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

Executive summary report

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This study was funded by the European Commission as Study Service Contract to provide an Analysis at an EU-level of health, socio-economic and environmental impacts in connection with possible amendments to Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Contract no: VC/2009/0023).

1 INTRODUCTION

In 2000 there were more than 1.1 million cancer deaths recorded in the European Union. The main causes of premature death are lung cancer, colorectal cancer and breast cancer in women. Recent research in Britain has shown that approximately one in twenty cancer deaths may be attributable to work (about 8% in men and 2% in women), with mesothelioma, sinonasal, lung, nasopharyngeal and breast in women having the greatest proportion of cases due to work. The main causal agents are asbestos, shift-work involving night work, mineral oils, solar radiation, silica, diesel engine exhaust, coal tars and pitches, occupation as a painter or welder, dioxins, environmental tobacco smoke, radon, tetrachloroethylene, arsenic and strong inorganic acid mists. The proportion of cancers attributable to work and the main causal agents is expected to be broadly similar throughout the EU.

In Europe the main legislative instrument to ensure control of occupational carcinogens is Directive 2004/37/EC on the Protection of Workers from the Risks Related to Exposure to Carcinogens or Mutagens at Work (the Carcinogens Directive). The European Commission DG for Employment, Social Affairs & Inclusion (COM) has sponsored the work described in this report to undertake a socioeconomic, health and environmental analysis of possible changes to the Carcinogens Directive for 25 occupational carcinogenic substances identified by DG Employment. Further details of the work are provided in an extended summary report and in a series of separate substance dossiers. The work also included a review of procedures for setting occupational exposure limits (OELs) and an evaluation of the requirements contained in Article 5 for the Carcinogens Directive (for the Prevention and Reduction of Exposure), which we also reported separately.

2 METHODS

The work involved collecting available published information about the uses and/or circumstances of exposure for each substance along with additional information provided by stakeholders. These data were used to assess the exposures in the European working population, which in turn provided the basis for assessing the cancer burden from past and future use. Health costs and benefits were evaluated for no intervention and then for the introduction of up to three possible OELs. Compliance costs were separately estimated for the intervention scenarios. OEL values were either suggested by DG Employment or were identified as being “typical” of values in EU member states. The study was carried out in accordance with the Commission Impact Assessment Guidelines. Further details of the methods used for the socioeconomic assessment in this study in relation to the Commission Guidelines are described in a separate report.

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

The costs and benefits are provided in a number of forms, including qualitative descriptions, quantification of impacts and monetary valuation, where possible. This allows the impacts of intervention to be understood on a variety of levels (recognising, for example, that monetary valuation of non-market impacts is a controversial area).

All of the health assessments were made in relation to cancer risks from exposure to the identified substances and do not include any other disease that may also be caused by exposure to these substances. For many of the substances there are therefore likely to be additional baseline health costs and further unquantified health benefits from introducing an OEL.

3 SUMMARY OF RESULTS

Eleven of the substances considered were accepted human carcinogens (International Agency for Research on Cancer - category 1), four were probably human carcinogens (IARC 2a) and ten were possible human carcinogens (IARC 2b). The 25 substances considered are listed in Table 1.1.

Table 1.1 Substances to be evaluated

Substance or mixture	EU carcinogen	IARC	OEL Values Evaluated (mg/m^3)		
			Lower	Mid	Higher
Hard wood dust, as inhalable dust[#]	NA	1	1	5	
Vinyl chloride monomer (VCM)	1	1	2.56	5.11	7.67
Trichloroethylene	2	2a	50	273	
Beryllium and beryllium compounds	2	1	0.002		
Chrome VI (hexavalent chrome)	2	1	0.025	0.05	0.1
Acrylamide	2	2a	0.03		
Rubber process fume	NA	1	0.6		
Rubber process dust	NA	1	6		
Respirable crystalline silica	NA	1	0.05	0.1	0.2
4, 4'-methylenedianiline	2	2b	0.08	0.8	
4,4'-methylene bis 2-chloroaniline (MbOCA) †	2	2a	5	15	
1, 3 Butadiene	1	1	1.14	2.28	11.4
Ethylene oxide	2	1	1.8		
Diesel engine exhaust emissions (DEE)	NA	2a	0.1		
Refractory ceramic fibres (RCF) ‡	2	2b	0.1	1	
Hydrazine	2	2b	0.013	0.13	
1, 2-Epoxypropane	2	2b	4.8	12	
1, 2-Dichloroethane	2	2b	4	20	
1, 2-Dibromoethane	2	2b	0.8		
o-Toluidine	2	1	0.4	4.4	
Hexachlorobenzene	2	2b	0.002	0.025	
Mineral oils as used engine oil□	NA	1	NA		
Benzo[a]pyrene	2	1	0.002		
2-Nitropropane	2	2b	19		
Bromoethylene	2	2a	22		
1-Chloro-2, 3-epoxypropane	2	2a	1.9		

a separate report is available reviewing methods of measuring inhalable hard wood dust
† units for MbOCA are □mol/mol in urine sample
‡ units for RCF are fibres/ml
□ risks to skin from dermal contact - setting an OEL was considered inappropriate

There are more than ten different types of cancer that may be caused by exposure to these substances; most commonly lung and bladder cancer. For some of these tumour types there are very good chances that workers will survive, e.g. non-melanoma skin cancer that may be caused by mineral oils as used engine oil or benzo[a]pyrene, although for most of the cancers survival after diagnosis is relatively poor.

The table also shows the OEL values that have been evaluated in the study. The values for five substances were suggested by the Commission: hard wood dust, vinyl chloride monomer, chrome VI, respirable crystalline silica and 1,3 Butadiene. All others were selected as “typical” of existing values amongst EU member states.

The results from the baseline assessments are briefly summarised in Table 1.2.

Table 1.2 Summary of baseline assessments

Substance or mixture	Number of workers exposed ('000)	Baseline health impact *	Baseline health costs (€m)
Hard wood dust	3,000	14,000	€3,900 - €17,000
Vinyl chloride monomer	19	300	€190 - €470
Trichloroethylene	74	4,800	€1,600 - €5,700
Beryllium and beryllium compounds	65	430	€200 - €530
Chrome VI	920	24,000	€9,000 - €29,000
Acrylamide	53	250	€160 - €330
Rubber process fume and dust	57	710	€720 - €860
	172	3,600	€2,961 - €3,930
Respirable crystalline silica	720	470,000	€190,000,000 - €490,000,000
4, 4' methylenedianiline (MDA)	390 - 3,900	NA	NA
4,4'-Methylene bis 2-chloroaniline (MbOCA)	2.5	280	€45 - €350
1, 3 Butadiene	28	160	€41 - €167
Ethylene oxide	16	0	€ 0
Diesel engine exhaust emissions	3,600	270,000	€99,000 - €260,000
Refractory ceramic fibres	10	60	€33 - €83
Hydrazine	2,100	2,500	€500 - €3,000
1, 2-Epoxypropane	<1.2	0	€2.5 - €11
1, 2-Dichloroethane	<3	NA	NA
1, 2-Dibromoethane	<8	NA	NA
o-Toluidine	5.5	490	€86 - €700
Hexachlorobenzene	Unknown	NA	NA
Mineral oils as used engine oil	1,000	130,000	€450 - €2,800
Benzo[a]pyrene (lung+bladder)	7,000	13,000	€6,300 - €19,000
(NMSC)		18,000	€45 - €450
2-Nitropropane	50	NA	NA
Bromoethylene	<1	0	€ 0
1-Chloro-2, 3-epoxypropane	44	2,600	€1,400 - €2,800

* incident cancers 2010 - 2069
NA = not assessed
NMSC = non-melanoma skin cancer

For six substances there are probably more than a million workers in the EU currently exposed and for six substances there are less then 10,000 exposed workers. The greatest number of exposed workers arises for three process-generated substances: benzo[a]pyrene (7 million), diesel engine exhaust (3.6 million) and hardwood dust (3 million). There is some uncertainty about the number of workers who may be exposed to 4,4’-methylenedianiline (MDA), although there are probably more than about

400,000 people exposed. The number exposed to hexachlorobenzene is unknown, although use of this substance is banned in the EU.

For ten substances it was estimated there would be more than 1,000 cancers occurring in the next 60 years if no action is taken; total estimated attributable cancer deaths over this period were in excess of 700,000. The greatest numbers of excess incident cancers were predicted for respirable crystalline silica (470,000 over the next 60 years), diesel engine exhaust (270,000) and mineral oils as used engine oils (130,000). In contrast there were ten substances where the baseline health assessment suggested there will be less than 1,000 attributable incident cancers over the next 60 years, i.e. on average less than 20 cases throughout the EU each year. For five substances the information about cancer risks to humans was insufficient to allow a baseline health assessment to be made.

The baseline health costs over the coming 60 years, accounting for uncertainties in the estimation process, were estimated to be possibly above €1,000 million for the ten substances described above where more than 1,000 cancers may occur. The two largest estimated health impacts were for respirable crystalline silica (between €190,000,000 and €490,000,000 million) and diesel engine exhaust (€99,000 to €260,000 million).

Table 1.3 summarises the assessed impacts from the setting of an OEL.

In fourteen of the 44 substance-OEL combinations assessed (e.g. hard wood dust at 1 mg/m^3) exposure is estimated to already be below the possible OEL (<1% exposed above the limit). However, in eleven cases the proportion exposed above the OEL exceeded 10%, with the highest proportions being for hydrazine at an OEL value of 0.013 mg/m^3 (75%), refractory ceramic fibres at 0.1 fibres/ml (50%), 1,3 Butadiene at 1.14 mg/m^3 (46%) and respirable crystalline silica at 0.05 mg/m^3 (41%).

There were only seven substances-OEL combinations where there was a substantial health benefit from introducing or reducing an OEL shown in Table 1.3, in terms of avoided cancer cases over the next 60 years giving between 0.2% and 39% reduction in cancers from the baseline estimate. The main potential health impacts were for respirable crystalline silica (between 80,000 and 110,000 fewer cancer cases over the next 60 years, depending on the OEL), hardwood dust (3,900 fewer cases at 1 mg/m^3), chrome VI (1,400 to 1,800 fewer cases for limits of 0.05 or 0.025 mg/m^3) and rubber process fume (1,400 fewer cases). For 26 of the 36 substance-OEL combinations where a health assessment was possible there were minimal health benefits from the introduction of an OEL, i.e. less than 20 cancer cases avoided over the next 60 years.

The monetized health benefits from introducing an OEL were greatest for respirable crystalline silica (between €21,000 and €74,000 million, depending on the OEL and the uncertainties involved in the estimation). Health benefits were also large for the introduction of OELs for chrome VI (around €500 - €1,300 million for a limit of 0.025 mg/m^3) and rubber process fume (€580 - €1,200 million). For 26 of the substance-OEL combinations the monetised benefits were negligible.

Table 1.3 Impacts arising from setting an OEL for each of the substances evaluated

Substance or mixture	OEL values evaluated (mg/m^3)	% exposures more than suggested OEL	Extent of decrease in health risks (avoided cases)	Impact on SMEs	Health benefits from introducing OEL (€m)	Compliance costs (€m)	Benefit to cost ratio (range)
Hard wood dust	3	1	500	Min	11 - 51	0	
	1	8	3,900	Yes	61 - 297	3,800 - 8,600	0.029 (0.007 - 0.07)
Vinyl chloride monomer	7.67	1	0	Min	0	0	
	5.11	2	0		0	3 - 30	0
	2.56	4	0		1 - 3	40 - 185	0.018 (0.005 - 0.075)
Trichloroethylene	273	2	10	Min	0	61	0
	50	28	580	Pos	120 - 430	428	0.64 (0.028 - 1.0)
Beryllium and beryllium compounds	0.002	10	50	Yes	11 - 30	18,000 - 34,000	0.0008 (0.0003 - 0.001)
Chrome VI	0.1	2	600	Pos	159 - 456	9,000 - 37,000	0.013 (0.004 - 0.05)
	0.05	4	1,400	Pos	340 - 991	18,000 - 67,000	0.016 (0.005 - 0.05)
	0.025	8	1,800	Pos	461 - 1,327	30,000 - 115,000	0.012 (0.004 - 0.04)
Acrylamide	0.03	10	0	Min	0	0	
Rubber process fume and dust	6 (dust)	14	20	Min	24 - 46	55 - 280	0.200 (0.086 - 0.83)
	0.6 (fume)	37	1,400	Min	580 - 1,200	470 - 3,200	0.490 (0.18 - 2.5)
Respirable crystalline silica	0.2	14	80,000	Min	21,000 - 56,000	10,000	3.800 (2.1 - 5.6)
	0.1	26	99,000	Yes	26,000 - 68,000	19,000	2.500 (1.4 - 3.6)
	0.05	41	110,000	Yes	28,000 - 74,000	34,000	1.500 (0.8 - 2.2)
MDA	0.8	NK		Min	NA	1,400 - 29,000	
	0.08			Min	NA	1,400 - 29,000	
MbOCA	15µmol/mol	5	0	Min	1 - 7	560 - 1,100	0.005 (0.0009 - 0.01)
	5µmol/mol	16	20	Min	1 - 11	1,500 - 3,000	0.003 (0.0003 - 0.007)
1, 3 Butadiene	11.4	4	0	Min	0	2 - 7	0
	2.28	28	0	Min	0	17 - 63	0
	1.14	46	0	Min	0	27 - 100	0
Ethylene oxide	1.8	0	0	Min	0	0	
Diesel engine exhaust emissions	0.1	1	0	Min	0	25 - 250	0
Refractory ceramic fibres	1 f/ml	10	0	Pos	1 - 2	0	
	0.1 f/ml	50	0	Pos	1 - 2	60 - 2,500	0.001 (0.0004 - 0.03)
Hydrazine	0.13	8	0	Min	0	15 - 47	0
	0.013	75	0	Min	0	62 - 200	0
1, 2-Epoxypropane	12	<1	0	Min	0	0	
	4.8	<1	0	Min	0	0	
1, 2-Dichloroethane	20	<1		Min	NA	0 - 13	
	4	13		Min	NA	0 – 43	
1, 2-Dibromoethane	0.8	8		Min	NA	0	
o-Toluidine	4.4	0	0	Min	0	0	
	0.4	2	0	Min	0	0	
Hexachlorobenzene	0.002	0		Min	NA	0	
	0.025	0		Min	NA	0	
Mineral oils as used engine oil	NA	NA	NA	Min	NA	46 - 920	
Benzo[a]pyrene	0.002	0	0	Min	0	0	
		NA	0	Min	0	0	
2-Nitropropane	19	0		Min	0	0	
Bromoethylene	22	0	0	Min	0	0	
1-Chloro-2, 3-epoxypropane	1.9	0	0	Min	0	0	

NK = Not known
NA = Not assessed

Estimated compliance costs ranged from zero to over €100,000m over the next 60 years. It was judged that for 14 substance-OEL combinations the compliance cost could exceed €1,000 million. Highest costs were for Chrome VI, respirable crystalline silica, MDA and beryllium and beryllium compounds. Four substance-OEL combinations were judged as likely to have a substantial negative impact on small and medium size enterprises (SMEs) and in a further six cases it is possible there could be a substantial negative impact on SMEs from introducing the proposed OEL.

The monetised benefit-to-cost ratio was less than one in all cases except for respirable crystalline silica (all three potential OEL values exceeded one showing a net estimated benefit from introducing an OEL). This is an indication that the costs of intervention might be less than the benefits, but not a definitive answer, given that not all costs/benefits were quantified and given the uncertainties involved. Accounting for the uncertainties in assessing the costs the benefit-to-cost ratio may be greater than one for at least two other substance-OEL combinations: rubber process fume and trichloroethylene (50 mg/m^3). It should be noted that these comparisons are strongly dependant on the rate used for discounting of future costs because the majority of the compliance costs occur now whereas the majority of the benefits occur in the future. As noted above, no account has been taken of the possible additional benefits from reduced non-cancer disease arising from the introduction of an OEL.

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

The report highlights the limited information available on the hazards and risks for many of the substances assessed. We consider that it would be of substantial benefit for the future to more proactively collect information about occupational carcinogens in the EU. Priority, in particular, should be given to collect better information about MDA and mineral oil as used engine oil, where the potential health impacts are large and the uncertainties are greatest.

4 SETTING OELS

A review was undertaken of the methods currently employed by regulators and others for the management of carcinogenic risks in the workplace, wider environment and in relation to food, drinking water and consumer products. The report set out to:

- Assess the value of using quantitative risk assessment in setting OELs versus an "As Low As Reasonably Practicable" (ALARP) approach;
- Identify the most appropriate methodologies for undertaking quantitative risk assessment (QRA); and
- Identify appropriate risk criteria for use with the recommended methodologies plus a commentary on what might be appropriate if other methodologies of risk quantification are adopted.

Overall, we recommend that a flexible approach to setting OELs for carcinogens within the EU is retained, but that this approach is underpinned by suitable guidance developed as a consensus view of experts. We also recommend that the following issues are taken into account in the proposed guidance:

1. The extent to which the results of QRA are taken into account in setting OELs should reflect the certainty of the data.
2. The extent to which animal data are taken into account should reflect study quality and the whether it is likely that the toxicological mechanisms leading to cancer and reported tumours could reasonably be expected to be relevant to humans.
3. Health impact assessment should be used as a tool to inform the setting of OELs. Where possible the number of cases avoided within the EU as a result of imposing OELs at different levels should be estimated together with an indication of the timescale over which these benefits would accrue, taking account of foreseeable changes in patterns of use.
4. There is a need to determine a minimum dataset that satisfies a number of criteria including relevance to human exposure, data quality, dosing regime and cancer response for QRA to be used for genotoxic carcinogens.
5. There is also a need develop a clear set of options that can be employed where it is not appropriate to use QRA. To a great extent, some of these possible approaches are addressed in current procedures within the EU. Other options might include consideration of analogous substances, for example, for RCF a worst-case cancer risk estimate could be based on risk estimates for chrysotile (as we have done in the evaluation in the main part of our report).

5 EVALUATION OF ARTICLE 5 OF THE CARCINOGENS DIRECTIVE

The report also provides a review of the strengths and weaknesses of the requirements in Article 5 of the Carcinogens Directive (for the Prevention and Reduction of Exposure) in relation to the requirements to prevent or minimise the exposure of workers and the role of OEL values. The work comprises two main strands, a review of the published scientific literature and engagement with knowledgeable stakeholders through a series of workshops and a questionnaire survey.

For most of the control options specified in Article 5 there is no scientific information to determine how effective the approach is at reducing exposure levels, i.e. the magnitude of the reduction that might be expected. Elimination or substitution of the carcinogenic hazard with an alternative should, in principle, be the most effective solution. However, the scientific literature identifies that this process is not always straightforward and that it is particularly difficult for SMEs to implement. There are some good examples within the EU where industry sectors have had an effective programme to substitute carcinogenic chemicals, e.g. the rubber industry.

Local ventilation can typically reduce average exposure levels by about 80% and general ventilation and enclosure by about 50%. However, there is a great deal of variation in the effectiveness from one ventilation system to another. The effectiveness of respiratory protective equipment has also been studied fairly extensively in workplace situations. In these studies the typical effectiveness of half-mask respirators is about 95% and powered air purifying respirators generally are about 99% effective. However, there is a great deal of inter-individual variation in respirator effectiveness.

In the stakeholder consultation, the overwhelming majority of participants thought that the Carcinogens Directive was comprehensive and appropriate to control exposures, and that provisions in Article 5 are comprehensive and suitable. Several suggestions were made for improving the clarity of the text and in suggesting specific issues where the requirements could be improved. There was strong agreement that elimination and substitution of carcinogenic substances along with manufacturing and use of carcinogenic substances within closed systems should be the main priorities for risk reduction. However, participants highlighted that substitution is often complex and particularly difficult for SMEs to undertake successfully. Suggestions were made for improving the uptake of substitution of carcinogenic chemicals at work. The stakeholders considered OELs an important part of the regulatory system for controlling the risks from carcinogens at work.