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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

2-Nitropropane

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SUMMARY

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

This report considers the likely health, socioeconomic and environmental impacts associated with possible changes to the Carcinogens Directive, in particular the possible introduction of an 8-hour occupational exposure limit (OEL) of 19 mg/m³ (5 ppm). Current OELs in the EU range from 3.6 mg/m³ (1 ppm) to 37 mg/m³ (10 ppm).

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

It is difficult to provide a good estimate of the number of people exposed. We have relied upon Labour Force Survey data in identifying likely industrial uses, but we accept that these data are likely to provide an overestimate of the numbers exposed. Currently we estimate that less than about 50,000 individuals exposed, although in the past there could have been more than ten times this number exposed. There are very little data on the level of exposure to 2-nitropropane in industry. However, based on the available data we consider it is likely that none would be exposed in excess of the typical OEL of 19 mg/m³ (our worst-case estimate suggests levels are below 6 mg/m³) in manufacturing. Exposures are assumed to have been decreasing over recent years by about 7% per annum.

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

There are no predicted health benefits from setting an OEL. It is assumed there will be no additional costs to comply with an OEL of 19 mg/m³. There are also no social or macro-economic costs associated with introducing an OEL.

There are no significant environmental impacts foreseen.

1 PROBLEM DEFINITION

1.1 OUTLINE OF THE INVESTIGATION

Based on animal data 2-nitropropane may cause cancer, although there is no evidence that it causes cancer in humans. 2-nitropropane has been classified as a Group 2b carcinogen (Possibly carcinogenic to humans) by the International Agency for Research on Cancer (IARC)¹ and as a Cat 2 carcinogen in the EU under the classification and labelling legislation². 2-nitropropane is therefore already regulated as a carcinogen throughout the EU. In this assessment, we consider the impacts of introducing an exposure limit for 2-nitropropane 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 for 2-nitropropane of 19 mg/m³ (5 ppm).

1.2 OELS/ EXPOSURE CONTROL

Current available national occupational exposure limits (OELs) for EU member states are shown in Table 1.1. These are given as long-term 8-hour time-weighted averages (TWAs), which are representative of a standard working day and/or as short-term exposure limits that address peak exposures over a 10 or 15-minute period. Limits obtained for non-EU countries have also been included for comparison.

Table 1.1 Existing International Occupational Exposure Limits for 2-Nitropropane

Country	Limit value - 8 hours TWA		Limit value - Short term	
	ppm	mg/m ³	ppm	mg/m ³
Austria	5	18	20	72
Belgium	10	37	-	-
Denmark	5	18	10	36
Hungary	-	-	-	18
Spain	5	19	-	-
Sweden	2	7	6	20
The Netherlands	1	3.6	-	-
United Kingdom	5	19	-	-
Canada-Quebec	10	36	-	-
Switzerland	5	18	-	-
USA-OSHA	25	90	-	-

Source: Available at: <http://bgia-online.hnbg.de/LIMITVALUE> (2010)

The 8-hour average OELs across the available EU data range from 1 ppm (3.6 mg/m³) to 10 ppm (37 mg/m³). Three countries have short-term limits, which range from 6 ppm (20 mg/m³) to 20 ppm (72 mg/m³).

We have identified a limit of 5 ppm (19 mg/m³) as the typical OEL in Europe.

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

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

1.3 DESCRIPTION OF DIFFERENT USES

2-nitropropane is a clear, colourless liquid with a mild, fruity odour. It is flammable and can explode when exposed to heat, an open flame or oxidisers. It is also known as 2-NP; dimethylnitropropane; iso-nitropropane; nitroisopropane; β -nitropropane and sec-nitropropane.

The US EPA (1980) identified the manufacture of printing inks and surface coatings as the major non-intermediate use, with minor applications given as explosives taggants, rocket propellants, adhesives, gasoline additives, dyes, pesticides, rubber and chemical reactions.³ Its use as a solvent in food processing for fractionation of partially-saturated vegetable oil was also indicated.

Within coating, adhesive and paint formulations, 2-nitropropane was used principally in blends with other solvents to impart desirable characteristics, such as greater solvency, better flow characteristics and film integrity, greater pigment dispersion, increased wetting ability, improved electrostatic spraying properties, or reduced drying time.⁴

As 2-nitropropane was not prescribed as a detection agent within the 1991 Montreal Convention on the marking of explosives, its use as a taggant in the manufacturing process should have reduced significantly, as the Convention requirements were enacted into the national legislation of the various signatory countries.⁵

No quantitative information was available on the amount of 2-nitropropane used in formulations which are manufactured or imported into the EU, for example within printing inks, resins or adhesives. However, information received from the European Council of the Paint, Printing Inks and Artists' Colours Industry (CEPE), which represents around 85% of the manufacturers and importers of paints, printing inks and artists' colours in the EU, showed that 2-nitropropane has been on the European Print Industry Association (EuPIA) Exclusion List since 1996. Qualitative data from CEPE/EuPIA have indicated that 2-nitropropane was used in the manufacture of solvent-based printing inks until the early 1980s, however as of the mid-1980s its use was discontinued and it is no longer listed on the manufacturers' raw materials inventories.⁶

A very limited number of references to specialist uses, for example in aerospace coatings, have been noted in current manufacturers' literature.⁷

No information on the prevalence of 2-nitropropane in the manufacture and use of adhesives and epoxy resins was available. These uses are identified throughout the literature as minor in comparison with other purposes^{3,4,5}, therefore the volumes used and numbers of employees exposed are estimated to be limited.

No information on the quantity of 2-nitropropane used for research and development applications in the EU was available; however it is assumed these amounts are also limited.

³ US Environmental Protection Agency (US EPA) (1980): Materials Balance: 2- Nitropropane, Level I – Preliminary

⁴ World Health Organization International Agency For Research On Cancer (IARC), Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 71, (1999)

⁵ International Civil Aviation Organisation The Convention on the Marking of Plastic Explosives for the Purpose of Detection (1991)

⁶ European Print Industry Association: Communication (2010)

⁷ Huntsman Ltd. Rhodofthal 200ES MSDS Available at: <http://www.lindberg-lund.no/files/Tekniske%20datablad/VAN-200ES-TD.pdf> (2010)

The full implementation of the 1991 Montreal Convention regarding permitted explosives marker substances is assumed to have reduced any EU use of 2-nitropropane for this purpose to zero.

The use of 2-nitropropane as a solvent within food production has been discouraged by the WHO⁸, therefore it is considered unlikely that this application is still relevant. The IARC concluded in 1999 that 2-nitropropane was produced in low volume and that occupational exposures occurred primarily in its production and use as a solvent in inks, adhesives, paints and coatings. It is assumed that this latter application has since decreased further, as evidenced by the information received from the trade association CEPE.⁹

1.4 RISKS TO HUMAN HEALTH

1.4.1 Introduction

Animal toxicity studies have shown that inhalation of 2-nitropropane can cause hepatocellular carcinomas in male rats and hepatocellular nodules in rats of both sexes. When IARC reviewed the available information they excluded an inhalation study in rabbits because it was considered to provide inadequate data about any cancer risk.

1.4.2 Summary of the available epidemiological literature on risk

Severe liver damage, as well as some kidney damage, has been observed in workers poisoned from acute (short-term) inhalation exposure to 2-nitropropane. Chronic (long-term) inhalation exposure to 2-nitropropane has caused nausea, vomiting, diarrhoea, severe headaches, and pulmonary irritation in workers (US EPA, 2000).

The only available epidemiological information comes from an unpublished report of a retrospective mortality study of Dow workers at Sterlington, Louisiana before or after the beginning of production of 2-nitropropane (Miller and Temple, 1979; Bolender, 1983, both unpublished studies, reported in Dow (2005)). The initial study included 1,815 employees that had worked at the plant from 1946 to 1977, and an updated study included 1,915 employees that were employed from 1946 to 1981. The relationship of race, sex, county of residence, work activity (direct, indirect or no exposure to 2 nitropropane) and years of employment (both prior to and after the start of 2-nitropropane production) to the type of death coded according to the eighth revision of the International Classification of Diseases was examined. The results indicated that there were no clear trends between years of direct or indirect exposure to 2-nitropropane, and the numbers (or types) of deaths. In the first study, the only disease-related type of death that was increased was "other lymphatic cancer" in white or black, male employees. In the follow-up study, the incidence of "other lymphatic cancer" was not increased in white males. In both studies, the increase in "other lymphatic cancer" in black males was due to bleeding gastric ulcer-lymphosarcoma in one individual and mycosis fungoides in another. The report concludes that these findings appeared to be unrelated and not due to employment. No deaths resulted from malignant cancer of liver, which includes hepatocellular carcinoma and there were no cases of benign neoplasms of the liver. It should be noted that the report describes the results as above and no quantitative results are presented.

⁸ Joint FAO/WHO Expert Committee on Food Additives, Food Additives Series 26, Available at: <http://www.inchem.org/documents/jecfa/jecmono/v26je09.htm> (2009)

⁹ European Print Industry Association: communication (2010)

1.4.3 Choice of risk estimates to assess health impact

Although effects in the liver have been observed in animals chronically exposed to 2-nitropropane by inhalation the epidemiological evidence for carcinogenicity in humans appears to be negative. No appropriate risk estimate can be selected for this substance.

2 BASELINE SCENARIOS

2.1 STRUCTURE OF THE SECTOR

Current world production figures are not available. Data searches were carried out to determine manufacturing sites currently producing 2-nitropropane. According to the European Chemical Substances Information System (ESIS) there is only one supplier of 2-nitropropane in the EU.¹⁰

The single production facility is understood to be supplying a small volume of 2-nitropropane to external customers, for use as a taggant in C4 explosives production and within research and development laboratories. The manufacturer is not aware of any consumer applications of 2-nitropropane and the majority (> 99 per cent) of this production is used as an intermediate for producing amino-alcohols.¹¹

The International Council of Chemical Associations Working List from 2005 identified 2-nitropropane as a high production volume (HPV) chemical in both the EU and US, i.e. it is produced or imported in quantities greater than 1,000 tonnes (1 million lbs in the US) per annum¹². No information on the total production or importation volumes was available for the EU. The literature suggests that the annual world production of 2-nitropropane was estimated to have reduced to 2500 tonnes by 1986¹³.

2.2 PREVALENCE OF 2-NITROPROPANE EXPOSURE IN THE EU

2.2.1 Historic Exposure Prevalence

A 1982 study carried out on behalf of the current sole manufacturer considered all distributors, manufacturers and users of 2-nitropropane, estimated the total number of exposed employees in the US to be 38,600, with an upper boundary set of 126,600 employees. It further estimated that significant exposure, defined as exposure to 9.1mg/m³ or 2.5 ppm (10% of the US OSHA exposure limit), ranged from 4,000 (best estimate) to 10,600 (upper boundary) employees¹⁴.

A US NIOSH National Exposure Survey (1981-1983) estimated that 9,815 employees in the USA were exposed to 2-nitropropane or to trade-name products containing 2-nitropropane¹⁴.

No data on the number of employees exposed historically within the EU have been obtained and this has therefore been estimated for 1995.

¹⁰ European Commission Joint Research Centre Institute for Health and Consumer Protection, High Production Volume chemicals list Available at: <http://ecb.jrc.ec.europa.eu/esis/index.php?PGM=hpv> (2010)

¹¹ Dow Chemicals (2010) Product Safety Assessment: 2-Nitropropane Available at: <http://www.dow.com/productsafety/finder/>

¹² International Council of Chemical Associations: High Production Volume Working List. Available at: <http://www.cefic.be/activities/hse/mgt/hpv/ICCA%20Working%20List%20-%20October%202005.xls> (2010)

¹³ U.S. Dept. of Health & Human Services, Public Health Service, National Toxicology Program; Report on Carcinogens, 11th Edition (2005)

¹⁴ World Health Organisation International Programme On Chemical Safety: Environmental Health Criteria 138 "2-Nitropropane" (1992) Available at: <http://www.inchem.org/documents/ehc/ehc/ehc138.htm>

The work activities involving potential exposures to 2-nitropropane across various occupations and industry sectors were identified and are shown in Table 2.1. It is assumed that exposures during these activities occur predominantly via inhalation of vapours and dermal contact with the liquid form and subsequent absorption.¹⁵

Table 2.1 Potential Exposure to 2-nitropropane by Work Activity, Occupation and Industry Sector

Industry/ Process	NACE Code (rev 1.1) ¹⁶	Relevant Work Activities (potential exposures in all cases assumed to occur via inhalation and dermal routes)	Occupations Involved in Activities (ISCO categories) ¹⁷
Manufacture of vegetable and animal oils and fats	15.4	Addition of solvent to fats during hot fractionation	300: Technicians and associated professionals 810: Stationary plant and related operators 930: Labourers in mining, construction, manufacturing and transport
Manufacture of veneer sheets, plywood, laminboard, particleboard, fibreboard and other panels and boards	20.2	Mixing of adhesives Application/ curing of adhesives	300: Technicians and associated professionals 810: Stationary plant and related operators 820: Machine operators and assemblers 930: Labourers in mining, construction, manufacturing and transport
Printing	22.22	Preparation of inks Preparation and use of presses Cleaning of presses and other equipment Disposal of waste materials	300: Technicians and associated professionals 730: Precision handicraft, printing and related trades employees
Manufacture of basic chemicals (2 nitropropane production)	24.1	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 basic chemicals (other chemicals)	24.1	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 paints, varnishes and similar coatings, printing ink and	24.3	Pigment milling and production Drum filling Quality assurance/	300: Technicians and associated professionals 810: Stationary plant and

¹⁵ ANGUS Chemicals Product Safety Assessment 2 Nitropropane. Available at: <http://www.dow.com/> (2010)

¹⁶ Eurostat: SCL - Statistical Classification of Economic Activities in the European Community (2002)

¹⁷ International Standard Classification of Occupations. Available at: <http://www.ilo.org/public/english/bureau/stat/isco/index.htm> (2008)

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Industry/ Process	NACE Code (rev 1.1)¹⁶	Relevant Work Activities (potential exposures in all cases assumed to occur via inhalation and dermal routes)	Occupations Involved in Activities (ISCO categories)¹⁷
mastics		process sampling Spillage control	related operators 930: Labourers in mining, construction, manufacturing and transport
Manufacture of explosives	24.61	Dissolution of process chemicals in solvent Evaporation of solvent Quality assurance/ process sampling	300: Technicians and associated professionals 810: Stationary plant and related operators 930: Labourers in mining, construction, manufacturing and transport
Manufacture of rubber products	25.1	Chemical processing of rubber	300: Technicians and associated professionals 810: Stationary plant and related operators 820: Machine operators and assemblers 930: Labourers in mining, construction, manufacturing and transport
Manufacture of tanks, reservoirs and containers of metal	28.21	Preparation of paint Preparation of surfaces Paint spraying Hand Painting Gun/Brush cleaning	300: Technicians and associated professionals 720: Metal machinery and related trades 810: Stationary plant and related operators 820: Machine operators and assemblers 930: Labourers in mining, construction, manufacturing and transport
Treatment and coating of metals	28.51	Preparation of paint Preparation of surfaces Paint Spraying Guncleaning	300: Technicians and associated professionals 720: Metal machinery and related trades 810: Stationary plant and related operators 820: Machine operators and assemblers 930: Labourers in mining, construction, manufacturing and transport
Manufacture of steel drums and similar containers	28.71	Preparation of paint Preparation of surfaces Paint spraying Hand painting Gun/brush cleaning	300: Technicians and associated professionals 720: Metal machinery and related trades 810: Stationary plant and related operators 820: Machine operators and assemblers 930: Labourers in mining, construction, manufacturing and transport

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Industry/ Process	NACE Code (rev 1.1) ¹⁶	Relevant Work Activities (potential exposures in all cases assumed to occur via inhalation and dermal routes)	Occupations Involved in Activities (ISCO categories) ¹⁷
Manufacture of light metal packaging	28.72	Preparation of paint Preparation of surfaces Spraying Gun/brush cleaning	300: Technicians and associated professionals 720: Metal machinery and related trades 810: Stationary plant and related operators 820: Machine operators and assemblers 930: Labourers in mining, construction, manufacturing and transport
Manufacture of other fabricated metal products	28.75	Preparation of paint Preparation of surfaces Paint spraying Hand painting Gun/brush cleaning	300: Technicians and associated professionals 720: Metal machinery and related trades 810: Stationary plant and related operators 820: Machine operators and assemblers 930: Labourers in mining, construction, manufacturing and transport
Manufacture of aircraft and spacecraft	35.3	Preparation of paint Preparation of surfaces Spraying of coating Guncleaning	300: Technicians and associated professionals 720: Metal machinery and related trades 810: Stationary plant and related operators 820: Machine operators and assemblers 930: Labourers in mining, construction, manufacturing and transport
Recycling of non-metal waste and scrap	37.2	Storage and sampling of waste solvents and formulations Incineration of waste solvents	300: Technicians and associated professionals 810: Stationary plant and related operators 930: Labourers in mining, construction, manufacturing and transport

It was assumed that all employees within the occupation codes given above were exposed to 2-nitropropane in the past: this is likely to be an overestimate, as not all individuals in each group would in fact have been exposed.

The proportion of employees in the above occupational groups as a percentage of the total number within NACE Group D was calculated for each country from the 2006 Labour Force Survey available from Eurostat.¹⁸

¹⁸ Available at: <http://epp.eurostat.ec.europa.eu/portal/page/portal/statistics/themes> (2010)

The sum of the percentages for each occupation was applied to the total number of employees within Group D, giving the total number of people employed in the relevant exposed occupations across the whole of Group D by country.

The proportion of employees in each NACE Group D sub-code compared with the Group D total was then calculated for each country from the Eurostat Structural Business Statistics.¹⁹ Statistical data from 1999 were used for the majority of countries and industry sectors, to reflect historical employment patterns: information prior to this time was not available for Germany, which has a major manufacturing base.

Where these were not available, data from 2006 were used as an estimate, both to provide the widest possible range of country-level information and to be consistent with the 2006 Labour Force data used. The use of the 2006 statistics may however have led to an overestimate of total numbers for those countries in comparison with the rest of the dataset, as the total numbers in manufacturing have decreased slightly over the period 1999 to 2006 across the majority of EU countries.

The proportion of employees in each occupation code was then applied to the number of employees calculated above for the whole of Group D, to give the total number of employees in exposed occupations by NACE sub-code and country.

Across the EU, the number of female employees in manufacturing industries is approximately 30% compared with 70% male.²⁰ The number of male and female employees within each sub-code was estimated using this proportion.

These estimated data are given in Table 2.2, with data from 2006 shown in italics.

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

¹⁹ Eurostat: SCL - Statistical Classification of Economic Activities in the European Community (2002)

²⁰ Average % gender split taken from Eurostat database across Code D: Manufacturing (2010)

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Table 2.2 Estimated number of employees exposed for relevant occupations in 1975 (based on 1999 and 2006 data) (NA=Not Available)

Country	NACE Code														Grand Total
	15.4	20.2	22.22	24.1	24.3	24.61	25.1	28.21	28.51	28.71	28.72	28.75	35.3	37.2	
Austria	142	896	284	1,143	517	39	1101	892	1,570	89	419	2,664	34	43	9,833
Belgium	166	870	446	3,203	511	22	1610	732	2,255	227	465	1,768	831	193	13,299
Bulgaria	536	1,476	184	1,669	317	125	2437	783	736	68	1314	3,870	20	5	13,540
Cyprus	33	NA	84	9	55	0	6	52	6	0	NA	168	0	15	428
Czech Republic	235	1,748	355	2,597	225	207	5228	3,859	6,521	957	1040	9,455	819	20	33,266
Denmark	78	383	244	277	281	3	575	586	1,442	61	885	4,236	87	NA	9,138
Estonia	NA	831	24	111	69	NA	178	71	312	0	NA	1,253	NA	18	2,867
Finland	91	1,786	255	1,035	243	61	671	675	895	88	98	1,898	97	2	7,895
France	455	2,493	886	7,698	1,931	576	19544	1,637	11,059	434	4784	10,293	7804	NA	69,594
Germany	866	4,615	6,036	23,439	5,223	452	17464	6,185	20,994	1817	6146	33,770	7621	582	135,210
Greece	484	833	398	376	298	3	304	547	782	186	827	1,962	493	NA	7,493
Hungary	81	866	430	1,167	154	25	2363	1,209	1,398	345	1152	3,225	101	11	12,527
Ireland	8	228	244	997	76	NA	460	267	213	0	NA	824	479	9	3,805
Italy	728	3,578	3,316	6,959	2,326	89	14708	4,970	20,477	899	3238	40,876	4134	175	106,473
Latvia	36	1,679	111	100	134	2	74	94	35	71	354	580	2	5	3,277
Lithuania	17	646	87	416	45	0	55	NA	342	25	125	1,298	49	36	3,141
Luxembourg	NA	NA	7	NA	3	NA	270	NA	NA	0	0	13	NA	1	294
Malta	NA	NA	0	NA	0	0	0	NA	NA	0	NA	0	NA	NA	0
Netherlands	477	144	688	4,585	1,161	NA	1125	2,137	3,597	343	1178	3,517	681	174	19,807
Poland	666	4,501	944	6,294	1,119	296	7855	3,275	3,909	1627	2375	17,155	2502	249	52,767
Portugal	311	660	660	520	442	51	1219	811	1,342	68	1084	4,575	191	28	11,962
Romania	650	3,220	219	3,208	618	86	4717	3,466	1,727	266	370	5,589	794	201	25,131
Slovenia	27	976	50	259	127	NA	1667	151	428	138	402	4,147	3	15	8,390
Slovakia	216	2,313	135	1,762	165	0	2966	671	1,160	332	382	4,176	NA	51	14,329
Spain	1878	4,457	1,755	4,867	2,213	243	12184	609	1,267	163	455	1,630	1624	78	33,423
Sweden	134	565	223	1,007	263	65	2258	321	1,813	NA	NA	10,878	814	5	18,346
United Kingdom	213	1,668	3,832	7,038	2,767	183	10260	1,669	8,705	670	2350	14,571	11566	283	65,775
Total	8,528	41,432	21,897	80,736	21,283	2,528	111,299	35,669	92,985	8,874	29,443	184,391	40,746	2,199	682,010

The total number of employees historically exposed is therefore estimated as 682,010, across the NACE sub-codes and countries outlined above.

It has been assumed that, as the numbers of employees in the whole manufacturing industry across the majority of EU states has decreased since 1975²¹ because of globalisation and process automation, the total of 682,010 may be lower than the actual numbers exposed historically. This potential underestimation is however mitigated by the non-universal exposure of employees in each occupation code.

2.2.2 Current Exposure Prevalence

NACE CODE 24.3: Manufacture of Basic Chemicals (2-Nitropropane production)

Within NACE code 24.3: Manufacture of Basic Chemicals, it is estimated that 2-nitropropane is only used in one plant in Germany, with an estimated 100 employees exposed to low levels during the manufacture of derivatives. There may also be a low risk of exposure for an estimated additional five employees during shipping and transportation of the material from port to the plant.

Across the EU, the number of female employees in manufacturing industries is approximately 30% compared with 70% male. Of these 100 employees in the German plant, it is therefore estimated that 70 are male and 30 female.

Other NACE codes

With reference to the above decrease in general downstream usage of 2-nitropropane, it is estimated that current exposures to the substance for downstream uses are only likely to occur in NACE codes 35.3 (Manufacture of Aircraft and Spacecraft) and possibly at very low levels in 37.2 (Recycling of Non-Metal Waste and Scrap).

The numbers of employees in each code per country were estimated using the method given in section 2.1 above based on 2006 Eurostat data, and are presented in Table 2.3.

As indicated previously, these figures are likely to overestimate the actual numbers employed in each exposed occupation within the industry sub-code as not all individuals in each occupational group will be exposed.

The estimated number of male and female employees in each industry group in each EU member state is shown in Appendix 8.2. These data were obtained by applying the average male to female employee ratio for the industry group for each country to the total number of employees. Male to female employee ratios were calculated with data from the Labour Force Survey available from the Eurostat database (single digit NACE Codes). Managers, salespeople and office clerks were excluded from these calculations as they were assumed to be unexposed.

²¹ International Labour Organisation: Labour Market Trends and Globalization's Impact on Them, Available at: <http://actrav.itclio.org/actrav-english/telearn/global/ilo/seura/mains.htm>

Table 2.3 Estimated current number of employees exposed for relevant occupations
NACE codes 35.3 and 37.2 (based on 2006 data)

Country	NACE Code 35.3	NACE Code 37.2	Grand Total
Austria	113	81	194
Belgium	832	206	1038
Bulgaria	22	34	56
Cyprus	0	15	15
Czech Republic	747	35	782
Denmark	123	NA*	123
Estonia	NA	18	18
Finland	92	7	99
France	9945	557	10502
Germany	9171	1036	10207
Greece	493	0	493
Hungary	101	35	136
Ireland	546	35	581
Italy	4535	401	4936
Latvia	8	16	24
Lithuania	49	36	85
Luxembourg	NA	1	1
Malta	NA	NA	0
Netherlands	892	271	1163
Poland	2253	534	2787
Portugal	NA	83	83
Romania	794	201	995
Slovenia	9	16	25
Slovakia	NA	45	45
Spain	2127	248	2375
Sweden	738	18	756
United Kingdom	12934	912	13846
Total	46722	4847	51569

* NA = Not Available

Classification of Industries

A list of the types of industries that potentially used 2-nitropropane in 1975 was collated from a literature search reported in the previous sections. This information, together with the corresponding NACE codes and an estimation of the degree of potential inhalation and dermal exposure is given in Table 2.4.

Exposure to 2-nitropropane has been categorised as high, medium or low using the historical exposure measurement information given above. No information on dermal exposure levels has been found; therefore the classification has been estimated for this route of exposure.

Table 2.4 Classification of Industries by Exposure levels (1975)

Industry	NACE (rev 1.1)	Exposure Level (inhalation)	Exposure Level (dermal)
Manufacture of veneer sheets, plywood, laminboard, particleboard, fibreboard and other panels and boards	20.2	Low	Low
Printing n.e.c.	22.22	High	Medium
Manufacture of basic chemicals	24.1	Low	Low
Manufacture of paints, varnishes and similar coatings, printing ink and mastics	24.3	Medium	Medium
Manufacture of explosives	24.61	Low	Low
Manufacture of rubber products	25.1	Medium	Low
Manufacture of tanks, reservoirs and containers of metal	28.21	Medium	Medium
Treatment and coating of metals	28.51	Medium	Medium
Manufacture of steel drums and similar containers	28.71	Medium	Medium
Manufacture of light metal packaging	28.72	Medium	Medium
Manufacture of other fabricated metal products	28.75	Medium	Medium
Manufacture of motor vehicles	34.1	Medium	Medium
Manufacture of aircraft and spacecraft	35.3	Medium	Low
Recycling of non-metal waste and scrap	37.2	Medium	Low
Research and experimental development on natural sciences and engineering	74.1	Low	Low

2.3 LEVEL OF EXPOSURE TO 2-NITROPROPANE

2.3.1 Estimation of exposure levels

The main downstream uses of 2-nitropropane appear to have significantly decreased over the last 30 years because of health and environmental concerns, for example its inclusion as a solvent in printing inks, coatings and paints.

Estimates of exposure across those NACE codes where exposure may still occur have been calculated assuming a decrease of 7% per annum (Creely *et al*, 2007), based on the worst case 8-hour TWA levels from the most recent relevant study noted below in Table 2.6 and Table 2.7. The results of these estimates for 2010 exposures are given in Table 2.5. As these estimates are based on worst-case measurements rather than

average values, it should be noted that not all employees will be exposed to these levels.

Table 2.5 Estimated 2010 Exposures across relevant NACE codes (assuming 7% reduction per annum)

Industry	NACE (rev 1.1)	Worst Case Measured Exposure Level (mg/m ³)	Year Obtained/ Reported	2010 Estimate of Exposure Level 8 hr TWA (mg/m ³)
Manufacture of basic chemicals (2 nitropropane production)	24.1	36	1986	6
Manufacture of aircraft and spacecraft ^[1]	35.3	36	1986	6

^[1] Estimated from exposure data from automotive manufacturing

It is possible that there could still be some exposure to 2-nitropropane in recycling of non-metal waste and scrap (NACE 37.2), but given that the range of uses of this substance has decreased markedly in recent years it seems probable that this would be irregular and at a very low level.

The sole manufacturer has indicated that a limited number of employees are involved in the production, distillation and storage of 2-nitropropane on their US plant. As the process is carried out in a closed system to reduce the risk of fire and explosion, the manufacturer has assessed that there is a low potential for skin and airborne exposure, which would only occur during sampling, material transfer operations and during unexpected releases.²² It has been assumed that these types and levels of exposure would be mirrored in the German derivative production facility.

There may also be current usage of 2-nitropropane within Code 35.3: Manufacture of aircraft and spacecraft. Exposures of employees in this sector are estimated to be at most 6 mg/m³, and are therefore much lower than the possible OEL value of 19 mg/m³.

In summary, it is estimated that there would be a limited number of employees across the EU exposed to levels of 2-nitropropane and it is likely that none would be exposed in excess of the proposed limit value of 19 mg/m³.

2.3.2 Temporal change in exposure

Limited historical monitoring data obtained from studies in the US have indicated that exposure levels were highly variable between industries and work tasks, with the highest manufacturing-related short-term exposures occurring during transfers/ drum filling and spillage control activities (2,111-6,000 mg/m³, in 1962).²³ A summary of the results of these studies is shown in Table 2.6 and Table 2.7. Table 2.6 shows long-term data from a variety of sources,

²² Dow Chemicals, Robust Summaries & Test Plan: 2-Nitropropane; Revised Summaries 201-15898B. EPA Submission 2007

²³ World Health Organisation, International Programme On Chemical Safety Environmental Health Criteria 138 2-Nitropropane (1992)

Table 2.6 Historical Long-term Exposure Measurements

Activity	NACE Code (rev 1.1)	Result (mg/m ³)	Year of Study/ Year Reported
Manufacture of 2-NP	24.1	3.64	1977
Manufacture of 2-NP	24.1	0.7-364: 98% of samples were <36.4	1979
2-NP storage & transfer area (1962: drum filling operation)	24.1	2111-6000	Study from 1962, reported in 1986
Painting (bus maintenance)		0.11	1981
	34.1		
Painting (railway cars)		1.46	1980
	34.1		
Painting (battery cases)		36.4-109	1947
	28.75		
Pigment production facility (1970)		109-2745	1986
	24.3		
Manufacturing (Coating forms)		72.8-164	1947
	28.75		
Printing		Approx. 40	1982
	22.22		
Vulcanising tyres		0-0.18	1978
	25.1		
Solvent extraction		167.4	1985
	37.2		
Laboratory		14.6	1986
	73.1		

Additional exposure data relating to long-term and short-term peak exposure levels was also gathered by the World Health Organisation and these data are shown in Table 2.7. Note that the exposure data given in the 1986 study are likely to relate to earlier years, although no detail on the actual measurement dates was available.

Table 2.7 Short-term Historical Exposure Data

Process	NACE Code (rev 1.1)	Date(s) of Study*	Exposure Concentration	
			TWA mg/m ³	STEL mg/m ³
Manufacture of 2-NP	24.1	1940-1955	25-91	> 218
Manufacture of 2-NP Sterlington, Louisiana, US	24.1	1946-1982	3.6-36	91-5970
Chemical company, US	24.1	1986*	3.6-36	65.6-364
Chemical distillation, Mexico	24.1	1986*	36-55	>91
Paint manufacturing, Germany	24.3	1986*	40-91	-
Paint manufacturing, Mexico	24.3	1986*	3.6	< 91
Coatings manufacturing, Mexico	24.3	1986*	14.6-91	237-251
Automotive manufacturing, USA	34.1	1986*	3.6-36	142
Ink manufacturing, Mexico	24.3	1986*	11-18	73-80
Printing company, USA	22.22	1986*	1.8-87	2.5-124
Extraction of triglycerides, USA	15.4	1980-1986*	3.6-193	109-473
Extraction plant, Sweden	37.2	1986*	3.6-18.2	73-364

*The exposure data given in the 1986 study are likely to relate to earlier years, however no detail on the actual measurement dates was available.

The most recent values obtained during general production activities in the 2-nitropropane manufacturing plant ranged from 3.6 to 36 mg/m³.

The historical measured long-term exposure levels of operators in downstream processes such as printing, painting and solvent extraction appear to be much higher on occasion, with concentrations in air of 2,745 mg/m³ in a pigment production facility (1970), 87 mg/m³ in a printing plant (reported in 1986) and up to 167 mg/m³ in a solvent extraction plant in 1985. Levels of up to 193 mg/m³ were also recorded in a triglyceride extraction plant. Concentrations of 0.18 mg/m³ in air were measured at a tyre manufacturing plant during rubber vulcanisation.

In addition to inhalation, it is likely that dermal exposure of employees may have occurred in situations where 2-nitropropane was used as a solvent. No data on dermal exposure have been obtained.

2.4 HEALTH IMPACT FROM CURRENT EXPOSURES

Because there is no information about the carcinogenicity of 2-nitropropane in humans we have not carried out a health impact assessment. The number of people exposed

to this substance is probably less than about 50,000 and exposure levels are likely to be relatively low.

2.5 POSSIBLE COSTS ASSOCIATED WITH NOT MODIFYING THE DIRECTIVE

2.5.1 Health impacts – possible costs under the baseline scenario

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

3 POLICY OPTIONS

3.1 DESCRIPTION OF MEASURES

Exposure can occur either in a facility that manufactures 2-nitropropane or in the few industrial or manufacturing facilities that still use this product. Those working with this product in manufacturing operations could be exposed during maintenance, sampling, testing, or other procedures.

Existing controls employed by the sole identified EU manufacturer include²⁴:

- Closed transport and reaction vessels to minimise losses by evaporation during normal process operation;
- Appropriate local and general ventilation;
- Employee training programmes;
- The use of safety goggles, along with chemical impervious gloves and aprons to prevent dermal exposure during sampling tasks
- The use of self-contained breathing apparatus (SCBA) by employees during spillage control activities.

Good personal hygiene and glove usage routines are necessary for the prevention of dermal exposures²⁵.

As demonstrated by the estimates of 2010 exposure levels given above, it is believed that exposures below the proposed limit of 19 mg/m³ can be, and are, achieved by the use of these controls within the manufacturing site.

Current exposures are also believed to be less than 19mg/m³ in the main potential downstream use, i.e. aircraft and spacecraft manufacture, with currently applied control

²⁴ Dow Chemicals (2010) Product Safety Assessment: 2-Nitropropane. Available at: <http://www.dow.com/productsafety/finder/>

²⁵ Fischer Scientific Safety Data Sheet 2-Nitropropane. Available at: <http://www.fishersci.se/safenet/pdf/04411500.pdf>

technology, e.g. general and local ventilation, along with glove and other personal protective equipment use.

3.2 LEVEL OF PROTECTION ACHIEVED (OELS)

Exposure limits in EU are typically around 5 ppm. The Netherlands has the lowest existing OEL of 1 ppm (3.6 mg/m³) and the highest OEL of 10 ppm (37 mg/m³) is in Belgium.

4 ANALYSIS OF IMPACTS

4.1 HEALTH IMPACTS FROM CHANGES TO THE EU DIRECTIVE

4.1.1 Health information

As it was not possible to estimate a link between exposure to 2-nitropropane and cancer, it is not possible to estimate the number of cancer registrations, deaths and life years lost from past and future exposure and how this would change with the introduction of an EU-wide OEL.

However, it is estimated that there would be a limited number of employees across the EU exposed to levels of 2-nitropropane and none would be exposed in excess of the proposed limit value of 19 mg/m³. Therefore, it is reasonable to assume there would be limited health benefits of introducing an EU-wide OEL at 19 mg/m³.

4.1.2 Monetised health benefits

Production of monetised health benefits from not modifying the directive to include 2-nitropropane was not possible for the reasons discussed above.

4.2 ECONOMIC IMPACTS

4.2.1 Operating costs and conduct of business

Number of Firms Affected

In Section 2.3.1, it is estimated that there would be a limited number of employees across the EU exposed to levels of 2-nitropropane and none would be exposed in excess of the possible OEL value of 19 mg/m³ (5 ppm). Exposures of employees in affected industries (NACE codes 24.3 and 35.3) are estimated to be at most 6 mg/m³.

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 on the Directive. However these measures should already be part of best practice in compliance with other legislative requirements (e.g. classification and labelling and the Chemicals Agents Directive).

Compliance Costs

Methods that are effective in controlling worker exposure to 2-nitropropane include typical industrial hygiene controls, such as:

- Process enclosure
- Local exhaust ventilation (LEV)
- Employee training programmes
- Personal protective equipment (PPE)^{26,27}

The unit costs of PPE and LEV are presented below. However, these are already assumed to be in place, along with closed systems, in the industry sectors concerned.

There are not expected to be any significant additional costs associated with PPE and employee training, which in any case would be considered to be good practice. It is assumed that costs range between €500 and €2,000 per year per enterprise (including costs of equipment, training and the cost of time spent of labour (e.g. administration costs associated with being on the Directive).

The use of LEVs to capture and remove process emissions at or close to their source of generation and prior to their escape into the workplace environment is common. The range of typical costs based on estimates from equipment suppliers is shown in Table 4.1.

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

Type of cost	Stationary Machinery
Capital Cost ('000)	€40 – 240
Annual Maintenance ('000)	1,000
Filter changes every 5 years ('000)	3,000
Total annualised cost* ('000)	€4.6 – 19.3

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

It should be remembered that, as described in Section 2.3.1, it is assumed that exposure will continue to decline at a rate of 7% per annum under the baseline.

Conduct of employers

Employees may need to change their working practice to ensure that Risk Management Measures (RMM) 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.

²⁶ Dow Chemicals, Robust Summaries & Test Plan: 2-Nitropropane; Revised Summaries 201-15898B. EPA Submission 2007

²⁷ Fischer Scientific Safety Data Sheet 2-Nitropropane <http://www.fishersci.se/safenet/pdf/04411500.pdf>

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 19 mg/m³ 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 19 mg/m³ 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. However, there is unlikely to be any practical difference.

Administrative costs to employers and public authorities

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

Table 4.2 Administrative burdens to employers

Type of administrative cost	Relevant article(s)	Type of cost	Significance
1. Change in practice to use closed systems when using the substance.	5 – Prevention and reduction of exposure	These costs are already estimated in the cost of compliance section - This will only affect those firms that do not have or use closed systems	Estimated elsewhere
2. Develop/update health and safety and best practice guidance for: <ul style="list-style-type: none"> ○ Minimising use and exposure to workers to the substance ○ Redesign work processes and engineering controls to avoid/minimise release of carcinogens or mutagens ○ Hygiene measures, in particular regular cleaning of floors, walls and other surfaces ○ Information for workers ○ Warnings and safety signs ○ Drawing up plans to deal with emergencies likely to result in abnormally high exposure 	5 – Prevention and reduction of exposure 7 – Unforeseen exposure 8 – Foreseeable exposure 9 – Access to risk areas 10 – Hygiene and individual protection	Firms will already have been required to develop/update health and safety and best practice guidance. The guidance and procedures may be required to be updated as control measures may change in light of a more stringent OEL. Some firms may need to redesign work practices to minimise exposure to workers and the number of workers exposed. The costs of implementing controls on exposure (such as LEV or PPE) are already estimated in the costs of compliance section.	Low
3. Additional costs of training new and existing staff in line with requirements of the Directive	11 – Information and training of workers	Firms will already have been required to ensure training and adequate aware of risks and control measures to reduce/minimise exposure.	Low
4. Additional costs of making information available to employees	12 – Information for workers	Largely one-off cost if the revised OEL requires a change in control measures/working practice.	
5. Consultation with employees on compliance with the Directive	13 – Consultation and participation with workers		

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

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

Table 4.3 Administrative burdens to Competent Authorities

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

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

Third countries

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

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

4.2.2 Impact on innovation and research

Impacts on innovation and research from introducing an EU-wide OEL of 19 mg/m³ 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 are not expected to be any company closures, there should not be any change in supply of products relative to the baseline scenario.

4.4 ENVIRONMENTAL IMPACTS

The achievement of the possible OEL via the measures described in this report might lead to more direct or more concentrated emissions of 2-nitropropane to the environment (through ventilation), but it is unlikely that this would lead to an increased overall environmental burden. However, any such effect will probably be negligible because it is estimated that exposure is already controlled below 19 mg/m³. Furthermore the quantities and concentrations involved are relatively low. It is therefore assumed that an OEL would not increase the level of environmental harm.

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

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

Table 5.2 Comparison of economic impacts by scenario

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

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

Table 5.3 Comparison of social impacts by scenario

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

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

6 CONCLUSIONS

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

It is difficult to provide a good estimate of the number of people exposed. We have relied upon Labour Force Survey data identifying likely industrial uses, but we accept that these data are likely to provide an overestimate of the numbers exposed. Currently we estimate that less than about 50,000 people are exposed, although in the past there could have been more than ten times this number exposed. There are very little data on the level of exposure to 2-nitropropane in industry. However; based on the available data, we consider it is likely that no employees would be exposed in excess of the typical OEL of 19 mg/m³. Exposures are assumed to have been decreasing over recent years by about 7% per annum.

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

There are no predicted health benefits from setting an OEL. It is assumed there will be no additional costs to comply with an OEL of 19 mg/m³. There are also no social or macro-economic costs associated with introducing an OEL.

There are no significant environmental impacts foreseen.

7 REFERENCES

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8 APPENDIX

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

Table 8.1.1 Historic number of workers exposed to 2-Nitropropane by Member State and NACE code – males and females

Country	NACE code														
	15.4			20.2			22.22			24.1			24.3		
	Total	Male	Female	Total	Male	Female	Total	Male	Female	Total	Male	Female	Total	Male	Female
Austria	142	99	42	896	627	269	284	199	85	1,143	800	343	517	362	155
Belgium	166	116	50	870	609	261	446	312	134	3,203	2,242	961	511	358	153
Bulgaria	536	376	161	1,476	1,033	443	184	129	55	1,669	1,168	501	317	222	95
Cyprus	33	23	10	Not Available			84	59	25	9	6	3	55	39	17
Czech Republic	235	165	71	1,748	1,224	524	355	249	107	2,597	1,818	779	225	158	68
Denmark	78	54	23	383	268	115	244	171	73	277	194	83	281	196	84
Estonia	Not Available			831	582	249	24	17	7	111	78	33	69	48	21
Finland	91	63	27	1,786	1,251	536	255	179	77	1,035	724	310	243	170	73
France	455	319	137	2,493	1,745	748	886	620	266	7,698	5,388	2,309	1,931	1,352	579
Germany	866	606	260	4,615	3,231	1,385	6,036	4,225	1,811	23,439	16,407	7,032	5,223	3,656	1,567
Greece	484	339	145	833	583	250	398	278	119	376	263	113	298	209	89
Hungary	81	57	24	866	606	260	430	301	129	1,167	817	350	154	108	46
Ireland	8	6	2	228	159	68	244	171	73	997	698	299	76	53	23
Italy	728	510	218	3,578	2,505	1,073	3,316	2,321	995	6,959	4,871	2,088	2,326	1,628	698
Latvia	36	25	11	1,679	1,175	504	111	78	33	100	70	30	134	94	40
Lithuania	17	12	5	646	452	194	87	61	26	416	291	125	45	31	13
Luxembourg	Not Available			Not Available			7	5	2	Not Available			3	2	1
Malta	Not Available			Not Available			0	0	0	Not Available			0	0	0
Netherlands	477	334	143	144	101	43	688	481	206	4,585	3,209	1,375	1,161	813	348
Poland	666	466	200	4,501	3,150	1,350	944	661	283	6,294	4,406	1,888	1,119	784	336
Portugal	311	217	93	660	462	198	660	462	198	520	364	156	442	309	133
Romania	650	455	195	3,220	2,254	966	219	153	66	3,208	2,246	962	618	432	185

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Country	NACE code														
	15.4			20.2			22.22			24.1			24.3		
	Total	Male	Female	Total	Male	Female	Total	Male	Female	Total	Male	Female	Total	Male	Female
Slovenia	27	19	8	976	683	293	50	35	15	259	181	78	127	89	38
Slovakia	216	151	65	2,313	1,619	694	135	95	41	1,762	1,233	529	165	115	49
Spain	1878	1315	563	4,457	3,120	1,337	1,755	1,228	526	4,867	3,407	1,460	2,213	1,549	664
Sweden	134	94	40	565	395	169	223	156	67	1,007	705	302	263	184	79
United Kingdom	213	149	64	1,668	1,168	500	3,832	2,683	1,150	7,038	4,926	2,111	2,767	1,937	830
Total	8528	5970	2557	41432	29002	12429	21897	15329	6569	80736	56512	24220	21283	14898	6384

Country	NACE code														
	24.61			25.1			28.21			28.51			28.71		
	Total	Male	Female	Total	Male	Female	Total	Male	Female	Total	Male	Female	Total	Male	Female
Austria	39	28	12	1101	770	330	892	624	268	1,570	1,099	471	89	62	27
Belgium	22	16	7	1610	1127	483	732	512	220	2,255	1,578	676	227	159	68
Bulgaria	125	88	38	2437	1706	731	783	548	235	736	515	221	68	48	20
Cyprus	0	0	0	6	4	2	52	36	16	6	4	2	0	0	0
Czech Republic	207	145	62	5228	3660	1569	3,859	2,701	1,158	6,521	4,565	1,956	957	670	287
Denmark	3	2	1	575	402	172	586	410	176	1,442	1,009	432	61	43	18
Estonia	Not Available			178	125	53	71	50	21	312	218	94	0	0	0
Finland	61	43	18	671	470	201	675	472	202	895	627	269	88	61	26
France	576	403	173	19544	13681	5863	1,637	1,146	491	11,059	7,741	3,318	434	304	130
Germany	452	317	136	17464	12225	5239	6,185	4,330	1,856	20,994	14,696	6,298	1817	1272	545
Greece	3	2	1	304	213	91	547	383	164	782	547	235	186	130	56
Hungary	25	18	8	2363	1654	709	1,209	846	363	1,398	978	419	345	242	104
Ireland	Not Available			460	322	138	267	187	80	213	149	64	0	0	0
Italy	89	62	27	14708	10296	4412	4,970	3,479	1,491	20,477	14,334	6,143	899	629	270
Latvia	2	1	1	74	52	22	94	66	28	35	24	10	71	50	21
Lithuania	0	0	0	55	39	17	Not Available			342	239	103	25	18	8
Luxembourg	Not Available			270	189	81	Not Available			Not Available			0	0	0
Malta	0	0	0	0	0	0	Not Available			Not Available			0	0	0

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Country	NACE code														
	24.61			25.1			28.21			28.51			28.71		
	Total	Male	Female	Total	Male	Female	Total	Male	Female	Total	Male	Female	Total	Male	Female
Netherlands	Not Available			1125	788	338	2,137	1,496	641	3,597	2,518	1,079	343	240	103
Poland	296	207	89	7855	5498	2356	3,275	2,293	983	3,909	2,737	1,173	1627	1139	488
Portugal	51	36	15	1219	854	366	811	568	243	1,342	939	402	68	48	20
Romania	86	60	26	4717	3302	1415	3,466	2,426	1,040	1,727	1,209	518	266	186	80
Slovenia	Not Available			1667	1167	500	151	106	45	428	300	128	138	96	41
Slovakia	0	0	0	2966	2076	890	671	470	201	1,160	812	348	332	233	100
Spain	243	170	73	12184	8529	3655	609	427	183	1,267	887	380	163	114	49
Sweden	65	46	20	2258	1581	677	321	225	96	1,813	1,269	544	Not Available		
United Kingdom	183	128	55	10260	7182	3078	1,669	1,168	501	8,705	6,093	2,611	670	469	201
Total	2528	1772	762	111299	77912	33388	35669	24969	10702	92985	65087	27894	8874	6213	2662

Country	NACE code														
	28.72			28.75			35.3			37.2			Grand Total		
	Total	Male	Female	Total	Male	Female	Total	Male	Female	Total	Male	Female	Total	Male	Female
Austria	419	293	126	2,664	1,865	799	34	24	10	43	30	13	9,833	6,882	2,950
Belgium	465	325	139	1,768	1,238	530	831	582	249	193	135	58	13,299	9,309	3,989
Bulgaria	1314	920	394	3,870	2,709	1,161	20	14	6	5	3	1	13,540	9,479	4,062
Cyprus	Not Available			168	117	50	0	0	0	15	10	4	428	298	129
Czech Republic	1040	728	312	9,455	6,619	2,837	819	574	246	20	14	6	33,266	23,290	9,982
Denmark	885	620	266	4,236	2,965	1,271	87	61	26	Not Available			9,138	6,395	2,740
Estonia	Not Available			1,253	877	376	Not Available			18	13	5	2,867	2,008	859
Finland	98	69	29	1,898	1,328	569	97	68	29	2	2	1	7,895	5,527	2,367
France	4784	3349	1435	10,293	7,205	3,088	7804	5463	2341	Not Available			69,594	48,716	20,878
Germany	6146	4302	1844	33,770	23,639	10,131	7621	5334	2286	582	408	175	135,210	94,648	40,565
Greece	827	579	248	1,962	1,373	589	493	345	148	Not Available			7,493	5,244	2,248
Hungary	1152	806	346	3,225	2,258	968	101	71	30	11	8	3	12,527	8,770	3,759
Ireland	Not Available			824	577	247	479	335	144	9	7	3	3,805	2,664	1,141
Italy	3238	2266	971	40,876	28,613	12,263	4134	2894	1240	175	123	53	106,473	74,531	31,942

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Country	NACE code												Grand Total		
	28.72			28.75			35.3			37.2					
	Total	Male	Female	Total	Male	Female	Total	Male	Female	Total	Male	Female	Total	Male	Female
Latvia	354	248	106	580	406	174	2	2	1	5	4	2	3,277	2,295	983
Lithuania	125	88	38	1,298	909	390	49	35	15	36	25	11	3,141	2,200	945
Luxembourg	0	0	0	13	9	4	Not Available			1	1	0	294	206	88
Malta	Not Available			0	0	0	Not Available			Not Available			0	0	0
Netherlands	1178	825	353	3,517	2,462	1,055	681	477	204	174	122	52	19,807	13,866	5,940
Poland	2375	1663	713	17,155	12,009	5,147	2502	1751	751	249	174	75	52,767	36,938	15,832
Portugal	1084	759	325	4,575	3,203	1,373	191	134	57	28	19	8	11,962	8,374	3,587
Romania	370	259	111	5,589	3,912	1,677	794	556	238	201	141	60	25,131	17,591	7,539
Slovenia	402	281	121	4,147	2,903	1,244	3	2	1	15	11	5	8,390	5,873	2,517
Slovakia	382	267	115	4,176	2,923	1,253	Not Available			51	36	15	14,329	10,030	4,300
Spain	455	318	136	1,630	1,141	489	1624	1137	487	78	55	23	33,423	23,397	10,025
Sweden	Not Available			10,878	7,615	3,263	814	570	244	5	4	2	18,346	12,844	5,503
United Kingdom	2350	1645	705	14,571	10,200	4,371	11566	8096	3470	283	198	85	65,775	46,042	19,732
Total	29443	20610	8833	184391	129075	55319	40746	28525	12223	2199	1543	660	682,010	477,417	204,602

8.2 ESTIMATED CURRENT (2006) NUMBER OF EMPLOYEES IN EACH INDUSTRY GROUP – MEMBER STATE BREAKDOWN – MALES AND FEMALES

Table 8.2.1 Current (2006) number of workers exposed to 2-Nitropropane by Member State and NACE code – males and females

Country	NACE code						Grand Total		
	Total	35.3 Male	Female	Total	37.2 Male	Female	Total	Male	Female
Austria	113	79	34	81	57	24	194	136	58
Belgium	832	582	250	206	144	62	1038	726	312
Bulgaria	22	16	7	34	24	10	56	40	17
Cyprus	0	0	0	15	10	4	15	10	4
Czech Republic	747	523	224	35	25	11	782	548	235
Denmark	123	86	37	Not Available			123	86	37
Estonia	Not Available			18	13	5	18	13	5
Finland	92	64	28	7	5	2	99	69	30
France	9945	6962	2984	557	390	167	10502	7352	3151
Germany	9171	6419	2751	1036	725	311	10207	7144	3062
Greece	493	345	148	0	0	0	493	345	148
Hungary	101	71	30	35	24	10	136	95	40
Ireland	546	382	164	35	25	11	581	407	175
Italy	4535	3175	1361	401	281	120	4936	3456	1481
Latvia	8	6	3	16	11	5	24	17	8
Lithuania	49	35	15	36	25	11	85	60	26
Luxembourg	Not Available			1	1	0	1	1	0
Malta	Not Available			Not Available			0	0	0
Netherlands	892	624	268	271	190	81	1163	814	349
Poland	2253	1577	676	534	373	160	2787	1950	836
Portugal	Not Available			83	58	25	83	58	25
Romania	794	556	238	201	141	60	995	697	298
Slovenia	9	7	3	16	11	5	25	18	8
Slovakia	Not Available			45	32	14	45	32	14
Spain	2127	1489	638	248	174	74	2375	1663	712
Sweden	738	517	222	18	13	5	756	530	227
United Kingdom	12934	9054	3880	912	638	274	13846	9692	4154
Total	46722	32722	14020	4847	3394	1453	51569	36116	15473

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