WORKING FOR A HEALTHY FUTURE

IOM Research Project: P937/12
May 2011

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

Ethylene Oxide

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SUMMARY

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.

1 PROBLEM DEFINITION

1.1 OUTLINE OF THE INVESTIGATION

Exposure to ethylene oxide (EO) in workplace air is associated with increased risks of leukaemia. Ethylene oxide has been classified as a group 1 carcinogen (Carcinogenic to humans) carcinogen by IARC based on the results of epidemiological and toxicological studies, supported with relevant mechanistic data[1]. It is classified as a Cat 2 carcinogen in the EU under the classification and labelling legislation[2]. It is therefore already regulated as a carcinogen throughout the EU. In this assessment we consider the impacts of introducing an OEL for ethylene oxide 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 ethylene oxide.

1.2 OELS/EXPOSURE CONTROL

Existing national occupational exposure limits (OELs) in EU member states are presented in Table 1.1. These values 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		OEL - STEL	
	ppm	mg/m³	ppm	mg/m³
Austria	1	2	4	8
Belgium	1	1.8	-	-
Denmark	1	1.8	2	3.6
France	1		5	-
Germany	-	-	-	-
Hungary	-	-	-	1.8
Italy	-	-	-	-
Poland	-	1	-	3
Spain	1	1.8	-	-
Sweden	1	2	5	9
The Netherlands	-	0.84	-	-
United Kingdom	5	9.2	-	-
Canada - Quebec	1	1.8	-	-
Japan	1	-	-	-
Switzerland	1	2	-	-
USA - OSHA	1	-	5	-

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

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

The long-term OELs from the EU member states and outside jurisdictions range from 1 – 5 ppm (1.8 – 9.2 mg/m^3). Austria, Denmark, France, Hungary and Sweden have STELs ranging from 1 – 5 ppm. For the purposes of this report an OEL of 1 ppm (1.8 mg/m^3) is considered typical for the EU and this is the value used for the impact assessment in this report.

1.3 DESCRIPTION OF DIFFERENT USES

Ethylene oxide is produced from the oxidation of ethylene by a direct vapour-phase oxidation process using a silver catalyst at 10 – 30 atm and 200 – 300 °C.[3]

Approximately a quarter of the worldwide production of ethylene oxide occurs in Europe. The 2008 IARC monograph on ethylene oxide reports that in 2004 the western European production volume was 2,840,000 tonnes and the eastern European production was 950,000 tonnes (Table 1.2). The western European production was all within EU countries; however, the eastern European countries that produce ethylene oxide were not reported and it unknown how much of the substance that was produced in Eastern Europe was produced within EU member states.[4]

Table 1.2 2004 Production of Ethylene Oxide

Region	Number of Producers	Production Volume (thousand tonnes)
Belgium	2	770
France	1	215
Germany	4	995
Netherlands	2	460
Spain	1	100
United Kingdom	1	300
Eastern Europe	Not Reported	950
Total	**>12**	**3790**

Source: IARC Monographs Volume 97: Ethylene Oxide (2008)

The majority of all ethylene oxide produced is used in the manufacture of ethylene oxide derivatives, which are used in the production of consumer goods. Over half of all ethylene oxide produced worldwide (43% in Europe) is used to manufacture ethylene glycols (including monoethylene glycol, polyethyene glycol, diethylene glycol and triethylene glycol). Monoethylene glycol is used as antifreeze and as a precursor to polymers; diethylene glycol is used in the production of polyurethanes, polyesters, softeners, and in gas drying; triethylene glycol is used in the manufacture of lacquers, solvents, and in gas drying; polyethylene glycols are used in cosmetics, ointments, pharmaceutical preparations, lubricants, solvents, and plasticizers. Ethylene oxide is also used in the manufacture of ethylene glycol ethers; ethanolamines; and ethoxylation products of fatty alcohols, fatty amines, alkyl phenols, cellulose and poly(propylene) glycol.[4]

The second largest outlet for ethylene oxide consumption is in surface active agents[5], primarily non-ionic alkylphenol ethoxylates (APEs) and detergent alcohol ethoxylates (AEs). Other minor uses include its application in the manufacture of rocket propellant

[3] IARC Monographs Volume 97: Ethylene Oxide (2008)
[4] IARC Monographs Volume 97: Ethylene Oxide (2008)
[5] ICIS (2008) *Ethylene Oxide Uses and Market Data*.

and petroleum demulsifiers. It is used for the control of insects in stored products and for the control of bacteria in spices and natural seasonings. Ethylene oxide is also present as a formulant or component of a formulant in pest control products at concentrations up to 0.4%.

About 0.05% of ethylene oxide produced is used in its gaseous form as a sterilizing agent for heat sensitive equipment (particularly for medical equipment and products, pharmaceuticals, and veterinary products), as a fumigant or as an insecticide.[6]

1.4 RISKS TO HUMAN HEALTH

1.4.1 Introduction

Occupational exposure to ethylene oxide compounds has been linked with increased risks for lymphatic and haematopoietic cancers and for cancers of the breast, stomach, pancreas and brain[7]. However, the strongest association is with leukaemia and it is this we focus on in this report.

There are four main types of leukaemia: acute lymphoblastic leukaemia (ALL), chronic myeloid leukaemia (CML), acute myeloid (AML) and chronic lymphocytic leukaemia (CLL), although the last two account for about two-thirds of all leukaemias diagnosed. Overall it is the 12th commonest occurring cancer accounting for about 2.6% of all cases diagnosed in the EU (Ferlay *et al*, 2007). There are roughly equal numbers of leukaemias diagnosed in men and women (Ferlay *et al*, 2007).

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).

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 also thought that leukaemia may be 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

The initial concern about the health risk of ethylene oxide was raised by studies in Sweden when a cluster of cancer cases was observed among ethylene oxide-exposed workers in 1979 (Hogstedt *et al*, 1979). The study investigated mortality and cancer incidence in a cohort of Swedish workers employed by a company producing ethylene

[6] IARC Monographs Volume 97: Ethylene Oxide (2008)

[7] Note, IARC now identify that lymphoid tumours (NHL, chronic lymphocytic leukaemia and multiple myeloma.) and breast cancers are linked to EO exposure (Baan *et al* (2009) A review of human carcinogens—Part F: Chemical agents and related occupations. Lancet Oncology; 10 (12): 1143-1144).

oxide since the 1940s. The cohort consisted of 241 men and was followed up between 1961 and 1977. A total of nine cancers were observed (SMR=2.65, 95%CI=1.12-5.02), of which two were from leukaemia (SMR=14.3, 95%CI=1.71-51.6). Among maintenance workers there was one leukaemia death (SMR=7.69, 95%CI=0.20-42.9). No leukaemia cases were seen among unexposed workers. Updates of the cohort increased the size to 733 exposed workers (Hogstedt *et al*, 1986, Hogstedt, 1988). In this analysis eight cases of leukaemia were observed, with 0.8 expected. This resulted in a SMR of 10.0 (95%CI=4.32-19.7).

A meta-analysis of a number of cohorts of ethylene oxide exposed workers (Shore *et al*, 1993) estimated a meta-SMR of 1.06 (95%CI=0.73-1.48), based on 31 leukaemia deaths among 29,800 workers. An update of this meta-analysis, including 17 studies of ten unique cohorts of nearly 33,000 exposed workers with more than 800 cancers found a total cancer meta-SMR of 0.94 (95%CI=0.85-1.05), and for leukaemia (based on 35 observed cases) of 1.08 (95%CI=0.61-1.93) (Teta *et al*, 1999). However, for leukaemia, if the Swedish studies of Hogstedt were removed then the meta-SMR was reduced to 0.95 (95%CI=0.64-1.35).

In an extended follow-up of a British cohort included in the meta-analysis Coggon *et al* (2004) investigated cancer risk among 2,876 men and women with definite or potential exposure to ethylene oxide in the chemical industry or in hospital sterilising units. The cohort was ascertained after 1956 from 12 different locations (four industrial manufacturers and eight sterilising units), and followed-up to the end of 2000. There were a total of 188 cancer deaths observed (SMR=1.02, 95%CI=0.88-1.18), 120 among chemical manufacturers (SMR=1.11, 95%CI=0.92-1.32) and 68 among hospital workers (SMR=0.90, 95%CI=0.70-1.14). There were only five leukaemia deaths (SMR=1.08, 95%CI=0.35-2.51), four among chemical manufacturers (SMR=1.41, 95%CI=0.39-3.62) and one in hospitals (SMR=0.55, 95%CI=0.01-3.06). Among the chemical workers all of the deaths were among workers with definite exposure to ETHYLENE OXIDE (SMR=2.29, 95%CI=0.62-5.85), and those in hospital were among workers with continual exposure (SMR=1.08, 95%CI=0.03-5.99).

In an update of the largest cohort, 18,235 workers were followed-up through 1998 (Steenland *et al*, 2004). In total there were 2,852 deaths, 860 from cancer (SMR=0.92, 95%CI=0.86-0.98). There were a total of 29 leukaemia deaths resulting in an SMR of 0.99 (95%CI=0.71-1.36). A negative exposure-response relationship was found reducing from an SMR of 1.15 (95%CI 0.55-2.11) for cumulative exposure 0-1199ppm-days to SMR 0.43 (95%CI 0.09-1.26) for cumulative exposure greater than 13500 days. However, internal analyses found positive trends for lymphohaematopoietic cancers which were limited to males (15-year lag). The trend was driven by lymphoid tumours (non-Hodgkin's lymphoma, myeloma, lymphocytic leukaemia).

1.4.3 Choice of risk estimates to assess health impact

Since the series of reports by Hogstedt and colleagues (1979, 1986) that raised concern about the potential for ethylene oxide to cause leukaemia there have been several studies in different countries varying in size, quality and results. Using results for the highest exposed groups from the study by Coggon *et al* (2004) a risk estimate of 1.08 has been used for medical workers and workers in research institutes and 2.29 for the manufacturing sectors. For those with low exposure an estimated relative risk of

1.0 has been used based on the meta-analysis by Teta *et al* (1999) excluding the Swedish studies.

2 BASELINE SCENARIOS

2.1 STRUCTURE OF THE SECTOR

Approximately a quarter of the worldwide production of ethylene oxide is in Europe. It is estimated that, in 2004, Western European production volume was 2.84 million tonnes and Eastern European production was approximately 0.95 million tonnes (although it is unclear what proportion of this is imported). It is estimated that that there are at least 12 plants producing ethylene oxide within the EU. Individual plant capacities are in the range of 100,000-995,000 tonnes per year.

2.2 PREVALENCE OF ETHYLENE OXIDE EXPOSURE IN THE EU

The prevalence of exposure to ethylene oxide was estimated from the Finnish CAREX estimate of 2007, the Spanish CAREX estimate of 2004 and the Italian CAREX estimate of 2000 – 2003 (Mirabelli and Kauppinen, 2005). The proportion of exposed workers in each industry was taken from each of these three CAREX estimates and the average proportion exposed across all three countries was found for each industry. The average proportion of exposed workers was applied to information on the number of employees in each industry obtained from the structural business statistics and the Labour Force Survey available on the Eurostat database.[8] The average proportion of exposed workers was multiplied by the number of workers employed in each industry in each country. For Finland, Spain, and Italy the proportion of exposed workers from their respective CAREX updates were used rather than the average proportion.

The number of employees in some industry groups and countries was not available on the Eurostat database. Where possible, missing data has been substituted with 2005 data for the applicable industry and country. When the 2005 data were also unavailable we have indicated that data were unavailable for the industry and country.

The estimated exposure prevalence for the EU member states based on 2006 employment data is shown in Table 2.1. Approximately 15,600 workers in the EU were potentially exposed to ethylene oxide in 2006.

The estimated number of male and female employees in each industry group in each EU member state is shown in Appendix 8.1. The estimates were obtained by applying the average male to female employee ratio for the industry group for each country to the total number of employees. Male to female employee ratios were calculated with data from the Labour Force Survey. Mangers, salespeople and office clerks were excluded from these calculations as they were assumed to be unexposed.

[8] Eurostat Database Available at: http://epp/ec/europa.eu/

Table 2.1 Number of workers exposed to ethylene oxide by country and NACE code

	NACE CODE								
Country	**15**	**17**	**24**	**33**	**73**	**75**	**80**	**85**	**Grand Total**
Austria	8	1	21	3	5	5	22	191	257
Belgium	10	3	55	2	6	8	37	274	396
Bulgaria	11	3	21	1	0	4	21	90	153
Cyprus	1	0	1	0	0	1	2	8	13
Czech Republic	NK[1]	5	33	7	6	7	28	179	264
Denmark	NK	1	24	4	6	3	21	281	339
Estonia	2	1	2	0	0	1	6	22	34
Finland	0	1	7	0	0	6	0	178	192
France	NK	8	217	27	42	48	176	1665	2183
Germany	82	10	362	65	94	58	206	2285	3162
Greece	9	2	14	0	9	8	30	115	186
Hungary	12	2	25	4	6	6	31	155	242
Ireland	NK	0	20	5	2	2	13	116	158
Italy	0	0	0	0	58	0	152	0	210
Latvia	4	1	3	0	1	2	9	29	48
Lithuania	5	2	5	1	1	2	13	61	89
Luxembourg	NK	NK	1	0	NK	0	1	11	14
Malta	NK	NK	NK	NK	NK	0	1	6	8
Netherlands	13	1	50	5	34	11	53	715	883
Poland	45	8	85	10	4	18	112	485	768
Portugal	11	8	17	1	1	7	31	187	263
Romania	21	7	39	3	23	10	41	221	364
Slovakia	NK	1	10	1	4	3	16	87	124
Slovenia	2	1	11	1	3	1	7	32	59
Spain	78	8	262	18	13	12	105	1533	2030
Sweden	NK	1	34	5	NK	5	48	416	510
United Kingdom	44	8	169	22	103	41	251	1980	2618
TOTAL	356	83	1489	190	424	269	1433	11323	15567

[1] NK = Not Known

Classification of Industries by Exposure Level

Industries in which exposure to ethylene oxide occurs have been classified as having high or low exposure based on an evaluation of the peer-reviewed literature, information from industry and expert judgement. The industries, grouped by NACE code were identified from the CAREX data. The exposure classification by industry is presented in Table 2.2.

Although only a small percentage of the total volume of ethylene oxide produced is used in the sterilization of equipment (especially medical equipment) the majority of ethylene oxide exposure occurs within the health care industry because other uses are mainly in totally enclosed processes. Ethylene oxide is highly explosive and reactive and so during its manufacture the processes take place within closed, tightly controlled automated systems meaning that exposures within these manufacturing processes occur infrequently and generally at low levels. When exposure to ethylene oxide does occur within the chemical manufacturing industry it is generally during loading or unloading of transport tanks, product sampling, or equipment maintenance.[9]

Table 2.2 Classification of industries by exposure level

Industry	NACE (rev 1.1)	Historical Exposure Classification[1]	Exposure classification in 1990	Number of People Exposed 2006[2]
Extraction of crude petroleum and natural gas; service activities incidental to oil and gas extraction, excluding surveying	11	Low	Low	0
Manufacture of Food Products	15	Low	Low	356
Manufacture of Textiles	17	Low	Low	83
Manufacture of chemicals and chemical products	24	Medium	Low	1489
Manufacture of medical, precision and optical instruments, watches and clocks	33	High		190
Research and Development	73	High	Low	424
Public Administration and Defence	75	High	Low	269
Education	80	High	Low	1433
Health and Social Work	85	High	Low	11323
Total				**15567**

[1] Relevant to 1975 Exposure Levels – from the early 1980s all groups would be "Low"
[2] Prevalence estimation methods are described at the beginning of this section.

2.3 LEVEL OF EXPOSURE TO ETHYLENE OXIDE

2.3.1 Estimation of exposure levels

No ethylene oxide exposure data were available from industry. The peer-reviewed scientific literature was reviewed for ethylene oxide occupational exposure data and the available exposure data for the three main uses of ethylene oxide are outlined below.

Chemical manufacturing (NACE 24)

No recent ethylene oxide exposure data in the chemical manufacturing industry are available. The World Health Organization Concise International Chemical Assessment Document (CICAD) on ethylene oxide has reported that due to the highly explosive and reactive nature of ethylene oxide it is tightly enclosed in automated systems during its manufacture.[10] Exposures can occur during loading or unloading of transport tanks, product sampling procedures, and equipment maintenance and repair but these

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[9] World Health Organization (2003) Concise International Chemical Assessment Document 54 (Ethylene Oxide)
[10] World Health Organization (2003) Concise International Chemical Assessment Document 54 (Ethylene Oxide)

exposures are intermittent and, in many cases, respiratory protective equipment is used during these tasks (Currier *et al*, 1984). It is therefore likely all workers in the chemical manufacturing industry in the EU who are potentially exposed to ethylene oxide are exposed at eight hour time-weighted average (TWA) concentrations well below 1 ppm.

In a 1989 study of 1,470 workers with potential ethylene oxide exposure in four UK manufacturing companies that produce and/or use ethylene oxide, Gardner *et al* (1989) reported that since 1977 long-term exposure concentrations have been less than 5 ppm in the majority of jobs and below 1 ppm in many jobs. Geometric mean exposure levels were not reported in the study. The IARC monograph on ethylene oxide includes a summary of exposure data since the 1940's.[11] The European data are presented in Table 2.3. This data suggests that typical TWA geometric mean exposures have been below 1 ppm since the 1980s in many facilities.

Table 2.3 European Ethylene Oxide exposure data summary – Chemical Manufacturing

Country	Year of Sampling	Duration of Sampling	Personal or Area	Range (ppm)	Geometric Mean
Sweden	1941 - 1947	Not Reported	Not Reported	<13.9	Not Reported
Sweden	1948 - 1963	Not Reported	Not Reported	5.6 - 27.0	Not Reported
Germany	1978 - 1979	2 hours	Not Reported	<5	Not Reported
Netherlands	1974 - 1981	8 hours	Personal	<0.05 - 8 .0	<0.01 (1974, 1978 and 1980) 0.12 (1981)
Sweden	1963 - 1982	8 hours	Personal	5.0 - 8.0	Not Reported
Sweden	1977 - 1982	8 hours	Personal	1.0 - 2.0	Not Reported
Czechoslovakia	1982 - 1984	Not Reported	Not Reported	0 - 4.6	Not Reported

Note: Each study was conducted in one facility. The number of samples taken per study were not reported
Source: IARC Monographs Volume 97: Ethylene Oxide (2008)

Industrial Sterilization (NACE 33)

No recent data are available for exposure to ethylene oxide during industrial sterilization; however, the available data again suggest that workers are not exposed to ethylene oxide above long-term average concentrations of 1 ppm. Hornung *et al* (1994) developed a multiple regression model to retrospectively assess exposure to ethylene oxide in the industrial sterilization industry. The model was built using data from twenty US facilities where ethylene oxide was used in sterilization and was validated using measurement data that were not used in the development of the model,

[11] IARC Monographs Volume 97: Ethylene Oxide (2008)

and estimated exposure levels from a panel of 11 industrial hygienists from the sterilization industry. The model was found to explain 90% of the variation in ethylene oxide exposure data and it demonstrated that exposure levels dropped rapidly after 1979 when ethylene oxide was identified as a potential carcinogen and control measures such as local exhaust ventilation, enclosure, and recirculation of exhausted ethylene oxide gas were introduced. Prior to 1979 typical ethylene oxide concentrations in the sterilization industry were over 4 ppm and by 1986 typical exposure levels had decreased to below 0.5 ppm. Hagmar *et al* (1991) reported that measurements taken from two Swedish sterilization facilities indicated that between 1970 and 1885 exposures decreased from 35 – 40 ppm to <0.2 – 0.75 ppm among workers involved in sterilization and packing; from 5 – 20 ppm to <0.2 ppm among store workers and development engineers and from 1 – 4 ppm to <0.2 ppm among other workers. The sharp reduction in ethylene oxide exposures in the sterilization industry described by Hornung *et al* (1994) is likely representative of exposures in Europe as well as in the United States.

Hospital sterilization (NACE 73, 75, 80, 85)

Of all the industries in which ethylene oxide exposure occurs, exposures have typically been highest in hospital sterilization.[12] However they are typically short-term and over a full work shift average exposures have been similar to those seen in other industries. Exposures can occur when valves or sterilizer door gaskets leak, when the sterilizer door is opened at the end of a cycle, during improper ventilation of the sterilizer, during changing of pressurized ethylene oxide gas cylinders, or during removal of a sterilized load.

Recent exposure data suggests that ethylene oxide exposures in hospitals are generally controlled below 1 ppm. A French study of two sterilization units reported eight hour time-weighted average concentrations of 0.03 – 0.4 ppm from five area samples placed in the breathing zone beside sterilizers between 1988 and 1995 (Sobaszek *et al*, 1999). LaMontagne *et al* (2004) analysed 87,852 eight-hour personal exposure samples from 2,265 hospitals in the US and found that in 1988 21% of hospitals recorded samples that exceeded an eight hour TWA exposure level of 1 ppm one or more times per year. By 2001 only 0.09% of hospitals exceeded an eight hour TWA of 1 ppm once or more (LaMontagne *et al*, 2004). This decline was attributed to the implementation by the Occupational Safety and Health Administration (OSHA) of a short-term excursion limit of 5 ppm in 1988 and an eight hour TWA exposure limit of 1 ppm in 1984. Although not all EU member states currently have TWA exposures limits of 1 ppm, it is likely that ethylene oxide exposures are maintained below 1 ppm in EU hospitals to reduce the risk of explosion or combustion.

A 1989 report by the US Department of Health and Human Services, National Institute for Occupational Safety and Health (NIOSH) on the control of ethylene oxide during hospital sterilization concluded that hospital sterilizers can be controlled to maintain TWA exposures below 0.1 ppm (Mortimer and Kercher, 1989). It was also reported that three emission sources account for most of the ethylene oxide released from sterilizers: (1) ethylene oxide is released from an air gap a the connection of the drain to the outlet of the vacuum pump; (2) ethylene oxide can be released when the

[12] World Health Organization (2003) Concise International Chemical Assessment Document 54 (Ethylene Oxide)

sterilizer door is opened at the completion of the sterilization cycle; and (3) exposure can occur when the operator transfers the sterilization load from the sterilizer to the aerator. Although the controls required will vary between sterilizers (due to differences in load, sterilization duration, location of sterilizer and other factors) the authors of the report suggest that in-chamber aeration substantially eliminates exposure and is the most effective control measure. If in-chamber aeration is not possible, local exhaust ventilation above the sterilizer door and around the sterilizer drain are recommended as the next most effective controls (Mortimer and Kercher, 1989).

2.3.2 Temporal change in exposure

The IARC monograph on ethylene oxide includes a summary of exposure data available from the 1980's.[13] The European data are presented in Table 2.4. The measured concentrations range widely from measurements ranging from 0 – 0.1 ppm taken from 24 sites in Finland in 1981 to 19 samples taken from six Italian sites (prior to 1984) where leaking sterilizers were used ranging from 3.7 – 20.0 ppm.

Table 2.4 European Ethylene Oxide historical exposure data summary – hospital sterilization

Country	Year of Sampling	Number of Sites	Job or operation	Duration of sampling (hours)	Number of samples	Concentration (ppm)	
						Range	Mean
Finland	1981	24	Sterilizer operators	8	NR	0 – 0.1	
France	NR [1] (published 1983)	4	Sterilizer operators	6 - 8	14	0.1 – 5	
Belgium	NR (published 1983)	3	Sterilizer operators	8	28	0.2 – 2.5	0.28 – 1.61
Belgium	NR (published 1983)	1	Sterilizer operators (leaking equipment)	8	16	0.3 – 18.3	7.8
Italy	NR (published 1984)	6	Sterilizer operators (old sterilizers)	8	19	3.7 – 20.0	10.7
		6	Sterilizer operators (new sterilizer)	8	NR	0.2 – 0.5	0.35
Italy	NR (published 1985)	1	Sterilization operators	8	10	1.1 – 2.6	
Czechoslovakia	1984	1	Sterilization operators	8	NR	0 – 2.7	
Italy	NR (published 1987)	2	Sterilization operators	7 - 8	4	6.4 – 9.3	7.9
Italy	NR (published 1991)	5	Sterilization operators	6.5	5	0.38	

[1] NR = Not Reported

The data demonstrate that exposures below 1 ppm have been achieved in many European hospitals since the 1980's. Based on the data presented in Table 2.4 it is not

[13] IARC Monographs Volume 97: Ethylene Oxide (2008)

possible to estimate the average exposure levels in the EU in the 1980's however it was likely in the range of 1 – 5 ppm.

2.4 HEALTH IMPACT FROM CURRENT EXPOSURES

2.4.1 Background data

The occupational cancers associated with exposure to ethylene oxide are shown in Table 2.5 along with a summary of the information used in the health impact assessment.

Table 2.5 Occupational cancers associated with exposure to ethylene oxide

Cancer site	Leukaemia	
ICD-10 code	C91-C95	
IARC group for carcinogen	1	
Strength of evidence for cancer site (1)	Strong	
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[14]	
Exposure levels	***Relative Risk (RR)***	***Source of RR***
"High"	2.29 (0.62, 5.86)	Coggon *et al* (2004)
"Medium"	1.08 (0.03, 6.02)	Coggon *et al* (2004)
"Low"	0.95 (0.64, 1.35), set to 1	Teta *et al* (1999)

(1) Based on Siemiatycki *et al*, 2004

2.4.2 Exposed numbers and exposure levels

Industry sectors, their NACE codes, classifications to High/Medium/Low/Background exposure as applicable for about 1975 plus classifications for the mid-1990's and numbers exposed in 2006 are given in Table 2.2 in the previous section on the exposure.

There is insufficient exposure measurement data to estimate a mean (GM) or GSD, and no change in exposure levels during the risk exposure period is assumed. However, all exposed groups are classified as having "Low" exposure from the 1980s onwards. Forecasts of attributable numbers were based on the baseline assumption of no change to current exposure levels or exposed numbers, and an assumption of full compliance to a standard of 1ppm (1.8 mg/m^3).

2.4.3 Forecast cancer numbers

Around 2,000 there were probably about 5 deaths from leukaemia and 8 cancer registrations per year attributed to occupational exposure to ethylene oxide prior to about the early 1980s. This would have corresponded to an attributable fraction of about 0.01% There would have been about 75 Years of Life Lost (YLLs) each year and about 82 Disability Adjusted Life Years (DALYs) per year.

[14] IARC, GLOBOCAN database, available at: http://www-dep.iarc.fr/globocan/database.htm

From 2010 onwards there are no deaths or registrations for leukaemia that are attributed to occupational ethylene oxide exposure.

2.5 POSSIBLE COSTS ASSOCIATED WITH NOT MODIFYING THE DIRECTTIVE

2.5.1 Health impacts – possible costs under the baseline scenario

The health data (cancer registrations and Years of Life Lost - 'YLL') for the baseline scenario in which there are no further modifications to the Carcinogens Directive (i.e. no introduction of an EU wide OEL) are described in section 2.4 of this report. The data predicts there to be zero cancer registrations and zero YLLs from leukaemia resulting from future exposure to ethylene oxide. Therefore we conclude that there is no cancer risk for ethylene oxide and hence no health impacts.

3 POLICY OPTIONS

3.1 DESCRIPTION OF MEASURES

Existing national 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. OELs in countries outside the EU are also presented for information. The long term OELs from the EU member states and outside jurisdictions range from one to 5 ppm (1.8 – 9.28 mg/m^3). From this it can be concluded that the typical OEL in the EU level is set at 1ppm.

This report looks at the impact of the potential implementation of an EU-wide OEL at 1 ppm (1.8 mg/m^3).

Examples of control measures to reduce exposure to ethylene oxide are summarised in Table 3.1.

Table 3.1 General measures to reduce exposure to ethylene oxide

Organisational measures	Personnel measures	Technical measures
ethylene oxide production and ethoxylation industry sectors[15]		
Improvement of storage facilities to reduce fugitive emissions	Use of personal protective equipment (PPE)	Use of rupture disks to minimise low-leave leakage from pressure relief devices
Install suitable loading/ unloading equipment to reduce fugitive emissions.	Use of respiratory protective equipment (RPE)	Use of chemical scrubbers
Implement closed sampling devices at process sampling locations		Implement a Leak Detection and Repair (LDAR) programme
Install explosion-proof equipment		

[15] Personal communication with Lesni Equipment Company, September 2009.

Organisational measures	Personnel measures	Technical measures
ethylene oxide production and ethoxylation industry sectors[15]		
Sterilisation (Mortimer and Kercher, 1989)		
Install liquid/gas separation units to prevent fugitive emissions during chamber evacuation	Use of personal protective equipment (PPE)	Adequate local exhaust ventilation (LEV) around the steriliser door and steriliser drain
	Use of respiratory protective equipment (RPE)	In-chamber aeration

Consultation with Lesni, a manufacturer of ethylene and propylene oxide abatement equipment, has revealed that the majority of ethylene oxide exposure occurs during sterilisation operations[16]. Although the highest volume of ethylene oxide is used in the production of glycols (and other chemicals) processes generally take place within closed, tightly controlled automated systems meaning that exposures occur infrequently (this use is as an 'intermediate' in chemical synthesis, an activity which typically has low associated levels of exposure).

According to the IARC, a "very small proportion (0.05%) of the annual production of ethylene oxide is used directly in the gaseous form as a sterilizing agent, fumigant and insecticide, either alone or in non-explosive mixtures with nitrogen, carbon dioxide or dichlorofluoromethane. Ethylene oxide is also used as a fumigant and sterilant for microbial organisms in a variety of applications. An estimated [4-5 million tonnes] of ethylene oxide were used in 2002 to sterilise drugs, hospital equipment, disposable and reusable medical items, packaging materials, foods, books, museum artefacts, scientific equipment, clothing, furs, railcars, aircraft, beehives and other items[17]" In particular, health care workers may be at risk of exposure to ethylene oxide during sterilisation of a variety of products, such as medical equipment and products (surgical products, single-use medical devices, etc.), disposable health care products, pharmaceutical and veterinary products.[18]

These uses, and releases associated with the sterilisation process, are assumed to be the main source of human exposure to ethylene oxide and thus the main areas affected by occupational exposure controls. The two most important ethylene oxide sterilization methods are:

1. the gas chamber method; and
2. the micro-dose method.

Traditionally, ethylene oxide is delivered by flooding a large chamber with a combination of ethylene oxide and other gases used as dilutants (such as HCFCs, HFCs or carbon dioxide). Three key sources of emissions from these sterilisers have been identified (Mortimer and Kercher, 1989):

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[16] Personal communication with Lesni Equipment Company, September 2009.
[17] Lacson, J. (2003) CEH Marketing Research Report — Ethylene Oxide, Zurich, SRI Consulting
[18] IARC (1994). Some Industrial Chemicals. IARC Monographs on the Evaluation of Carcinogenic Risk of Chemicals to Humans, vol. 60. Lyon, France: International Agency for Research on Cancer. 560 pp

1. emissions released from an air gap at the connection of the drain to the outlet of the vacuum pump;
2. emissions released when the steriliser door is opened; and
3. emissions when the operator transfers the sterilisation load from the steriliser to the aerator.

It has been suggested that the implementation of improved equipment reduces occupational exposure levels to below 1 ppm.

4 ANALYSIS OF IMPACTS

4.1 HEALTH IMPACTS FROM CHANGES TO THE EU DIRECTIVE

4.1.1 Health information

It is judged that with current technology and uses of ethylene oxide, EU industry is in compliance with the proposed OEL. Therefore there are no additional health benefits that will accrue form the introduction of an OEL at 1ppm (1.8 mg/m^3).

4.1.2 Monetised health benefits

As set out in the exposure assessment section, the main uses where there has historically been greatest potential for exposure now appear to be associated with occupational exposure that is lower than the level at which an OEL has been considered (1ppm):

- For industrial sterilisation, the available data again suggests that workers are not exposed above TWA concentrations of 1 ppm. A sharp reduction in ethylene oxide exposures in the sterilization industry occurred, with exposure dropping off rapidly after 1979 when ethylene oxide was identified as a potential carcinogen and control measures such as local exhaust ventilation, enclosure, and recirculation of exhausted ethylene oxide gas were introduced.
- In relation to hospital sterilisation (where exposure has historically been highest), recent exposure data suggests that ethylene oxide exposures in hospitals are generally controlled below 1 ppm. Although not all EU member states currently have TWA exposure limits of 1 ppm, it is likely that ethylene oxide exposures are maintained below 1 ppm in EU hospitals to reduce the risk of explosion or combustion.

Given the above, it is concluded – based on the exposure assessment – that there would be no additional health benefit in terms of reduced cancer incidence through introduction of an EU-wide OEL at the level at which most national-level OELs are currently set (1ppm).

4.2 ECONOMIC IMPACTS

4.2.1 Operating costs and conduct of business

Compliance costs

According to the literature, workers exposed to ethylene oxide will be those involved in: chemical manufacturing, industrial sterilisation and hospital sterilisation. It is estimated that there were approximately 15,600 workers potentially exposed to ethylene oxide in Europe in 2006.

The exposure data presented in Section 2.3 indicated that:

- In the chemical manufacturing industry it is likely that all workers who are potentially exposed to ethylene oxide are exposed to concentrations well below 1ppm.
- In the industrial sterilisation industry workers are not exposed above long-term (8-hr) average concentrations of 1ppm.
- In hospital sterilisation ethylene oxide exposures are generally controlled below 1ppm.

Based on exposure data, it is reasonable to make the following observation (assumption):

- Given that affected industries already have exposures that are less than 1ppm it is likely that most enterprises in Europe are complying, or could fairly easily comply, with a limit of 1ppm. Therefore it is assumed there will not be a significant cost to achieve the 1ppm OEL.

Control measures and best practice measures described above are required in order to maintain ethylene oxide exposures below 1ppm. According to experts, in-chamber aeration is recommended as the most effective control measure for reducing ethylene oxide exposure in hospital sterilisation procedures. If in-chamber aeration is not possible, local exhaust ventilation above the steriliser door and around the steriliser drain are recommended as the next most effective controls (Mortimer and Kercher, 1989). Cost data for ventilation units are based on estimates from ventilation suppliers. Because ethylene oxide is highly explosive, ventilation systems must be of maximum explosion-proof design[19]. The range of costs is shown in Table 4.1.

[19] Ethylene Oxide Material Safety Data Sheet. Available at: http://www.balchem.com/images/pdfs/EOMSDS.pdf

Table 4.1 Capital costs per enterprise for ventilation units for stationary machinery

	Stationary Machinery
Capital Cost ('000)	€42 – 252
Annual Maintenance ('000)	€1
Annual Testing ('000)	€1-5
Filters changes every 5 years ('000)	€3
Total annualised cost* ('000)	€5.7 - 25

Notes: It is assumed that ventilation equipment last for 20 years and filters last 5 years. Costs are based on a 4% discount rate as recommended by the EC IA guidelines (2009)

As set out in the exposure assessment section, it is measures such as this (enclosure and LEV) that have allowed exposure levels to be reduced in industrial sterilisation to below 1ppm.

In a case study conducted at Mary Hitchcock Memorial Hospital in Maryland, United States, total annualised costs of ethylene oxide sterilisation equipment are estimated at approximately €38,500. These costs are shown in Table 4.2.

Table 4.2 Costs of emissions control for ethylene oxide sterilisation equipment at Mary Hitchcook Memorial Hospital[20]

	Costs (€)[3]
Capital costs	
New emission control equipment for existing EO unit ('000)	23.5
Renovation and construction ('000)	18.8
2 Sterrad units ('000) [1]	200
Annual Operating Costs	
Emissions control ('000)	9
Spill response and staff training ('000)	5
Alarm system maintenance, testing, EO monitoring ('000)	5
Sterrad operating costs ('000)	2
TOTAL ANNUALISED COST[2] ('000)	**38.55**

Notes:
[1] Because EO operations are limited to one load per day, the addition of two non-EO are required to meet the sterilization needs of the hospital
[2] It is assumed that emissions control equipment and Sterrad units last for 20 years. Costs are based on a 4% discount rate as recommended by the EC IA guidelines (2009)
[3] Historic FX have been applied to convert original currency (USD) into Euros (rate: 1.06106) and are presented in 2002 prices.

However, it is assumed that there would be no compliance costs associated with introducing an EU-wide OEL at 1ppm, given that the evidence presented above suggests that exposure is already controlled to below this level.

Conduct of employers

The introduction of an EU-wide OEL of 1ppm may require certain companies to reorganise their workplace to ensure that exposure to ethylene oxide emissions is

[20] USEPA (2002) 'Replacing Ethylene Oxide and Glutaraldehyde', *JCAHO Environment of Care Standards'*

minimised. There may also be additional training and authorisation of personnel handling the substance required to ensure that employees minimise their exposure by adhering to good practice in order to reducing exposure (e.g. good personal hygiene, wearing protective clothing, 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 the OEL because no substantial compliance costs are likely to be incurred.

Potential impacts for specific types of companies

There are not expected to be any particular impacts for specific types of companies, since there are not expected to be any additional costs of meeting an OEL of 1ppm relative to the baseline scenario or any other substantial changes to companies' operations.

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 4.3 Administrative burdens to employers

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

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

The following table (Table 4.4) 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 4.4 Administrative burdens to Competent Authorities

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

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

Third Countries

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

As shown in Table 1.1 some non-EU countries have a pre-existing OEL in place. A harmonised EU-wide OEL may encourage other countries outside the EU to implement an OEL into national legislation.

4.2.2 Impact on innovation and research

Impacts on innovation and research from introducing an EU-wide OEL of 1ppm are estimated to be minimal. However, there is evidence that some hospitals are considering replacing ethylene oxide sterilisation units with non-ethylene oxide alternatives[21]. Alternative technologies to ethylene oxide under development for use in healthcare facilities include vaporised hydrogen peroxide, vapour phase peracetic acid, gaseous chlorine dioxide, ionizing radiation or pulsed light[22]. The development of alternatives may have benefits for research and development.

4.2.3 Macroeconomic impact

World consumption of ethylene oxide in 2007 was 19.9 million tonnes. Approximately 15% of this was consumed in the EU (2.95 million tonnes). Imports and exports of

[21] USEPA (2002) 'Replacing Ethylene Oxide and Glutaraldehyde', *JCAHO Environment of Care Standards'*

[22] CDC (2008) 'Guideline for Disinfection and Sterilisation in Healthcare Facilities'. Available at: www.cdc.gov/ncidod/dhqp/.../guidelines/Disinfection_Nov_2008.pdf

ethylene oxide are reportedly negligible due to its explosive nature. Ethylene oxide demand is expected to grow at around 5% per year globally during 2009-2014[23]. Good growth is expected in its two largest end uses, ethylene glycols and surface-active agents with growth slowest in consumption for glycol ethers and rapid growth expected for use in ethanolamines. However, there is some concern that planned increases in production capacity will outpace demand growth in the 2008-2011 period, leading to some overcapacity[24].

In the event that additional exposure controls are required, short-term spending on risk management measures may be good for the economy as equipment manufacturers (ventilation systems, equipment to support leak detection and repair), 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 research and development, meaning the wider economy would not benefit from increased spending). However, since it is expected that exposure is already being controlled to a level below the possible OEL of 1ppm, it is likely in practice that there would be no need for any further implementation of these risk management measures. Therefore, there are not expected to be any macroeconomic impacts relative to the baseline scenario from introducing an EU-wide OEL at 1ppm.

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

The majority of ethylene oxide is used in the production of MEG. This is not expected to change from the introduction of an EU-wide OEL relative to the baseline scenario.

4.4 ENVIRONMENTAL IMPACTS

Information reported in the CICAD for ethylene oxide[25] reports that ethylene oxide has a vapour pressure of 146kPa at 20^{o}C, a log K_{ow} of -0.30 and is infinitely soluble in water. Owing to its high vapour pressure, a spill of ethylene oxide to soil will result in most volatilising to the atmosphere, with only a small fraction infiltrating the soil. Evaporation will continue within the soil, but at a reduced rate. Ethylene oxide is expected to hydrolyse and be biodegraded relatively rapidly in most soils (half-lives for hydrolysis in groundwater and soil are estimated to be between 10.5 and 11.9 days) and have a low bioaccumulation potential.

Release of ethylene oxide to the atmosphere is unlikely to result in transfer to other environmental compartments in significant quantities. Reaction half-lives in the

[23] SRI Consulting (2010) *Ethylene Oxide*. Available at: http://www.sriconsulting.com
[24] ICIS (2008) *Ethylene Oxide Uses and Market Data*.
[25] WHO (2003) Concise International Chemical Assessment Documents (CICADs) 54: *Ethylene Oxide.* Available at: http://www.inchem.org/documents/cicads/cicads/cicad54.htm

atmosphere may be relatively long (between 38 and 382 days). Although water solubility suggests that washout from the atmosphere by precipitation could be important, its high vapour pressure and rapid volatilisation rate limit the effectiveness of this process.

Information on the toxicity of ethylene oxide to natural aquatic and terrestrial organisms is limited. Ethylene oxide hydrolyses to ethylene glycol in aqueous environments. Ethylene oxide is slightly toxic to marine invertebrates. The estimated value for algae LC_{50} (48hr) is 196mg/L for *Daphnia magna* and 490-1000 mg/L for brine shrimp (*Artemia salinia*). Fish are the most susceptible aquatic organisms to ethylene oxide and its main degradation product in saline water, 2-chloroethanol, which is also toxic. The estimated value for LC_{50} (96hr) for the fathead minnow (*Pimephales promelas)* is 57-84 mg/L and for the goldfish (*Carassis auratus)* is 90mg/L. It does not have a tendency to bioaccumulate.

There is no harmonised classification or labelling of ethylene oxide at EU level in relation to environmental effects (under Regulation (EC) No 1272/2008).

Ethylene oxide is, however, a volatile organic compound which can contribute to the formation of ground-level ozone.

There are potentially some environmental impacts associated with ethylene oxide releases to the environment. However, based on the above information, it appears that controls on ethylene oxide in the workplace that would be needed to meet the possible OEL of 1 ppm have apparently already been implemented. It is therefore not expected that achievement of the OEL would lead to any significant change in releases to the environment or in associated environmental impacts.

5 COMPARISON OF OPTIONS

The main impacts of introducing a an OEL of 1ppm for Ethylene oxide that were discussed in section 4 are summarised in the tables below, which are broken down by the main types of impacts (economic, social, macroeconomic and environmental).

Table 5.1 Comparison of options

	Baseline Scenario		Introduce OEL=1ppm	
Type of impact	**Costs**	**Benefits**	**Costs**	**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.
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.
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
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.	
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.	

6 CONCLUSIONS

We estimate that around 2000 in the EU there were about 5 deaths each year from leukaemia and about 8 cancer registrations per year that might be attributable to workplace exposure to ethylene oxide before the early 1980s, which corresponds to about 0.012% of all leukaemia deaths. 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 from 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.

There are no predicted health benefits from setting an OEL at 1ppm and no significant additional costs for employers to comply with this limit. There are also no social or macro-economic costs associated with introducing an OEL at this level.

There are no significant environmental impacts foreseen.

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8 APPENDIX

8.1 ESTIMATED NUMBER OF EMPLOYEES IN EACH INDUSTRY GROUP – MEMBER STATE BREAKDOWN – MALES AND FEMALES

Table 8.1 Number of workers exposed to ethylene oxide by Member State and NACE code – males and females

	NACE CODE														
	15			17			24			33			73		
	Total	Male	Female	Total	Male	Female	Total	Male	Female	Total	Male	Female	Total	Male	Female
Austria	8	6	1	1	1	0	21	17	4	3	3	1	5	4	2
Belgium	10	8	2	3	3	1	55	45	11	2	1	0	6	4	2
Bulgaria	11	6	5	3	2	2	21	11	10	1	1	1	0	0	0
Cyprus	1	1	0	0	0	0	1	1	0	0	0	0	0	0	0
Czech Republic	Not Available[1]			5	3	2	33	21	11	7	5	3	6	4	2
Denmark	Not Available			1	1	0	24	17	6	4	3	1	6	4	2
Estonia	2	1	1	1	0	0	2	1	1	0	0	0	0	0	0
Finland	0	0	0	1	1	0	7	5	2	0	0	0	0	0	0
France	Not Available			8	6	2	217	167	50	27	21	6	42	28	14
Germany	82	64	18	10	8	2	362	282	80	65	51	14	94	60	34
Greece	9	7	2	2	1	0	14	11	3	0	0	0	9	5	4
Hungary	12	8	5	2	1	1	25	16	9	4	3	1	6	4	2
Ireland	Not Available			0	0	0	20	15	5	5	4	1	2	2	1
Italy	0	0	0	0	0	0	0	0	0	0	0	0	58	37	22
Latvia	4	2	1	1	0	0	3	2	1	0	0	0	1	1	1
Lithuania	5	3	2	2	1	1	5	3	2	1	0	0	1	0	0
Luxembourg	Not Available			Not Available			1	1	0	0	0	0	Not Available		
Malta	Not Available			Not Available			Not Available			Not Available			Not Available		
Netherlands	13	11	2	1	1	0	50	42	9	5	4	1	34	24	10
Poland	45	30	15	8	6	3	85	57	28	10	7	3	4	3	1
Portugal	11	6	4	8	4	3	17	10	7	1	1	1	1	1	1
Romania	21	11	9	7	4	3	39	21	18	3	2	1	23	15	8
Slovakia	Not Available			1	1	1	10	6	4	1	1	1	4	3	2

	NACE CODE														
	15			17			24			33			73		
	Total	Male	Female	Total	Male	Female	Total	Male	Female	Total	Male	Female	Total	Male	Female
Slovenia	2	1	1	1	1	0	11	7	4	1	1	0	3	2	1
Spain	78	61	17	8	6	2	262	204	58	18	14	4	13	9	5
Sweden	Not Available			1	1	0	34	27	8	5	4	1	Not Available		
United Kingdom	44	36	8	8	6	1	169	137	32	22	18	4	103	70	33
TOTAL	**356**	**260**	**95**	**83**	**58**	**25**	**1489**	**1127**	**363**	**190**	**144**	**46**	**424**	**278**	**146**

	NACE CODE											
	75			80			85			Total		
	Total	Male	Female	Total	Male	Female	Total	Male	Female	Total	Male	Female
Austria	5	3	2	22	6	15	191	46	146	257	86	171
Belgium	8	5	3	37	12	26	274	69	206	396	146	250
Bulgaria	4	3	1	21	7	15	90	24	66	153	54	99
Cyprus	1	0	0	2	1	2	8	2	5	13	6	8
Czech Republic	7	3	3	28	7	21	179	36	143	264	79	185
Denmark	3	2	1	21	9	12	281	50	230	339	86	253
Estonia	1	0	0	6	1	5	22	2	20	34	7	28
Finland	6	3	3	0	0	0	178	20	159	192	28	164
France	48	26	22	176	60	116	1665	400	1266	2183	707	1476
Germany	58	30	28	206	41	164	2285	434	1851	3162	970	2191
Greece	8	5	2	30	11	19	115	41	73	186	82	104
Hungary	6	3	3	31	8	24	155	37	118	242	80	163
Ireland	2	1	1	13	3	9	116	22	94	158	47	111
Italy	0	0	0	152	36	115	0	0	0	210	73	137
Latvia	2	1	1	9	2	7	29	5	24	48	12	36
Lithuania	2	1	1	13	2	11	61	9	52	89	19	70
Luxembourg	0	0	0	1	1	1	11	3	8	14	5	9
Malta	0	0	0	1	0	1	6	1	5	8	2	6

	NACE CODE											
	75			**80**			**85**			**Total**		
	Total	**Male**	**Female**	**Total**	**Male**	**Female**	**Total**	**Male**	**Female**	**Total**	**Male**	**Female**
Netherlands	11	7	4	53	21	32	715	129	587	883	239	644
Poland	18	10	9	112	27	85	485	97	388	768	236	532
Portugal	7	5	2	31	8	22	187	34	154	263	69	194
Romania	10	6	4	41	11	30	221	51	170	364	120	244
Slovakia	3	2	2	16	3	13	87	16	70	124	32	91
Slovenia	1	1	1	7	2	6	32	6	26	59	20	38
Spain	12	8	4	105	39	66	1533	368	1165	2030	709	1321
Sweden	5	2	3	48	12	36	416	71	345	510	117	393
United Kingdom	41	23	18	251	73	178	1980	416	1564	2618	779	1839
TOTAL	**269**	**151**	**118**	**1433**	**402**	**1031**	**11323**	**2389**	**8934**	**15567**	**4809**	**10758**

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