WORKING FOR A HEALTHY FUTURE

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

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

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SUMMARY

1-chloro-2,3-epoxypropane (epichlorohydrin) has been classified by the International Agency for Research on Cancer (IARC) as probably carcinogenic to humans based on animal toxicity and other supporting information (IARC category 2a). Under the classification and labelling legislation in Europe it is classified as a Cat 2 carcinogen and is therefore within the scope of the EU Carcinogens Directive. However, there is no occupational exposure limit (OEL) for 1-chloro-2,3-epoxypropane specified in the Directive.

This report considers the likely health, socioeconomic and environmental impacts associated with possible changes to the Carcinogens Directive, in particular the possible introduction of an occupational exposure limit (OEL) of 1.9 mg/m^3 (0.5 ppm).

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

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

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

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

2060 from 331 to 446 years per annum for lung cancer and from 332 to 395 years per annum for brain cancer. Total estimated health costs associated with inaction range from €1,362m to €2,752m.

Current exposures in the EU are judged to be well below 1.9 mg/m^3 and so there are no predicted health benefits and no important costs associated with compliance with the suggested OEL. There are also no social or macro-economic costs associated with introducing an OEL at either of these levels.

There are no significant environmental impacts foreseen.

1 PROBLEM DEFINITION

1.1 OUTLINE OF THE INVESTIGATION

1-chloro-2,3-epoxypropane (epichlorohydrin) may cause lung and central nervous system (CNS) cancer. Exposure to 1-chloro-2,3-epoxypropane has been classified as a group 2a carcinogen (Probably carcinogenic to humans) by the International Agency for Research on Cancer (IARC)[1], based on the available toxicology data plus mechanistic and other relevant data. It is also classified as a Cat 2 carcinogen in the EU under the classification and labelling legislation[2]. 1-chloro-2,3-epoxypropane is therefore already regulated as a carcinogen throughout the EU. In this assessment we consider the impacts of introducing an exposure limit for bromoethylene within the EU Carcinogens and Mutagens 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 exposure limit of 1.9 mg/m^3 (0.5 ppm).

1.2 OELS/EXPOSURE CONTROL

Current available national occupational exposure limits (OELs) for EU member states are shown in Table 1.1.[3] These are given as long-term eight-hour time-weighted averages (TWAs) which are representative of a standard working day and/or as short term exposure limits which address peak exposures over a ten or fifteen minute period.

The 8-hour TWA OELS across the EU range from 1 mg/m3 to 18.9 mg/m3 (0.25 to 5 ppm). For the purposes of this report an OEL of 1.9 mg/m3 (0.5 ppm) is considered typical for the EU.

[1] Available at: http://monographs.iarc.fr/ENG/Classification/ClassificationsAlphaOrder.pdf
[2] Available at: http://ecb.jrc.ec.europa.eu/esis/
[3] Dow Chemicals: Product Stewardship Manual: Epichlorohydrin : Safe Handling and Storage (2007) Available at: http://www.dow.com

Table 1.1 Existing EU Exposure Limits for 1-chloro-2,3-epoxypropane

Country	Limit Value: 8 hour TWA / mg/m^3	Short-term Limit Value / mg/m^3
Austria	11.3	45.4
Belgium	7.6	-
Bulgaria	7.6	-
Czech Republic	1.0	-
Denmark	1.9	-
Estonia	1.9	-
Finland	1.9	-
France	-	7.6
Greece	9.5	18.9
Hungary	-	1.9
Ireland	1.9	5.7
Italy	1.9	-
Latvia	1.0	-
Lithuania	1.9	3.8
Netherlands	1.9	-
Norway	1.9	-
Poland	1.0	-
Portugal	18.9	-
Romania	1.0	5.3
Slovakia	11.3	-
Slovenia	11.3	45.4
Spain	1.9	-
Sweden	1.9	3.8
Switzerland	7.6	-
United Kingdom	1.9	5.7

1.3 DESCRIPTION OF DIFFERENT USES

1-chloro-2, 3-epoxypropane is a colourless flammable liquid with a sweet, pungent chloroform-like odour.[4] The odour threshold is around 40 mg/m^3 and most people can detect it at about 95 mg/m^3 (10 to 25 ppm).[5] The presence of both an epoxide ring and a chlorine atom in the molecule facilitates its use in a variety of chemical reactions with a wide range of compounds.

The main manufacturer has sites in Freeport, Texas, and Stade, Germany. The other two main producers have plants in China and Western Europe/ USA respectively.[6] The European Commission Institute for Health and Consumer Protection (2010) lists 15 High Volume (>1,000 tonnes per annum) producers or importers of 1-chloro-2,3-epoxypropane within the European Union in the following member states: Germany (4),

[4] Dow Chemicals Product Safety Assessment Epichlorohydrin (2010). Available at: http://www.dow.com/productsafety/finder/epi.htm

[5] Available at: http://dow-answer.custhelp.com/app/answers/detail/a_id/5438/~/epichlorohydrin---health-and-safety

[6] SRI Consulting (2010). Available at: http://www.sriconsulting.com/CEH/Public/Reports/642.3000/

Netherlands (3). United Kingdom (2), Italy (2), Sweden (1), Finland (1), Austria (1) and Belgium (1).[7]

The main manufacturer's primary production process for 1-chloro-2,3-epoxypropane consists of three steps: chlorination of propylene to form allyl chloride followed by reaction with hypochlorous acid to produce glycerol dichlorohydrin. The glycerol dichlorohydrin isomers are then reacted with sodium hydroxide or calcium hydroxide to produce 1-chloro-2,3-epoxypropane.[8]

Natural glycerine has become widely available as a by-product from biodiesel manufacturing and a process involving the conversion of glycerine into 1-chloro-2,3-epoxypropane via the addition of hydrochloric acid has also been developed recently by one manufacturer.[9]

1-chloro-2,3-epoxypropane is used as a feedstock in the manufacture of a wide range of products.

1.3.1 Epoxy Resin Production: Manufacture of other basic organic chemicals (NACE[10] Code 24.14)

About 75% of the 1-chloro-2,3-epoxypropane used in the EU is used in the production of epoxy resins[8], via a condensation reaction with bisphenol A to give a basic epoxy resin molecule.

Epoxy resins are used for a large number of applications where corrosion resistance, solvent and chemical resistance, hardness and adhesion properties are required. They are widely used as coatings for food and drink containers.

The resins are also used in structural applications such as printed circuit board laminates; semiconductor encapsulants; tooling, moulding and casting; flooring; and adhesives, paints and other coatings, for example powders for electrostatic paint processes.[11]

Epoxy resin coatings are used for marine vessels and structures to withstand temperature variations and substrate flexion and to guard against salt water penetration (Rempel *et al*, 1991).

1-chloro-2,3-epoxypropane is also used to produce both anion- and cation-exchange cross-linked resins for water and air purification applications and chromatography.[12] Exposures during manufacture of these resin types are assumed to be similar to those for other resin materials.

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[7] European Commission Institute for Health and Consumer Protection (2010)
[8] Dow Chemicals Product Safety Assessment Epichlorohydrin (2010). Available at: http://www.dow.com/productsafety/finder/epi.htm
[9] Solvay Chemicals. Chlorinated Organics: EPICEROL Process information sheet (2010). Available at: http://www.solvaychlorinatedorganics.com
[10] Eurostat: SCL - Statistical Classification of Economic Activities in the European Community (2002)
[11] Screening Assessment for the Challenge Environment Canada Health Canada (2008)
[12] Dow Chemicals Product Safety Assessment Epichlorohydrin (2010). Available at: http://www.dow.com/productsafety/finder/epi.htm

Voluntary limits on residual unreacted 1-chloro-2,3-epoxypropane in bisphenol A and bisphenol F epoxy resins (the most commonly produced epoxy resins), reactive diluents and mixtures were set by the PlasticsEurope trade association in 1996: these are 5 ppm in unmodified liquid resins; 20 ppm in reactive diluents and 10 ppm in mixtures of these resins and the diluents.[13] The levels of free 1-chloro-2,3-epoxypropane in prepared resin materials are therefore likely to be very low and unlikely to contribute significantly to inhalation or dermal exposure. Those who work only with epoxy resins (and not pure 1-chloro-2,3-epoxypropane) are thus considered unexposed.

1.3.2 Manufacture of pulp, paper and paperboard (NACE Code 21); Manufacture of dyes and pigments (24.12) and Manufacture of paints, varnishes and similar coatings, printing inks and mastics (NACE Code 24.3)

1-chloro-2,3-epoxypropane-based materials account for more than 90% of the resins used as wet-strength sizing for tissue, food packaging and other similar papers (Braga, *et al*, 2009). The resin sizing solution is pre-prepared from polyamides modified with 1-chloro-2,3-epoxypropane or from the reaction product of 1-chloro-2,3-epoxypropane and an alkylene amine, and so exposure to 1-chloro-2,3-epoxypropane during addition of size is considered unlikely.

1-chloro-2,3-epoxypropane-polyhydroxy compounds and their esters are used in the production of special printing inks and textile print pastes, to give flexible and chemically inert films. Current exposures to 1-chloro-2,3-epoxypropane related to these applications are most likely to occur during manufacture of the inks and pastes rather than during use of the finished resin products.[12] In the past, 1-chloro-2,3-epoxypropane may also have been produced on-site as an additive in anthraquinone dye plants (Delzell *et al*, 1989).

Although some references[12,14] have indicated that 1-chloro-2,3-epoxypropane is used as a solvent in cellulose and other paints and finishes, no current manufacturers' information has been found to support this application and it is likely that it is not currently used for this purpose. Although epoxy resins are used in the manufacture of paints, there is unlikely to be any exposure to pure 1-chloro-2,3-epoxypropane during paint manufacturing.

1.3.3 Textile Manufacture: Preparation and Spinning of cotton-type fibres (NACE Code 17.11) and Preparation and spinning of woollen-type fibres (NACE Code 17.12)

1-chloro-2,3-epoxypropane is used to modify the carboxyl groups of wool to give improved resistance to moths. It is also used to improve acid dye take up and mould/ insect resistance in other fibres such as cotton. Reports on the use of hazardous substances in the textile industry produced by the US Environmental Protection Agency and the European Agency for Safety and Health at Work have indicated that pure 1-

[13] Dow Chemicals Ltd. Dow Answer Centre (2010). Available at: http://dow-answer.custhelp.com/app/answers/detail/a_id/5328/~/dow-epoxy---residual-epichlorohydrin-guidelines
[14] Screening Assessment for the Challenge Environment Canada Health Canada (2008)

chloro-2,3-epoxypropane is added to the textile suggesting the potential for exposure to occur [15,16]

1-chloro-2,3-epoxypropane-polyamide resins are used to impart wrinkle resistance to fabrics via the Chlor-Hercosett process. This involves the chlorination of the textile followed by addition of the resin. 1-chloro-2,3-epoxypropane resins are also used as antistatic agents and textile sizings.[17, 18]

1-chloro-2,3-epoxypropane has also been used in the production of polyvinyl chloride, polyacrylonitrile, polyvinyl alcohol and other synthetic fibres.[19] It is unclear from the available references whether the additives are in the form of pure 1-chloro-2,3-epoxypropane or are used as epoxy resin compounds.

1.3.4 Manufacture of synthetic rubber in primary forms (NACE Code 24.17)

Elastomers produced from 1-chloro-2,3-epoxypropane are stable over a wide range of temperatures and are resistant to gasoline, oil, ozone and aging and are commonly used in aircraft parts, seals, gaskets, wire and cable jackets, adhesives, packing materials, hoses and belting, rubber-coated fabrics and energy-absorbing units.[17]

Other Applications: Production of Pharmaceuticals and Cosmetics (NACE Code 24.14), Manufacture of starches and starch products (NACE Code 15.62) Starch Production and Manufacture of pesticides and other agrochemicals (NACE Code 24.2)

1-chloro-2,3-epoxypropane is used in the chemical synthesis of pharmaceutical products including synthetic glycerine, polyols for the production of rigid polyurethane foams and surface active agents for washing products and toiletries[20]. Polymers manufactured with 1-chloro-2,3-epoxypropane may also be used in the production of some cosmetic products, including hair dyes, lipsticks, eye and face makeup, and nail lacquers.[21] These applications are assumed to be classified under NACE Code 24.14: Manufacture of basic organic chemicals.

1-chloro-2,3-epoxypropane has also been used as a stabilising, cross-linking agent in food starches, however this use appears to have been discontinued: the Joint WHO/FAO Expert Committee on Food Additives does not include 1-chloro-2,3-epoxypropane in its most recent food-grade specification for modified starches.[22] This application and any related exposures may therefore now be very limited.

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[15] US Environmental Protection Agency (1984) Health Assessment Document Epichlorohydrin

[16] European Agency for Safety and Health at Work (2010) e-fact Sheet: Occupational Safety and Health in the Textiles Sector. Available at: http://osha.europa.eu/en/publications/e-facts/efact30

[17] Dow Chemicals Product Safety Assessment Epichlorohydrin (2010) http://www.dow.com/productsafety/finder/epi.htm

[18] Australian Wool Innovation Ltd. (2010) Treatment methods http://www.wool.com/Topmaking_Fibre-Modification_Treatment-Methods.htm

[19] US Environmental Protection Agency (1996): Hazardous Waste Management System; Federal Register: Vol. 61, No.158. Available at: http://www.epa.gov/osw/hazard/wastetypes/wasteid/solvents/frnotice.txt

[20] Solvay Chemicals (2002): Applications of Epichlorohydrin. Available at: http://www.solvaychlorinatedorganics.com/docroot/chlo_org/static_files/attachments/applications_epichlorohydrin.pdf

[21] Screening Assessment for the Challenge Environment Canada Health Canada (2008)

[22] Joint FAO/WHO Expert Committee on Food Additives. (2001). Available at:

1-chloro-2,3-epoxypropane has previously been used as a pesticide[23] and as a stabiliser in the production of pesticide formulations[24,25] however pure 1-chloro-2,3-epoxypropane is not currently authorised in the EU as a pesticide and is not shown on the list of active agents on the UK Health and Safety Executive approved pesticides register.[26] Pesticide registration information from the US EPA[27] (1998/ 2008) identified 1-chloro-2,3-epoxypropane as a stabiliser (approximately 1% by volume) in the pesticides Telone and Alachlor. The manufacturers' safety data sheets for these products do not, however, list it as being present. The approval for Telone is currently under review by the EU. It has been assumed that some exposures during pesticide manufacture are possible.

Dow[28] (2007) also indicated the following potential applications for 1-chloro-2,3-epoxypropane and its derivatives, however no current data on the manufacture or use of these products has been collected: asphalt improvers, corrosion inhibitors, electrical insulation for wire, filament sizing, fire-retardant urethanes, liners for polyethylene bottles, linoleum and linoleum cements, lubricant additives, petroleum production aids, photographic film bases, rubber latex coagulation aids, waterproofing compounds and zinc electroplating compounds.

As it is listed on Annex XVII of the REACH Regulation as a category 2 carcinogen, 1-chloro-2,3-epoxypropane (and mixtures containing the substance above a defined threshold) cannot be placed on the market for sale to the general public.

1.4 RISKS TO HUMAN HEALTH

1.4.1 Introduction

Lung cancer is the most common malignant neoplasm among men in most countries and incidence has been steadily increasing among women. In the EU the incidence is about 30 per 100,000 persons, with about 290,000 new cases each year.[29] The main environmental cause is cigarette smoking, although other factors, such as genetic susceptibility, poor diet, and indoor air pollution, may act in conjunction with tobacco consumption as risks for lung cancer. Among both men and women, the incidence of lung cancer is low in individuals aged less than 40 years and increases up to age 70 or 75 (Quinn *et al*, 2001). In most European countries, the risk of lung cancer among men is regularly two to three times higher in lower than higher socio-economic classes (Quinn *et al*, 2005).

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http://www.fao.org/ag/agn/jecfa-additives/specs/Monograph1/Additive-287.pdf
[23] University of Hertford. Pesticide Properties Database. Available at: http://sitem.herts.ac.uk/aeru/footprint/en/index.htm
[24] Dow Chemicals Product Safety Assessment Epichlorohydrin (2010). Available at: http://www.dow.com/productsafety/finder/epi.htm
[25] World Health Organisation(1987) International Programme On Chemical Safety: Health and Safety Guide No. 8 Epichlorohydrin
[26] Health and Safety Executive (2011). Available at: http://www.pesticides.gov.uk/publications.asp?id=1326
[27] US Environmental Protection Agency Re-registration Eligibility Decision : Telone EPA 738-R-98-016
[28] Dow Chemicals: Product Stewardship Manual: Epichlorohydrin : Safe Handling and Storage (2007). Available at: http://www.dow.com
[29] Available at: http://globocan.iarc.fr/factsheets/populations/factsheet.asp?uno=990

Lung cancer is highly fatal, so the trends in incidence and mortality are closely similar. In Europe about 10% of lung cancer patients survive for more than 5-years post diagnosis (Verdecchia *et al*, 2007). Lung cancer accounted for 15.5% of all cancers in men in Europe, and 6.9% of such cases in females (Ferlay *et al*, 2007).

There are a number of occupational agents that are known or suspected of causing lung cancer. Rushton *et al*, (2010) estimated that in Great Britain occupational exposures account for about 21% of male lung cancers and 5% of female lung cancers.

There are more than 100 different types of brain and other CNS cancers, with about 20% of these tumours occurring in the spinal cord. About half of brain tumours in adults are gliomas and 25% are meningiomas. In the European Union the age-standardised incidence rate is 5.6 per 100,000, which makes this group of tumours the 14th commonest malignant neoplasm (about 41,000 incident cases in 2008 and 31,000 deaths – about 2.5% of all cancer deaths).[30]

Brain tumours can occur at any age and they are the commonest type of solid tumours in young people. Amongst adults most brain and CNS cancers occur in people over the age of 50. There is relatively little known about the causes of brain and other CNS cancers. People who received high doses of radiation to the head in childhood (radiotherapy) are at an increased risk of developing brain tumours in later life. Exposure to electromagnetic radiation form cell phones, nitrosamides or nitrosamines, and some solvents have been suggested as possible environmental causes of brain cancer but the evidence is inconclusive. In addition, increased risks have been seen in people employed in farming, the manufacture of synthetic rubber and polyvinyl chloride, the refining of crude oil, the production of petroleum-based chemicals, and the manufacture of pharmaceuticals. People employed as electrical workers, chemists, embalmers, pathologists, and artists may also be at increased risk, but again the evidence is equivocal.[31]

CNS cancers are mostly fatal, with only about 16% to 18% surviving for 5 years after diagnosis.[32]

There is inadequate evidence that 1-chloro-2,3-epoxypropane is carcinogenic to humans, however, there is sufficient evidence that it is carcinogenic in experimental animal IARC has classified 1-chloro-2,3-epoxypropane as a Group 2a carcinogen, i.e. as probably carcinogenic to humans (IARC, 1999).

1.4.2 Summary of the available epidemiological literature on risk

Exposure to liquid 1-chloro-2,3-epoxypropane has been found to cause skin burns and the vapour can cause irritation of the eyes, nose and throat (IARC, 1999). Skin sensitisation also commonly occurs amongst people with regular contact with the liquid. Experimental inhalation toxicology studies have produced cancers in the nasal cavity in male rats.

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[30] Available at: http://globocan.iarc.fr/factsheets/populations/factsheet.asp?uno=990
[31] Available at: http://www.cancer.gov/cancertopics/factsheet/Risk/brain-tumor-study
[32] Available at: http://www.cancer.org/research/cancerfactsfigures/globalcancerfactsfigures/global-cancer-facts-figures-2007

A small study of 606 workers exposed to 1-chloro-2,3-epoxypropane at four European plants found no excess from any cancers (Tassignon *et al*, 1983).

Delzell *et al* (1989) carried out a cohort study of 2,642 male workers employed for at least six months between 1952 and 1985. 106 cancer deaths were observed (97 expected). Seven cancers were observed (7.3 expected) among 230 workers in the plastics and additives production area where there was potential for exposure to 1-chloro-2,3-epoxypropane. An excess of lung cancer was observed among the 44 workers who had been employed in the production of 1-chloro-2,3-epoxypropane, which had been manufactured at the plant between 1961 and 1965 (levels of exposure not reported) (standardized mortality ratio (SMR=4.4; 4 observed versus 0.91 expected; p = 0.03). Nested case–control studies for lung (Barbone *et al*, 1992) and central nervous system (Barbone *et al*, 1994) neoplasms from this cohort study assessed exposure on an ordinal scale based on job titles, work areas, and potential for contact. An association was observed for lung cancer with potential 1-chloro-2,3-epoxypropane exposure (odds ratio (OR=1.7; 95% CI, 0.7–4.1) after adjustment for smoking. No association was observed with duration or cumulative level of exposure. In addition an association was observed for central nervous tumour cancers with potential exposure to 1-chloro-2,3-epoxypropane (OR=4.2; 95% CI, 0.7–26) and the magnitude of this association increased with both duration of exposure (p = 0.11 for trend test) and cumulative level of exposure (p = 0.08 for trend test).

The most recent update of the cohort included 3266 workers employed for at least 6 months at the plant. Plant production areas were South Dyes, where anthraquinone dyes and intermediates were produced; North Dyes, where azo dyes and intermediates were produced; and plastics and additives, where various resins and additives for plastics were made (Sathiakumar and Delzell, 2000). Cancer excesses were limited to white men and included an excess of lung cancer in Maintenance workers (SMR=153; 95%CI 109, 208) and in South Dyes workers (SMR=168 95%CI 115,237), an excess of stomach cancer (SMR=386 95%CI 125, 901), bladder cancer (SMR=515 95%CI 140, 1318) and central nervous system cancer (SMR=517 95%CI 168, 1206) in North Dyes workers and an excess from central nervous system cancer in plastics and additives (SMR=500 95%CI 103, 1461) . None of these increases was concentrated in work area subgroups with long duration of employment and long potential induction time. The authors concluded that the excess of bladder cancer probably was due to exposure to carcinogenic arylamines at another facility where some employees had worked before coming to the study plant and that the other cancer increases may be attributable to chance, to uncontrolled confounding by smoking, or to an unidentified occupational exposure.

Tsai *et al* (1996) updated results for a small cohort of 863 workers employed at two chemical manufacturing facilities between 1948 and 1965 in the United States who were potentially exposed to 1-chloro-2,3-epoxypropane and isopropanol. A previous paper had reported and excess risk from leukaemia (Enterline *et al*, 1990). Exposure was classified by a panel of industrial hygienists and current and former employees as nil, light, moderate or heavy. Exposures during ‘early production periods’ were estimated to be 10–20 ppm [38–76 mg/m3]. Excess risk was found for cancer of the prostate (SMR, 2.3; 95% CI, 1.0–4.5; n = 8) and malignant melanoma (SMR, 3.2; 95% CI, 0.7–9.4; n = 3) among workers at least 20 years after first exposure, but the risks did not vary with estimated level of exposure. The SMR for lung cancer was 0.7 (95% CI, 0.5–1.1; 23 cases) in the total population and did not increase with level of exposure or time since first exposure.

Olsen *et al* (1994) reported on the results of a retrospective mortality study of 1064 men employed in the epoxy resin, glycerine and allyl chloride/1-chloro-2,3-epoxypropane production areas of a large chemical facility in the US between 1957 and 1986. Average exposures to 1-chloro-2,3-epoxypropane were estimated to be generally below 1 ppm [3.8 mg/m3] in the epoxy resin area, in the allyl chloride/1-chloro-2,3-epoxypropane area and, after 1970, in the glycerine area. Exposures to 1-chloro-2,3-epoxypropane were estimated to be between 1 and 5 ppm [3.8 and 18.9 mg/m3] in the glycerine area before 1970 and occasionally in some jobs in the allyl chloride/1-chloro-2,3-epoxypropane area, although respiratory protection may have been worn by these workers. There were 66 deaths (SMR, 0.8; 95% CI, 0.6–1.0). Ten cancers were observed (SMR, 0.5; 95% CI, 0.2–0.9, compared with national rates) in the entire cohort and no associations between site-specific cancer risks and exposure to 1-chloro-2,3-epoxypropane were observed.

Bond *et al* (1986) conducted a nested case–control study of lung cancer among a cohort of 19608 male chemical workers in the United States (Bond *et al*, 1985). Ever having been exposed to 1-chloro-2,3-epoxypropane was associated with a decreased risk of lung cancer (odds ratio, 0.3; 95% CI, 0.1–0.9; 5 exposed cases).

1.4.3 Choice of risk estimates to assess health impact

Raised risks from lung cancer and central nervous system cancer have been found in some epidemiological studies although not consistently across all studies and with weak associations with level of exposure. In addition there is potential for exposure to other substances as well as 1-chloro-2,3-epoxypropane in several studies. The nested case-control studies by Barbone *et al*, (1992, 1994) have been chosen for the risk estimates as these are adjusted for smoking and have more specific exposure assessment than some of the cohort studies. For medium exposure OR=1.7 (95% CI, 0.7–4.1) has been selected for lung cancer and OR=4.2 (95% CI, 0.7–26) has been selected for central nervous system cancer. As risk estimates less than 1 have been found in some studies RR=1 has been chosen for the low exposure group.

2 BASELINE SCENARIOS

2.1 STRUCTURE OF THE SECTOR

Annual global production is estimated at around 900,000 tonnes per annum, with around 400,000 tonnes produced by one manufacturer with sites in the US and Germany.[33] The historic ratio between the EU and the US in terms of global production is estimated at around 40%:50%,[34,35] therefore it is estimated that the amount produced in the EU per annum is approximately 360,000 tonnes.

[33] Dow Chemicals Product Safety Assessment Epichlorohydrin (2010) Available at: http://www.dow.com/productsafety/finder/epi.htm

[34] Available at: http://dow-answer.custhelp.com/app/answers/detail/a_id/5438/~/epichlorohydrin---health-and-safety

Estimated annual world production in 1990 was 455,000 tonnes, with around 50% being produced in the US, 40% in Europe and the majority of the remainder being made in Japan (Bailey and Koleske, 1990). Assuming this ratio of US production amounts to the global values, the estimated worldwide amounts of 1-chloro-2,3-epoxypropane produced were 312,000 tonnes (1973), 500,000 tonnes (1975) and 426,000 tonnes (1978).[36]

For 1-chloro-2,3-epoxypropane the following sectors have been identified:

- Preparation and spinning of cotton-type fibres (NACE Code 17.11)
- Preparation and spinning of woollen-type fibres (NACE Code 17.12)
- Manufacture of dyes and pigments (NACE Code 24.12)
- Manufacture of other organic basic chemicals (NACE Code 24.14)
- Manufacture of synthetic rubber in primary forms (NACE Code 24.17)
- Manufacture of pesticides and other agro-chemical products (NACE Code 24.2)
- Recycling non-metal waste and scrap (NACE Code 37.2)

2.2 PREVALENCE OF 1-CHLORO-2,3-EPOXYPROPANE EXPOSURE IN EU

According to the National Occupational Exposure Survey (NOES) conducted by NIOSH between 1981 and 1983, over 95,000 workers in the USA were potentially exposed to 1-chloro-2,3-epoxypropane.[37] From the industry and occupation descriptions given in this study, the total appears to include downstream users of 1-chloro-2,3-epoxypropane-based epoxy resins, for example in construction and manufacturing, as well as those exposed directly to 1-chloro-2,3-epoxypropane in its unreacted form.

The CAREX database of carcinogen use in the EU indicates that approximately 48,000 workers were exposed to 1-chloro-2,3-epoxypropane in 1990-1993 (Kaupinnen *et al*, 2000). As for the NIOSH NOES, the CAREX data appear to include applications in which 1-chloro-2,3-epoxypropane is used in its resin form, for example within the paper-making industry or in the manufacture of metal equipment. As the amounts of residual 1-chloro-2,3-epoxypropane in resin materials are now negligible, it is unlikely that significant exposures continue to occur in these industries and the exposure estimates from the early 1990s are unlikely to be representative of current exposures. 1-chloro-2,3-epoxypropane was not included in the Finnish 2007 CAREX update so it is not possible to estimate current 1-chloro-2,3-epoxypropane exposure prevalence

[35] SRI Consulting (2010) Available at: http://www.sriconsulting.com/CEH/Public/Reports/642.3000/

[36] International Programme on Chemical Safety; Environmental Health Criteria 33 Epichlorohydrin (1984)

[37] US Environmental Protection Agency National Advisory Committee (2008) Interim Acute Exposure Guideline Levels: Epichlorohydrin. Available at: http://www.epa.gov/opptintr/aegl/pubs/epichlorohydrin_interim_dec_2008_v1.pdf

based on CAREX data. Instead, the proportion of employees in each industry was instead estimated from the 2006 Labour Force Survey and the 2006 data from the Structural Business Statistics, both available from Eurostat.[38]

For each industry we have identified the International Standard Classification of Occupations (ISCO)[39] job categories in which exposure is likely and we have assumed that all workers in potentially exposed job categories and industries are exposed. The ISCO job categories that have been identified as “exposed” are listed for each exposed industry in Table 2.1. This table also identifies the work activities associated with exposure in the literature. Exposures during these activities occur predominantly via inhalation of vapours and dermal contact with the liquid and vapour forms and subsequent absorption.[40]

Table 2.1 Estimated current exposure to 1-chloro-2,3-epoxypropane by Work Activity, Occupation and Industry Sector

Industry/ Process	NACE Code (Rev. 1.1)	Relevant Work Activities (potential exposures in all cases assumed to occur via inhalation and dermal routes)	Occupations Involved in Activities (ISCO categories)
Preparation and spinning of cotton-type fibres	17.11	• Drum filling • Preparation of cotton fibres for fabrics: addition of liquid 1-chloro-2,3-epoxypropane to cotton and other similar materials. • Spillage control	300:Technicians and associated professionals 730: Precision handicraft, printing and related trades workers 810: Stationary plant and related operators 930: Labourers in mining, construction, manufacturing and transport trades employees
Preparation and spinning of woollen-type fibres	17.12	• Drum filling • Preparation/ treatment of wool for moth resistance/ spinning into yarn: addition of liquid 1-chloro-2,3-epoxypropane to raw wool. • Spillage control	300:Technicians and associated professionals 730: Precision handicraft, printing and related trades workers 810: Stationary plant and related operators 930:Labourers in mining, construction, manufacturing and transport d trades employees
Manufacture of dyes and pigments	24.12	• Drum filling • Quality assurance/process sampling • Spillage control	300: Technicians and associated professionals 810: Stationary plant and related operators 930:Labourers in mining, construction, manufacturing and transport
Manufacture of other basic organic chemicals	24.14	• Manufacture of epoxy resins from reaction of 1-chloro-2,3-epoxypropane with bis-phenol A and other substances. • Drum filling • Tank loading • Quality assurance/ process sampling • Spillage control	300: Technicians and associated professionals 810: Stationary plant and related operators 930:Labourers in mining, construction, manufacturing and transport

[38] Available at: http://epp.eurostat.ec.europa.eu/portal/page/portal/statistics/themes (2010)
[39] International Standard Classification of Occupations. Available at: http://www.ilo.org/public/english/bureau/stat/isco/index.htm (2008)
[40] Dow Chemicals Product Safety Assessment Epichlorohydrin (2010). Available at: http://www.dow.com/productsafety/finder/epi.htm

Industry/ Process	NACE Code (Rev. 1.1)	Relevant Work Activities (potential exposures in all cases assumed to occur via inhalation and dermal routes)	Occupations Involved in Activities (ISCO categories)
Manufacture of synthetic rubber in primary forms	24.17	• Addition of 1-chloro-2,3-epoxypropane as a stabiliser to process mixtures during rubber manufacture • Drum filling • Quality assurance/ process sampling • Spillage control	300: Technicians and associated professionals 810: Stationary plant and related operators 930:Labourers in mining, construction, manufacturing and transport
Recycling of non-metal waste and scrap	37.2	• Drum filling/ emptying • Storage and sampling of waste organic materials and formulations • Incineration of waste organic materials	300: Technicians and associated professionals 810: Stationary plant and related operators 930:Labourers in mining, construction, manufacturing and transport

The number of workers in each ISCO job category was not available by four digit NACE code and was only available for the manufacturing industry as a whole (NACE D). The proportion of workers in each ISCO job category in the manufacturing industry was assumed to be constant across manufacturing sub-industries. These proportions were estimated from the 2006 Labour Force Survey data for each member state.

The estimated proportion of workers in exposed ISCO job categories in each sub-industry was then applied to the 2006 employment figures from the Eurostat Structural Business Statistics to estimate the number of exposed workers per industry and member state.

These estimated numbers of exposed workers in each industry and member state are given in Table 2.2. The total estimated number of exposed workers in the EU is 43,813 (30,669 male/ 13,144 female). This figure is likely to be an overestimate; the ISCO job categories that have been defined as exposed probably include some workers who are unexposed.

Across the EU, the number of female employees in manufacturing industries is approximately 30% compared with 70% male.[41] The number of male and female employees within each sub-code was estimated using this ratio. The estimated number of male and female employees in each industry group in each EU member state is shown in Appendix 8.1.

[41] Average % gender split taken from Eurostat database across Code D: Manufacturing (2010)

Table 2.2 Estimated Number of Employees Exposed to 1-chloro-2,3-epoxypropane in 2010 by Country and NACE code (Rev. 1.1)

	NACE Code							
Country	**17.11**	**17.12**	**24.12**	**24.14**	**24.17**	**24.2**	**37.2**	**Grand Total**
Austria	16	12	NA*	226	NA	38	100	**392**
Belgium	51	110	174	1423	104	72	314	**2248**
Bulgaria	237	200	3	83	NA	NA	50	**573**
Cyprus	NA	NA	NA	NA	NA	19	16	**35**
Czech Republic	240	18	NA	329	8	NA	177	**772**
Denmark	NA	NA	49	NA	NA	NA	NA	**49**
Estonia	NA	20	NA	21	NA	NA	33	**74**
Finland	NA	10	112	172	65	NA	20	**379**
France	87	43	390	2932	173	642	1574	**5841**
Germany	556	NA	1176	5625	NA	808	1509	**9674**
Greece	700	3	44	NA	NA	89	NA	**836**
Hungary	83	12	23	102	NA	65	75	**360**
Ireland	NA	NA	NA	962	NA	29	47	**1038**
Italy	1236	1097	NA	1689	NA	291	1118	**5431**
Latvia	103	5	NA	49	NA	3	25	**185**
Lithuania	28	157	NA	38	NA	NA	53	**276**
Luxembourg	NA	NA	NA	NA	NA	NA	3	**3**
Malta	NA	NA	NA	NA	NA	NA	NA	**NA**
Netherlands	36	NA	249	1592	66	95	456	**2494**
Norway	NA	NA	27	158	NA	NA	34	**219**
Poland	468	226	95	1277	1	236	833	**3136**
Portugal	456	NA	NA	NA	NA	46	144	**646**
Romania	374	76	54	237	6	84	304	**1135**
Slovenia	NA	NA	136	33	NA	NA	37	**206**
Slovakia	NA	NA	NA	160	0	2	110	**272**
Spain	768	113	354	666	84	306	460	**2751**
Sweden	NA	1	14	272	NA	NA	60	**347**
United Kingdom	91	429	NA	1876	175	456	1414	**4441**
TOTAL	5530	2532	2900	19922	682	3281	8966	**43813**

*NA=Not Available

Classification of Industries by Exposure Level

A list of the types of industries that potentially used 1-chloro-2,3-epoxypropane in 1975 was collated from published literature. This information, together with the corresponding NACE codes and an estimation of the degree of potential inhalation exposure is given in Table 2.3.

Exposure to 1-chloro-2,3-epoxypropane has been categorised as high, medium or low using the historical exposure measurement information given above.

It is notable that 1-chloro-2,3-epoxypropane is flammable and this must have influenced handling to minimise the potential for fires.

Table 2.3 Classification of Industries by Exposure Levels (1975)

Industry	NACE (rev 1.1)	Exposure Level (inhalation)
Manufacture of starches and starch products	15.62	Medium
Preparation and spinning of cotton-type fibres	17.11	Medium
Preparation and spinning of woollen-type fibres	17.12	Medium
Manufacture of dyes and pigments	24.12	Low
Manufacture of other basic organic chemicals: 1-chloro-2,3-epoxypropane/epoxy resin/glycerine production	24.14	Low
Manufacture of synthetic rubber in primary forms	24.17	Medium
Manufacture of pesticides and other agro-chemical products	24.2	Low
Manufacture of paints, varnishes and similar coatings, printing ink and mastics	24.3	Low
Recycling of non-metal waste and scrap	37.2	Low

2.3 LEVEL OF EXPOSURE TO 1-CHLORO-2,3-EPOXYPROPANE

2.3.1 Estimation of exposure levels

Historical inhalation exposure

- 1-chloro-2,3-epoxypropane Manufacture and Processing

1-chloro-2,3-epoxypropane concentrations at a US chemical facility ranged from 38 to 76 mg/m^3 between 1948-1955.[42]

Oser (1980) found that exposures of chemical operators in two 1-chloro-2,3-epoxypropane production plants had ranged from below the limit of detection (0.19 mg/m^3) to 8 mg/m^3. Operators unloading tank cars in both of the plants had exposures of 1.1 mg/m^3 (Oser, 1980).

De Jong *et al* (1988) measured a mean 1-chloro-2,3-epoxypropane concentration of 25 mg/m^3 (range: <0.1-204 mg/m^3) at a US petrochemical complex in 1977. The mean concentration measured in 1978 was 4.9 mg/m^3 (range: 0.1-12 mg/m^3).

From a survey of 1-chloro-2,3-epoxypropane exposure in European manufacturing plants in 1977-78, Tassignon *et al*, (1983) reported that personal exposures were at, or below, 3.8 mg/m^3 (TWA).

[42] US Environmental Protection Agency National Advisory Committee (2008) Interim Acute Exposure Guideline Levels: Epichlorohydrin. Available at: http://www.epa.gov/opptintr/aegl/pubs/epichlorohydrin_interim_dec_2008_v1.pdf

Boogaard *et al* (1993) reported personal exposure levels for workers exposed to 1-chloro-2,3-epoxypropane between 1980 and 1991 at an organochlorine plant (Table 2.4). Measurements were taken during normal operation of the plant and during specific activities with higher potential for exposure such as maintenance. Before 1985 sampling (over 5 hours) did not cover the full work shift whilst the results from 1985 onwards are reported as 8-hr TWAs.

Table 2.4 Exposure levels during 1-chloro-2,3-epoxypropane production at an organochlorine plant

Period	No.	n	GM (mg/m3)	GSD	AM (mg/m3)	95% CI (mg/m3)	P95 (mg/m3)	Plant status
May-80	11	56	0.17	2.68	0.27	(0.21-0.36)	0.86	Normal operation
Aug-80	13	45	0.09	6.33	0.45	(0.26-0.79)	1.87	Normal operation
Oct-80	6	88	0.1	2.14	0.13	(0.11-0.16)	0.35	Normal operation
Feb-81	5	14	0.13	1.82	0.15	(0.11-0.22)	0.35	Normal operation
Jun-81	7	20	0.36	2.23	0.49	(0.33-0.72)	1.35	Normal operation
Sep-81	9	28	0.22	2.35	0.31	(0.22-0.44)	0.9	Normal operation
Dec-81	5	19	0.14	2.92	0.24	(0.14-0.40)	0.82	Normal operation
Mar-82	8	32	0.17	2.34	0.24	(0.18-0.33)	0.69	Normal operation
Jun-82	-	15	0.2	2.43	0.29	(0.17-0.48)	0.86	Maintenance
Sep-82	7	20	0.29	2.36	0.41	(0.27-0.62)	1.19	Normal operation
Dec-82	5	14	0.3	1.27	0.31	(0.27-0.36)	0.44	Normal operation
Mar-83	18	18	0.31	1.73	0.36	(0.27-0.47)	0.76	Normal operation
Mar-84	14	14	0.15	2.27	0.2	(0.12-0.33)	0.58	Normal operation
Aug-87	44	44	0.07	2.5	0.11	(0.08-0.14)	0.32	Normal operation
Apr-90	2	8	0.18	1.62	0.2	(0.13-0.31)	0.4	Shut down
Apr 1991*	3	3	0.27	1.7	0.3	(0.06-1.49)	0.65	Shut down

No. = numbers of workers monitored; n = number of air measurements; GM (GSD) = geometric mean and standard deviation (log normal distribution); AM = arithmetic mean; 95% CI = 95% confidence interval of AM; P95 = estimated concentration where 95% of the measurements were below this value

Exposure levels (119 samples) at batch operating processes with a bulk supply of 1-chloro-2,3-epoxypropane were measured over 1988 to 1991 in a number of industrial sites in the UK. The exposures were all below 3.78 mg/m^3, with 94% below 1.9 mg/m^3 and 61% below 0.4 mg/m^3.[43]

In the same study, between 1989 and 1991, a plant engaged in continuous batch processing with bulk supply 1-chloro-2,3-epoxypropane and intermittent batch processes with bulk supply of 1-chloro-2,3-epoxypropane reported that 20 full-shift (12-hr) TWA exposures were all below 0.08 mg/m^3.

- Production of Epoxy Resin, Glycerol and Other Products from 1-chloro-2,3-epoxypropane

In a 1996 study by Luo *et al* (2004), workers in a factory producing epoxy resin, printed circuit boards and artificial leather were categorised as having high or low exposure to 1-chloro-2,3-epoxypropane. Tasks involving high 1-chloro-2,3-epoxypropane exposure (defined as >0.76 mg/m^3, 8 hr TWA) included unloading of 1-chloro-2,3-epoxypropane, research and development and maintenance activities in epoxy resin production. The mean measured personal exposure level for these 29 workers was 4.6 mg/m^3 (SD= 5.1; range = 0.76-15 mg/m^3).

Workers with low 1-chloro-2,3-epoxypropane exposure (defined as <0.76 mg/m^3, 8 hr TWA) carried out tasks which included dipping, assembly of printed circuit boards, materials mixing and quality control in printed circuit board production. The mean measured exposure level amongst these 22 workers was 0.3 mg/m^3 (SD = 0.18; range = 0.038-00.42 mg/m^3).

Data from seven plants in the USA engaged in the production of 1-chloro-2,3-epoxypropane, glycerol, or epoxy resins, from 1973-1976, showed that 7-h or 8-h time-weighted-average exposures to 1-chloro-2,3-epoxypropane ranged from <0.04 mg/m^3 to 57 mg/m^3. The median was < 8 mg/m^3 (Oser, 1980).[44]

In two other epoxy resin plants, Shellenberger *et al* (1979) found that the time-weighted-average exposures for 1973-76 were generally <3.8 mg/m^3, except for those of laboratory personnel in one of the plants, which varied between 3.8 and 18.9 mg/m^3.

In glycerol-manufacturing plants in the USSR, Petko *et al* (1966) measured concentrations ranging from 12-21 mg/m^3, however it was not reported whether these values were time-weighted-averages over a working day.

Olsen *et al* (1994) reported on a cohort of 1,064 men employed in the epoxy resin, glycerine and allyl chloride/1-chloro-2,3-epoxypropane production areas of a large chemical facility between 1957 and 1986. Average exposures to 1-chloro-2,3-epoxypropane were estimated to be generally <3.8 mg/m^3 in both the epoxy resin production and allyl chloride/ 1-chloro-2,3-epoxypropane production areas. Exposures to 1-chloro-2,3-epoxypropane in the glycerine area before 1970 were estimated to be between 3.8 and 18.9 mg/m^3. These higher levels were also found on occasion for workers within the allyl chloride/1-chloro-2,3-epoxypropane production area, where

[43] Health and Safety Executive (1993): EH65/6: Epichlorohydrin- Criteria document for an occupational exposure limit
[44] International Programme on Chemical Safety; Environmental Health Criteria 33 Epichlorohydrin (1984)

company procedures required respiratory protection to be worn. After 1970, exposures in the glycerine production area were also estimated at <3.8 mg/m^3.

1-chloro-2,3-epoxypropane levels in a Taiwanese polyurethane factory were measured in 1997 (Kuo *et al*, 2001). In this study, the mean background level was 23.4 mg/m^3 (SD = 6.2; range 0.5-131.5 mg/m^3), and the mean personal exposure level calculated from 28 samples was 8.4 mg/m^3 (SD= 10.5; range= < limit of detection to 63 mg/m^3)

In 1999 further sampling was undertaken in the Kuo *et al* (2001) study following changes to the tasks and the personal protective equipment worn. Production had also decreased from 4.2 million yards of polyurethane in 1997 to 1.81 million yards in 1999. Background levels (4 samples chosen from 28 possible locations) were also measured again over 60-180 minutes (mean= 0.39 mg/m^3; SD=0.21; range = 0.20-0.67 mg/m^3)

Full shift personal samples were taken from the same 37 workers as in 1997, with 16 samples being taken in total. For these samples, a mean concentration of 0.18 mg/m^3 (SD= 0.20; range= limit of detection - 0.46 mg/m^3) was obtained.

Plna *et al* (2000) reported that workers at a Swedish resin production plant were exposed to levels ranging from <0.4 mg/m^3 (during general reactor operations and maintenance work) to 1.9 mg/m^3 (during transfer of 1-chloro-2,3-epoxypropane from railway wagons to storage containers).

Table 2.5 summarises the above exposure information.

Current exposure levels

The results of the Boogard *et al* (1993) study of a Dutch chemical manufacturing plant in the 1980s demonstrate that exposures well below 1.9 mg/m^3 have been achieved in some European facilities for the past twenty to thirty years. It is considered likely that since the 1980s all European facilities have achieved this level of control. The measurements taken by Plna *et al* (2000) during epoxy resin manufacture in Sweden ranged from <0.4 to 1.9 mg/m^3 further supporting this conclusion. Current EU exposure levels in the chemical manufacturing industry (NACE 24.3, 24.12, 24.17 and 24.2) are likely to be at or below the levels reported by Boogard *et al* for a 1987 survey of 44 workers during normal plant operation (Geometric Mean (GM): 0.07 mg/m^3; Geometric Standard Deviation (GSD): 2.5). There were no data available for NACE Codes 17.11 and 17.12 but exposures in these industries are likely to be similar to exposures in the chemical manufacturing industry.

An estimate of exposure to 1-chloro-2,3-epoxypropane in NACE Code 37.2 (Recycling of non-metal waste and scrap) was based on the 1990 results from the Boogard *et al* (1993) study (GM 0.18 mg/m^3, GSD 1.62 mg/m^3) which were obtained during plant shutdown conditions. These work activities, where there may have been exposures to open tanks during cleaning and other maintenance work, were assumed to be representative of work in NACE Code 37.2 which is likely to include similar tasks during material recycling.

Table 2.5 Summary of measured exposure levels for manufacture and use of 1-chloro-2,3-epoxypropane (epichlorohydrin) and associated products

Date/ Period of Measurement	Process description	No. of workers	No. of samples taken	GM (mg/m^3)	GSD	AM (mg/m^3)	SD (mg/m^3)	Median (mg/m^3)	Range (mg/m^3)	Author	Country	Year Reported	Comments
1948-1955	Epichlorohydrin manufacture	-	-	-	-	-	-	-	38-76	Enterline *et al*	US	1990	-
1973	Epichlorohydrin manufacture	-	20	-	-		-	0.8	<0.04-8.0	Oser	US	1980	Production operators
1973	Epichlorohydrin manufacture	-	-	-	-	-	-	-	1.1	Oser	US	1980	Tank car loader
1977	Epichlorohydrin manufacture	-	-	-	-	25		-	<0.1-204	de Jong *et al*	US	1988	Study referenced by US EPA in 2008
1978	Epichlorohydrin manufacture	-	-	-	-	-	-	-	0.1-12	de Jong *et al*	US	1988	Study referenced by US EPA in 2008
1977-1978	Epichlorohydrin manufacture	-	-	-	-	-	-	-	<3.8	Tassignon *et al*	EU	1983	Reported by WHO/ Inchem in 1984
May-80	Epichlorohydrin manufacture	11	56	0.17	2.68	0.27	-	-	-	Boogaard *et al*	Netherlands	1993	Normal plant operation
Aug-80	Epichlorohydrin manufacture	13	45	0.09	6.33	0.45	-	-	-	Boogaard *et al*	Netherlands	1993	Normal plant operation
Oct-80	Epichlorohydrin manufacture	6	88	0.1	2.14	0.13	-	-	-	Boogaard *et al*	Netherlands	1993	Normal plant operation
Feb-81	Epichlorohydrin manufacture	5	14	0.13	1.82	0.15	-	-	-	Boogaard *et al*	Netherlands	1993	Normal plant operation
Jun-81	Epichlorohydrin manufacture	7	20	0.36	2.23	0.49	-	-	-	Boogaard *et al*	Netherlands	1993	Normal plant operation
Sep-81	Epichlorohydrin manufacture	9	28	0.22	2.35	0.31	-	-	-	Boogaard *et al*	Netherlands	1993	Normal plant operation
Dec-81	Epichlorohydrin manufacture	5	19	0.14	2.92	0.24	-	-	-	Boogaard *et al*	Netherlands	1993	Normal plant operation

Date/ Period of Measurement	Process description	No. of workers	No. of samples taken	GM (mg/m³)	GSD	AM (mg/m³)	SD (mg/m³)	Median (mg/m³)	Range (mg/m³)	Author	Country	Year Reported	Comments
Mar-82	Epichlorohydrin manufacture	8	32	0.17	2.34	0.24	-	-	-	Boogaard *et al*	Netherlands	1993	Normal plant operation
Jun-82	Epichlorohydrin manufacture	-	15	0.2	2.43	0.29	-	-	-	Boogaard *et al*	Netherlands	1993	Maintenance
Sep-82	Epichlorohydrin manufacture	7	20	0.29	2.36	0.41	-	-	-	Boogaard *et al*	Netherlands	1993	Normal plant operation
Dec-82	Epichlorohydrin manufacture	5	14	0.3	1.27	0.31	-	-	-	Boogaard *et al*	Netherlands	1993	Normal plant operation
Mar-83	Epichlorohydrin manufacture	18	18	0.31	1.73	0.36	-	-	-	Boogaard *et al*	Netherlands	1993	Normal plant operation
Mar-84	Epichlorohydrin manufacture	14	14	0.15	2.22	0.2	-	-	-	Boogaard *et al*	Netherlands	1993	Normal plant operation
Aug-87	Epichlorohydrin manufacture	44	44	0.07	2.5	0.11	-	-	-	Boogaard *et al*	Netherlands	1993	Normal plant operation
Apr-90	Epichlorohydrin manufacture	2	8	0.18	1.62	0.2	-	-	-	Boogaard *et al*	Netherlands	1993	Plant shutdown
Apr-91	Epichlorohydrin manufacture	3	3	0.27	1.7	0.3	-	-	-	Boogaard *et al*	Netherlands	1993	Plant shutdown: RPE worn
1957-1966	Glycerol manufacture	-	-	-	-	-	-	-	3.8-18.9	Olsen *et al*	US	1994	-
1966	Glycerol manufacture	-	-	-	-	-	-	-	Dec-21	Petko *et al*	USSR	1984	Not known if 8hr TWA or short term
1970 onwards	Glycerol manufacture	-	-	-	-	-	-	-	<3.8	Olsen *et al*	US	1994	-
1957-1966	Epoxy resin/ allyl chloride/ epichlorohydrin production	-	-	-	-	-	-	-	<3.8	Olsen *et al*	US	1994	Production areas
1973 – 1980	Epoxy resin manufacture	39	-	-	-	-	-	-	<3.0	Oser	US	1980	Production operators
1973 - 1980	Epoxy resin manufacture	1	-	-	-	-	-	-	5	Oser	US	1980	Area sample in pump room

Date/ Period of Measurement	Process description	No. of workers	No. of samples taken	GM (mg/m³)	GSD	AM (mg/m³)	SD (mg/m³)	Median (mg/m³)	Range (mg/m³)	Author	Country	Year Reported	Comments
1973-1976	Epoxy resin manufacture	-	-	-	-	-	-	-	<3.8	Shellenberger *et al*	US	1979	Production staff. Referenced by WHO/ Inchem in 1984
1973-1976	Epoxy resin manufacture	-	-	-	-	-	-	-	3.8-18.9	Shellenberger *et al*	US	1979	Laboratory staff. Referenced by WHO/ Inchem in 1984
1996-1997	Epoxy resin manufacture	-	29	-	-	4.6	5.1	-	0.76-14.7	Luo *et al*	Taiwan	2004	Workers categorised in study as "high exposure"
1996-1997	Epoxy resin manufacture	-	22	-	-	0.3	0.18	-	0.038-0.42	Luo *et al*	Taiwan	2004	Workers categorised in study as "low exposure"
1997	Epoxy resin / printed circuit board/ synthetic leather manufacture	37	28	-	-	8.4	10.5	-	<limit of detection – 63.0	Kuo *et al*	Taiwan	2001	No detail given on work tasks carried out.
1999	Epoxy resin / printed circuit board/ synthetic leather manufacture	37	16	-	-	0.18	0.2	-	<limit of detection – 0.46	Kuo *et al*	Taiwan	2001	No detail given on work tasks carried out. Same processes/ workers as 1997 sampling programme.
2000	Epoxy resin manufacture	-	-	-	-	-	-	-	<0.4	Plna *et al*	Sweden	2000	Production areas

Date/ Period of Measurement	Process description	No. of workers	No. of samples taken	GM (mg/m^3)	GSD	AM (mg/m^3)	SD (mg/m^3)	Median (mg/m^3)	Range (mg/m^3)	Author	Country	Year Reported	Comments
2000	Epoxy resin manufacture	-	-	-	-	-	-	-	1.9	Plna *et al*	Sweden	2000	During transfer from railcars to tanks

GM = Geometric mean; GSD = Geometric Standard Deviation; AM = Arithmetic mean; SD = Standard Deviation

The overall weighted GM and GSD were estimated across all industries in the EU using @Risk© (Palisade Corporation, New York). Exposures were simulated using the estimated GM and GSD for each industry. The number of values each industry contributed was weighted according to the number of workers exposed in that industry. The estimated GM is 0.085 mg/m^3 and the estimated GSD is 2.53. At these exposure levels 99.96% of workers are estimated to be exposed at levels below the typical OEL of 1.9 mg/m^3. For the purposes of the current analysis, it is assumed that there are no workers exposed above the most commonly adopted EU OEL value of 1.9 mg/m^3.

There is very little evidence of change in exposure levels since the 1980s in the data that we have identified. Given the relatively low level of exposure we have assumed that the exposure levels have been stable since at least 1980.

2.4 HEALTH IMPACT FROM CURRENT EXPOSURES

2.4.1 Background data

The occupational cancers associated with exposure to 1-chloro-2,3-epoxypropane are shown in Table 2.6, along with a summary of the information used in the health impact assessment.

Table 2.6 Occupational cancers associated with exposure to 1-chloro-2,3-epoxypropane

Cancer site	**Lung**		**Central Nervous System (CNS) (Malignant neoplasm of meninges, brain and other parts of central nervous system)**	
ICD-10 code	C33-C34		C70-C72	
IARC group for carcinogen	2A		2A	
Strength of evidence for cancer site (1)	Suggestive		Suggestive	
Latency assumption	10-50 yrs		10-50 yrs	
Source of forecast numbers - deaths	Eurostat, 2006 for C32-C34		GLOBOCAN 2002	
Source of forecast numbers - registrations	GLOBOCAN 2002[45]		GLOBOCAN 2002	
Exposure levels	*Relative Risk (RR)*	*Source of RR*	*Relative Risk (RR)*	*Source of RR*
Medium	1.7 (0.7-4.1)	Barbone *et al*, (1992, 1994)	4.2 (0.7 – 26)	Barbone *et al*, (1992, 1994)
Low	1		1	

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

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

2.4.2 Exposed numbers and exposure levels

Industry sectors, their NACE codes, classifications to High/Medium/Low/Background exposure as applicable for the mid 1970's and numbers exposed in 2010 are given in Table 2.3 and Table 2.2, respectively, in the previous section on exposure. The estimated average exposure level (GM) and measure of variability (GSD) for NACE industries exposed to 1-chloro-2,3-epoxypropane are 0.085 mg/m^3 and 2.53 respectively for 2010 and a 0% decline (levels stable since 1980) is assumed.

We present data for a "baseline" scenario which for all industries assumes the annual declines as above in exposure levels and standard change in employed numbers up to the 2001-10 estimation interval and constant levels thereafter.

2.4.3 Forecast cancer numbers

Separate estimates for total numbers of deaths for lung (C32-C34, including larynx) cancer by age band are available from EUROSTAT for the 27 countries of the EU, for 2006, and for registrations for lung (C33-C34) cancer and for CNS cancer from GLOBOCAN for 2002. No European mortality estimates were available for CNS cancer (ICD10 C90-C92), so the estimates from GLOBOCAN for deaths in 2002 (for ages 15+ only as for registrations) were used. The forecast numbers of deaths and registrations by country used to estimate attributable numbers are in Appendix 8.2.

2.4.4 Results

The cancer deaths and registrations attributed to occupational exposure to 1-chloro-2,3-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 the total EU is in Table 2.7 below.

Table 2.7 Results for the baseline forecast scenario, total EU (27 countries), 1-chloro-2,3-epoxypropane, men plus women

Scenario	**All scenarios**		**Baseline (static) scenario (1) - Linear employment and exposure level trends assumed to 2001-10, constant thereafter.**			
EU Total	**2010**	**2020**	**2030**	**2040**	**2050**	**2060**
Numbers ever exposed	182,592	183,818	185,542	184,245	183,173	183,173
Proportion of the population exposed	0.051%	0.048%	0.048%	0.046%	0.046%	0.047%
Lung cancer						
Attributable Fraction	0.0073%	0.0073%	0.0074%	0.0073%	0.0073%	0.0075%
Attributable deaths	21	24	28	31	33	34
Attributable registrations	22	26	30	32	33	34
'Avoided' cancers						
YLLs	317	358	400	418	424	426
DALYs	331	373	418	437	443	446
CNS cancer						
Attributable Fraction	0.031%	0.031%	0.031%	0.031%	0.031%	0.032%
Attributable deaths	10	11	12	13	13	13
Attributable registrations	12	13	14	15	15	15
'Avoided' cancers						
YLLs	324	348	374	383	385	388
DALYs	332	356	382	391	393	395

In 2010 there are 21 predicted attributable deaths from lung cancer and 10 attributable deaths from CNS cancer as a consequence of past exposure to 1-chloro-2,3-epoxypropane. The number of registrations is similar to the deaths in each case because both types of tumour are highly fatal. In the period up to the decade starting 2060 the number of deaths increases to 34 for lung cancer and 13 for CNS cancer. The increases are entirely due to the increase in the longevity of the population. There is no change in exposure levels over the period of these calculations. The attributable fraction of lung cancers is 0.0073% and for CNS cancers it is 0.031%

DALYs and YLLs also increase over the period studied: for DALYs from 331 to 446 years per annum for lung and from 332 to 395 years per annum for brain cancer; and for YLLs from 317 to 426 years per annum for lung and 324 to 388 years per annum for CNS cancer.

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 are shown in section 2.4 of this report. Based on these data, there are predicted to be approximately

1,770 cancer registrations over the period 2010-2070[46] and around 23,430 YLLs over the period 2010-2070[46] from lung cancer mainly resulting from historical exposure to 1-chloro-2,3-epoxypropane. There is predicted to be an increase in registrations and YLLs over time as a result of ageing European populations and overall population increase where no change in average exposure levels is expected.

These data show that there are predicted to be approximately 850 cancer registrations over the period 2010-2070[46] and around 22,010 YLLs over the period 2010-2070[46] from lung cancer mainly resulting from historical exposure to 1-chloro-2,3-epoxypropane.

Method in brief

Using the health data (cancer registrations and Years of Life Lost - '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[47]). COI includes the direct and indirect costs of cancer but not the intangible costs (see below).
- Willingness to Pay (WTP) to avoid cancer – WTP in this study is used as an alternative method (high cost scenario) based on publically available, peer reviewed studies on what people would be willing to pay to avoid having cancer. This includes various intangible costs (such as disfigurement, functional limitations, pain and fear) and includes the costs associated with life years lost.

The cost variables used in this study are presented in Table 2.8 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 increasing value society attaches to its health (as economic growth typically increases over a long period of time)[48].

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[46] 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.

[47] ECHA (2008) "Applying SEA as part of restriction proposals under REACH"
Available at: http://echa.europa.eu/doc/reach/sea_workshop_proceedings_20081021.pdf

[48] This is consistent with some other European Commission studies and is standard practice for air quality under the Clean Air for Europe (CAFE) programme.

Table 2.8 Summary of cost variables used in this study (€ 2010 prices)

Cost/benefit elements	Low scenario	High scenario
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[49]. 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. an 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 'snap-shot' 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

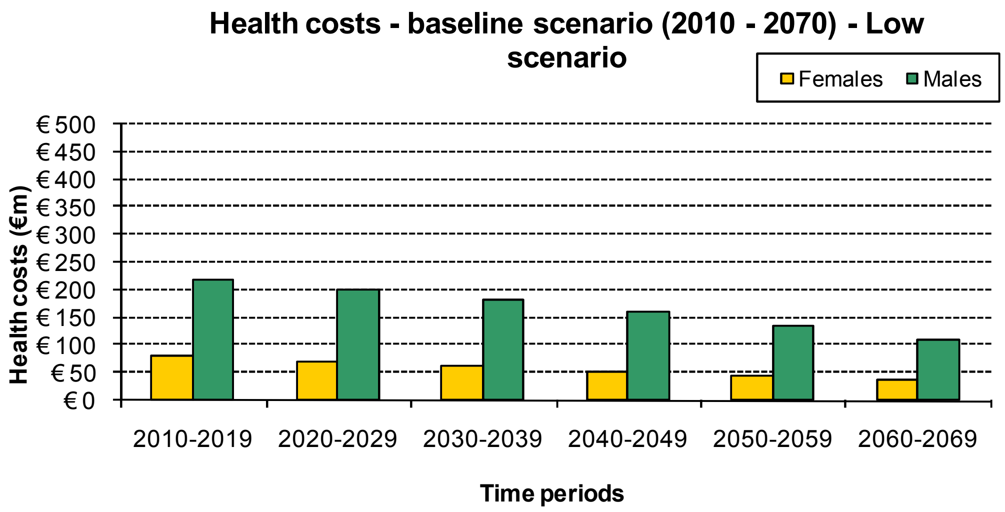
The health costs under the baseline scenario are presented in Table 2.9. The ranges are based on the high and low cost scenarios (see Table 2.8). Health-related costs are predicted to decline over time and are predominately the result of the discount rate applied (see Fibure 2.6). In Section 2.4 the number of cancer registrations and YLLs are estimated to increase over time, accounted for by an ageing population with no change in average exposure levels expected. The results are also illustrated in Figure 2.1.

[49] European Commission impact Assessment Guidelines (Jan 2009) - http://ec.europa.eu/governance/impact/commission_guidelines/docs/iag_2009_en.pdf

Table 2.9 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	81 to 120	72 to 108	64 to 98	54 to 85	45 to 71	37 to 60	81 to 542
Male	219 to 456	200 to 425	185 to 403	160 to 359	134 to 308	111 to 259	1009 to 2210
Total	300 to 576	272 to 534	249 to 501	214 to 444	179 to 380	148 to 319	1362 to 2752

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



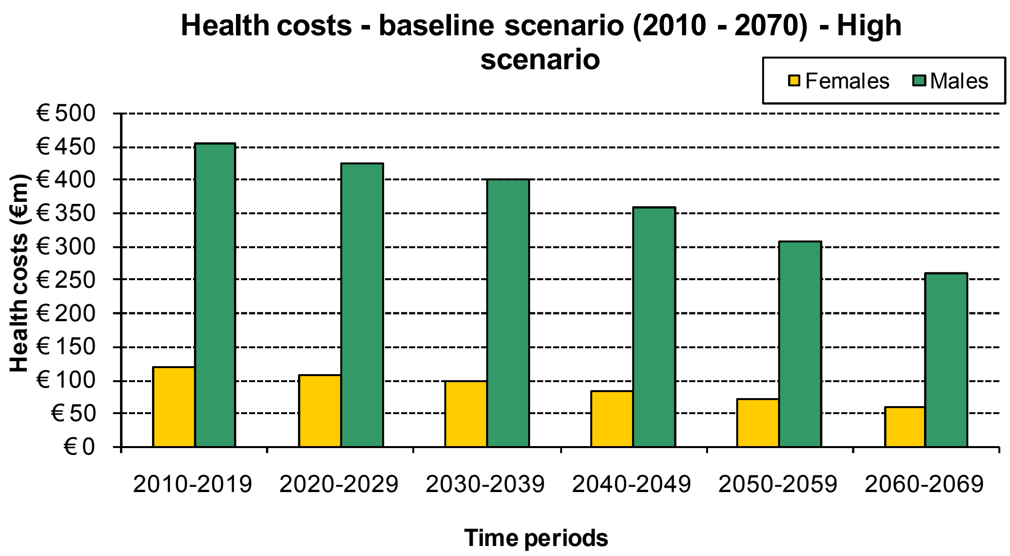


Figure 2.1 Health costs - baseline scenario – 2010 to 2070 (Present Value – 2010 €m prices)

These 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 2.3** shows that Italy, Poland and Greece are predicted to have relatively high health costs, with Spain and the UK following. The industrial sector estimated to be most affected under the baseline is the preparation and spinning of cotton-type fibres sector. The preparation and spinning of woollen-type fibres sector is affected less, due to the smaller numbers of people exposed. This is shown in **Figure 2.5**.

Detailed tables are included in Appendix 8.3.

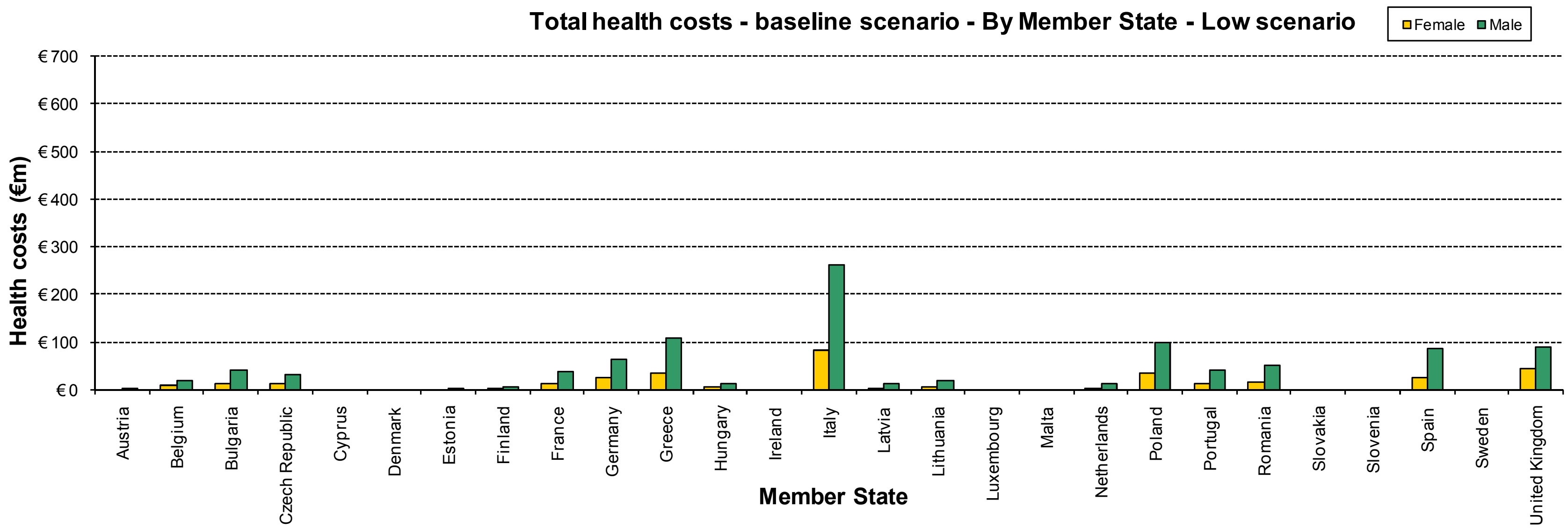


Figure 2.2a Total health costs- baseline scenario – By Member State (Present Value – 2010 €m prices)

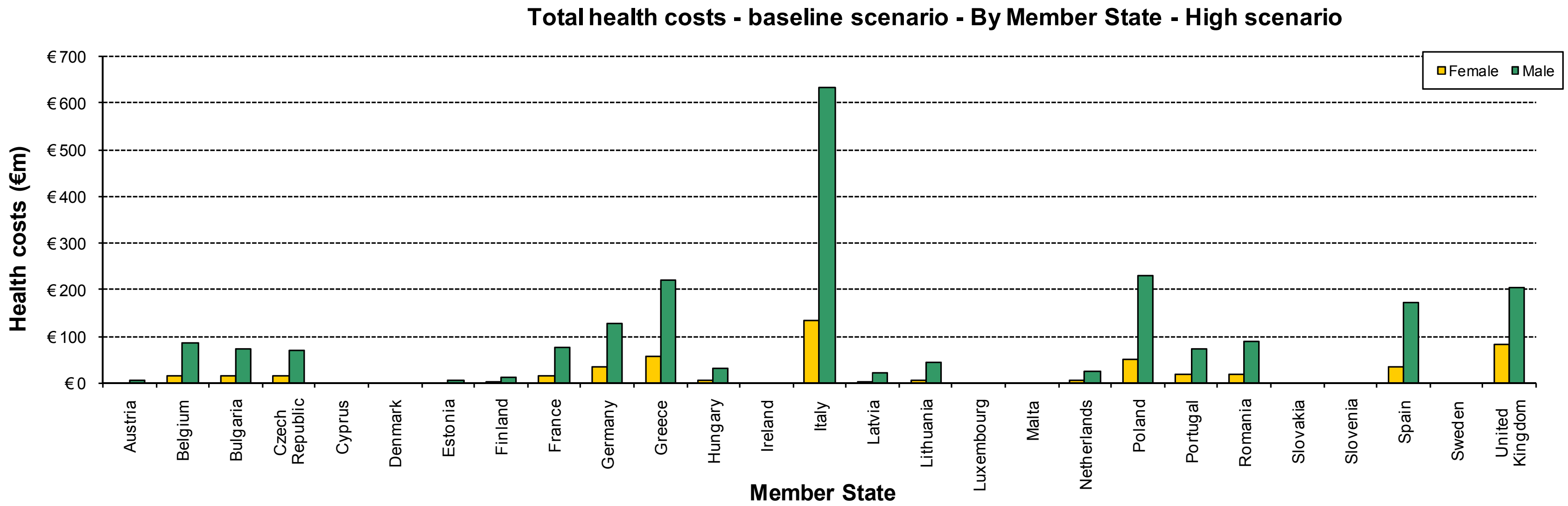


Figure 2.3b Total health costs- baseline scenario – By Member State (Present Value – 2010 €m prices)

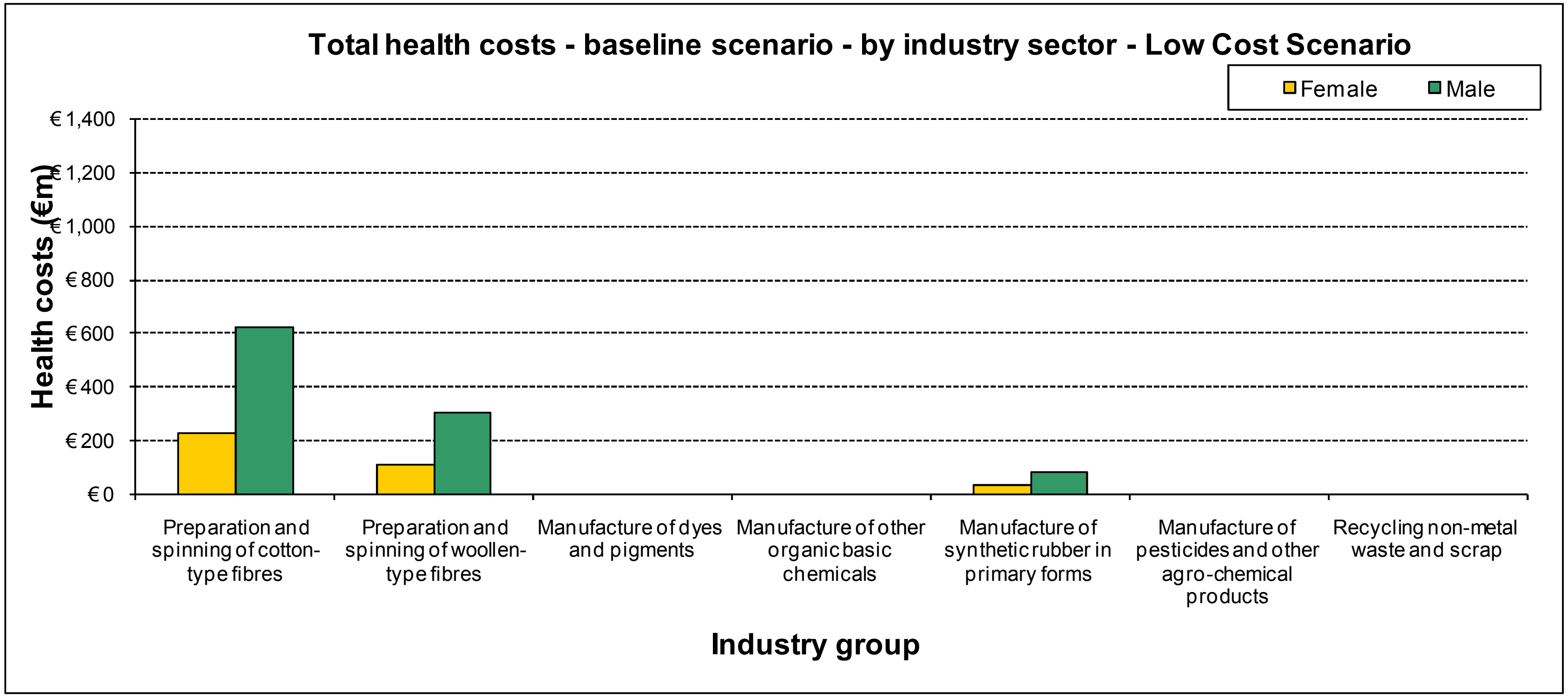


Figure 2.4a Total health costs - baseline scenario - by industry group (Present Value – 2010 €m prices)

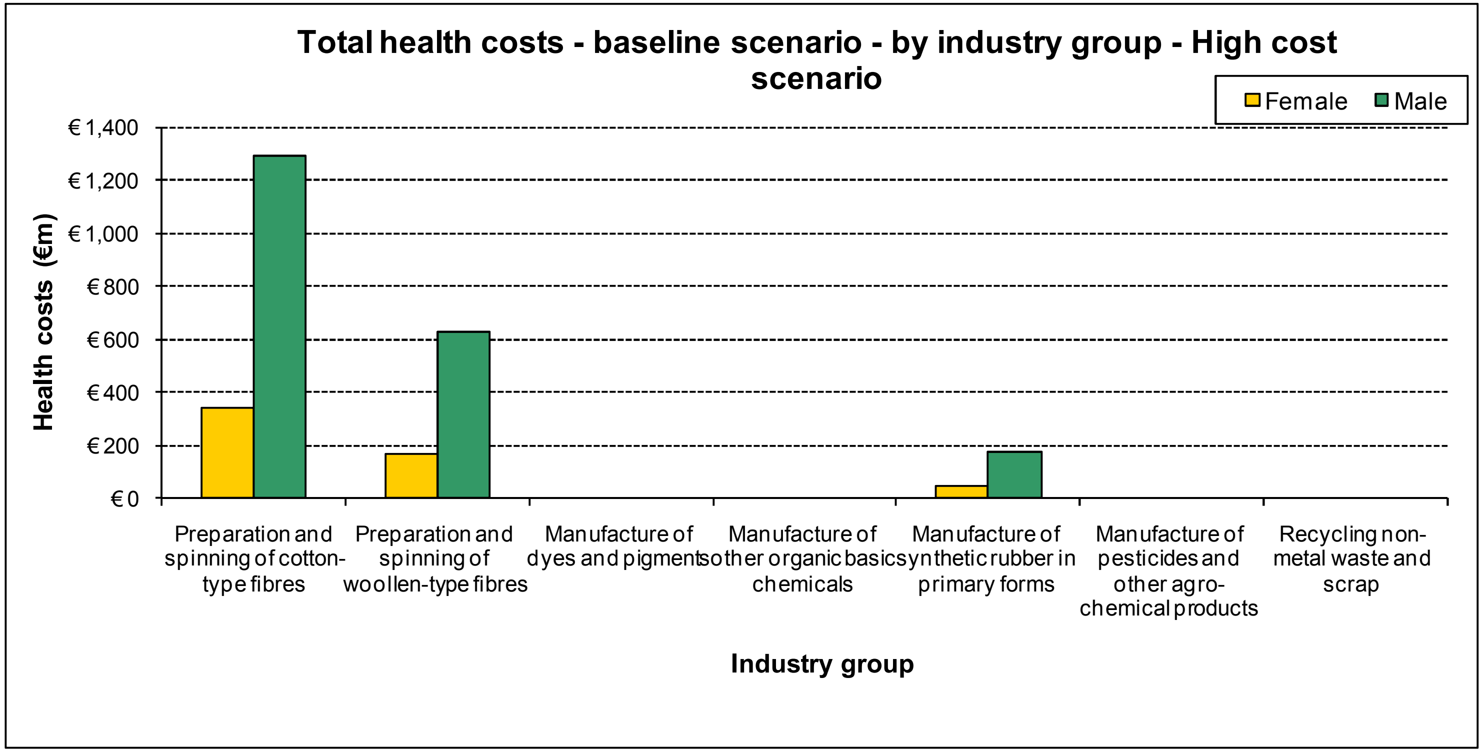
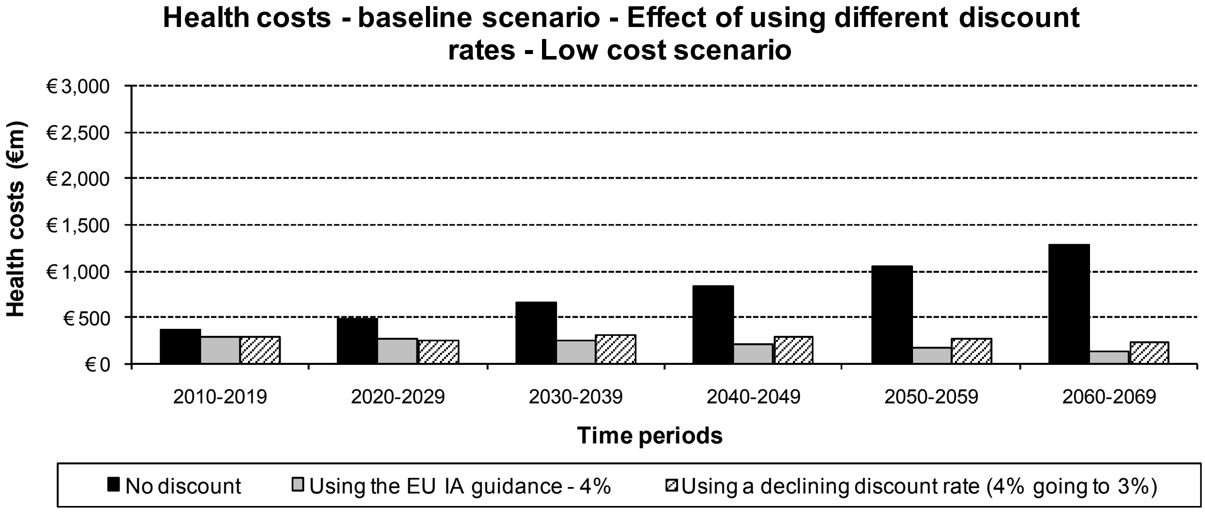


Figure 2.5b Total health costs - baseline scenario - by industry group (Present Value – 2010 €m prices)

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 2.6, the effects of different discount rates on the overall results are shown, indicating that the impacts of discounting become more pronounced the further in the future that the impact occurs. As the number of registrations and YLLs increase over time, the difference between using discounting and with no discounting becomes more evident.



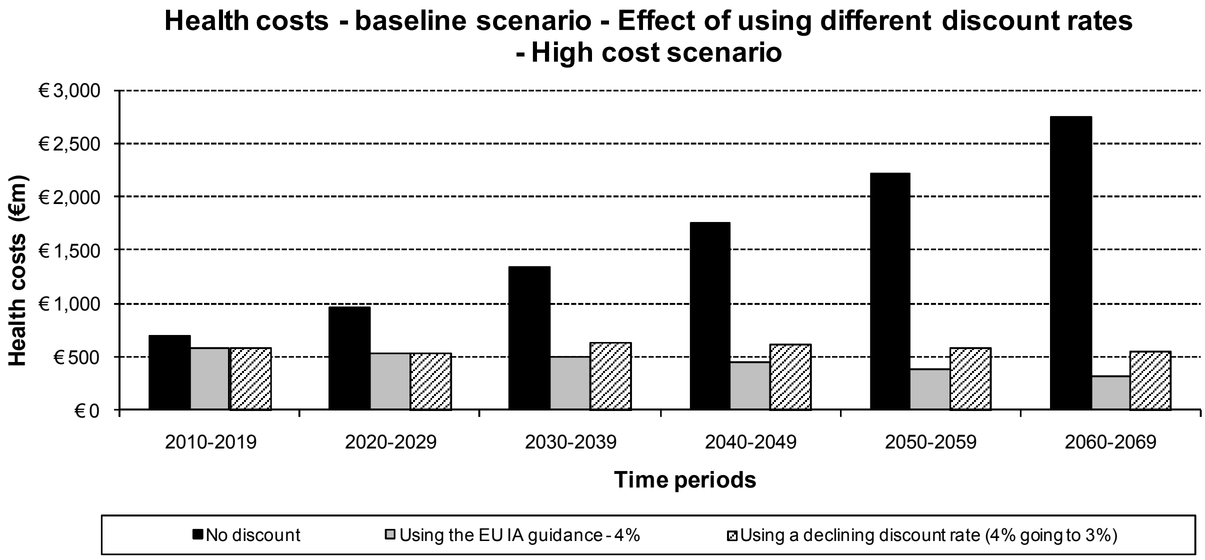


Figure 2.6 Impacts of discounting

3 POLICY OPTIONS

3.1 DESCRIPTION OF MEASURES

During manufacture of 1-chloro-2,3-epoxypropane, workers' inhalation and dermal exposures are controlled via the use of closed systems with engineering controls such as vapour return lines during product transfer, the dry disconnect style of fittings for transfer hoses and automated sampling systems. Personal protective equipment is also used to reduce inhalation and dermal exposure.[50] Significant exposures are therefore likely to occur only during maintenance activities, or during accidental releases.

1-chloro-2,3-epoxypropane is noted by one manufacturer as easily penetrating protective clothing, gloves and shoes,[51] thereby necessitating the use of butyl rubber, polyvinyl alcohol or polytetrafluoroethylene clothing and gloves. This manufacturer has also included a specific warning in their safety guidance against the use of leather personal protective equipment as contaminated leather articles allow diffusion of the 1-chloro-2,3-epoxypropane to the wearer's skin, with a significant potential for chemical burns.

The provision of showers and eye washes is also recommended to allow prompt skin and eye decontamination. The use of a suitable full face air purifying respirator or positive pressure supplied-air respirator is recommended for those normal operations where there is a higher risk of exposure. For emergencies and other conditions in which the exposure guideline may be greatly exceeded, the use of an approved positive-pressure self-contained breathing apparatus (SCBA) or a positive-pressure supplied-air respirator with an auxiliary SCBA is recommended.

No information has been obtained on the controls used by downstream users of 1-chloro-2,3-epoxypropane and its products. It is likely that bulk materials are transported in closed systems, with potential inhalation and dermal exposures mainly occurring during transfer of materials to tanks, mixing of products, maintenance tasks and in laboratory/ quality control sampling activities.

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 1.9 mg/m^3. However, because the estimated exposures are all low and it is not expect that anyone is

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[50] Dow Chemicals: Product Stewardship Manual: Epichlorohydrin : Safe Handling and Storage (2007) http://www.dow.com

[51] Solvay Chemicals (2002). Epichlorohydrin Properties. Available at: http://www.solvaychemicals.us/static/wma/pdf/5/0/7/9/epi3chem.pdf

currently exposed above the typical OEL there are no health benefits from introducing the limit.

4.1.2 Monetised health benefits

As indicated previously, it is assumed that there are currently no individuals are exposed above the possible OEL of 1.9 mg/m^3. As such, it is assumed that there would be no health benefits of introducing an OEL at the most commonly adopted level amongst the EU Member States. (The terms of reference for the project require that the impact that the most commonly adopted value, or range of values, would have if adopted at EU level.)

Given the level of health costs under the baseline, the introduction of an OEL would need to be significantly lower in order to lead to health benefits. However, this has not been investigated here.

4.2 ECONOMIC IMPACTS

4.2.1 Operating costs and conduct of business

Number of Firms Affected

It is estimated that there are approximately 43,000 employees across the EU exposed to levels of 1-chloro-2,3-epoxypropane (see Appendix 8.1). However, as set out in Section 2.3.1, it is assumed that none would be exposed in excess of the possible OEL value of 1.9 mg/m^3.

Therefore there is not expected to be a need for additional direct control measures to comply with the OEL but there may be costs associated with the administrative and workplace requirements that arise from using a substance that is on the Directive. However, some of these measures may already be part of best practice in achieving compliance with other legislative requirements (e.g. as a result of classification and labelling and the Chemicals Agents Directive). Specifically, it has not been identified that any additional control measures would be required to comply with an EU-wide OEL at that level as compared to control measures already in place.

Conduct of employers

Employees may need to change their working practice to ensure that any Risk Management Measures (RMMs) put into place as a result of being on the Directive are adhered to correctly (if they are not doing so already through any legislation). However, there is no indication that RMMs are not being adhered to and current exposure already seems to be below the possible OEL of 1.9 mg/m^3.

Potential for closure of companies

There is not expected to be any significant additional potential for closure of companies as a result of introducing an EU-wide OEL of 1.9 mg/m^3 because compliance costs are likely to be minimal.

Potential impacts for specific types of companies

There are not expected to be any particular impacts for specific types of companies, since any additional costs of meeting an OEL of 1.9 mg/m^3 relative to the baseline scenario are likely to be minimal (or nil).

The main advantage of an EU-wide OEL would be to create consistency in regulation across the EU and remove any competitive disadvantage to those Member States that previously had more stringent national OELs in place (Czech Republic, Latvia, Poland and Romania all have OELs of 1.0 mg/m^3 in place). However, there is unlikely to be any practical difference.

Administrative costs to employers and public authorities

The following table (Table 4.1) 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 4.1 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

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 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 4.2) 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 4.2 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 of 1.9 mg/m^3 will have significant impacts on affected industries, there is not expected to be any significant impact on third countries such as redistribution of investment, jobs or sales.

As shown in the 8-hour TWA OELs across the EU range from 1 mg/m^3 to 18.9 mg/m^3 (0.25 to 5 ppm). For the purposes of this report an OEL of 1.9 mg/m^3 (0.5 ppm) is considered typical for the EU.

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 or to harmonise existing OELs with the EU-wide one.

4.2.2 Impact on innovation and research

Impacts on innovation and research from introducing an EU-wide OEL of 1.9 mg/m^3 are expected to be minimal.

4.2.3 Macroeconomic impact

Since compliance with an OEL would not involve changing the current manufacturing process there is unlikely to be any significant change to macro-economic impacts.

4.3 SOCIAL IMPACTS

4.3.1 Employment and labour markets

There are not expected to be any noticeable changes to the numbers of workers required as a result of introducing an EU-wide OEL.

4.3.2 Changes in end products

There are not expected to be any noticeable changes to the end product since control measures do not change the characteristics of the product and no additional control measures are expected to be required. Since there is not expected to be any closure of companies, there should not be any change in supply of products relative to the baseline scenario.

4.4 ENVIRONMENTAL IMPACTS

Any effect on the environment of introducing an EU-wide OEL will probably be negligible because it is estimated that exposure is already controlled to levels below 1.9 mg/m^3.

5 COMPARISON OF OPTIONS

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

Table 5.1 Comparison of health impacts by scenario

Baseline Scenario		Intervention scenario (2) – Assumes full compliance for OEL = 1.9 mg/m^3	
Health Costs	**Health Benefits**	**Health Costs**	**Health Benefits**
As set out in section 2.5, the health costs of cancer (lung and CNS) over the period 2010-70 are estimated to be: - Females: €81m to €542m - Males: €1009 m to €2210m - Total: €1362m to €2752m This range takes into consideration tangible costs (e.g. lost income, lost output from reduced productivity, medical costs, life years lost) and intangible costs (e.g. emotional and physical suffering from having cancer).	As a static baseline has been assumed due to historical exposure being fairly constant, there are not expected to be health benefits from reduced exposure over time.	None.	None – exposure is already estimated to be below the possible OEL.

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

Table 5.2 Comparison of economic impacts by scenario

Baseline Scenario		Intervention scenario (2) – Assumes full compliance for OEL = 1.9 mg/m^3	
Economic Costs	**Economic Benefits**	**Economic Costs**	**Economic Benefits**
In the analysis presented, a static baseline is assumed. Therefore, no firms will incur costs to reduce exposure under the baseline scenario	-	It is estimated that, under the baseline scenario, firms are already achieving exposures less than 1.9 mg/m^3. Therefore there are not expected to be any significant additional costs of meeting an OEL of 1.9 mg/m^3 relative to the baseline scenario other than administrative costs.	Having an EU-wide OEL level should remove any EU competitive distortions between EU Member States with different OELs.

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

Table 5.3 Comparison of social impacts by scenario

Baseline Scenario		Intervention scenario (2) – Assumes full compliance for OEL = 1.9 mg/m^3	
Social Costs	**Social Benefits**	**Social Costs**	**Social Benefits**
There are not expected to be any noticeable social impacts under the baseline scenario at an EU level.		There are not expected to be any noticeable changes to the numbers of workers required as a result of introducing an EU-wide OEL.	

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

Baseline Scenario		Intervention scenario (2) – Assumes full compliance for OEL = 1.9 mg/m^3	
Marco-economic Costs	**Marco-economic Benefits**	**Marco-economic Costs**	**Marco-economic Benefits**
There are not expected to be any noticeable macroeconomic impacts under the baseline scenario.		Since there are not expected to be any significant economic impacts, there are not expected to be any significant changes in macroeconomic impacts relative to the baseline scenario from introducing an EU-wide OEL.	

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

Table 5.5 Comparison of environmental impacts by scenario

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

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

6 CONCLUSIONS

This report considers the likely health, socioeconomic and environmental impacts associated with possible changes to the Carcinogens Directive, in particular the possible introduction of an occupational exposure limit (OEL) of 1.9 mg/m^3 (0.5 ppm).

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

Exposure levels are judged to currently be low and it is unlikely that anyone is exposed to levels above 1.9 mg/m^3. We have no information about temporal trends and we have assumed that there has been no change in exposure levels over more recent years.

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

We estimate that in 2010 in the EU there will be about 22 incident case or death from lung cancer that might be attributable to past exposure to 1-chloro-2,3-epoxypropane. This corresponds to about 0.0073% of all lung cancer cases amongst the exposed workers. The corresponding number of incident CNS cancers is about 12, with a similar number of deaths. If no specific actions are taken to reduce exposure to 1-chloro-2,3-epoxypropane then the predicted numbers of cancer cases increases to 34 cases of lung cancer and 15 cases of brain cancer up to the decade starting 2060. The main cause of the increase is the increase in survival amongst the population as a consequence of improving general health. Estimated DALYs increase over the period up to 2060/70 from 331 to 446 years per annum for lung cancer and from 332 to 395 years per annum for brain cancer. Total estimated health costs associated with inaction range from €1,362m to €2,752m.

Current exposures in the EU are judged to be well below 1.9 mg/m^3 and so there are no important costs associated with compliance with the suggested OEL. There are also no social or macro-economic costs associated with introducing an OEL at either of these levels.

There are no significant environmental impacts foreseen.

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8 APPENDIX

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

Table 8.1.1 Number of workers exposed to epichlorohydrin by member state and NACE code – males and female

	NACE Code														
	17.11			17.12			24.12			24.14			24.17		
Country	**Total**	**Male**	**Female**	**Total**	**Male**	**Female**	**Total**	**Male**	**Female**	**Total**	**Male**	**Female**	**Total**	**Male**	**Female**
Austria	16	11	5	12	8	4		Not Available		226	158	68		Not Available	
Belgium	51	36	15	110	77	33	174	122	52	1423	996	427	104	73	31
Bulgaria	237	166	71	200	140	60	3	2	1	83	58	25		Not Available	
Cyprus		Not Available			Not Available			Not Available			Not Available			Not Available	
Czech Republic	240	168	72	18	13	5		Not Available		329	230	99	8	6	2
Denmark		Not Available			Not Available		49	34	15		Not Available			Not Available	
Estonia		Not Available		20	14	6		Not Available		21	15	6		Not Available	
Finland		Not Available		10	7	3	112	78	34	172	120	52	65	46	20
France	87	61	26	43	30	13	390	273	117	2932	2052	880	173	121	52
Germany	556	389	167		Not Available		1176	823	353	5625	3938	1688		Not Available	
Greece	700	490	210	3	2	1	44	31	13		Not Available			Not Available	
Hungary	83	58	25	12	8	4	23	16	7	102	71	31		Not Available	
Ireland		Not Available			Not Available			Not Available		962	673	289		Not Available	
Italy	1236	865	371	1097	768	329		Not Available		1689	1182	507		Not Available	
Latvia	103	72	31	5	4	2		Not Available		49	34	15		Not Available	
Lithuania	28	20	8	157	110	47		Not Available		38	27	11		Not Available	
Luxembourg		Not Available			Not Available			Not Available			Not Available			Not Available	
Malta		Not Available			Not Available			Not Available			Not Available			Not Available	
Netherlands	36	25	11		Not Available		249	174	75	1592	1114	478	66	46	20
Norway		Not Available			Not Available		27	19	8	158	111	47		Not Available	

Country	NACE Code 17.11 Total	Male	Female	17.12 Total	Male	Female	24.12 Total	Male	Female	24.14 Total	Male	Female	24.17 Total	Male	Female
Poland	468	328	140	226	158	68	95	67	29	1277	894	383	1	1	0
Portugal	456	319	137	Not Available			Not Available			Not Available			Not Available		
Romania	374	262	112	76	53	23	54	38	16	237	166	71	6	4	2
Slovenia	Not Available			Not Available			136	95	41	33	23	10	Not Available		
Slovakia	Not Available			Not Available			Not Available			160	112	48	0	0	0
Spain	768	538	230	113	79	34	354	248	106	666	466	200	84	59	25
Sweden	Not Available			1	1	0	14	10	4	272	190	82	Not Available		
United Kingdom	91	64	27	429	300	129	Not Available			1876	1313	563	175	123	53
TOTAL	5530	3871	1659	2532	1772	760	2900	2030	870	19922	13943	5980	682	479	205

Country	NACE Code 24.2 Total	Male	Female	37.2 Total	Male	Female	Grand Total Total	Male	Female
Austria	38	27	11	100	70	30	**392**	**274**	**118**
Belgium	72	50	22	314	220	94	**2248**	**1574**	**674**
Bulgaria	Not Available			50	35	15	**573**	**401**	**172**
Cyprus	19	13	6	16	11	5	**35**	**24**	**11**
Czech Republic	Not Available			177	124	53	**772**	**541**	**231**
Denmark	Not Available			Not Available			**49**	**34**	**15**
Estonia	Not Available			33	23	10	**74**	**52**	**22**
Finland	Not Available			20	14	6	**379**	**265**	**115**
France	642	449	193	1574	1102	472	**5841**	**4088**	**1753**
Germany	808	566	242	1509	1056	453	**9674**	**6772**	**2903**
Greece	89	62	27	Not Available			**836**	**585**	**251**
Hungary	65	46	20	75	53	23	**360**	**252**	**110**
Ireland	29	20	9	47	33	14	**1038**	**726**	**312**

	NACE Code								
	24.2			37.2			Grand Total		
Country	Total	Male	Female	Total	Male	Female	Total	Male	Female
Italy	291	204	87	1118	783	335	**5431**	**3802**	**1629**
Latvia	3	2	1	25	18	8	**185**	**130**	**57**
Lithuania	Not Available			53	37	16	**276**	**194**	**82**
Luxembourg	Not Available			3	2	1	**3**	**2**	**1**
Malta	Not Available			Not Available			**Not Available**		
Netherlands	95	67	29	456	319	137	**2494**	**1745**	**750**
Norway	Not Available			34	24	10	**219**	**154**	**65**
Poland	236	165	71	833	583	250	**3136**	**2196**	**941**
Portugal	46	32	14	144	101	43	**646**	**452**	**194**
Romania	84	59	25	304	213	91	**1135**	**795**	**340**
Slovenia	Not Available			37	26	11	**206**	**144**	**62**
Slovakia	2	1	1	110	77	33	**272**	**190**	**82**
Spain	306	214	92	460	322	138	**2751**	**1926**	**825**
Sweden	Not Available			60	42	18	**347**	**243**	**104**
United Kingdom	456	319	137	1414	990	424	**4441**	**3109**	**1333**
TOTAL	3281	2296	987	8966	6278	2690	**43813**	**30669**	**13144**

8.2 ESTIMATED DEATHS AND REGISTRATIONS IN THE EU FROM 1-CHLORO-2,3-EPOXYPROPANE

Table 8.2.1 Forecast number of lung and central nervous system cancers in ages 15+ (ages 25+ for lung cancer deaths), based on projected EU country populations

Lung cancer deaths	***MEN***						***WOMEN***					
FTY	**2010**	**2020**	**2030**	**2040**	**2050**	**2060**	**2010**	**2020**	**2030**	**2040**	**2050**	**2060**
Austria	2,698	3,346	3,956	4,483	4,711	4,745	1,129	1,290	1,459	1,611	1,705	1,687
Belgium	0	0	0	0	0	0	0	0	0	0	0	0
Bulgaria	3,127	3,202	3,344	3,500	3,456	3,149	590	604	627	634	624	588
Cyprus	146	199	257	320	389	456	38	50	66	82	96	113
Czech Republic	4,741	5,771	6,660	7,492	8,086	8,078	1,582	1,790	2,024	2,204	2,278	2,323
Denmark	2,342	2,915	3,363	3,606	3,695	3,745	1,819	2,137	2,380	2,529	2,552	2,563
Estonia	610	666	751	847	937	982	154	166	172	182	189	183
Finland	1,686	2,167	2,617	2,783	2,822	2,923	592	693	786	824	818	817
France	24,854	29,288	33,628	36,549	38,217	39,689	6,697	7,502	8,353	9,042	9,293	9,389
Germany (including ex-GDR from 1991)	33,102	39,458	44,318	48,341	48,129	46,049	12,629	14,018	14,868	15,581	15,458	14,585
Greece	5,779	6,593	7,578	8,628	9,275	9,333	1,070	1,265	1,388	1,542	1,665	1,705
Hungary	6,068	6,634	7,398	8,125	8,599	8,624	2,437	2,557	2,746	2,803	2,814	2,785
Ireland	1,175	1,595	2,112	2,691	3,299	3,759	720	932	1,209	1,512	1,815	2,051
Italy	29,397	34,515	40,206	46,091	49,731	49,259	7,857	8,917	9,911	10,930	11,683	11,548
Latvia	1,025	1,091	1,220	1,355	1,483	1,502	220	231	239	256	265	264
Lithuania	1,384	1,538	1,764	1,982	2,138	2,164	267	286	313	344	352	350
Luxembourg	176	228	291	350	386	413	52	61	75	89	96	102
Malta	146	192	235	255	275	299	20	21	22	23	24	23
Netherlands	7,177	9,325	11,423	12,679	12,877	12,754	3,444	4,079	4,583	4,835	4,782	4,720
Poland	19,813	24,204	28,329	31,413	34,266	34,929	5,717	6,552	7,274	8,001	8,124	7,952
Portugal	3,111	3,600	4,173	4,708	5,070	5,188	677	778	878	977	1,046	1,073
Romania	8,342	9,179	10,368	11,480	11,726	11,057	1,935	2,100	2,335	2,521	2,626	2,589
Slovakia	1,963	2,488	3,057	3,508	3,884	3,932	438	508	608	709	742	773
Slovenia	944	1,168	1,406	1,545	1,581	1,552	282	317	353	379	379	370
Spain	20,051	24,629	30,491	36,512	40,400	40,734	2,942	3,503	4,051	4,536	4,903	5,021
Sweden	2,078	2,503	2,886	3,122	3,340	3,542	1,659	1,862	2,064	2,198	2,302	2,390

Lung cancer deaths	MEN						WOMEN					
FTY	2010	2020	2030	2040	2050	2060	2010	2020	2030	2040	2050	2060
United Kingdom	21,915	26,107	30,805	34,784	38,234	41,219	15,291	17,180	19,778	22,297	24,098	25,562
European Union (27 countries)	210,064	249,072	289,493	323,680	342,919	348,763	70,053	79,186	88,770	96,845	100,598	100,564

Lung cancer registration	MEN						WOMEN					
FTY	2010	2020	2030	2040	2050	2060	2010	2020	2030	2040	2050	2060
Ages 15+												
Austria	3,195	3,838	4,514	4,960	5,120	5,164	1,214	1,357	1,526	1,653	1,691	1,679
Belgium	7,322	8,692	10,013	10,852	11,262	11,628	1,292	1,445	1,593	1,703	1,753	1,779
Bulgaria	2,684	2,717	2,857	2,967	2,899	2,741	513	529	545	553	541	514
Cyprus	0	0	0	0	0	0	0	0	0	0	0	0
Czech Republic	5,691	6,740	7,663	8,472	8,896	8,764	1,447	1,647	1,808	1,937	2,003	1,988
Denmark	2,325	2,806	3,129	3,278	3,289	3,392	1,648	1,877	2,063	2,137	2,166	2,201
Estonia	630	684	762	847	921	949	142	148	156	161	163	163
Finland	1,681	2,142	2,375	2,420	2,462	2,527	609	716	780	795	789	788
France	26,745	31,101	34,491	36,630	37,854	39,219	5,039	5,699	6,221	6,585	6,689	6,754
Germany (including ex-GDR from 1991)	38,324	44,013	49,121	51,188	50,140	48,059	11,541	12,457	13,257	13,586	13,278	12,593
Greece	6,094	6,934	7,896	8,787	9,161	8,965	1,059	1,189	1,307	1,413	1,454	1,415
Hungary	6,802	7,380	8,170	8,966	9,417	9,471	2,371	2,499	2,628	2,710	2,719	2,683
Ireland	1,252	1,689	2,180	2,721	3,274	3,530	716	932	1,193	1,470	1,747	1,894
Italy	34,941	40,490	46,453	51,486	52,717	51,737	7,555	8,466	9,366	10,142	10,308	9,994
Latvia	951	1,015	1,110	1,226	1,296	1,278	181	183	191	198	200	196
Lithuania	1,385	1,524	1,745	1,956	2,094	2,138	226	238	261	277	279	278
Luxembourg	252	326	405	467	507	544	60	73	86	97	107	114
Malta	146	186	213	228	246	256	25	30	34	35	37	38
Netherlands	8,745	11,124	12,938	13,657	13,484	13,607	2,635	3,038	3,312	3,421	3,423	3,370
Poland	22,877	27,302	31,024	34,644	36,831	36,566	5,119	5,745	6,372	6,806	6,831	6,624
Portugal	2,875	3,318	3,829	4,280	4,552	4,608	628	711	793	859	897	892
Romania	7,766	8,440	9,584	10,539	10,779	10,354	1,701	1,842	2,018	2,197	2,264	2,208
Slovakia	2,512	3,125	3,739	4,299	4,667	4,649	456	534	616	676	706	697

Lung cancer registration	MEN						WOMEN					
FTY	2010	2020	2030	2040	2050	2060	2010	2020	2030	2040	2050	2060
Slovenia	988	1,219	1,418	1,534	1,555	1,485	284	317	347	361	357	341
Spain	21,064	25,941	31,814	36,979	39,486	38,712	2,341	2,769	3,238	3,632	3,854	3,807
Sweden	1,965	2,314	2,570	2,754	2,899	3,067	1,342	1,479	1,609	1,701	1,772	1,816
United Kingdom	27,363	32,395	37,148	40,910	43,779	47,708	16,430	18,564	21,109	23,352	24,834	26,443
European Union (27 countries)	234,922	275,404	314,082	343,072	356,383	358,425	66,807	75,248	83,431	89,518	91,591	90,888

Central nervous system deaths	MEN						WOMEN					
FTY	2010	2020	2030	2040	2050	2060	2010	2020	2030	2040	2050	2060
Austria	280	325	368	398	407	409	206	229	259	281	288	286
Belgium	491	564	630	674	695	714	422	473	527	566	584	594
Bulgaria	244	242	249	253	243	227	191	191	193	192	182	169
Cyprus	0	0	0	0	0	0	0	0	0	0	0	0
Czech Republic	410	469	522	563	581	572	383	423	457	481	491	484
Denmark	239	271	287	294	299	305	185	206	221	228	231	234
Estonia	39	41	42	45	45	43	35	35	35	35	33	31
Finland	184	214	231	234	236	240	157	174	184	186	184	182
France	1,838	2,116	2,338	2,485	2,564	2,653	1,387	1,582	1,747	1,861	1,892	1,908
Germany (including ex-GDR from 1991)	3,232	3,623	3,903	3,995	3,898	3,715	2,639	2,840	3,033	3,104	3,035	2,883
Greece	667	750	846	933	966	945	506	565	618	668	686	666
Hungary	399	426	463	502	522	522	379	401	419	435	443	438
Ireland	146	183	225	262	283	298	94	121	152	183	214	231
Italy	1,740	1,975	2,183	2,313	2,336	2,294	1,395	1,549	1,698	1,805	1,820	1,765
Latvia	78	79	83	88	88	86	68	68	68	70	67	63
Lithuania	95	100	107	116	115	113	89	93	95	98	95	88
Luxembourg	21	26	31	35	38	41	24	28	34	40	44	47
Malta	22	26	28	30	31	32	11	12	13	14	15	15
Netherlands	579	680	743	769	763	761	392	445	481	490	491	484
Poland	1,410	1,588	1,755	1,903	1,949	1,905	1,252	1,395	1,516	1,614	1,622	1,564
Portugal	355	403	458	504	529	534	253	284	314	338	349	346

Central nervous system deaths	MEN						WOMEN					
FTY	2010	2020	2030	2040	2050	2060	2010	2020	2030	2040	2050	2060
Romania	732	779	858	911	906	861	564	592	631	658	649	615
Slovakia	194	225	259	286	294	286	156	178	199	217	222	214
Slovenia	78	87	94	97	93	88	66	73	77	79	76	72
Spain	1,383	1,668	1,988	2,237	2,327	2,279	1,210	1,429	1,672	1,881	1,984	1,954
Sweden	364	407	440	465	484	500	271	295	319	335	350	356
United Kingdom	2,072	2,330	2,544	2,753	2,918	3,083	1,460	1,615	1,780	1,927	2,041	2,133
European Union (27 countries)	17,233	19,557	21,606	23,026	23,547	23,508	13,732	15,274	16,725	17,758	18,073	17,870

Central nervous system registrations	MEN						WOMEN					
FTY	2010	2020	2030	2040	2050	2060	2010	2020	2030	2040	2050	2060
Austria	334	385	428	456	466	466	286	314	347	374	381	378
Belgium	571	636	692	731	749	767	447	493	539	574	589	597
Bulgaria	226	223	228	229	217	203	177	175	176	173	163	151
Cyprus	0	0	0	0	0	0	0	0	0	0	0	0
Czech Republic	375	417	457	482	487	477	374	400	430	447	445	434
Denmark	231	259	275	282	286	291	205	225	241	247	250	253
Estonia	44	45	46	49	49	47	40	40	40	40	38	36
Finland	203	225	236	239	239	241	174	184	190	191	188	186
France	2,895	3,240	3,505	3,676	3,785	3,908	2,114	2,362	2,559	2,693	2,734	2,760
Germany (including ex-GDR from 1991)	3,552	3,902	4,120	4,176	4,061	3,862	2,758	2,945	3,091	3,129	3,055	2,894
Greece	894	997	1,110	1,202	1,231	1,204	686	758	821	875	890	866
Hungary	424	447	482	516	531	528	375	392	407	420	423	416
Ireland	171	213	259	301	324	340	129	161	197	232	267	287
Italy	2,562	2,883	3,151	3,303	3,324	3,264	1,948	2,156	2,328	2,436	2,444	2,372
Latvia	61	61	62	65	62	59	58	57	57	57	53	49
Lithuania	116	122	130	141	140	136	109	113	116	119	115	107
Luxembourg	26	33	39	43	47	50	21	25	30	34	37	40
Malta	17	19	20	22	22	22	11	12	13	14	15	15
Netherlands	626	723	782	797	795	793	383	426	454	462	461	453

Central nervous system registrations	MEN						WOMEN					
FTY	2010	2020	2030	2040	2050	2060	2010	2020	2030	2040	2050	2060
Poland	1,941	2,113	2,295	2,451	2,438	2,346	1,646	1,779	1,901	2,003	1,964	1,865
Portugal	438	493	552	598	621	625	367	409	449	478	488	484
Romania	737	776	840	875	856	808	565	585	614	627	609	573
Slovakia	209	236	267	288	291	282	164	183	201	215	216	208
Slovenia	75	86	95	99	97	92	57	62	65	67	64	61
Spain	1,838	2,204	2,575	2,804	2,854	2,802	1,686	1,986	2,289	2,508	2,594	2,558
Sweden	334	361	383	399	413	418	258	274	291	301	312	313
United Kingdom	2,730	3,062	3,353	3,611	3,834	4,049	2,026	2,225	2,438	2,639	2,778	2,905
European Union (27 countries)	21,511	24,043	26,182	27,591	28,016	27,878	16,946	18,611	20,094	21,098	21,320	21,028

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	€ 1	€ 3	€ 4	Austria	€ 2	€ 6	€ 7
Belgium	€ 10	€ 19	€ 29	Belgium	€ 18	€ 87	€ 105
Bulgaria	€ 13	€ 43	€ 56	Bulgaria	€ 16	€ 73	€ 89
Czech Republic	€ 13	€ 33	€ 46	Czech Republic	€ 18	€ 71	€ 88
Cyprus	€ 0	€ 0	€ 0	Cyprus	€ 0	€ 0	€ 0
Denmark	€ 0	€ 0	€ 0	Denmark	€ 0	€ 0	€ 0
Estonia	€ 1	€ 2	€ 3	Estonia	€ 1	€ 5	€ 6
Finland	€ 3	€ 7	€ 10	Finland	€ 4	€ 14	€ 18
France	€ 13	€ 39	€ 52	France	€ 18	€ 77	€ 95
Germany	€ 25	€ 63	€ 89	Germany	€ 34	€ 127	€ 162
Greece	€ 35	€ 109	€ 145	Greece	€ 57	€ 219	€ 277
Hungary	€ 5	€ 14	€ 19	Hungary	€ 8	€ 31	€ 39
Ireland	€ 0	€ 0	€ 0	Ireland	€ 0	€ 0	€ 0
Italy	€ 84	€ 262	€ 346	Italy	€ 135	€ 634	€ 769
Latvia	€ 4	€ 12	€ 16	Latvia	€ 4	€ 24	€ 28
Lithuania	€ 6	€ 19	€ 25	Lithuania	€ 8	€ 45	€ 53
Luxembourg	€ 0	€ 0	€ 0	Luxembourg	€ 0	€ 0	€ 0
Malta	€ 0	€ 0	€ 0	Malta	€ 0	€ 0	€ 0
Netherlands	€ 5	€ 12	€ 18	Netherlands	€ 6	€ 27	€ 33
Poland	€ 35	€ 98	€ 133	Poland	€ 52	€ 232	€ 283
Portugal	€ 14	€ 43	€ 56	Portugal	€ 21	€ 74	€ 95
Romania	€ 16	€ 50	€ 66	Romania	€ 20	€ 88	€ 108
Slovakia	€ 0	€ 0	€ 0	Slovakia	€ 0	€ 0	€ 0
Slovenia	€ 0	€ 0	€ 0	Slovenia	€ 0	€ 0	€ 0
Spain	€ 26	€ 88	€ 114	Spain	€ 36	€ 173	€ 208
Sweden	€ 0	€ 0	€ 0	Sweden	€ 0	€ 0	€ 0
United Kingdom	€ 45	€ 91	€ 135	United Kingdom	€ 83	€ 204	€ 288
TOTAL	€ 353	€ 1,009	€ 1,362	**TOTAL**	€ 542	€ 2,210	€ 2,752

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

Low	Female	Male	Total
Preparation and spinning of cotton-type fibres	€ 229	€ 624	€ 854
Preparation and spinning of woollen-type fibres	€ 113	€ 305	€ 418
Manufacture of dyes and pigments	€ 0	€ 0	€ 0
Manufacture of other organic basic chemicals	€ 0	€ 0	€ 0
Manufacture of synthetic rubber in primary forms	€ 31	€ 85	€ 116
Manufacture of pesticides and other agro-chemical products	€ 0	€ 0	€ 0
Recycling non-metal waste and scrap	€ 0	€ 0	€ 0
TOTAL	€ 373	€ 1,015	€ 1,388

High	Female	Male	Total
Preparation and spinning of cotton-type fibres	€ 341	€ 1,296	€ 1,636
Preparation and spinning of woollen-type fibres	€ 167	€ 632	€ 799
Manufacture of dyes and pigments	€ 0	€ 0	€ 0
Manufacture of other organic basic chemicals	€ 0	€ 0	€ 0
Manufacture of synthetic rubber in primary forms	€ 46	€ 176	€ 222
Manufacture of pesticides and other agro-chemical products	€ 0	€ 0	€ 0
Recycling non-metal waste and scrap	€ 0	€ 0	€ 0
TOTAL	€ 554	€ 2,103	€ 2,657

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	€ 1	€ 3	€ 5	Austria	€ 2	€ 7	€ 9
Belgium	€ 13	€ 24	€ 36	Belgium	€ 22	€ 111	€ 133
Bulgaria	€ 16	€ 54	€ 70	Bulgaria	€ 20	€ 93	€ 112
Czech Republic	€ 17	€ 41	€ 58	Czech Republic	€ 22	€ 90	€ 113
Cyprus	€ 0	€ 0	€ 0	Cyprus	€ 0	€ 0	€ 0
Denmark	€ 0	€ 0	€ 0	Denmark	€ 0	€ 0	€ 0
Estonia	€ 1	€ 3	€ 4	Estonia	€ 1	€ 6	€ 8
Finland	€ 4	€ 9	€ 13	Finland	€ 5	€ 17	€ 23
France	€ 16	€ 49	€ 64	France	€ 22	€ 95	€ 117
Germany	€ 32	€ 80	€ 111	Germany	€ 43	€ 162	€ 205
Greece	€ 45	€ 139	€ 183	Greece	€ 73	€ 279	€ 352
Hungary	€ 7	€ 17	€ 24	Hungary	€ 10	€ 39	€ 49
Ireland	€ 0	€ 0	€ 0	Ireland	€ 0	€ 0	€ 0
Italy	€ 106	€ 332	€ 437	Italy	€ 171	€ 806	€ 977
Latvia	€ 4	€ 15	€ 20	Latvia	€ 5	€ 30	€ 36
Lithuania	€ 7	€ 25	€ 32	Lithuania	€ 11	€ 58	€ 68
Luxembourg	€ 0	€ 0	€ 0	Luxembourg	€ 0	€ 0	€ 0
Malta	€ 0	€ 0	€ 0	Malta	€ 0	€ 0	€ 0
Netherlands	€ 7	€ 15	€ 22	Netherlands	€ 8	€ 35	€ 42
Poland	€ 43	€ 125	€ 168	Poland	€ 65	€ 298	€ 363
Portugal	€ 17	€ 54	€ 71	Portugal	€ 27	€ 94	€ 120
Romania	€ 20	€ 64	€ 83	Romania	€ 26	€ 112	€ 138
Slovakia	€ 0	€ 0	€ 0	Slovakia	€ 0	€ 0	€ 0
Slovenia	€ 0	€ 0	€ 0	Slovenia	€ 0	€ 0	€ 0
Spain	€ 35	€ 117	€ 152	Spain	€ 47	€ 232	€ 280
Sweden	€ 0	€ 0	€ 0	Sweden	€ 0	€ 0	€ 0
United Kingdom	€ 54	€ 110	€ 164	United Kingdom	€ 101	€ 249	€ 351
TOTAL	€ 443	€ 1,274	€ 1,718	**TOTAL**	€ 683	€ 2,814	€ 3,497

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

Low	**Female**	**Male**	**Total**
Preparation and spinning of cotton-type fibres	€ 289	€ 790	€ 1,079
Preparation and spinning of woollen-type fibres	€ 140	€ 382	€ 523
Manufacture of dyes and pigments	€ 0	€ 0	€ 0
Manufacture of other organic basic chemicals	€ 0	€ 0	€ 0
Manufacture of synthetic rubber in primary forms	€ 39	€ 106	€ 145
Manufacture of pesticides and other agro-chemical products	€ 0	€ 0	€ 0
Recycling non-metal waste and scrap	€ 0	€ 0	€ 0
TOTAL	€ 468	€ 1,278	€ 1,747

High	**Female**	**Male**	**Total**
Preparation and spinning of cotton-type fibres	€ 433	€ 1,654	€ 2,086
Preparation and spinning of woollen-type fibres	€ 210	€ 798	€ 1,007
Manufacture of dyes and pigments	€ 0	€ 0	€ 0
Manufacture of other organic basic chemicals	€ 0	€ 0	€ 0
Manufacture of synthetic rubber in primary forms	€ 58	€ 221	€ 279
Manufacture of pesticides and other agro-chemical products	€ 0	€ 0	€ 0
Recycling non-metal waste and scrap	€ 0	€ 0	€ 0
TOTAL	€ 700	€ 2,672	€ 3,373

Table 8.3.5 Summary

Costs by Gender (€m)	**2010-2019**	**2020-2029**	**2030-2039**	**2040-2049**	**2050-2059**	**2060-2069**
Female	81 to 120	72 to 108	82 to 125	76 to 119	69 to 110	63 to 101
Male	219 to 456	200 to 425	235 to 513	225 to 503	207 to 476	189 to 441
Total	300 to 576	272 to 534	317 to 637	301 to 622	277 to 586	252 to 542

Table 8.3.6 Health costs – baseline scenario – Member State breakdown - Based on a no discounting

Low	Female	Male	Total	High	Female	Male	Total
Austria	€ 4	€ 9	€ 13	Austria	€ 7	€ 19	€ 26
Belgium	€ 34	€ 64	€ 98	Belgium	€ 61	€ 304	€ 364
Bulgaria	€ 42	€ 144	€ 187	Bulgaria	€ 54	€ 255	€ 310
Czech Republic	€ 45	€ 114	€ 158	Czech Republic	€ 62	€ 256	€ 317
Cyprus	€ 0	€ 0	€ 0	Cyprus	€ 0	€ 0	€ 0
Denmark	€ 0	€ 0	€ 0	Denmark	€ 0	€ 0	€ 0
Estonia	€ 2	€ 8	€ 10	Estonia	€ 3	€ 18	€ 21
Finland	€ 11	€ 25	€ 36	Finland	€ 15	€ 47	€ 62
France	€ 41	€ 126	€ 166	France	€ 56	€ 249	€ 305
Germany	€ 86	€ 217	€ 303	Germany	€ 119	€ 448	€ 567
Greece	€ 122	€ 380	€ 502	Greece	€ 200	€ 779	€ 979
Hungary	€ 18	€ 47	€ 65	Hungary	€ 28	€ 109	€ 138
Ireland	€ 0	€ 0	€ 0	Ireland	€ 0	€ 0	€ 0
Italy	€ 287	€ 910	€ 1,197	Italy	€ 470	€ 2,242	€ 2,712
Latvia	€ 12	€ 43	€ 55	Latvia	€ 15	€ 85	€ 100
Lithuania	€ 19	€ 68	€ 87	Lithuania	€ 29	€ 165	€ 194
Luxembourg	€ 0	€ 0	€ 0	Luxembourg	€ 0	€ 0	€ 0
Malta	€ 0	€ 0	€ 0	Malta	€ 0	€ 0	€ 0
Netherlands	€ 17	€ 42	€ 60	Netherlands	€ 21	€ 96	€ 117
Poland	€ 118	€ 347	€ 465	Poland	€ 181	€ 849	€ 1,030
Portugal	€ 46	€ 146	€ 193	Portugal	€ 73	€ 260	€ 333
Romania	€ 53	€ 172	€ 226	Romania	€ 71	€ 315	€ 387
Slovakia	€ 0	€ 0	€ 0	Slovakia	€ 0	€ 0	€ 0
Slovenia	€ 0	€ 0	€ 0	Slovenia	€ 0	€ 0	€ 0
Spain	€ 104	€ 355	€ 459	Spain	€ 145	€ 719	€ 864
Sweden	€ 0	€ 0	€ 0	Sweden	€ 0	€ 1	€ 1
United Kingdom	€ 135	€ 275	€ 410	United Kingdom	€ 257	€ 635	€ 891
TOTAL	€ 1,197	€ 3,493	€ 4,690	**TOTAL**	€ 1,867	€ 7,852	€ 9,719

Table 8.3.7 Health costs – baseline scenario – Industry group breakdown - Based on a declining discount rate

Low	Female	Male	Total
Preparation and spinning of cotton-type fibres	€ 789	€ 2,174	€ 2,963
Preparation and spinning of woollen-type fibres	€ 375	€ 1,029	€ 1,403
Manufacture of dyes and pigments	€ 0	€ 0	€ 0
Manufacture of other organic basic chemicals	€ 0	€ 0	€ 0
Manufacture of synthetic rubber in primary forms	€ 103	€ 282	€ 385
Manufacture of pesticides and other agro-chemical products	€ 0	€ 0	€ 0
Recycling non-metal waste and scrap	€ 0	€ 0	€ 0
TOTAL	€ 1,266	€ 3,485	€ 4,751

High	Female	Male	Total
Preparation and spinning of cotton-type fibres	€ 1,197	€ 4,634	€ 5,831
Preparation and spinning of woollen-type fibres	€ 568	€ 2,189	€ 2,757
Manufacture of dyes and pigments	€ 0	€ 0	€ 0
Manufacture of other organic basic chemicals	€ 0	€ 0	€ 0
Manufacture of synthetic rubber in primary forms	€ 155	€ 600	€ 756
Manufacture of pesticides and other agro-chemical products	€ 0	€ 0	€ 0
Recycling non-metal waste and scrap	€ 0	€ 0	€ 0
TOTAL	€ 1,920	€ 7,423	€ 9,344

Table 8.3.8 Summary

Costs by Gender (€m)	2010-2019	2020-2029	2030-2039	2040-2049	2050-2059	2060-2069
Female	99 to 146	130 to 195	171 to 261	214 to 334	263 to 416	322 to 515
Male	267 to 554	360 to 766	492 to 1073	632 to 1417	783 to 1801	958 to 2241
Total	365 to 701	490 to 961	663 to 1335	846 to 1750	1046 to 2217	1280 to 2756

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