for which there are scientific evaluations are: elimination or substitution, local ventilation and some other source controls, general ventilation and respiratory protection.

For substitution of hazardous chemicals there are a number of good descriptions of systematic methodologies that can be used to identify appropriate substitutions. There are also several sources of good guidance, much available on the internet, that is available to employers to enable safer chemicals to be identified. Several well publicised instances of successful elimination of hazardous substances have been published, for example the elimination of the bladder carcinogen 2-naphthylamine in the rubber industry. However, in some evaluations of specific substitution efforts there have been mixed results, e.g. the introduction of citrus based oils in place of trichloroethylene for cleaning clothes, which were later identified to contain skin allergens. The message from these types of study is that substitution is generally complex and often perceived as difficult to achieve, i.e. given a low priority by employers. Often there is a lack of reliable information about the hazards of alternative chemicals. It may be that industry, regional or national initiatives to promote substitution (or reduction in the use of hazardous substances), such as the ASA register in Finland or the Massachusetts Toxics Use Reduction Act, can provide a useful stimulus to increase substitution. Such initiatives can be seen as improving factors related to normative beliefs amongst employers. There are no mandatory Europe-wide initiatives to promote substitution or elimination but there are some industry initiatives that aim to do this, for example within the European rubber industry there is a focus on identifying and where possible removing carcinogens from the rubber mix.

Local ventilation can typically reduce average exposure levels by about 80% and general ventilation and enclosure by about 50%. However, there is a great deal of variation from one ventilation system to another and the 25th and 75th percentiles of the effectiveness of local ventilations systems range from about 20% up to 95% reduction; some poorly designed systems probably have no effect on exposures.

The effectiveness of respiratory protective equipment has also been studied fairly extensively in workplace situations. In these the typical effectiveness of half-mask respirators is about 95% and powered air purifying respirators (PAPRs) generally are about 99% effective, with the corresponding lower bound of the effectiveness being about 75% for half-masks and 85% for PAPRs.

It is often asserted that workers use respiratory protective equipment incorrectly and so control measures at source are to be preferred. However, there is little objective evidence that this is the case. Respiratory protection generally has a higher level of effectiveness in reducing exposure levels than does controls at source, although the discomfort of wearing respirators for long periods of time generally means that they are used for specific tasks where higher exposures are likely to be encountered.

Case-study analyses of three substances (trichloroethylene, vinyl chloride monomer (VCM) and hardwood dust) illustrate the complex nature of controlling exposure to carcinogens. No single best solution was available to ensure compliance with the OEL in these situations and several control options had to be introduced to enable a satisfactory solution. These different control measures were typically introduced over a period of months or years, even when there was intense regulatory pressure on industry such as in the case of VCM exposure in the 1970s.

In all three of the case-studies there was documentary information showing exposure levels decreasing over time. From the published literature there is good evidence that for the last 30-40 years the average exposure levels in most industries have been decreasing by between about 5% and 15% per annum, with the best estimate of average reduction in exposure being about 8% per annum. There is no evidence that any technological barrier to further exposure reductions has been reached and so it may be presumed that exposures will generally continue to decrease in the future.

There is no clear insight as to why exposure levels have been decreasing, although when employers are questioned about changes that they have introduced the often cite the introduction of new standards within the industry, health and safety or environmental regulatory initiatives, changes in production methods and economic pressures leading to outsourcing of components as key drivers of change.

To achieve the observed reductions in exposures employers probably need to be making regular control interventions that have modest effects on overall exposure, i.e. about once every year making an intervention to reduce overall average exposure by between about 10% to 50%. Given the necessity to have a more-or-less continuous programme of interventions that result in reduced exposure it seems plausible that the main reason for such changes is to improve the efficiency of the production process and the consequent reduction is exposure is perhaps an fortunate by-product.

The introduction of new regulations or a tighter OEL will probably provide extra impetus in reducing exposures but it is difficult to discern such effects in the types of longitudinal studies that are carried out and those investigations that have looked for effects of changes in OELs have not seen any positive benefits. This may be a limitation of the data rather than the absence of any effect. There is no evidence that employers stop efforts to reduce exposures once they are in compliance with an OEL.

The final part of the research involved the stakeholder consultations with a small group of knowledgeable stakeholders from industry, regulators, independent consultants and academia. The information derived from these studies cannot be considered definitive but they are probably a good indication of the range of opinions that might be encountered amongst those concerned with health and safety in relation to carcinogenic chemicals.

The overwhelming majority of participants in these exercises thought that the Carcinogens Directive was comprehensive and appropriate to control exposures, and that provisions in Article 5 are comprehensive and suitable. However, there were some criticisms of the clarity of the text in Article 5, for example in relation to the use of personal protective equipment, and what were considered to be small omissions, e.g. the necessity to maintain control measures to ensure continued effectiveness. Overall, the workshop participants thought the risk management measures were suitable, although the way that these are framed in the legislation could be improved to reflect the practical difficulties employers have in implementing a rigid framework of requirements. It was considered important that the text should help promote a good safety culture, mainly through strong requirements for training of workers.

There was strong agreement that elimination and substitution of carcinogenic substances along with manufacturing and use within closed systems should be the main priorities for risk reduction in most situations. However, some flexibility was considered necessary to account for situations where substitution is impracticable, e.g. for many process generated substances. Workshop participants highlighted that substitution is often complex and particularly difficult for small or medium size companies to undertake successfully. Some participants suggested that Regulators should take the lead in promoting substitutions, as for example already happens in some Member States for some key carcinogenic substances. Some suggested that more informal networking could achieve similar objectives, for example via manufacturers and suppliers. A number of delegates and respondents highlighted the likely impact of the REACH regulations in relation to elimination or substitution.

Occupational Exposure Limits were considered an very important part of the regulatory system for controlling the risks from carcinogens at work. There was discussion about the role of “best practice” in relation to OELs and the use of biological monitoring guidance values, which in the questionnaire was supported by about two-thirds of respondent for some or all substances covered by the Directive.

There was surprisingly little consensus about the relative importance of different control measures in achieving adequate control. One general theme that came through was the importance of information and training in helping to create a knowledgeable workforce. Some in the workshop sessions suggested formal certification schemes for workers handling carcinogenic chemicals while others stressed the importance of effective engagement between management and workers to help promote a positive attitude to control of exposures. However, as we have noted earlier there is little objective information to support the effectiveness of such approaches.

The review makes several constructive suggestions for improving the text of Article 5 of the Directive and highlights some of the other essential elements that should be in place to ensure effective control of carcinogens in European industry.

# 10 SETTING OELS FOR CARCINOGENS: A REVIEW

This chapter briefly summarises a review of methods used to set occupational exposure limits (OELs) in the EU. The full report is available as IOM report 937/Work Package 6.

## 10.1. OVERVIEW AND AIMS

This work package reviews the methods currently employed by regulatory and other authorities in the EU and elsewhere for the management of carcinogenic risks in the workplace, wider environment and in relation to food, drinking water and consumer products. The aims were to:

- Assess the value of using quantitative risk assessment in setting OELs versus an "ALARP"[5] approach;

- Identify the most appropriate methodologies for undertaking quantitative risk assessment; and

- Identify appropriate risk criteria for use with the recommended methodologies plus a commentary on what might be appropriate if other methodologies of risk quantification are adopted.

## 10.2. ADVANTAGES AND DISADVANTAGES OF USING QRA TO INFORM OELS

The major attractions of using QRA are that it would potentially enable consistent regulation of the cancer risks associated with different substances, provide reassurance that risks are controlled to a numerically defined low level and permit the calculation of the benefits associated with the imposition of OELs at different levels. The major problem with the use of QRA is that the uncertainties in the calculated risks may span several orders of magnitude. These uncertainties arise because of the limitations in the data available to inform QRA. There are relatively few substances for which sufficient human data are available to enable an informed risk estimate to be made and differences in the approach taken to risk estimation can give rise to order of magnitude differences in risk estimates even when these are based on relatively good data. There are little or no human data for most carcinogenic substances and the quality of animal data is highly variable.

One source of uncertainty is the difficulty in reliably detecting the presence or absence of an excess risk of cancer in workers or in an animal experiment where the expected incidence rate is low. Animal experiments normally employ high doses to increase the likelihood of detecting a cancer excess. There are a range of uncertainties associated with extrapolating from the findings of high dose animal experiments to human risk assessment at very much lower levels of exposure. The data from animal experiments may involve tumours at a variety of sites with different apparent exposure-response relationships for each site, both in terms of dose and in terms of the type of function that gives the best fit curve. In addition, the tumour response may be very different in different species or even different strains of the same species and the relative

*[5] Reducing exposure to levels that are "as low as reasonably practicable"*

susceptibility of humans is highly uncertain. Many cancers appear to be species specific or even strain specific and unless mechanistic data are available, the relevance to humans is uncertain. Most animal experiments employ very few dose levels and there are usually insufficient data points to characterise the shape of the exposure-response function. It may be possible to fit a variety of different shaped curves to the available data, giving rise to very different estimated levels of risk at doses outside of the observed data range. There is no certainty that the curve giving the best statistical fit within the observed data range is the most appropriate for risk estimation at much lower dose levels which may be associated with very different disease or cellular defence mechanisms. There are also often considerable uncertainties in the dose information available to QRA. Traditionally, epidemiological studies in humans focussed on establishing whether or not an excess of cancer was associated with a particular agent or industry and the information underlying exposure estimates in epidemiological studies is often fairly sparse and there are considerable uncertainties in the exposure estimates used to inform QRA. There are also uncertainties in scaling from animal dose data to equivalent human doses. Different authorities take different approaches resulting in order of magnitude differences between risk estimates based on a common data set.

## 10.3. APPROPRIATE METHODOLOGIES

A range of approaches to QRA are available together with alternative approaches to risk management. The different mechanisms by which different substances may cause cancer and very different data availability for different substances mean that different approaches to QRA may be appropriate under different circumstances. There are also circumstances where QRA is unlikely to be appropriate. In order develop authoritative guidance on when to use which approach, it is necessary to gain a consensus view among relevant experts and we recommend that is achieved through a workshop hosted by SCOEL. A provisional framework is outlined in the Table below. In terms of risk communication, it might be preferable to express risks in terms of a margin of exposure relative to the estimated dose associated with a 10% cancer response ($BMDL_{10}$). In terms of lifetime cancer risks of $10^{-3}$, $10^{-5}$, $10^{-6}$ and $10^{-7}$, this would equate to margins of exposure of 100, 10000, 100000 and 1000000.

**Table 10.1** Summary of Steps towards developing an OEL

| ***Data availability*** | ***Steps towards determining an OEL*** |
|---|---|
| Good human epidemiological data; good understanding of mechanisms underlying carcinogensis | Review mechanistic information to establish whether threshold is likely to exist; use mechanistic information to establish threshold level of exposure in humans if possible or to inform QRA based on human epidemiological data. If no threshold apparent, use QRA to establish exposure levels associated with $10^{-3}$, $10^{-5}$, $10^{-6}$ and $10^{-7}$ lifetime cancer risks, establish health benefits in terms of cancers avoided across EU at each exposure level. If threshold identified, use as basis of OEL taking account of uncertainty in data. |
| Good human epidemiological data; poor understanding of mechanisms underlying carcinogensis | Use epidemiological data to establish exposure response relationships, examine evidence for a threshold, undertake QRA to establish exposure levels associated with $10^{-3}$, $10^{-5}$, $10^{-6}$ and $10^{-7}$ lifetime cancer risks, establish health benefits in terms of cancers avoided across EU at each level. If threshold identified, use as basis of OEL taking account of data uncertainties. If no threshold, review QRA taking account of uncertainties. If data inadequate to reliably establish exposure levels associated with $10^{-3}$, $10^{-5}$, $10^{-6}$ and $10^{-7}$ lifetime cancer risks, use comparison of cancer incidence under different exposure regimes (eg low to high exposure groups) to estimate number of cancers avoided by imposing different OELs. |
| Limited human data, good quality animal data, good understanding of mechanisms | Examine mechanistic data to confirm carcinogenic process relevant to humans and determine whether there is a threshold for effect. If threshold exists, establish equivalent human exposure level and use as basis of OEL. In no threshold, undertake QRA to establish exposure levels associated with $10^{-3}$, $10^{-5}$, $10^{-6}$ and $10^{-7}$ lifetime cancer risks, establish health benefits in terms of cancers avoided across EU at each exposure level. Review results of QRA taking account of uncertainties and assess plausibility against findings of workplace studies. |
| Very limited or no human data, good quality animal data | Consider potential mechanisms underlying carcinogenic process and likely relevance to humans and whether a threshold is likely. In absence of a threshold, undertake QRA to establish exposure levels associated with $10^{-3}$, $10^{-5}$, $10^{-6}$ and $10^{-7}$ lifetime cancer risk, establish health benefits in terms of cancers avoided across EU at each level. Review QRA results taking account of uncertainties and assess plausibility against findings of workplace studies. If no and/or lowest effects levels identified and a threshold seems likely, use as basis for OEL with appropriate scaling factors to account for uncertainties. |
| **Very limited or no human data, poor quality animal data** | QRA will give rise to highly uncertain results and should not be used as main rationale underlying an OEL. Given that it is desirable to set an OEL avoid excessive exposures, it may be appropriate to determine a generic low level of exposure that is applied as an OEL for suspected carcinogens where the data are inadequate to assess relative potency compared with other carcinogens. If there are data that allow estimation of potency relative to other carcinogens, OEL could be derived by comparison with OELs for other similar substances. If work-related cancers, OELs should be set that will reduce exposure levels. |

## 10.4. RISK TOLERABILITY

There is no societal agreement on the level of calculated cancer risk that is considered acceptable or as to whether or how judgement of risk acceptability might take account of uncertainties in the database. Risk tolerability varies widely in different situations. Higher levels of risk are likely to be tolerated in the workplace than for wider population exposure.

OELs have generally been set at levels that are believed to be achievable and there are substantial variations in the effectiveness of exposure control and levels of exposure to carcinogens in different industry sectors.

Guidance produced by ECHA for the derivation of DMELs suggests that a lifetime cancer risk of $10^{-5}$ should be regarded as tolerable for workplace exposure to chemicals and we have asked by the Commission to consider $10^{-5}$, $10^{-6}$ and $10^{-7}$ as the potential criteria for acceptable risk. These are considerably lower levels of risk than currently regarded as tolerable for workplace exposures in some member states ($10^{-3}$ to $10^{-4}$). The benefits of setting OELs that based on $10^{-6}$ or $10^{-7}$ cancer risks over an OEL based on a $10^{-5}$ cancer risk are dubious. It is unlikely that sufficient workers would be exposed to a substance across Europe for this reduction in risk to lead to any avoided cases. Socio-economic considerations may play a role in the determination of risk tolerability for individual carcinogens.

## 10.5. RECOMMENDATIONS

We recommend that a flexible approach to setting OELs for carcinogens within the EU is retained, but that is approach is underpinned by suitable guidance developed as a consensus view of experts at a SCOEL-hosted workshop. We also recommend that the following issues are taken into account in the proposed guidance:

1 The extent to which the results of QRA are taken into account in setting OELs should reflect the certainty of the data.

2 The extent to which animal data are taken into account should reflect study quality and the whether it is likely that the toxicological mechanisms leading to cancer and reported tumours could reasonably be expected to be relevant to humans.

3 Health impact assessment should be used as a tool to inform the setting of OELs. Where possible the number of cases avoided within the EU as a result of imposing OELs at different levels should be estimated together with an indication of the timescale over which these benefits would accrue, taking account of foreseeable changes in patterns of use.

4 There is a need to determine a minimum dataset that satisfies a number of criteria including relevance to human exposure, data quality, dosing regime and cancer response for QRA to be used for genotoxic carcinogens.

5 There is also a need develop a clear set of options that can be employed where it is not appropriate to use QRA. To a great extent, some of these possible approaches are addressed in current SCOEL procedures. Other options might include

consideration of analogous substances, for example, for RCF a worst-case cancer risk estimate could be based on risk estimates for chrysotile.

# 11 CONCLUSIONS

The results seem to indicate that the strongest cases for introducing an OEL are for: respirable crystalline silica, hexavalent chrome and hardwood dust. Other substances where the evidence may support the introduction of a limit include: diesel engine exhaust emissions, rubber fume, benzo[a]pyrene, trichloroethylene, hydrazine, epichlorohydrin, o-toluidine, mineral oils and used engine oil and MDA. Respirable crystalline silica is the only case where the benefit to cost ratio is greater than one.

The report also provides a brief summary of two substantive reviews: one related to the procedures for setting OELs using quantitative risk criteria and the second that evaluates the strengths and weaknesses of the aspects of the Carcinogens Directive that relate to the elimination or control of risks form carcinogens at work. Both reports provide suggestions for consideration by the Commission.

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