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

## 1,2-Epoxypropane

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## SUMMARY

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 lymphopietic and haematopietic 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 not 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.

# 1 PROBLEM DEFINITION

## 1.1 OUTLINE OF THE INVESTIGATION

Exposure to 1,2-epoxypropane (propylene oxide) in workplace air may be associated with increased risk leukaemia, based on the available epidemiological evidence and by analogy with ethylene oxide. 1,2-epoxypropane has been classified as a group 2b carcinogen (possibly carcinogenic to humans) by IARC based on the results of epidemiological and toxicological studies.<sup>1</sup> It is classified as a Cat 2 carcinogen in the EU under the classification and labelling legislation.<sup>2</sup> It is therefore already regulated as a carcinogen throughout the EU. In this assessment we consider the impacts of introducing an OEL for 1,2-epoxypropane within the Directive.

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

## 1.2 OELS/EXPOSURE CONTROL

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

**Table 1.1** Occupational exposure limits in various EU member states and selected countries outside the EU

Country	OEL - long term (ppm)	OEL - STEL (ppm)
Austria	2.5	10
Belgium	2	-
Denmark	5	10
France	100	-
Hungary	-	2
Spain	5	-
Netherlands	2.5	-
United Kingdom	5	-
Canada - Quebec	20	-
Switzerland	2.5	-
USA - OSHA	100	-

Source: [http://www.dguv.de/bgia/en/gestis/limit\\_values/index.jsp](http://www.dguv.de/bgia/en/gestis/limit_values/index.jsp)

The long-term OEL from the EU member states and outside jurisdictions range from 2.5 to 100 ppm. Austria, Denmark and Hungary have STELs ranging from 2 to 10 ppm. For the purposes of this report OELs of 2 and 5 ppm are considered typical for the EU.

<sup>1</sup> Available at: <http://monographs.iarc.fr/ENG/Classification/ClassificationsAlphaOrder.pdf>

<sup>2</sup> Available at: <http://ecb.jrc.ec.europa.eu/esis/>

We note that SCOEL have considered 1,2-epoxypropane and make a recommendation of a long-term limit of 1 ppm with an associated biological limit value (BLV) of 3 nmol N-(3-hydroxypropyl) valine/ g globin in blood haemoglobin.<sup>3</sup>

### 1.3 DESCRIPTION OF DIFFERENT USES

1,2-Epoxypropane (also known as propylene oxide or PO) is produced in the EU using two different production methods. Production is thought to be split approximately equally between the two processes.<sup>4</sup> One of the processes is known as the chlorhydrin process. It involves the reaction of propylene with hypochlorous acid to produce propylene chlorohydrin which is then epoxidised by dehydrochlorinating at 105°C with excess Ca(OH)<sub>2</sub> or NaOH. The product of the dehydrochlorination is then distilled to leave raw 1,2-epoxypropane. The other process is known as indirect oxidation and involves the oxidation of propylene. Propylene is oxidised with either t-butyl hydroperoxide (which has been created by the oxidation of isobutene with air or pure oxygen) or with ethylbenzene hydroperoxide (which has been created by the oxidation of ethylbenzene). The production capacity for 1,2-epoxypropane within the EU is 2.75 million tonnes per year. In 2009 actual production was 2.02 million tonnes.<sup>5</sup> Production of 1,2-epoxypropane in the EU takes place in the following member states:

- Belgium (1 facility)
- France (1 facility)
- Germany (3 facilities)
- Netherlands (4 facilities)
- Poland (1 facility)
- Slovakia (1 facility)
- Spain (2 facilities)
- Romania (1 facility)

In addition to the 1,2-epoxypropane produced in the EU 10,000 to 50,000 tonnes are imported per year.<sup>6</sup> Combining the maximum production volume with the maximum import volume, the maximum amount of 1,2-epoxypropane used in the EU on an annual basis is 2.8 million tonnes. The actual figure is likely to be less than this as it is based on production capacity and excludes any extra-EU exports.

The major use of 1,2-epoxypropane in the EU is to make 1,2-epoxypropane polymers called polyether polyols that are used in the manufacture of polyurethane foams. 1,2-epoxypropane is polymerised with a base catalyst (KOH) in a polyhydric alcohol. Beratergremium für Umweltrelevante Altstoffe (BUA) estimated that in 1982 72% of all 1,2-epoxypropane used in the EU is used in the production of polyether polyols. The 2002 European Risk Assessment Report (RAR) on 1,2-epoxypropane assumed that 1982 usage proportions of 1,2-epoxypropane were representative of 2002 use as there was no evidence to suggest otherwise.

<sup>3</sup> Recommendation from the Scientific Committee on Occupational Exposure Limits for propylene oxide. SCOEL/SUM/161. August 2010.

<sup>4</sup> European Union Risk Assessment Report: Methyloxirane (Propylene Oxide). Volume 23. 2002

<sup>5</sup> Communication with CEFIC

<sup>6</sup> European Union Risk Assessment Report: Methyloxirane (Propylene Oxide). Volume 23. 2002

BUA estimated that 23% of all 1,2-epoxypropane used in the EU in 1982 was used in the production of propylene glycol, which is made by high pressure and temperature hydrolysis of 1,2-epoxypropane.

The remaining five percent of 1,2-epoxypropane is used in other applications including as a raw material for the manufacture of surfactants, flame retardants, propoxylated polymers, propylene carbonate, allyl alcohol and modified starch; as a stabiliser for dichloromethane, other chlorinated hydrocarbons, fuels and heating oils; as an anti-corrosion additive for liquid coolants; as a solvent for nitrocellulose, cellulose acetate, and adhesives; and in the preparation of tissue samples for electron microscope analysis. Only very small volumes are used in the preparation of samples for electron microscopy and exposures are expected to be low and intermittent. Only exposures within the chemical industry will be considered in this report.

1,2-epoxypropane has also been used as a fumigant for dried fruits, cocoa, spices, processed nutmeats, starch and gums and as a food additive however these uses do not occur in the EU.<sup>7</sup>

## 1.4 RISKS TO HUMAN HEALTH

### 1.4.1 Introduction

In animal studies the site of cancer associated with 1,2-epoxypropane is the nasal epithelium. The epidemiological evidence for a specific site of an increased cancer risk is equivocal, but we have chosen to focus on leukaemia because the available human data suggests the risk may be within lymphopoietic and haematopoietic cancer, and by analogy with ethylene oxide where there is clearer evidence for a leukaemia risk.<sup>8</sup>

Ferlay *et al* (2007) note that in Europe, 2.2% of all cancers are leukaemia's (10<sup>th</sup> commonest cancer). There is a similar incidence of these cancers in men and women.

Around 40% of people with leukaemia survive for at least five years after they are diagnosed, although the survival rate differs by leukaemia type. Survival rates for leukaemia have steadily increased over the last thirty years (Verdecchia *et al*, 2007), although there is considerable variation in prognosis depending on the type of cancer and the stage of development.

Leukaemia may be caused by ionising radiation, although this probably only accounts for a small proportion of cases. Other agents that are accepted risk factors are occupational exposure to ethylene oxide, benzene, work in boot and shoe manufacture and some drugs used in cancer chemotherapy. It is also thought that leukaemia may be

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<sup>7</sup> European Union Risk Assessment Report: Methyloxirane (Propylene Oxide). Volume 23. 2002

<sup>8</sup> The similarities between the toxicity of 1,2-epoxypropane (PO) and ethylene oxide are discussed in the SCOEL report. PO is the methyl homologue of ethylene oxide. Like ethylene oxide, it has alkylating properties. This leads to hydroxypropylation of biological macromolecules. Compared to ethylene oxide, the alkylating power of PO is about 4 times lower. The metabolism of both, ethylene oxide and PO, is qualitatively similar, via glutathione transferase and epoxide hydrolase, but differs quantitatively. At similar conditions of human industrial exposure, the levels of haemoglobin alkylation produced by PO are about 10 times lower compared to ethylene oxide exposure.



induced by some viruses, e.g. Epstein-Barr virus and Hepatitis B virus. People who smoke cigarettes are also at increased risk. Siemiatycki *et al* (2004) that there is suggestive evidence that occupational exposure to formaldehyde and nonarsenical insecticides, along with work in petroleum refining and the rubber industry may also cause leukaemia.

#### 1.4.2 Summary of the available epidemiological literature on risk

Several of the cohort studies that initiated concern about the effects of ethylene oxide also included some workers who were also exposed to 1,2-epoxypropane (Hogstedt *et al*, 1979, 1986; Hogstedt, 1988, Thiess 1981). No conclusion could be drawn about the risk for cancer in relation to exposure to 1,2-epoxypropane specifically. In the IARC monograph evaluating 1,2-epoxypropane one other study, a case-control study is identified (IARC 1994). This is a study by Ott *et al* (1989) that derived risk estimates for exposure to 1,2-epoxypropane and 20 other chemicals in a nested case-control study carried out at two large chemical manufacturing facilities and a research and development centre in the USA. The cases (52 of non-Hodgkin's lymphoma, 20 of multiple myeloma, 39 of non-lymphatic leukaemia and 18 of lymphatic leukaemia) were identified from underlying and contributory causes of death for male members of the cohort who died during 1940-78. Controls were selected from the total cohort in a ratio of 5:1 and were matched to cases by sex, decade of first employment and survival to the start of the same five-year period. Exposures were inferred from recorded job histories up to the beginning of the survival period of the case. Odds ratios for men ever versus never exposed to 1,2-epoxypropane (and the numbers of exposed cases) were: non-Hodgkin's lymphoma, 1.5 (four); multiple myeloma, 3.4 (three); non-lymphatic leukaemia, 1.3 (three); lymphatic leukaemia, 0 (zero). None of these associations was significant. The associations between non-Hodgkin's lymphoma and exposure to 1,2-epoxypropane were similar for men with less than five (OR 1.7) and at least five years' exposure (OR 1.3). No information is given in the paper on levels of exposure to 1,2-epoxypropane or on possible confounding effects of other exposures.

Since then only one epidemiological study has been conducted, that of a mortality study of workers formerly employed in an ethylene chlorohydrin and propylene chlorohydrin process plant (Olsen *et al*, 1997). The objective was to compare the SMRs at this plant with previous excess mortality from pancreatic cancer and lymphopoietic and haematopoietic cancer found among workers in another chlorohydrin unit. All male workers (N=1,361) who had worked in the ethylene or propylene production area for a month and worked at either manufacturing site for a year were included in the study. These workers were identified using work histories. Vital status was determined from 1940 to 1992. SMR was non-significantly elevated overall for lymphopoietic and haematopoietic cancers (SMR=129; 95%CI 62-238, observed 10 cases, expected 7.7), and not elevated for malignant neoplasms (SMR=94) and pancreatic cancer (SMR=25). With a latency of 25 years the SMR increased to 144 (95%CI 52-312) for lymphopoietic and haematopoietic cancers. Comparing the SMRs across plants gave similar results except for lymphopoietic and haematopoietic cancer deaths at one plant SMR=181 (95%CI 66-393, observed 6 cases and expected 3.3). Comparing SMRs across process gave similar non-significant results; however, including a latency of 25 years gave a SMR= 194 (95%CI 71-423, 6 observed, 3.1 expected,) for lymphopoietic and haematopoietic cancer among those employees with exposure only to the ethylene chlorohydrin process. There was no trend by duration of employment although there was a significant risk

ratio for 10-20 years of employment (RR 3.56, 95% CI 1.23-10.29) for lymphopietic and haematopietic cancer based on three observed deaths. No adjustment was made for cigarette smoking.

Ethylene oxide and 1,2-epoxypropane have similar reaction kinetics, although the mutagenic and genotoxic potential of 1,2-epoxypropane is much lower (WBK, 2002). The epidemiological data appear to confirm this.

### 1.4.3 Choice of risk estimates to assess health impact

Exposure to 1,2-epoxypropane occurs during chemical manufacture. In the few published epidemiological studies all haematopietic are shown to have raised risks. The mechanistic toxicology data suggests an analogy between the potential risks for ethylene oxide and 1,2-epoxypropane, and for ethylene oxide the main affect is leukaemia. For this reason we have restricted our risk estimation to leukaemia only. We recognise that there is considerable uncertainty in the health impact assessment because of the limited epidemiological information.

The epidemiological literature is restricted to studies of US workers. In all the available studies there are potential co-exposures to other chemicals, particularly ethylene oxide, and only small numbers of cases. There is also no information on risk by different levels of exposure. We have identified a single risk estimate for leukaemia from the study by Ott *et al* (1989), RR=1.3.

## 2 BASELINE SCENARIOS

### 2.1 STRUCTURE OF THE SECTOR

1,2-epoxypropane was first prepared in 1860, but commercial production did not begin until the early 1900s (IARC, 1994). World capacity for 1,2-epoxypropane production was estimated as 3,585,000 tonnes for 1990.<sup>9</sup>

See Section 1.3 for details of the 1,2-epoxypropane sector in Europe.

### 2.2 PREVALENCE OF 1,2 EPOXYPROPANE EXPOSURE IN THE EU

The prevalence of exposure to 1,2-epoxypropane has not been estimated by CAREX. There are several manufacturing facilities in the EU and an estimated 150 to 300 user facilities. The EU RAR has estimated that 35 to 70 workers across the EU are exposed to 1,2-epoxypropane during its manufacture, and 450 to 1,500 workers were exposed during its use as a chemical intermediate giving an estimated total exposure prevalence of 485 to 1,570 workers in the chemical industry. The distribution of these workers across EU member states was not estimated however prevalence is likely to be highest in the member states where 1,2-epoxypropane is manufactured: Belgium, France, Germany, the Netherlands, Poland, Slovakia, Spain and Romania. Many

<sup>9</sup> BUA (1992). GDCh - Advisory Committee on Existing Substances of Environmental Relevance (BUA). Propylene oxide. BUA Report 94 (June 1992), English version 1994. S Hirzel Verlag, Stuttgart.

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manufacturing facilities also use 1,2-epoxypropane as a chemical intermediate to make polyether polyols and/or propylene glycol.<sup>10</sup>

## 2.3 LEVEL OF EXPOSURE TO 1,2 EPOXYPROPANE

### 2.3.1 Estimation of exposure levels

#### *Inhalation*

The chemical manufacturing industry aims to keep exposure levels to 1,2-epoxypropane as low as reasonably achievable and during both manufacturing and use of 1,2-epoxypropane the substance is contained within closed systems. Exposures are therefore short term and intermittent. Exposures can occur during material sampling, filling of shipment tankers (during uncoupling of delivery line), planned routine breaches of the closed system (for example, to replace a catalyst), maintenance, and fugitive emissions. Respiratory protection is typically used as a precautionary measure during these activities. Exposures are therefore expected to be low in both manufacturing and in downstream use. The CEFIC Propylene Oxide and Propylene Glycols Sector Group submitted occupational exposure data for use in the development of the EU RAR. This included 458 eight-hour time-weighted average (TWA) personal air monitoring results taken during manufacturing and downstream use between 1991 and 1996. Three hundred and fifty of the samples came from seven manufacturing facilities, four of which were also involved in the use of 1,2-epoxypropane as a chemical intermediate – these four facilities submitted 108 samples of exposure during downstream use.

The exposure concentrations measured at the manufacturing facilities ranged from <0.01 ppm to 30 ppm. All measurements over 3.01 ppm were taken at one facility in 1991. Measurements taken between 1993 and 1996 at manufacturing facilities all ranged from <0.01 to 3.01 (Table 2.1). These later measurements are probably most representative of current exposure levels. The overall geometric mean (GM) and geometric standard deviation (GSDs) from all measurements were not provided therefore the distribution of the data is unknown and it is difficult to estimate the proportion of workers who would be exposed over these levels. A weighted average of all arithmetic means from all jobs and plants (with the exception of plant 7) was taken with medians substituted where means were not reported. For medians below the detection limit one half the detection limit was substituted. The estimated weighted average of all measurements taken during manufacturing from 1993 to 1996 was 0.14 ppm. Occupational exposure data are usually log-normally distributed and geometric standard deviations are typically around three. A log-normal distribution and a geometric standard deviation were assumed and exposure distributions were simulated with Monte Carlo simulation in @Risk using different geometric means. Ten thousand data points were generated per simulation. A distribution with a GM of 0.08 ppm and a GSD of 3 was found to have an arithmetic mean of 0.15 ppm. This is similar to the weighted average of 0.14 ppm therefore 0.08 ppm is a reasonable estimate of the GM. With a GM of 0.08 ppm and a GSD of 3 an estimated 0.17% of manufacturing workers would be expected to be exposed to TWAs above 2 ppm and only 0.01% of workers

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<sup>10</sup> European Union Risk Assessment Report: Methyloxirane (Propylene Oxide). Volume 23. 2002

would be exposed above 5 ppm. If exposure control has improved since 1996 it is possible that no workers are currently exposed above 2 ppm.

The exposure data measured during use of 1,2-epoxypropane as a chemical intermediate is presented in Table 2.2. The results range from 0 to 1 ppm suggesting that average exposures during downstream use are lower than during manufacturing.

The majority of workers exposed to 1,2-epoxypropane in the EU are exposed during downstream use so the data suggest that less than 0.2% of 1,2-epoxypropane exposed workers are exposed to TWA concentrations above 2 ppm and no workers are exposed above 5 ppm. A recent study on the use of biomarkers to assess 1,2-epoxypropane exposures supports this conclusion. Jones *et al* (2005) developed a competitive immunoassay to determine *N*-2-hydroxypropyl valine adducts in haemoglobin. Boogaard *et al* (1999) had previously found a strong correlation between *N*-2-hydroxypropyl valine adduct concentrations and 1,2-epoxypropane concentrations in air. Jones *et al* (2005) collected over 800 blood samples from plant operators, maintenance fitters and office staff at three 1,2-epoxypropane manufacturing sites in France and the Netherlands. The blood samples were analysed for *N*-2-hydroxypropyl valine adducts. Based on the correlation between adduct and air concentration seen by Boogaard *et al* (1999), Jones *et al* (2005) estimated that none of the monitored workers were exposed to TWA 1,2-epoxypropane concentrations above 0.1 ppm.

Exposure to 1,2-epoxypropane in all other applications is expected to be negligible.

**Table 2.1** Occupational Exposure to 1,2 Epoxypropane during manufacture

Plant	Year of Sampling	Job	Number of Samples	Range (ppm)	Arithmetic mean (ppm)	Median (ppm)
1	1996	plant operator	21	0.01-2.75	0.27	NR <sup>[1]</sup>
		maintenance	12	0.02-3.01	0.76	NR
		laboratory technician	8	0.02-2.46	0.54	NR
2	1996 - 1996	plant operator	72	<0.01 - 2.1	0.07	NR
		mini plant	5	<0.01 - 0.17	0.05	NR
		laboratory technician	8	0.01 - 0.45	0.23	NR
3	1993 - 1996	plant operator	25	<0.01 - 2.1	NR	0.13
4	1993 - 1995	plant operator	21	<0.12 - 1.2	NR	<0.1
		maintenance	21	<0.12 - 0.75	NR	<0.1
		tanker/drum filling	41	<0.12 - 0.87	NR	<0.1
		laboratory technicians	17	<0.12 - 1.1	NR	<0.1
5	1995	plant operator	4	<0.1 - 0.33	0.16	NR
6	1995	plant operator	15 <sup>[2]</sup>	0.1 - 0.16	0.23	NR
7	1991	shift officer	4	0 - 0.7 <sup>[3]</sup>	0.19	NR
		dashboard man	4	0 - 1.3	0.34	NR
		plant operator	30	0 - 6.7	1.08	NR
		laboratory technician	16	0 - 10.9	1.35	NR
		foreman	9	0 - 30	3.51	NR
		tank operator	8	0 - 1.3	0.44	NR
		waste operator	9	0 - 1.9	0.4	NR

Source: EU RAR: Methyloxirane (Propylene Oxide)

<sup>[1]</sup> NR = not reported

<sup>[2]</sup> Results include some static air sampling measurements

<sup>[3]</sup> No detection limit reported

**Table 2.2** Occupational Exposure to 1,2 Epoxypropane during use as a chemical intermediate

Plant	Year of Sampling	Job	Number of Samples	Range (ppm)	Arithmetic mean (ppm)	Median (ppm)
1 (off-site use)	NR <sup>a</sup>	unloading railcars	17	0.002 - 0.94	0.62	NR <sup>[1]</sup>
3 (on-site use)	1993 - 1996	plant operator	48	<0.01 - 1	NR	0.065
		laboratory technicians	8	<0.01 - 0.45	NR	NR
		pilot plant	5	<0.01 - 0.17	NR	NR
4 (on-site use)	1993 - 1995	plant operator	13	all <0.12	NR	NR
		maintenance	6	all <0.12	NR	NR
		laboratory technicians	9	all <0.12	NR	NR
5 (on-site use)	1996	plant operators	3	all <0.1	NR	NR

<sup>[1]</sup> NR = not reported

### *Dermal*

1,2-epoxypropane is absorbed through the skin but dermal exposure levels are expected to be very low. As the substance remains enclosed during manufacturing and use dermal exposure to condensed vapour is unlikely and exposure via splashes or spilling would only be possible during material sampling and pipe uncoupling. The EU RAR reports dermal exposure predictions from the EASE (Estimation and Assessment of Substance Exposure) model. The model predicts maximum dermal exposure levels of 0.1 mg/cm<sup>2</sup>/day. On most days exposures would be closer to zero.

### **2.3.2 Temporal change in exposure**

The available data suggest that exposure reductions took place during the late 1980's and early 1990's. For example, exposure measurements at Plant 7 (Table 2.1) were taken in 1991 and were higher than measurements taken between 1993 and 1996 at other plants. Although subsequent measurements were not reported at Plant 7 to demonstrate that exposure reductions took place at that plant, it is likely that the exposure concentrations measured there in 1991 are indicative of older 1,2-epoxypropane control regimes and since 1991 exposures at Plant 7 have likely been reduced at that plant as the industry objective is to maintain exposures as low as reasonably achievable.

## **2.4 HEALTH IMPACT FROM CURRENT EXPOSURES**

### **2.4.1 Background data**

The occupational cancers associated with 1,2 epoxypropane exposures are shown in Table 2.3 along with a summary of the information used in the health impact assessment.

**Table 2.3** Occupational cancers associated with exposure to 1,2 Epoxypropane

Cancer site	Leukaemia	
ICD-10 code	C91-C95	
IARC group for carcinogen	2B	
Strength of evidence for cancer site <sup>(1)</sup>	Inadequate human data, sufficient animal data	
Latency assumption	0-20 yrs	
Source of forecast numbers - deaths	Eurostat, 2006 (for C81-C96), adjusted to C91-C95 using E&W proportions	
Source of forecast numbers - registrations	GLOBOCAN, 2002 <sup>11</sup>	
Exposure levels	<b>Relative Risk (RR)</b>	<b>Source of RR</b>
Manufacturing	1.3	Ott <i>et al</i> (1989)
Downstream use	1.3	Ott <i>et al</i> (1989)

<sup>(1)</sup> Based on Siemiatycki *et al*, 2004

#### 2.4.2 Exposed numbers and exposure levels

Industry sectors, their NACE codes, classifications of exposure as applicable for the mid 1990's and numbers exposed in 2006 are given in the previous section on the exposure. No change in exposure levels during the risk exposure period is assumed. Therefore forecasts of attributable numbers are based on the baseline assumption of no change to current exposure levels or exposed numbers.

#### 2.4.3 Forecast cancer numbers

Separate estimates for total numbers of deaths for haematopoietic cancer by age band are available from EUROSTAT for the 27 countries of the EU, for 2006 and for registrations for leukaemia from GLOBOCAN for 2002. Deaths are adjusted to an estimate for leukaemia using proportions from data for England and Wales. The forecast numbers of deaths and registrations by country used to estimate attributable numbers are in Appendix 8.1.

#### 2.4.4 Results

The cancer deaths and registrations attributed to occupational exposure to 1,2-epoxypropane for the baseline scenario are presented per year for the target years given and are based on the all working age cohort of currently (2006) exposed workers. Attributable fractions and numbers of deaths and registrations, and Years of Life Lost (YLLs), Years Lived with Disability (YLDs) and Disability-Adjusted Life Years (DALYs), are estimated.

As the exposure data suggests that there is no change in exposure over time, a static baseline scenario has been used.

A summary of the results for leukaemia for the total EU is shown in Table 2.4 below.

<sup>11</sup> IARC, GLOBOCAN database, available at: <http://www-dep.iarc.fr/globocan/database.htm>

**Table 2.4** Results for the baseline forecast scenario, total EU (27 countries), men plus women<sup>12</sup>

Scenario	All scenarios		Baseline scenario (1) - Current (2005) employment and exposure levels are maintained			
	2010	2020	2030	2040	2050	2060
<b>EU Total</b>						
<i>Numbers ever exposed</i>	2,628	2,649	2,649	2,649	2,649	2,649
<i>Proportion of the population exposed</i>	0.001%	0.001%	0.001%	0.001%	0.001%	0.001%
<b>Leukaemia</b>						
<i>Attributable Fraction</i>	0.0002%	0.0002%	0.0002%	0.0003%	0.0003%	0.0003%
<i>Attributable deaths</i>	0	0	0	0	0	0
<i>Attributable registrations</i>	0	0	0	0	0	0
<i>'Avoided' cancers</i>						
<i>YLLs</i>	1	1	2	2	2	2
<i>DALYs</i>	1	2	2	2	2	2

There are no predicted attributable deaths or registrations from exposure to 1,2-epoxypropane over the entire 50-year time span (2010 to 2060). The estimated number of DALYs increases from 1 year in 2010 to 2 years in 2060 and the estimated attributable fraction increases from 0.0002% in 2010 to 0.0003% in 2060.

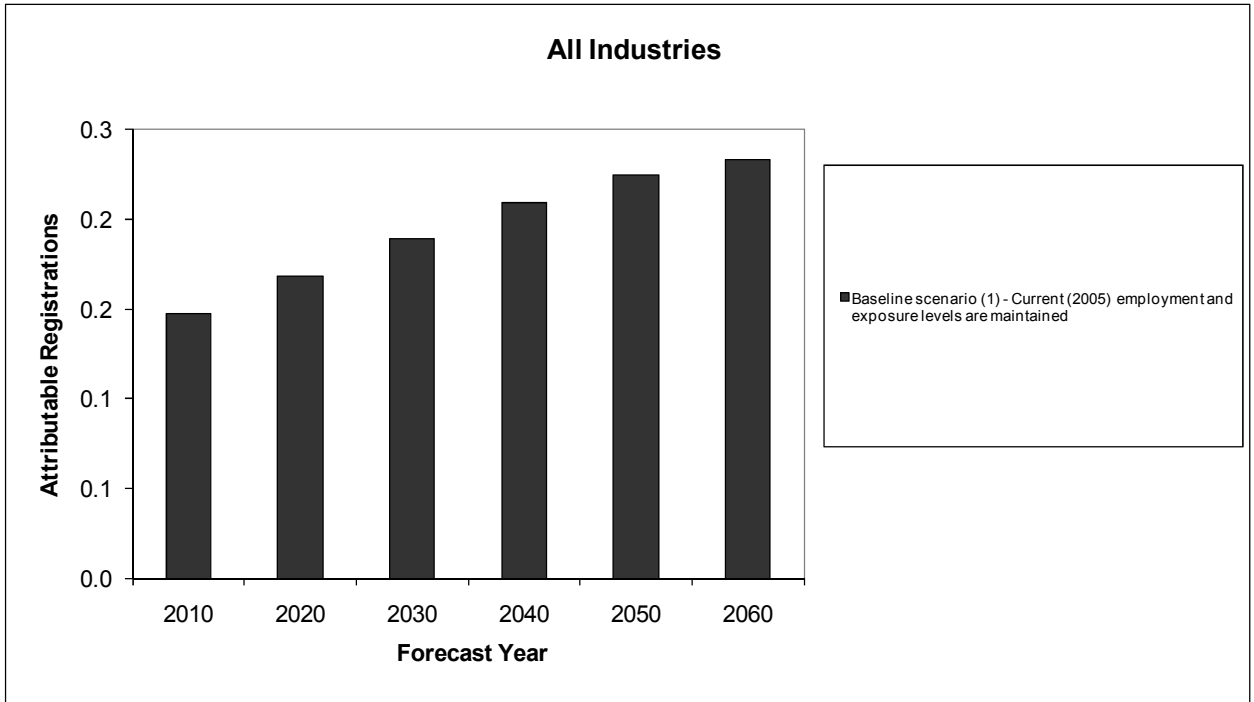
All change in forecast attributable numbers is entirely due to the estimated change in numbers employed to the present time, and to forecast cancer numbers, as no change in exposure levels is forecast.

As leukaemia has only a 0-20 year estimated latency, cancers occurring up to 2030 only are wholly or partly attributable to past and exposures up to 2010.

Results for the baseline scenario (1) are in Figure 2.1 (attributable registrations), Figure 2.2 (AFs) and Figure 2.3 (DALYs) for men plus women for the total EU (27 countries) for leukaemia.

Full results are given in Appendix 8.2 for men plus women by country in Tables 8.2.1 and 8.2.2. A breakdown of attributable numbers by industry is in Tables 8.2.3 and 8.2.4.

<sup>12</sup> Deaths and registrations are rounded to the nearest whole number. Where YLLs/YLDs/DALYs appear in association with zero deaths/registrations, this is due to rounding the deaths/registrations down to zero.

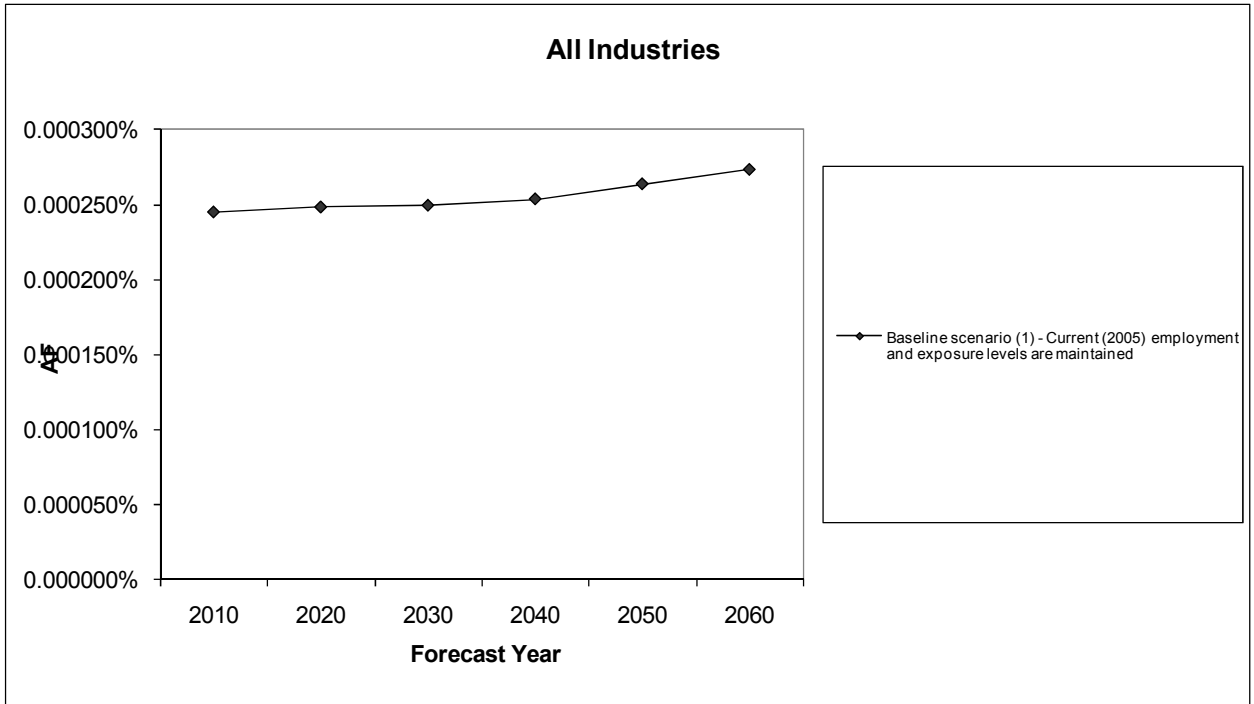


**Figure 2.1** Results for the baseline (1) scenario – Occupation Attributable cancer registrations, Leukaemia, men plus women

Figure 2.1 shows the number of registrations for leukaemia attributable to 1,2-epoxypropane exposure increasing slightly in the baseline scenarios over the next 50 years.

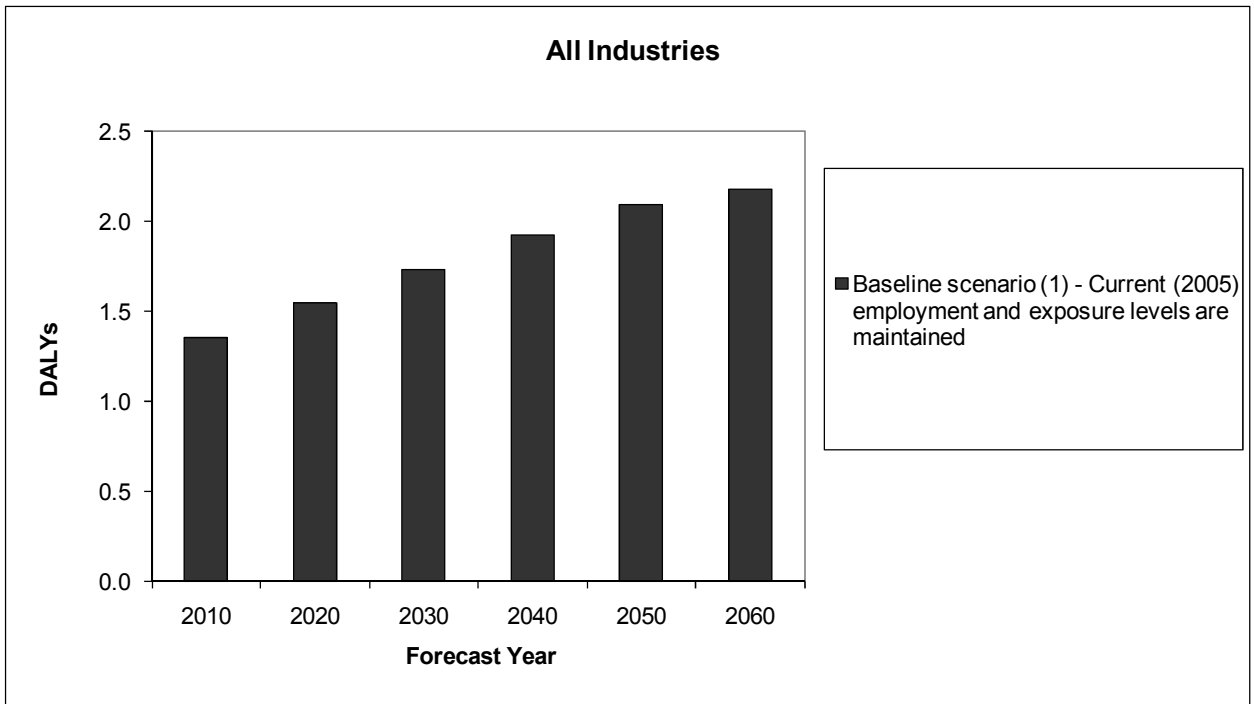
Figure 2.2 shows that the attributable fraction also increases slightly over the period up to 2060.





**Figure 2.2** Occupation Attributable Fractions, Leukaemia

The estimated DALYs increase slightly from just under 1.5 years in 2010 to just over 2.0 years in 2060 in the baseline scenario (Figure 2.3).



**Figure 2.3** Occupation Attributable DALYs, Leukaemia

## 2.5 POSSIBLE COSTS ASSOCIATED WITH NOT MODIFYING THE DIRECTIVE

### 2.5.1 Health impacts – possible costs under the baseline scenario

#### *Introduction*

The health data (cancer registrations and Years of Life Lost - 'YLL') for the baseline in which there are no further modifications to the Carcinogens Directive were described above in Section 2.4. These data indicate that there are predicted to be a low number of cancer registrations (around 10 over the period 2010-2070<sup>13</sup>) and YLLs (100 over the period 2010-2070<sup>13</sup>) from leukaemia cancer resulting from future exposure to 1,2-epoxypropane. (Whilst the annual numbers of registrations/YLLs presented in section 2.4.4 are quoted to be zero, the calculated values are small but non-zero, meaning that the total value over the 70-year period is as quoted here.)

There is a predicted increase in registrations and YLLs over the time period of this study (2010-2070) under the baseline scenario. This is perhaps due to a presumed increase in use either recently (with a lag in cancer development) or increase in the level of use in the future.

#### *Method in brief*

Using the health data (cancer registrations and YLL), it is possible to monetise the costs under the baseline by estimating the:

- Life years lost – This is calculated by using the YLL and multiplying this by a valuation of the Value of Life Year Lost (VLYL). This gives a value for the time (in years) lost as a result of premature death.
- Cost of Illness (COI) – This is a monetary cost of the time spent with cancer. In this study, a unit COI estimate is multiplied by the number of cancer registrations to give a total value for COI. (COI is often the main market-based approach in relation to health impact<sup>14</sup>). COI includes the direct and indirect costs of cancer but not the intangible costs (see below).
- Willingness to Pay (WTP) to avoid cancer – WTP is used as an alternative method (high cost scenario) based on publicly available, peer reviewed studies on what people would be willing to pay to avoid having cancer. This includes various intangible costs (e.g. disfigurement, functional limitations, pain and fear) and in some cases also includes the costs associated with life years lost.

The cost variables used in this study are presented in Table 2.5 in 2010 prices. For the purposes of this study, valuations are increased by 2% each year in the future in part to present costs in real terms (i.e. adjusting for inflation in prices) and to reflect the

<sup>13</sup> Note health estimates are provided for "snap-shot" years; 2010, 2020, 2030 etc. Results for a "snap-shot" year are assumed to be representative for the relevant time period (i.e. 2010 is also representative for 2010-2019) so impacts are multiplied by 10.

<sup>14</sup> ECHA (2008) "Applying SEA as part of restriction proposals under REACH" Available at: [http://echa.europa.eu/doc/reach/sea\\_workshop\\_proceedings\\_20081021.pdf](http://echa.europa.eu/doc/reach/sea_workshop_proceedings_20081021.pdf)

increasing value society's attaches to its health (as economic growth typically increases over a long period of time)<sup>15</sup>.

**Table 2.5** Summary of cost variables used in this study (€ 2010 prices)

<b>Cost/benefit elements</b>	<b>Low scenario</b>	<b>High scenario</b>
VLYL - Each year lost	€ 50,393	€ 0 (note 1)
COI or WTP - Unit cost (per cancer registration)	€ 49,302 (COI)	€ 1,793,776 (WTP)

(Note 1) – By using WTP (€1.8m) in the high scenario instead of COI, the WTP can include the costs of premature death and therefore there was a risk of double counting benefits if VLYL costs were included.

All costs and benefits over time in this study are discounted using a 4% discount rate as recommended by the European Commission's Impact Guidelines<sup>16</sup>. In order to assess the effect that discounting has on the results ('sensitivity analysis'), we have also presented estimates that take into consideration a declining discount rate for impacts occurring after 30 years and no discounting.

The health data shown in section 2.4 are snap-shots (i.e. estimation for the initial year of a ten year period) of the number of cancer registrations, deaths, YLLs in future years at 10 year intervals. In calculating the costs associated with these effects, each snapshot result is multiplied by 10 in order to derive an estimate for the whole assessment time period (for example, 2020 results are multiplied by 10 to give results over the period 2020-2029). This assumes that each snap-shot year is representative of the following 10 years.

The method to valuing health benefits is explained in more detail in the method paper titled "*Valuing health benefits – Method paper*".

### *Results*

Table 2.6 sets out the range of annual health costs for each representative decade. The ranges are based on the high and low cost scenarios (see Table 2.5). The results are also illustrated in Figure 2.4. The health costs decrease over time, despite the increase in actual health effects, due to the effect of discounting future costs.

It is important to recognise that these costs are average values based on numbers of cancer deaths/registrations that are expected to be less than one per year.

<sup>15</sup> This is consistent with some other European Commission studies and is standard practice for air quality under the Clean Air for Europe (CAFE) programme.

<sup>16</sup> European Commission impact Assessment Guidelines (Jan 2009) - [http://ec.europa.eu/governance/impact/commission\\_guidelines/docs/iag\\_2009\\_en.pdf](http://ec.europa.eu/governance/impact/commission_guidelines/docs/iag_2009_en.pdf)

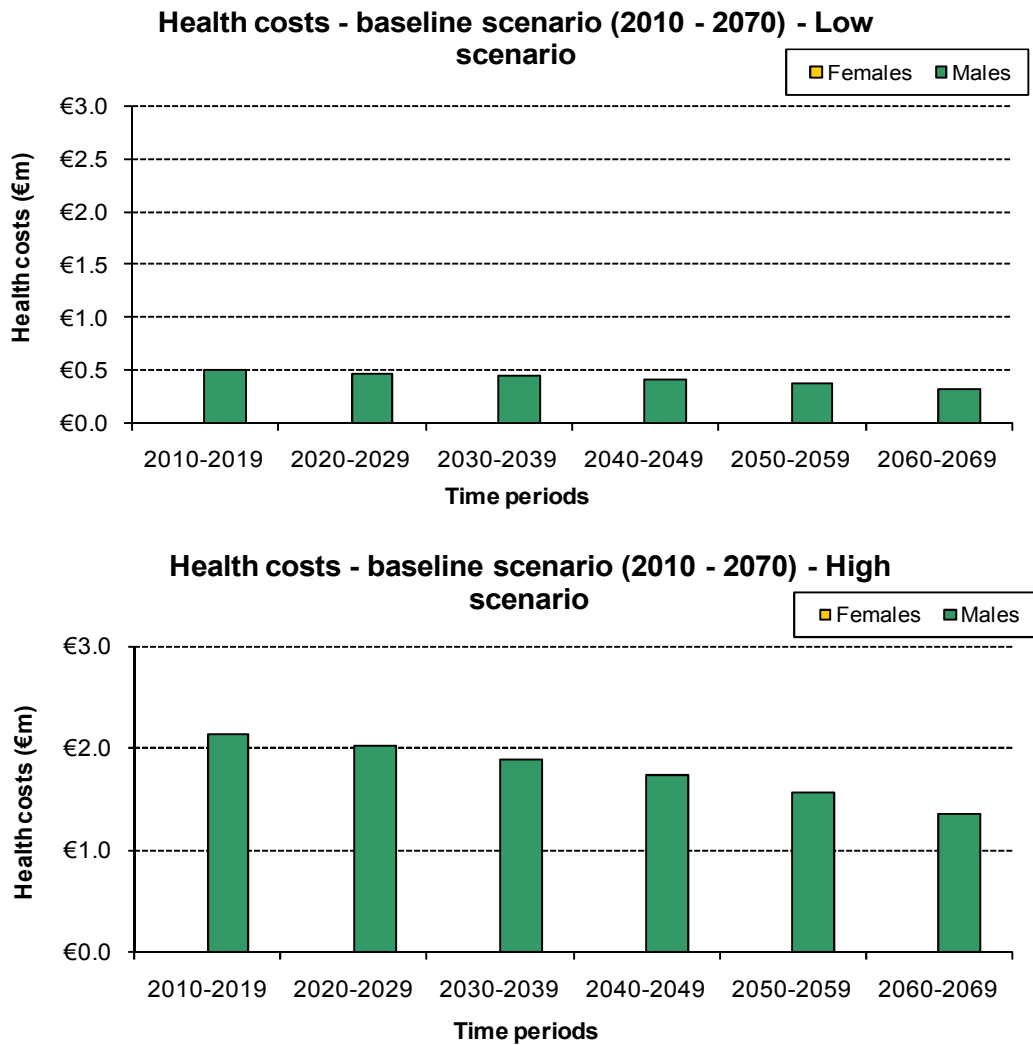
**Table 2.6** Health costs - baseline scenario – 2010 to 2070 (Present Value – 2010 €m prices)

Costs by Gender (€m)	2010-2019	2020-2029	2030-2039	2040-2049	2050-2059	2060-2069	Total
Female	0 to 0	0 to 0	0 to 0	0 to 0	0 to 0	0 to 0	0 to 0
Male	0.5 to 2.1	0.5 to 2	0.4 to 1.9	0.4 to 1.7	0.4 to 1.6	0.3 to 1.4	2.5 to 10.7
Total	0.5 to 2.1	0.5 to 2	0.4 to 1.9	0.4 to 1.7	0.4 to 1.6	0.3 to 1.4	2.5 to 10.7

Notes:

- All costs are presented in present value using a discount rate of 4%. The low range is based on low estimates for costs of illness and life years lost. The upper range of costs relate to WTP estimates to avoid having cancer, which include intangible costs associated with having cancer.

- Totals may not match to sums of females and male costs due to underlying small differences in raw data and rounding to whole number

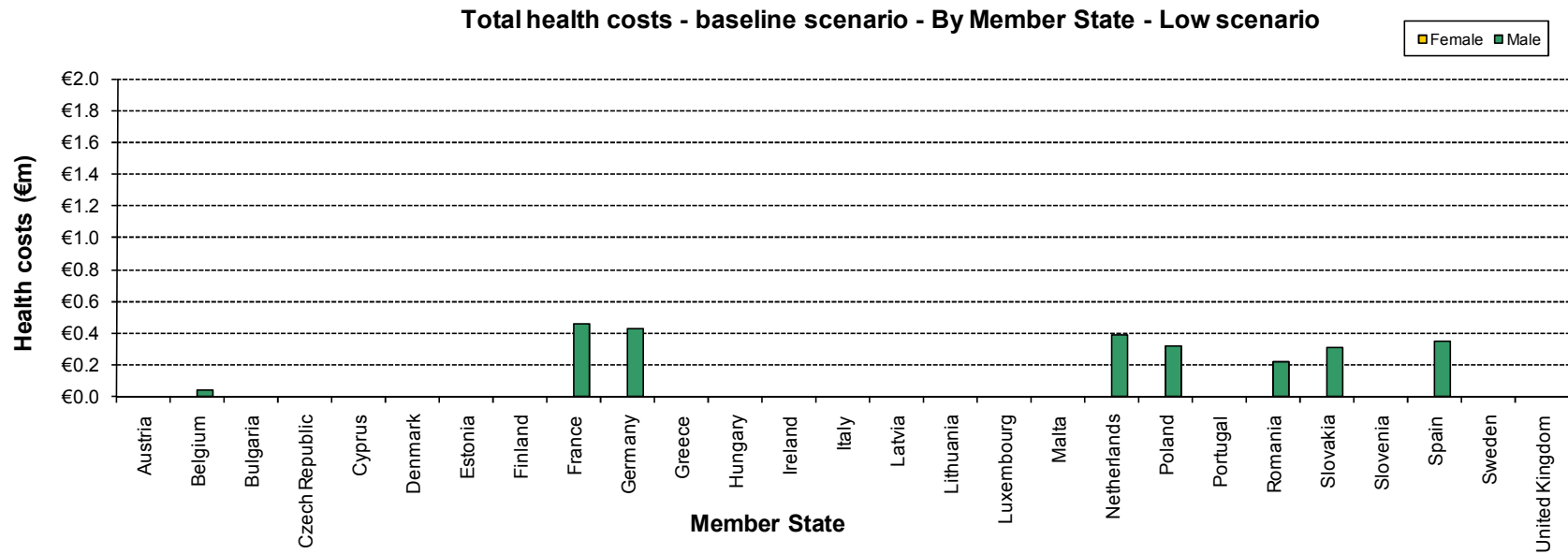


**Figure 2.4** Health costs - baseline scenario – 2010 to 2070 (Present Value – 2010 €m prices)

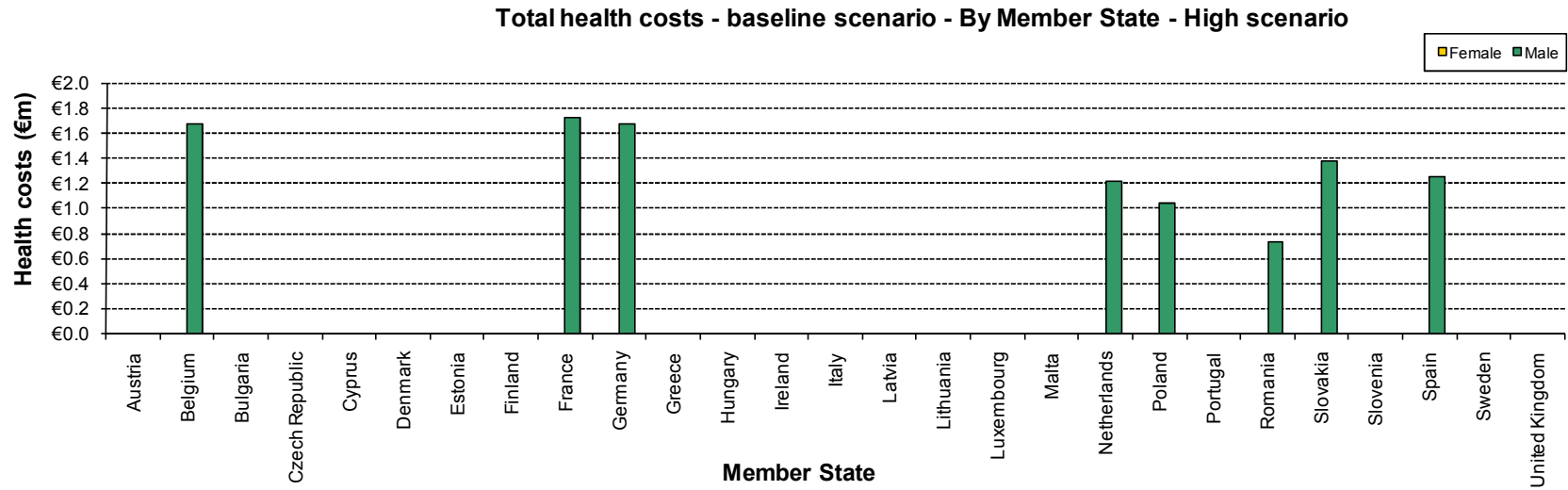
These predicted health costs will affect Member States differently depending upon the overall number of workers within affected industry groups, existing RMMs and the proportion of males and females within these groups.

Figure 2.6 shows that France, Germany, the Netherlands and Spain are predicted to have relatively high health costs, followed by Poland and Slovakia (all Member States with 1,2-epoxypropane production facilities). No health costs are expected in females, presumably due to the profile of the exposed workforce. The industrial sector estimated to be affected under the baseline is downstream use of 1,2-epoxypropane. It is likely that this sector is particularly affected as 1,2-epoxypropane is primarily used in the production of polymers and as an intermediate in the synthesis of other substances (see Section 1.3). This is shown in Figure 2.7.

Detailed tables are included in Appendix Section 8.3.



**Figure 2.5a** Total health costs- baseline scenario – By Member State (Present Value – 2010 €m prices)



**Figure 2.6b** Total health costs- baseline scenario – By Member State (Present Value – 2010 €m prices)

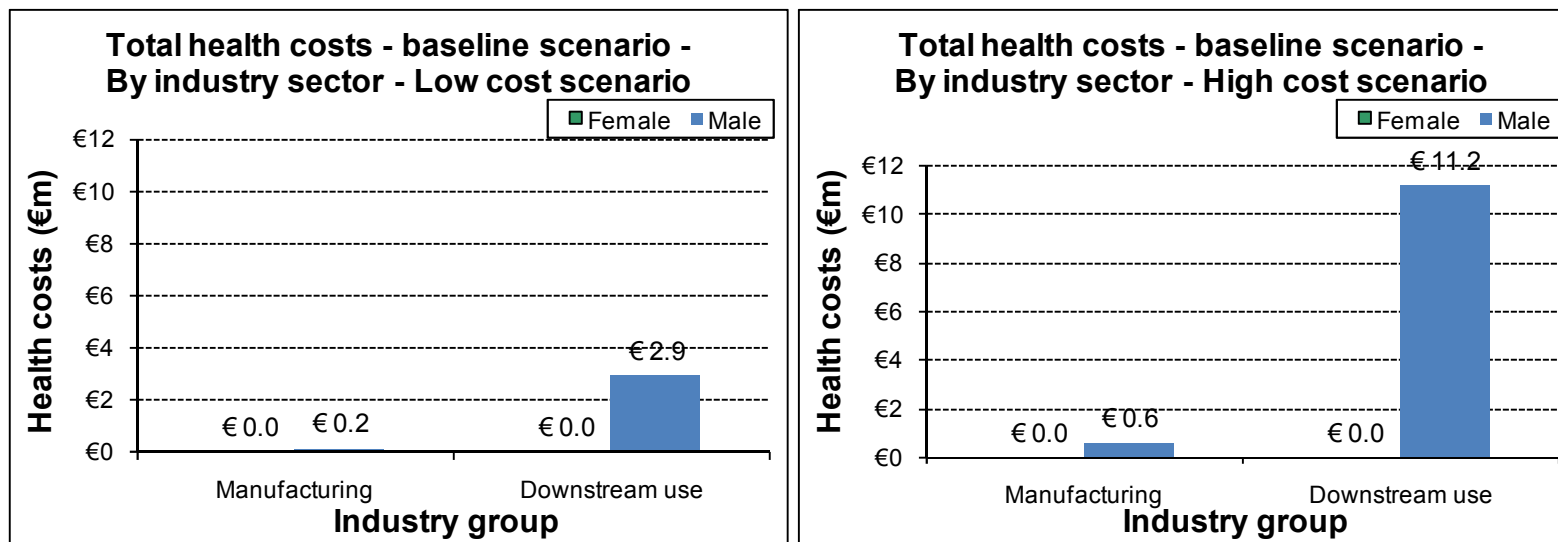
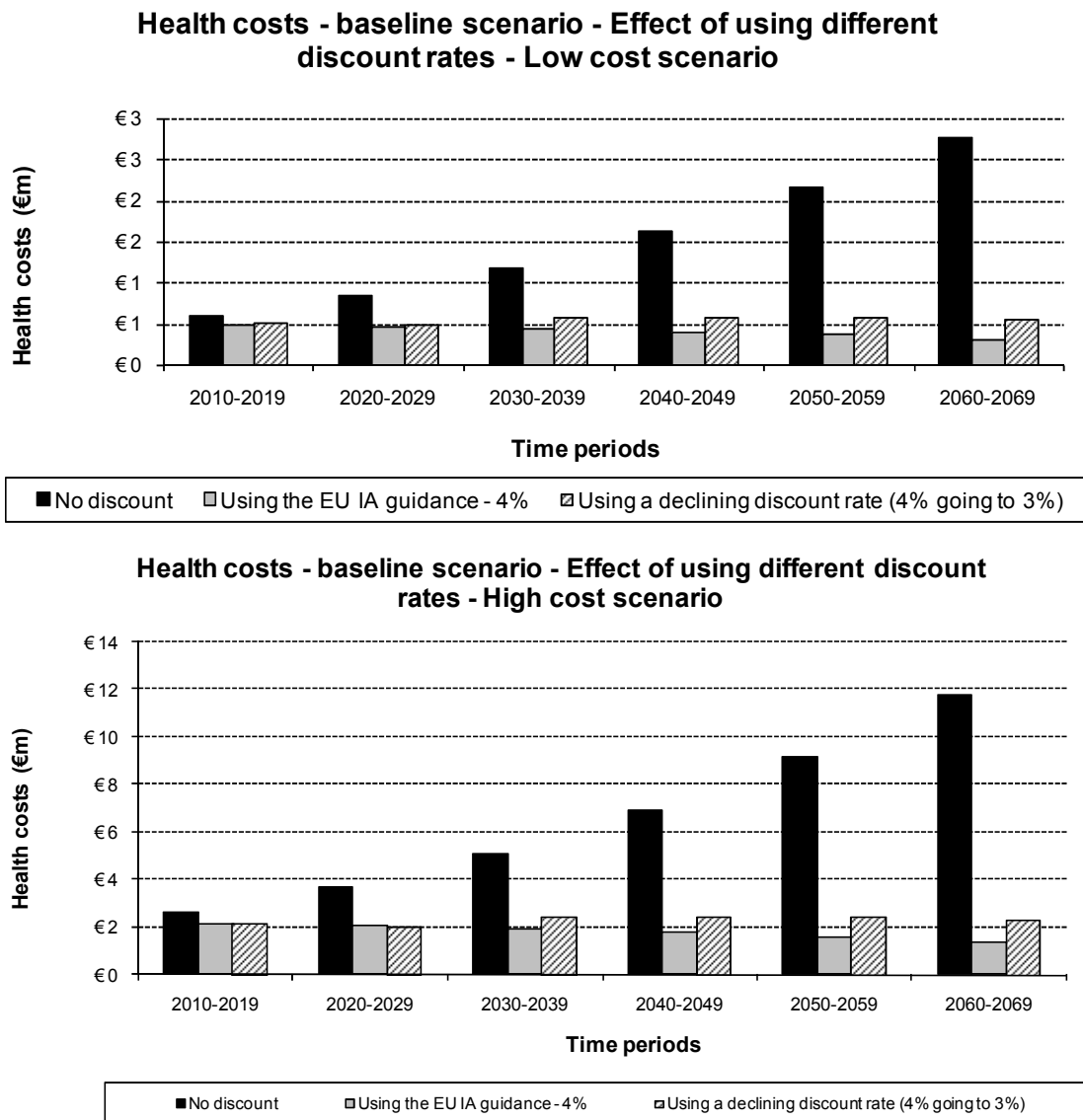


Figure 2.7 Total health costs - baseline scenario - by industry group (Present Value – 2010 €m prices)



In order to present all socio-economic costs and benefits consistently in present value terms, all future costs and benefits have been discounted. The primary approach was to apply the European Commission IA recommended 4% discount rate. Since most health impacts occur over a long period of time relative to costs, the impacts of discounting are significant.

In Figure 2.8 the effects of different discount rates on the overall results are shown, indicating that the impacts of discounting become more pronounced in the second assessment period (2020-2039). As the number of registrations and YLLs increase over time, the difference between the results when using discounting and with no discounting becomes more apparent.



**Figure 2.8** Impacts of discounting

### 3 POLICY OPTIONS

#### 3.1 DESCRIPTION OF MEASURES

Existing national OELs in EU Member States are presented in Table 1.1. From this it can be concluded that the typical OEL in the EU level is set at 2ppm and 5ppm. This report looks at the impact of the potential implementation of an EU-wide OEL at both of those levels.

Examples of control measures to reduce exposure to 1,2-epoxypropane, as recommended by a major producer of 1,2-epoxypropane, are summarised in Table 3.1.

**Table 3.1** General measures to reduce exposure to 1,2-epoxypropane

<b>Organisational measures</b>	<b>Personnel measures</b>	<b>Technical measures</b>
Implement closed systems	Use of personal protective equipment (PPE)	Rinse equipment with water and steam or flush with nitrogen before maintenance activities
Replace manual procedures with automatic ones where possible Install suitable loading/unloading equipment to reduce fugitive emissions. Install suitable bulk handling equipment Implement monitoring programs and/ or continuous detectors Formal emergency procedures should be in place to deal with various eventualities e.g. spills, leaks, fire-fighting and waste disposal	Use of respiratory protective equipment (RPE)	

Source: The Dow Chemical Company: *Propylene oxide storage and handling guidelines*. Available at: <http://www.dow.com/scripts/litorder.asp?filepath=propyleneoxide/pdfs/noreg/117-01736.pdf&pdf=true>

#### 3.2 LEVEL OF PROTECTION ACHIEVED (OELS)

The available exposure data indicate that 1,2-epoxypropane is currently well controlled in the chemical industry through enclosure and automation. Material sampling is generally done at dedicated sampling points that are enclosed with vapour capture. When 1,2-epoxypropane is used as a chemical intermediate at the same plant where it was manufactured or at a nearby plant it is transported in enclosed pipes. When it is transferred over longer distances it is transferred to and from transport tankers using coupling/uncoupling delivery lines. Small amounts of 1,2-epoxypropane can be released during uncoupling. Low-emission coupling connectors are used to minimise or eliminate emissions and if emissions are not eliminated respiratory protection is used during this task. During maintenance or system breaches equipment and lines

are emptied and rinsed with water and steam or flushed with nitrogen prior to opening. In order to minimise exposures from fugitive emissions magnetic delivery pumps are used at some plants to reduce the opportunity for fugitive emissions, and monitoring programs and/or continuous detectors are in place to detect emissions when they occur.<sup>17,18</sup>

## 4 ANALYSIS OF IMPACTS

### 4.1 HEALTH IMPACTS FROM CHANGES TO THE EU DIRECTIVE

#### 4.1.1 Health information

We have assessed the potential impact of introducing an OEL of 2 ppm. However, because the estimated exposures are all low and it is not expected that anyone is currently exposed above the typical OEL there are no health benefits from introducing the limit.

#### 4.1.2 Monetised health benefits

The available exposure data suggests that workers' 1,2-epoxypropane exposures are generally controlled well below 5ppm. Although not all EU member states currently have 8h TWA exposure limits of 5ppm or less, it is likely that 1,2-epoxypropane exposures are maintained below 5ppm. Given this, it is concluded – based on the exposure assessment - that there would be negligible human health benefits of introducing an OEL from 2010 at 5ppm. Therefore no monetised health benefits are expected.

The exposure data suggests that a very small proportion of workers (0.17%) are likely to be exposed above 8h TWA concentrations of 2ppm. Therefore, there may be possible health benefits (e.g. avoided healthcare costs and effects of having cancer and avoided life years lost) of introducing an OEL of 2ppm in 2010. Benefits from compliance with the OEL would be realised slightly earlier than what would have occurred under the baseline. Potential health benefits have not been monetised, but it is assumed that the maximum *benefits* that would be seen would be equivalent to the total health *costs* estimated under the baseline (see Section 2.5.1). In practice, the health benefits would be lower than this given the non-threshold nature of the effects of 1,2-epoxypropane, with the health benefits of a 2ppm OEL being a greater proportion of the baseline health costs than those under a 5ppm OEL.

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<sup>17</sup> European Union Risk Assessment Report: Methyloxirane (Propylene Oxide). Volume 23. 2002

<sup>18</sup> Communication with CEFIC

## 4.2 ECONOMIC IMPACTS

### 4.2.1 Operating costs and conduct of business

#### *Compliance costs*

In Section 2.2 it was estimated that there are between 485 and 1,570 workers typically exposed to 1,2-epoxypropane in the EU. The exposure data presented in Section 2.3 indicated that:

- The current geometric mean exposure of directly exposed workers is 0.08 ppm (with a geometric standard deviation of 3).

Based on this, the following assumptions have been made:

- Most firms within affected industries are assumed to meet the more stringent possible OEL (2ppm) given that the geometric mean exposure is 0.08 ppm (reflecting the fact that many firms will already have suitable control measures in place).
- It is estimated that, under the baseline scenario, firms are already moving towards reducing exposure, with an existing trend that would be expected to allow compliance with a 5 ppm OEL to be achieved. Therefore there is assumed there would not be a significant cost to achieve the 5ppm OEL.
- Currently some firms within affected industries would require further control measures to meet the more stringent limit given that the estimated GSD indicates that there will be some firms/ workers with exposure over 2ppm, although the number would be very small.

This information has been used to help determine the number of workers that will comply with the proposed OELs (see Table 4.1).

**Table 4.1** Estimated numbers of enterprises with exposure exceeding the possible OELs in affected industries

Sector	Assume full compliance for OEL = 5ppm			Assume full compliance for OEL = 2ppm		
	% Workers affected <sup>1</sup>	No of. workers affected <sup>2</sup>	No. of enterprises affected	% Workers affected	No of. workers affected	No. of enterprises affected
Chemical industry	<0.01%	0	0	0.17%	3	1

Notes:

- 1) Percentages of workers affected are based on an assumption that exposure follows a lognormal distribution with mean of 0.08ppm and standard deviation of 3.0 as stated in Section **Error! Reference source not found.** The percentage values were derived using these values and a lognormal probability density function developed using 10,000 iterations / sample points.
- 2) In Section 2.2 it was estimated that there are between 485-1,570 workers potentially exposed to PO in high exposure industries (chemical industry). The number of workers affected is calculated as a percentage of the 1,570 workers potentially exposed.

It is estimated that an EU-wide OEL of 5ppm would affect less than 0.01% of potentially exposed employees, whilst an OEL of 2ppm would affect only 0.17% of workers (one enterprise). These figures are subject to significant uncertainty but the overall picture

is that the percentage and number exposed at levels above the possible OELs is very low.

Based on consultation with CEFIC and available exposure data, it is understood that companies are already working according to strictly controlled conditions. The introduction of an EU-wide OEL of 2ppm may require companies not adhering to these strictly controlled conditions, to reorganise their workplace to ensure that exposure to 1,2-epoxypropane is minimised. There may also be additional training and authorisation of personnel handling the substance (e.g. batch log sheets, training documentation, cleaning procedures and safety instructions).

There are expected to be relatively low costs associated with improved training, enclosure, housekeeping, and RPE/ PPE, which in any case would be considered to be 'best practice'. It is assumed that these costs range between €1,000-2,000 per year per enterprise (including costs of equipment and the cost of time spent on e.g. cleaning and administration). Given the small number of companies involved, the overall costs of such measures would be relatively small (assumed to be of the order of a few thousand or tens of thousands of Euros).

#### *Conduct of employers*

The introduction of an EU-wide OEL at 2ppm or below may require certain enterprises to reorganise their workplace to ensure that exposure to 1,2-epoxypropane is minimised. Additional training and supervision of personnel handling the substance may be required to ensure that employees minimise their exposure by adhering to good practice in order to reduce exposure (e.g. good personal hygiene, wearing protective clothing, improved cleaning procedures and safety instructions). However in practice, it is expected that these activities are already taking place and thus there may well be no additional change beyond the baseline.

#### *Potential for closure of companies*

There is not expected to be any potential closure of companies as a result of introducing an EU-wide OEL because only a minimal increase in compliance costs relative to the baseline scenario is likely to be incurred. Furthermore, according to industry analysts<sup>19</sup>, demand for 1,2-epoxypropane has been growing in Europe at 3-4% per annum.

#### *Potential impacts for specific types of companies*

There are a limited number of EU companies involved in the manufacture of 1,2-epoxypropane. Based on data in the EU RAR (2002) typical individual plant capacity is estimated to range from 150,000-200,000 tonnes per annum. Given the typical size of firms, any potential increase in compliance costs (if indeed there is any relative to the baseline) is unlikely to have any significant impacts, since firms maybe able to pass through costs (given there may not be any readily available substitutes for this use in synthesis of other chemicals). Having an EU-wide OEL level should remove any EU competitive distortions between EU Member States with different OELs.

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<sup>19</sup> ICIS (2009) Propylene Oxide (PO) Uses and Market Data  
<http://www.icis.com/v2/chemicals/9076450/propylene-oxide/uses.html>

*Administrative costs to employers and public authorities*

The following table (Table 4.2) describes the administrative burden to employers already subject to the Carcinogens Directive but will now incur costs of introducing an EU wide OEL on to Annex III.

**Table 4.2** Administrative burdens to employers

Type of administrative cost	Relevant article(s)	Type of cost	Significance
1. Change in practice to use closed systems when using the substance.	5 – Prevention and reduction of exposure	These costs are already estimated in the cost of compliance section - This will only affect those firms that do not have or use closed systems	Estimated elsewhere
2. Develop/update health and safety and best practice guidance for: <ul style="list-style-type: none"> <li>○ Minimising use and exposure to workers to the substance</li> <li>○ Redesign work processes and engineering controls to avoid/minimise release of carcinogens or mutagens</li> <li>○ Hygiene measures, in particular regular cleaning of floors, walls and other surfaces</li> <li>○ Information for workers</li> <li>○ Warnings and safety signs</li> <li>○ Drawing up plans to deal with emergencies likely to result in abnormally high exposure</li> </ul>	5 – Prevention and reduction of exposure 7 – Unforeseen exposure 8 – Foreseeable exposure 9 – Access to risk areas 10 – Hygiene and individual protection	Firms will already have been required to develop/update health and safety and best practice guidance.  The guidance and procedures may be required to be updated as control measures may change in light of a more stringent OEL.  Some firms may need to redesign work practices to minimise exposure to workers and the number of workers exposed.  The costs of implementing controls on exposure (such as LEV or PPE) are already estimated in the costs of compliance section.	Low

Type of administrative cost	Relevant article(s)	Type of cost	Significance
3. Additional costs of training new and existing staff in line with requirements of the Directive	11 – Information and training of workers	Firms will already have been required to ensure training and adequate measures to reduce/minimise exposure.	Low
4. Additional costs of making information available to employees	12 – Information for workers	Largely one-off cost if the revised OEL requires a change in control measures/working practice.	
5. Consultation with employees on compliance with the Directive	13 – Consultation and participation with workers		

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

The following table (Table 4.3) describes the administrative burden to competent authorities already enforcing the Carcinogens Directive but will now incur costs of introducing an EU wide OEL on to Annex III.

**Table 4.3** Administrative burdens to Competent Authorities

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

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

### *Third countries*

Since it is not expected that the introduction of an EU-wide OEL will have a noticeable impact on companies, there is not expected to be any significant impact upon third countries such as through redistribution of investment, jobs or sales.

#### 4.2.2 Impact on innovation and research

Based on consultation with CEFIC and available literature, the vast majority of investment required to control exposure from the manufacture of 1,2-epoxypropane has already occurred in the last 20 years. Therefore the impacts on innovation and research from introducing an EU-wide OEL are estimated to be minimal.

#### 4.2.3 Macroeconomic impact

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.

### 4.3 SOCIAL IMPACTS

#### 4.3.1 Employment and labour markets

There are not expected to be any noticeable changes to jobs skills, patterns or the numbers of workers required as a result of introducing an EU-wide OEL because no significant behavioural response is expected to be required.

#### 4.3.2 Changes in end products

1,2-epoxypropane is used primarily as a chemical intermediate in the production of polyurethane polyols (60% to 65%), propylene glycols (20% to 25%) and glycol ethers (3% to 5%)<sup>20</sup>. This is not expected to change from the introduction of an EU-wide OEL relative to the baseline scenario.

### 4.4 ENVIRONMENTAL IMPACTS

1,2-epoxypropane is not classified in relation to effects on the environment under Regulation 1272/2008. The ESR risk assessment did not identify any need to limit risks to the environment associated with 1,2-epoxypropane, although it did identify a need to reduce risks to humans exposed via the environment in relation to carcinogenic/mutagenic effects (due to the non-threshold nature of the effects). However, based on the above information, it appears that engineering controls on 1,2-epoxypropane in the workplace (e.g. enclosure, automation) that would be needed to meet the possible OEL of 2ppm have apparently already been implemented. It is unlikely that the behavioural changes that may be needed in order to comply with a new limit for 1,2-epoxypropane would lead to significant changes in releases of the substance to the environment or in associated environmental impacts. There might theoretically be a very small impact in relation to humans exposed via the environment but this is expected to be minimal given the existing controls in place.

Likewise, because the changes required to meet a new limit are largely behavioural rather than technological, there are unlikely to be other significant environmental impacts (such as changes in energy use and associated emissions).

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<sup>20</sup> 11th Report on Carcinogens (ROC) (2002) Substance Profile: Propylene Oxide



## 5 COMPARISON OF OPTIONS

The main identified impacts of introducing an OEL of 2ppm and 5ppm for 1,2-epoxypropane (propylene oxide or PO) are shown in the following tables.

**Table 5.1** 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	<p>As set out in section 2.5, the health costs of cancer (leukaemia) over the period 2010-70 are estimated to be:</p> <ul style="list-style-type: none"> <li>- Females: €0m</li> <li>- Males: €1 m to €3m</li> <li>- Total: €1m to €3m</li> </ul> <p>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).</p>		<p>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.</p> <p>This has been estimated as a benefit.</p>	<p>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.</p>	<p><b>No change</b> - There are not expected to be any additional health costs relative to the baseline scenarios.</p>	<p><b>No change</b> – 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..</p>

**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)

Type of impact	Baseline Scenario		Introduce OEL=2 ppm		Introduce OEL=5 ppm	
	Costs	Benefits	Costs	Benefits	Costs	Benefits
Economic		<p>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.</p> <p>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.</p> <p>There would be administrative costs of implementing the OEL in national legislation and of demonstrating and verifying compliance</p>	<p>Having an EU-wide OEL should remove any EU competitive distortions between EU Member States with different limits.</p>	<p><b>Minimal</b> - The vast majority of investment required to control exposure associated with the manufacture of PO has already occurred in the last 20 years.</p>	<p><b>Minimal</b> - Having an EU-wide OEL level would remove any competitive distortions between EU Member States with different limits.</p>	

**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 (Present Value – 2010 €m prices)

Type of impact	Baseline Scenario		Introduce OEL=2 ppm		Introduce OEL=5 ppm	
	Costs	Benefits	Costs	Benefits	Costs	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.		<b>No change</b> - 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.	<b>No change</b> - 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 5.4** Comparison of macro-economic 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
Macro-economic	There are not expected to be any noticeable macroeconomic impacts under the baseline scenario.		<b>No change</b> - 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 5.5** Comparison of environmental 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
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)

## 6 CONCLUSIONS

There are 2.75 million tonnes of 1,2-epoxypropane produced within the EU each year. The major use of 1,2-epoxypropane in the EU is to make 1,2-epoxypropane polymers called polyether polyols (about 70%) that are used in the manufacture of polyurethane foams. The second most important use is in the production of propylene glycol (about 25%), 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).

We estimate the geometric mean level in the mid 1990s was 0.08 ppm and about 0.17% of manufacturing workers would have been expected to be 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. 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 2060. DALYs and YLL both increase from 1 to 2 years per annum over the period to 2060. Total estimated health costs associated with inaction range from €2.5m to €11m.

The health impact assessment is uncertain because of the limited epidemiological evidence for the carcinogenicity of 1,2-epoxypropane. It is possible that the risks may underestimate the attributable risk, but even if the risk applied to all lymphopoietic and haematopoietic cancer the number of cases attributed to 1,2-epoxypropane would only be two to three times that which we have predicted.

Current exposures in the EU are judged to be well below 2ppm and so there are no important costs to comply 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 not 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.

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## 8 APPENDIX

### 8.1 ESTIMATED DEATHS AND REGISTRATIONS IN THE EU FROM LEUKAEMIA

**Table 8.1.1:** Forecast number of leukaemia cases in ages 25+ (ages 15+ for registrations), based on projected EU country populations

	Leukaemia deaths <i>MEN</i>						<i>WOMEN</i>						
	FTY	2010	2020	2030	2040	2050	2060	2010	2020	2030	2040	2050	2060
Austria		349	439	540	651	728	730	298	334	398	475	535	532
Belgium		0	0	0	0	0	0	0	0	0	0	0	0
Bulgaria		162	164	175	186	193	191	108	112	116	117	119	114
Cyprus		24	33	44	55	68	81	16	22	29	36	44	51
Czech Republic		382	481	602	684	777	854	318	378	451	495	537	588
Denmark		249	317	389	428	457	459	176	207	257	287	310	314
Estonia		44	50	57	68	77	87	50	52	56	60	62	64
Finland		231	302	382	412	418	436	200	239	294	325	325	324
France		2,886	3,486	4,329	5,037	5,455	5,711	2,313	2,651	3,148	3,724	3,987	4,035
Germany (including ex-GDR from 1991)		3,692	4,615	5,278	6,106	6,377	6,060	3,103	3,541	3,894	4,403	4,673	4,375
Greece		473	551	631	753	868	923	366	456	503	586	667	708
Hungary		345	391	447	507	569	619	307	339	371	397	418	441
Ireland		177	242	328	424	534	645	114	146	194	249	309	374
Italy		3,069	3,670	4,288	5,003	5,662	5,747	2,558	2,930	3,294	3,757	4,214	4,258
Latvia		69	72	79	87	94	99	64	65	67	72	72	75
Lithuania		94	104	119	139	155	163	105	114	123	141	148	149
Luxembourg		19	24	32	39	45	48	18	21	27	34	40	43
Malta		16	22	28	32	34	38	7	9	11	12	13	13
Netherlands		682	887	1,128	1,281	1,338	1,315	525	626	787	916	981	955
Poland		1,187	1,456	1,788	2,070	2,264	2,484	993	1,167	1,383	1,566	1,628	1,727
Portugal		372	434	511	601	680	727	304	357	408	468	521	547
Romania		483	531	600	678	741	754	355	381	420	456	483	486
Slovakia		158	199	251	298	338	365	129	153	189	217	237	254
Slovenia		85	116	148	186	204	216	80	94	109	129	138	139

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	Leukaemia deaths <i>MEN</i>							<i>WOMEN</i>					
	FTY	2010	2020	2030	2040	2050	2060	2010	2020	2030	2040	2050	2060
Spain	1,665	2,011	2,487	3,125	3,736	4,003	1,336	1,568	1,868	2,294	2,710	2,904	
Sweden	431	525	637	697	760	812	344	390	464	509	547	580	
United Kingdom	2,733	3,269	3,913	4,453	4,974	5,327	2,062	2,294	2,718	3,147	3,543	3,757	
European Union (27 countries)	20,327	24,615	29,433	34,330	38,022	39,604	16,633	19,103	22,109	25,529	27,949	28,707	

	Leukaemia registrations <i>MEN</i>							<i>WOMEN</i>					
	FTY	2010	2020	2030	2040	2050	2060	2010	2020	2030	2040	2050	2060
Austria	560	660	762	829	853	858	425	471	530	576	589	585	
Belgium	847	978	1,111	1,200	1,238	1,279	586	651	722	775	797	810	
Bulgaria	265	269	281	292	297	289	205	207	210	210	204	192	
Cyprus	0	0	0	0	0	0	0	0	0	0	0	0	
Czech Republic	698	837	942	1,038	1,109	1,105	481	557	608	647	677	681	
Denmark	492	582	639	670	672	690	327	373	411	430	434	440	
Estonia	63	67	74	81	88	93	70	73	76	78	78	78	
Finland	222	270	295	299	303	310	187	221	241	245	243	244	
France	4,818	5,662	6,346	6,793	7,020	7,272	3,739	4,264	4,707	5,009	5,092	5,134	
Germany (including ex-GDR from 1991)	6,296	7,107	7,865	8,166	7,982	7,653	5,054	5,424	5,835	6,006	5,869	5,586	
Greece	829	934	1,060	1,193	1,263	1,236	584	652	714	775	804	782	
Hungary	656	733	802	894	989	1,017	562	607	636	665	692	693	
Ireland	240	316	400	491	585	629	142	181	228	274	324	351	
Italy	5,132	5,826	6,598	7,324	7,498	7,348	3,549	3,927	4,334	4,733	4,825	4,673	
Latvia	149	158	180	202	221	235	165	167	178	185	192	195	
Lithuania	206	226	258	287	309	316	209	220	243	258	260	261	
Luxembourg	43	54	66	75	81	87	28	35	42	48	53	57	
Malta	23	28	30	32	34	34	22	26	29	31	32	33	
Netherlands	884	1,083	1,229	1,292	1,275	1,280	626	724	806	844	838	828	
Poland	1,582	1,890	2,181	2,345	2,547	2,616	1,289	1,500	1,709	1,790	1,874	1,891	
Portugal	611	693	789	878	938	948	489	548	606	654	677	673	
Romania	698	745	817	902	949	938	545	578	620	664	677	658	

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Leukaemia registrations	<i>MEN</i>						<i>WOMEN</i>						
	FTY	2010	2020	2030	2040	2050	2060	2010	2020	2030	2040	2050	2060
Slovakia		276	346	416	474	530	542	204	236	267	292	305	299
Slovenia		110	134	154	166	169	161	86	96	107	113	114	110
Spain		2,679	3,209	3,874	4,520	4,853	4,745	2,067	2,425	2,834	3,202	3,394	3,340
Sweden		626	729	802	860	896	950	429	477	522	555	577	600
United Kingdom		4,231	4,910	5,550	6,082	6,467	7,000	2,939	3,289	3,718	4,105	4,342	4,624
European Union (27 countries)		33,068	38,259	43,388	47,343	49,194	49,568	24,892	27,858	30,891	33,221	34,075	33,880

## 8.2 SUPPLEMENTARY TABLES – HEALTH EFFECTS UNDER THE BASELINE SCENARIO

**Table 8.2.1:** Numbers and proportions of the population ever exposed for the baseline scenario, by country, men plus women

Scenario	Baseline scenario (1) - Current (2005) employment and exposure levels are maintained					
	Country	2010	2020	2030	2040	2050
	<i>Number ever exposed in the REP</i>					
Austria	0	0	0	0	0	0
Belgium	331	331	331	331	331	331
Bulgaria	0	0	0	0	0	0
Cyprus	0	0	0	0	0	0
Czech Republic	0	0	0	0	0	0
Denmark	0	0	0	0	0	0
Estonia	0	0	0	0	0	0
Finland	0	0	0	0	0	0
France	353	331	331	331	331	331
Germany	331	331	331	331	331	331
Greece	0	0	0	0	0	0
Hungary	0	0	0	0	0	0
Ireland	0	0	0	0	0	0
Italy	0	0	0	0	0	0
Latvia	0	0	0	0	0	0
Lithuania	0	0	0	0	0	0
Luxembourg	0	0	0	0	0	0
Malta	0	0	0	0	0	0
Netherlands	331	331	331	331	331	331
Poland	331	331	331	331	331	331
Portugal	0	0	0	0	0	0
Romania	331	331	331	331	331	331
Slovakia	331	331	331	331	331	331
Slovenia	0	0	0	0	0	0
Spain	288	331	331	331	331	331
Sweden	0	0	0	0	0	0
United Kingdom	0	0	0	0	0	0
<b>TOTAL</b>	<b>2,628</b>	<b>2,649</b>	<b>2,649</b>	<b>2,649</b>	<b>2,649</b>	<b>2,649</b>

Scenario	Baseline scenario (1) - Current (2005) employment and exposure levels are maintained					
	Country	2010	2020	2030	2040	2050
	<i>Proportion of the population exposed</i>					
Austria	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
Belgium	0.004%	0.004%	0.004%	0.004%	0.004%	0.004%
Bulgaria	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
Cyprus	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
Czech Republic	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
Denmark	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
Estonia	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
Finland	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
France	0.001%	0.001%	0.001%	0.001%	0.001%	0.001%
Germany	0.000%	0.001%	0.001%	0.001%	0.001%	0.001%
Greece	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
Hungary	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
Ireland	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
Italy	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
Latvia	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
Lithuania	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
Luxembourg	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
Malta	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
Netherlands	0.003%	0.002%	0.002%	0.003%	0.003%	0.003%
Poland	0.001%	0.001%	0.001%	0.001%	0.001%	0.001%
Portugal	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
Romania	0.002%	0.002%	0.002%	0.002%	0.002%	0.003%
Slovakia	0.007%	0.007%	0.008%	0.008%	0.009%	0.010%
Slovenia	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
Spain	0.001%	0.001%	0.001%	0.001%	0.001%	0.001%
Sweden	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
United Kingdom	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
TOTAL	0.001%	0.001%	0.001%	0.001%	0.001%	0.001%

**Table 8.2.2:** Results for the baseline scenario for leukaemia, by country, men plus women

Scenario	Baseline scenario (1) - Current (2005) employment and exposure levels are maintained					
Country	2010	2020	2030	2040	2050	2060
	<i>Attributable Fraction</i>					
Austria	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
Belgium	0.002%	0.002%	0.001%	0.001%	0.001%	0.001%
Bulgaria	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
Cyprus	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
Czech Republic	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
Denmark	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
Estonia	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
Finland	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
France	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
Germany	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
Greece	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
Hungary	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
Ireland	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
Italy	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
Latvia	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
Lithuania	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
Luxembourg	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
Malta	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
Netherlands	0.001%	0.001%	0.001%	0.001%	0.001%	0.001%
Poland	0.000%	0.000%	0.000%	0.000%	0.001%	0.001%
Portugal	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
Romania	0.001%	0.001%	0.001%	0.001%	0.001%	0.001%
Slovakia	0.003%	0.003%	0.003%	0.003%	0.003%	0.004%
Slovenia	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
Spain	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
Sweden	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
United Kingdom	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
TOTAL	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%

Scenario	Baseline scenario (1) - Current (2005) employment and exposure levels are maintained					
	Country	2010	2020	2030	2040	2050
	<b>Attributable Deaths</b>					
Austria	0	0	0	0	0	0
Belgium	0	0	0	0	0	0
Bulgaria	0	0	0	0	0	0
Cyprus	0	0	0	0	0	0
Czech Republic	0	0	0	0	0	0
Denmark	0	0	0	0	0	0
Estonia	0	0	0	0	0	0
Finland	0	0	0	0	0	0
France	0	0	0	0	0	0
Germany	0	0	0	0	0	0
Greece	0	0	0	0	0	0
Hungary	0	0	0	0	0	0
Ireland	0	0	0	0	0	0
Italy	0	0	0	0	0	0
Latvia	0	0	0	0	0	0
Lithuania	0	0	0	0	0	0
Luxembourg	0	0	0	0	0	0
Malta	0	0	0	0	0	0
Netherlands	0	0	0	0	0	0
Poland	0	0	0	0	0	0
Portugal	0	0	0	0	0	0
Romania	0	0	0	0	0	0
Slovakia	0	0	0	0	0	0
Slovenia	0	0	0	0	0	0
Spain	0	0	0	0	0	0
Sweden	0	0	0	0	0	0
United Kingdom	0	0	0	0	0	0
TOTAL	0	0	0	0	0	0

Scenario	Baseline scenario (1) - Current (2005) employment and exposure levels are maintained					
Country	2010	2020	2030	2040	2050	2060
<b>Attributable Registrations</b>						
Austria	0	0	0	0	0	0
Belgium	0	0	0	0	0	0
Bulgaria	0	0	0	0	0	0
Cyprus	0	0	0	0	0	0
Czech Republic	0	0	0	0	0	0
Denmark	0	0	0	0	0	0
Estonia	0	0	0	0	0	0
Finland	0	0	0	0	0	0
France	0	0	0	0	0	0
Germany	0	0	0	0	0	0
Greece	0	0	0	0	0	0
Hungary	0	0	0	0	0	0
Ireland	0	0	0	0	0	0
Italy	0	0	0	0	0	0
Latvia	0	0	0	0	0	0
Lithuania	0	0	0	0	0	0
Luxembourg	0	0	0	0	0	0
Malta	0	0	0	0	0	0
Netherlands	0	0	0	0	0	0
Poland	0	0	0	0	0	0
Portugal	0	0	0	0	0	0
Romania	0	0	0	0	0	0
Slovakia	0	0	0	0	0	0
Slovenia	0	0	0	0	0	0
Spain	0	0	0	0	0	0
Sweden	0	0	0	0	0	0
United Kingdom	0	0	0	0	0	0
TOTAL	0	0	0	0	0	0



Scenario	Baseline scenario (1) - Current (2005) employment and exposure levels are maintained					
Country	2010	2020	2030	2040	2050	2060
<i>Attributable Years of Life Lost (YLLs)</i>						
Austria	0	0	0	0	0	0
Belgium	0	0	0	0	0	0
Bulgaria	0	0	0	0	0	0
Cyprus	0	0	0	0	0	0
Czech Republic	0	0	0	0	0	0
Denmark	0	0	0	0	0	0
Estonia	0	0	0	0	0	0
Finland	0	0	0	0	0	0
France	0	0	0	0	0	0
Germany	0	0	0	0	0	0
Greece	0	0	0	0	0	0
Hungary	0	0	0	0	0	0
Ireland	0	0	0	0	0	0
Italy	0	0	0	0	0	0
Latvia	0	0	0	0	0	0
Lithuania	0	0	0	0	0	0
Luxembourg	0	0	0	0	0	0
Malta	0	0	0	0	0	0
Netherlands	0	0	0	0	0	0
Poland	0	0	0	0	0	0
Portugal	0	0	0	0	0	0
Romania	0	0	0	0	0	0
Slovakia	0	0	0	0	0	0
Slovenia	0	0	0	0	0	0
Spain	0	0	0	0	0	0
Sweden	0	0	0	0	0	0
United Kingdom	0	0	0	0	0	0
TOTAL	1	1	2	2	2	2

Scenario	Baseline scenario (1) - Current (2005) employment and exposure levels are maintained					
Country	2010	2020	2030	2040	2050	2060
	<i>Attributable Years of Life Lived with Disability (DALYs)</i>					
Austria	0	0	0	0	0	0
Belgium	0	0	0	0	0	0
Bulgaria	0	0	0	0	0	0
Cyprus	0	0	0	0	0	0
Czech Republic	0	0	0	0	0	0
Denmark	0	0	0	0	0	0
Estonia	0	0	0	0	0	0
Finland	0	0	0	0	0	0
France	0	0	0	0	0	0
Germany	0	0	0	0	0	0
Greece	0	0	0	0	0	0
Hungary	0	0	0	0	0	0
Ireland	0	0	0	0	0	0
Italy	0	0	0	0	0	0
Latvia	0	0	0	0	0	0
Lithuania	0	0	0	0	0	0
Luxembourg	0	0	0	0	0	0
Malta	0	0	0	0	0	0
Netherlands	0	0	0	0	0	0
Poland	0	0	0	0	0	0
Portugal	0	0	0	0	0	0
Romania	0	0	0	0	0	0
Slovakia	0	0	0	0	0	0
Slovenia	0	0	0	0	0	0
Spain	0	0	0	0	0	0
Sweden	0	0	0	0	0	0
United Kingdom	0	0	0	0	0	0
TOTAL	1	2	2	2	2	2

**Table 8.2.3:** Numbers and proportions of the EU population ever exposed, by industry, men plus women

Scenario	Baseline scenario (1) - Current (2005) employment and exposure levels are maintained					
Industry sector	2010	2020	2030	2040	2050	2060
<i>Number ever exposed in the REP</i>						
Manufacturing	134	135	135	135	135	135
Downstream use	2,493	2,514	2,514	2,514	2,514	2,514

Scenario	Baseline scenario (1) - Current (2005) employment and exposure levels are maintained					
Industry sector	2010	2020	2030	2040	2050	2060
<i>Proportion of the population exposed</i>						
Manufacturing	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
Downstream use	0.001%	0.001%	0.001%	0.001%	0.001%	0.001%

**Table 8.2.4:** Occupational attributable fractions, deaths, registrations, YLLs and DALYs for leukaemia by industry, men plus women

Scenario	Baseline scenario (1) - Current (2005) employment and exposure levels are maintained					
Industry sector	2010	2020	2030	2040	2050	2060
<i>Attributable Fraction</i>						
Manufacturing	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Downstream use	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%

Scenario	Baseline scenario (1) - Current (2005) employment and exposure levels are maintained					
Industry sector	2010	2020	2030	2040	2050	2060
<i>Attributable Deaths</i>						
Manufacturing	0	0	0	0	0	0
Downstream use	0	0	0	0	0	0

Scenario	Baseline scenario (1) - Current (2005) employment and exposure levels are maintained					
Industry sector	2010	2020	2030	2040	2050	2060
<i>Attributable Registrations</i>						
Manufacturing	0	0	0	0	0	0
Downstream use	0	0	0	0	0	0

Scenario	Baseline scenario (1) - Current (2005) employment and exposure levels are maintained					
Industry sector	2010	2020	2030	2040	2050	2060
<i>Attributable Years of Life Lost (YLLs)</i>						
Manufacturing	0	0	0	0	0	0
Downstream use	1	1	1	2	2	2

Scenario	Baseline scenario (1) - Current (2005) employment and exposure levels are maintained					
Industry sector	2010	2020	2030	2040	2050	2060
<i>Attributable Years of Life Lived with Disability (DALYs)</i>						
Manufacturing	0	0	0	0	0	0
Downstream use	1	1	2	2	2	2

### 8.3 SUPPLEMENTARY TABLES - COSTS UNDER THE BASELINE SCENARIO

**Table 8.3.1:** Health costs – baseline scenario – Member State breakdown - Based on a 4% discount rate

Low	Female	Male	Total	High	Female	Male	Total
Austria	€ 0.0	€ 0.0	€ 0.0	Austria	€ 0.0	€ 0.0	€ 0.0
Belgium	€ 0.0	€ 0.0	€ 0.0	Belgium	€ 0.0	€ 1.7	€ 1.7
Bulgaria	€ 0.0	€ 0.0	€ 0.0	Bulgaria	€ 0.0	€ 0.0	€ 0.0
Czech Republic	€ 0.0	€ 0.0	€ 0.0	Czech Republic	€ 0.0	€ 0.0	€ 0.0
Cyprus	€ 0.0	€ 0.0	€ 0.0	Cyprus	€ 0.0	€ 0.0	€ 0.0
Denmark	€ 0.0	€ 0.0	€ 0.0	Denmark	€ 0.0	€ 0.0	€ 0.0

937 – SHEcan 1,2-Epoxypropane

Low	Female	Male	Total	High	Female	Male	Total
Estonia	€ 0.0	€ 0.0	€ 0.0	Estonia	€ 0.0	€ 0.0	€ 0.0
Finland	€ 0.0	€ 0.0	€ 0.0	Finland	€ 0.0	€ 0.0	€ 0.0
France	€ 0.0	€ 0.5	€ 0.5	France	€ 0.0	€ 1.7	€ 1.7
Germany	€ 0.0	€ 0.4	€ 0.4	Germany	€ 0.0	€ 1.7	€ 1.7
Greece	€ 0.0	€ 0.0	€ 0.0	Greece	€ 0.0	€ 0.0	€ 0.0
Hungary	€ 0.0	€ 0.0	€ 0.0	Hungary	€ 0.0	€ 0.0	€ 0.0
Ireland	€ 0.0	€ 0.0	€ 0.0	Ireland	€ 0.0	€ 0.0	€ 0.0
Italy	€ 0.0	€ 0.0	€ 0.0	Italy	€ 0.0	€ 0.0	€ 0.0
Latvia	€ 0.0	€ 0.0	€ 0.0	Latvia	€ 0.0	€ 0.0	€ 0.0
Lithuania	€ 0.0	€ 0.0	€ 0.0	Lithuania	€ 0.0	€ 0.0	€ 0.0
Luxembourg	€ 0.0	€ 0.0	€ 0.0	Luxembourg	€ 0.0	€ 0.0	€ 0.0
Malta	€ 0.0	€ 0.0	€ 0.0	Malta	€ 0.0	€ 0.0	€ 0.0
Netherlands	€ 0.0	€ 0.4	€ 0.4	Netherlands	€ 0.0	€ 1.2	€ 1.2
Poland	€ 0.0	€ 0.3	€ 0.3	Poland	€ 0.0	€ 1.0	€ 1.0
Portugal	€ 0.0	€ 0.0	€ 0.0	Portugal	€ 0.0	€ 0.0	€ 0.0
Romania	€ 0.0	€ 0.2	€ 0.2	Romania	€ 0.0	€ 0.7	€ 0.7
Slovakia	€ 0.0	€ 0.3	€ 0.3	Slovakia	€ 0.0	€ 1.4	€ 1.4
Slovenia	€ 0.0	€ 0.0	€ 0.0	Slovenia	€ 0.0	€ 0.0	€ 0.0
Spain	€ 0.0	€ 0.3	€ 0.3	Spain	€ 0.0	€ 1.3	€ 1.3
Sweden	€ 0.0	€ 0.0	€ 0.0	Sweden	€ 0.0	€ 0.0	€ 0.0
United Kingdom	€ 0.0	€ 0.0	€ 0.0	United Kingdom	€ 0.0	€ 0.0	€ 0.0
<b>TOTAL</b>	€ 0.0	€ 2.5	€ 2.5	<b>TOTAL</b>	€ 0.0	€ 10.7	€ 10.7

**Table 8.3.2:** Health costs – baseline scenario – Industry group breakdown - Based on a 4% discount rate

<b>Low</b>	<b>Female</b>	<b>Male</b>	<b>Total</b>
Manufacturing	€ 0.0	€ 0.2	€ 0.1
Downstream use	€ 0.0	€ 2.9	€ 2.3
<b>TOTAL</b>	<b>€ 0.0</b>	<b>€ 3.1</b>	<b>€ 2.5</b>

<b>High</b>	<b>Female</b>	<b>Male</b>	<b>Total</b>
Manufacturing	€ 0.0	€ 0.6	€ 0.5
Downstream use	€ 0.0	€ 11.2	€ 8.9
<b>TOTAL</b>	<b>€ 0.0</b>	<b>€ 11.8</b>	<b>€ 9.4</b>

**Note:** Industry breakdown results may not equate exactly to Member State breakdown due to differences in underlying health data.

**Table 8.3.3:** Health costs – baseline scenario – Member State breakdown - Based on a declining discount rate

Low	Female	Male	Total	High	Female	Male	Total
Austria	€ 0.0	€ 0.0	€ 0.0	Austria	€ 0.0	€ 0.0	€ 0.0
Belgium	€ 0.0	€ 0.1	€ 0.1	Belgium	€ 0.0	€ 2.1	€ 2.1
Bulgaria	€ 0.0	€ 0.0	€ 0.0	Bulgaria	€ 0.0	€ 0.0	€ 0.0
Czech Republic	€ 0.0	€ 0.0	€ 0.0	Czech Republic	€ 0.0	€ 0.0	€ 0.0
Cyprus	€ 0.0	€ 0.0	€ 0.0	Cyprus	€ 0.0	€ 0.0	€ 0.0
Denmark	€ 0.0	€ 0.0	€ 0.0	Denmark	€ 0.0	€ 0.0	€ 0.0
Estonia	€ 0.0	€ 0.0	€ 0.0	Estonia	€ 0.0	€ 0.0	€ 0.0
Finland	€ 0.0	€ 0.0	€ 0.0	Finland	€ 0.0	€ 0.0	€ 0.0
France	€ 0.0	€ 0.6	€ 0.6	France	€ 0.0	€ 2.2	€ 2.2
Germany	€ 0.0	€ 0.5	€ 0.5	Germany	€ 0.0	€ 2.1	€ 2.1
Greece	€ 0.0	€ 0.0	€ 0.0	Greece	€ 0.0	€ 0.0	€ 0.0
Hungary	€ 0.0	€ 0.0	€ 0.0	Hungary	€ 0.0	€ 0.0	€ 0.0
Ireland	€ 0.0	€ 0.0	€ 0.0	Ireland	€ 0.0	€ 0.0	€ 0.0
Italy	€ 0.0	€ 0.0	€ 0.0	Italy	€ 0.0	€ 0.0	€ 0.0
Latvia	€ 0.0	€ 0.0	€ 0.0	Latvia	€ 0.0	€ 0.0	€ 0.0
Lithuania	€ 0.0	€ 0.0	€ 0.0	Lithuania	€ 0.0	€ 0.0	€ 0.0
Luxembourg	€ 0.0	€ 0.0	€ 0.0	Luxembourg	€ 0.0	€ 0.0	€ 0.0
Malta	€ 0.0	€ 0.0	€ 0.0	Malta	€ 0.0	€ 0.0	€ 0.0
Netherlands	€ 0.0	€ 0.5	€ 0.5	Netherlands	€ 0.0	€ 1.5	€ 1.5
Poland	€ 0.0	€ 0.4	€ 0.4	Poland	€ 0.0	€ 1.4	€ 1.4
Portugal	€ 0.0	€ 0.0	€ 0.0	Portugal	€ 0.0	€ 0.0	€ 0.0
Romania	€ 0.0	€ 0.3	€ 0.3	Romania	€ 0.0	€ 0.9	€ 0.9
Slovakia	€ 0.0	€ 0.4	€ 0.4	Slovakia	€ 0.0	€ 1.8	€ 1.8
Slovenia	€ 0.0	€ 0.0	€ 0.0	Slovenia	€ 0.0	€ 0.0	€ 0.0
Spain	€ 0.0	€ 0.5	€ 0.5	Spain	€ 0.0	€ 1.6	€ 1.6
Sweden	€ 0.0	€ 0.0	€ 0.0	Sweden	€ 0.0	€ 0.0	€ 0.0
United Kingdom	€ 0.0	€ 0.0	€ 0.0	United Kingdom	€ 0.0	€ 0.0	€ 0.0
<b>TOTAL</b>	€ 0.0	€ 3.2	€ 3.2	<b>TOTAL</b>	€ 0.0	€ 13.7	€ 13.7

**Table 8.3.4:** Health costs – baseline scenario – Industry group breakdown - Based on a declining discount rate

<b>Low</b>	<b>Female</b>	<b>Male</b>	<b>Total</b>
Manufacturing	€ 0.0	€ 0.2	€ 0.2
Downstream use	€ 0.0	€ 3.8	€ 3.8
<b>TOTAL</b>	<b>€ 0.0</b>	<b>€ 4.0</b>	<b>€ 4.0</b>

<b>High</b>	<b>Female</b>	<b>Male</b>	<b>Total</b>
Manufacturing	€ 0.0	€ 0.8	€ 0.6
Downstream use	€ 0.0	€ 14.3	€ 12.0
<b>TOTAL</b>	<b>€ 0.0</b>	<b>€ 15.0</b>	<b>€ 12.6</b>

**Note:** Industry breakdown results may not equate exactly to Member State breakdown due to differences in underlying health data.

**Table 8.3.5:** Summary

<b>Costs by Gender (€m)</b>	<b>2010-2019</b>	<b>2020-2029</b>	<b>2030-2039</b>	<b>2040-2049</b>	<b>2050-2059</b>	<b>2060-2069</b>
Female	0 to 0	0 to 0	0 to 0	0 to 0	0 to 0	0 to 0
Male	1 to 2	0 to 2	1 to 2	1 to 2	1 to 2	1 to 2
Total	1 to 2	0 to 2	1 to 2	1 to 2	1 to 2	1 to 2



**Table 8.3.6:** Health costs – baseline scenario – Member State breakdown - With no discounting

Low	Female	Male	Total	High	Female	Male	Total
Austria	€ 0.0	€ 0.0	€ 0.0	Austria	€ 0.0	€ 0.0	€ 0.0
Belgium	€ 0.0	€ 0.2	€ 0.2	Belgium	€ 0.0	€ 5.8	€ 5.8
Bulgaria	€ 0.0	€ 0.0	€ 0.0	Bulgaria	€ 0.0	€ 0.0	€ 0.0
Czech Republic	€ 0.0	€ 0.0	€ 0.0	Czech Republic	€ 0.0	€ 0.0	€ 0.0
Cyprus	€ 0.0	€ 0.0	€ 0.0	Cyprus	€ 0.0	€ 0.0	€ 0.0
Denmark	€ 0.0	€ 0.0	€ 0.0	Denmark	€ 0.0	€ 0.0	€ 0.0
Estonia	€ 0.0	€ 0.0	€ 0.0	Estonia	€ 0.0	€ 0.0	€ 0.0
Finland	€ 0.0	€ 0.0	€ 0.0	Finland	€ 0.0	€ 0.0	€ 0.0
France	€ 0.0	€ 1.6	€ 1.6	France	€ 0.0	€ 5.9	€ 5.9
Germany	€ 0.0	€ 1.6	€ 1.6	Germany	€ 0.0	€ 6.0	€ 6.0
Greece	€ 0.0	€ 0.0	€ 0.0	Greece	€ 0.0	€ 0.0	€ 0.0
Hungary	€ 0.0	€ 0.0	€ 0.0	Hungary	€ 0.0	€ 0.0	€ 0.0
Ireland	€ 0.0	€ 0.0	€ 0.0	Ireland	€ 0.0	€ 0.0	€ 0.0
Italy	€ 0.0	€ 0.0	€ 0.0	Italy	€ 0.0	€ 0.0	€ 0.0
Latvia	€ 0.0	€ 0.0	€ 0.0	Latvia	€ 0.0	€ 0.0	€ 0.0
Lithuania	€ 0.0	€ 0.0	€ 0.0	Lithuania	€ 0.0	€ 0.0	€ 0.0
Luxembourg	€ 0.0	€ 0.0	€ 0.0	Luxembourg	€ 0.0	€ 0.0	€ 0.0
Malta	€ 0.0	€ 0.0	€ 0.0	Malta	€ 0.0	€ 0.0	€ 0.0
Netherlands	€ 0.0	€ 1.4	€ 1.4	Netherlands	€ 0.0	€ 4.3	€ 4.3
Poland	€ 0.0	€ 1.2	€ 1.2	Poland	€ 0.0	€ 4.0	€ 4.0
Portugal	€ 0.0	€ 0.0	€ 0.0	Portugal	€ 0.0	€ 0.0	€ 0.0
Romania	€ 0.0	€ 0.8	€ 0.8	Romania	€ 0.0	€ 2.7	€ 2.7
Slovakia	€ 0.0	€ 1.2	€ 1.2	Slovakia	€ 0.0	€ 5.5	€ 5.5
Slovenia	€ 0.0	€ 0.0	€ 0.0	Slovenia	€ 0.0	€ 0.0	€ 0.0
Spain	€ 0.0	€ 1.3	€ 1.3	Spain	€ 0.0	€ 4.8	€ 4.8
Sweden	€ 0.0	€ 0.0	€ 0.0	Sweden	€ 0.0	€ 0.0	€ 0.0
United Kingdom	€ 0.0	€ 0.0	€ 0.0	United Kingdom	€ 0.0	€ 0.0	€ 0.0
<b>TOTAL</b>	€ 0.0	€ 9.2	€ 9.2	<b>TOTAL</b>	€ 0.0	€ 39.0	€ 39.0

**Table 8.3.7:** Health costs – baseline scenario – Industry group breakdown – With no discounting

<b>Low</b>	<b>Female</b>	<b>Male</b>	<b>Total</b>
Manufacturing	€ 0.0	€ 0.6	€ 0.6
Downstream use	€ 0.0	€ 10.6	€ 10.6
<b>TOTAL</b>	<b>€ 0.0</b>	<b>€ 11.2</b>	<b>€ 11.2</b>

<b>High</b>	<b>Female</b>	<b>Male</b>	<b>Total</b>
Manufacturing	€ 0.0	€ 2.2	€ 2.2
Downstream use	€ 0.0	€ 40.2	€ 40.2
<b>TOTAL</b>	<b>€ 0.0</b>	<b>€ 42.4</b>	<b>€ 42.4</b>

**Note:** Industry breakdown results may not equate exactly to Member State breakdown due to differences in underlying health data.

**Table 8.3.8:** Summary

<b>Costs by Gender (€m)</b>	<b>2010-2019</b>	<b>2020-2029</b>	<b>2030-2039</b>	<b>2040-2049</b>	<b>2050-2059</b>	<b>2060-2069</b>
Female	0 to 0	0 to 0	0 to 0	0 to 0	0 to 0	0 to 0
Male	1 to 3	1 to 4	1 to 5	2 to 7	2 to 9	3 to 12
Total	1 to 3	1 to 4	1 to 5	2 to 7	2 to 9	3 to 12

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