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

Bromoethylene

Authors:

JW Cherrie, M Gorman Ng, A Sánchez Jiménez, A Shafrir and M van Tongeren (IOM)

R Mistry, M Sobey and C Corden (AMEC Environment & Infrastructure UK Ltd)

L Rushton (Imperial College, MRC-HPA Centre for Environment and Health)

S Hutchings (Imperial College)

Other project team members:

A Searl (IOM), O Warwick and M-H Bouhier (AMEC Environment & Infrastructure UK Ltd), T Kaupinnen and P Heikkila (Finnish Institute of Occupational Health), H Kromhout (IRAS, University of Utrecht), L Levy (IEH, Cranfield University)

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SUMMARY

Bromoethylene (vinyl bromide) has been classified by the International Agency for Research on Cancer (IARC) as probably carcinogenic to humans, based on sufficient animal toxicity and mechanistic data (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) specified in the Directive for bromoethylene.

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 OEL for bromoethylene of 22 mg/m^3 (5 ppm). Current OELs in the EU range from 0.012 to 22 mg/m^3, with the lowest OEL in the Netherlands.

Bromoethylene is mostly used as a flame retardant in the production of acrylic fibres for carpet backing materials. Other uses include children's sleepwear and home furnishings. It has been available commercially since 1968.

The number of people potentially exposed in Europe is likely to be small, i.e. less than a few hundred, but we have no information to assess the actual extent of exposure. There are few measurement data for bromoethylene, and that which is available dates from the 1980s. It has been assumed that exposure levels have been decreasing over recent years by about 7% per annum. Based on the available measurements and the annual reduction in exposure we judge that occupational exposure levels are currently low, with the highest exposures probably about 3 mg/m^3.

There is clear evidence for the carcinogenicity of bromoethylene in experimental animals, and on mechanistic grounds it is assumed that it may act similarly to vinyl chloride causing liver cancer in humans. Based on this analogy we have identified the relative risk associated with high exposure should be 2.86 and for low exposure 1.89. Given the uncertainties around the number of exposed workers we have considered it is not possible to undertake a health impact assessment. However, if as we assume the current exposure levels are low and there are a limited number of people in Europe who are exposed then there is unlikely to be any important cancer risk for this substance. There are no estimates of health costs of inaction for this substance.

There are no predicted health benefits from setting an OEL at 22 mg/m^3, although we believe the impact would be relatively small because current exposures are estimated to be much lower than the proposed OEL. There are no additional costs associated with compliance with a limit of 22 mg/m^3. 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

Bromoethylene (vinyl bromide) may cause liver cancer. Exposure to bromoethylene 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 and mechanistic and other relevant data. For practical purposes, IARC consider that bromoethylene should be considered to act similarly to the human carcinogen vinyl chloride. It is also classified as a Cat 2 carcinogen in the EU under the classification and labelling legislation[2]. Bromoethylene 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 for bromoethylene of 22 mg/m^3 (5 ppm).

1.2 OELS/EXPOSURE CONTROL

Existing national Occupational Exposure Limits (OELs) in EU member states are presented in Table 1.1. These are expressed as long-term limits, averaged over an 8-hour working day (OEL-TWA) or short-term exposure limits (STELs), i.e. 15 minutes. OELs from Switzerland and the Threshold Limit Value (TLV) assigned by the American Conference of Governmental Industrial Hygienists (ACGIH) are also presented for comparison. The US OSHA does not have a regulation for bromoethylene.

Table 1.1 Occupational Exposure Limits (OELs)[1] to bromoethylene in Various EU Member States and Switzerland

	Long term 8-hrs-TWA mg/m³		**Short term OEL mg/m³**	
	ppm	**mg/m³**	**ppm**	**mg/m³**
Belgium	5	22		
Denmark	5	20	10	40
Hungary				22
Spain	0.5	2.2		
The Netherlands		0.012		
Canada - Québec	5	22		
Switzerland	5	22		
US OSHA	Not regulated			
ACGIH TLV[2]	0.5	2.2		

TLV: threshold limit value
[1] Source: http://bgia-online.hvbg.de/LIMITVALUE/WebForm_ueliste.aspx;
[2] Source: http://www.inchem.org/documents/icsc/icsc/eics0597.htm

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

The OELs were very similar across the EU member states; the 8-hrs OELs was 22 mg/m^3 (5 ppm) in all countries but Spain and The Netherlands where the OELs were 2.2 and 0.012 mg/m^3, respectively. STEL values were only available for Denmark (10 ppm).

We have selected 22 mg/m^3 (5 ppm) as a typical OEL value in the EU.

1.3 DESCRIPTION OF DIFFERENT USES

Bromoethylene or bromoethylene monomer (VBM) is a colourless, highly flammable gas with a characteristic pungent odour. It is insoluble in water.

Bromoethylene can be produced by the catalytic addition of hydrogen bromide to acetylene in the presence of mercury and copper halide catalysts or by partial dehydrobromination of ethylene dibromide with alcoholic potassium hydroxide.

It is mostly used as a flame retardant in the production of acrylic fibres for carpet backing materials. Other uses include sleepwear (mostly for children) and home furnishings. Its copolymer with vinyl chloride and used for preparing films, laminate fibres and as rubber substitutes. Bromoethylene also is used in leather and fabricated metal products. Polyvinyl bromide, made from vinyl bromide, is a polymer of little commercial value because it is unstable at room temperature. Bromoethylene also is used in the production of pharmaceuticals and fumigants (IARC, 1986).

Occupational exposure to bromoethylene can occur by inhalation and dermal contact. The National Institute for Occupational Safety and Health (NIOSH) has identified the following industries in which bromoethylene exposure occurs (NIOSH, 1978):

- chemicals and allied production;
- rubber and plastic production;
- leather and leather product production; and
- fabricated metal production for wholesale trade.

1.4 RISKS TO HUMAN HEALTH

1.4.1 Introduction

Liver cancer is the 9th commonest malignant neoplasm amongst men in Europe and the 14th in women, accounting for over 42,000 deaths in Europe each year (Ferlay *et al*, 2007). The main risk factors for liver cancer are cirrhosis from alcohol consumption, infection with hepatitis viruses and diabetes. People who are infected with hepatitis B or C virus have a higher risk for liver cancer if they smoke and the IARC have indicated that cigarette smoking is an independent risk factor for hepatocellular carcinoma, the main form of primary liver cancer (Altamirano and Bataller, 2010). Most cases of liver cancer occur in people over the age of 60 years (Nordenstedt *et al*, 2010).

The incidence rates of liver cancer are higher in Italy, Greece and France (more than about 10 per 100,000 in men) with lower rates in United Kingdom, Sweden and Poland (less than 5 per 100,000 in men)[3]. Incidence has been increasing steadily over the last 30 years. About 5% of patients survive for five years after diagnosis, with slightly better survival in women than men and better survival amongst younger patients.

There are a small number of occupational exposures that have been identified by IARC as possible causes of bladder cancer in humans, including: trichloroethylene, ionising radiation and vinyl chloride.

1.4.2 Summary of the available epidemiological literature on risk

Bromoethylene

Bromoethylene has been shown to carcinogenic in experimental animals. Both male and female rats exposed to bromoethylene by inhalation showed increased incidences of hepatic hemangiosarcoma, Zymbal gland carcinoma, liver neoplastic nodules, and hepatocellular carcinoma (IARC, 1986). These responses are similar to their responses to vinyl chloride monomer (VCM) although bromoethylene appears to be a more potent inducer of liver hemangiosarcoma, including angiosarcoma, in rats than is vinyl chloride. For these reasons IARC suggest that the carcinogenic effects of bromoethylene should be considered similarly to vinyl chloride (Grosse *et al*, 2007).

There appear to be no relevant epidemiological studies for bromoethylene. However, studies relating to VCM exposure could be used for selection of risk estimates.

Vinyl chloride

Table 1.2 summarises the results for liver cancers, primarily angiosarcomas, from several studies of workers exposed to VCM and also gives the summary risk estimate from Kielhorn *et al* (2000).

Table 1.2 Summary of findings for liver cancer[1] from epidemiologic studies on workers exposed to VCM[2]

Liver Cancer[2]	European Cohort	US Cohort	German Cohort	Russian Cohort	Canadian Cohort	French Cohort	All Studies
Reference	Simonato *et al* (1991)	Wong *et al* (1991)	Weber *et al* (1981)	Smulevich *et al* (1988)	Theriault and Allard (1981)	Laplanche *et al* (1992)	-
O/E	24/8.4	37/5.77	12/0.9		8/0.14	3	81/19.21
SMR	2.86	6.41	15.23	0/n.a	57.14	3 ASL	5.33
CI	1.83-4.25[a]	4.5-8.84[b]			8 ASL[c]		4.23-6.62

[1] Including ASL
[2] Adapted from Kielhorn *et al*, (2000)
n.a – not available
[a] of 17 liver cancers confirmed histologically, 16 were ASL.
[b] 15 cases of ASL from death certificates and 21 from international register.
[c] plus 2 undiagnosed ASL cases.

[3] http://globocan.iarc.fr/

An association between occupational VCM exposure and other forms of liver cancer is less well defined. Ward *et al* (2001) observed a marked exposure-response relationship for all liver cancers. However, the study included only a small number of hepatocellular carcinomas (HCC) cases and confounding factors, such as alcohol consumption and viral infection, were not adjusted for. In addition, Wong *et al*, (2003) have suggested a possible interaction between VCM exposure and HBV infection in the development of liver cancer. Similar suggestions have been made by Mastrangelo *et al*, (2004); these authors noted that VCM exposure appears to be an independent risk factor for HCC that synergistically interacts with alcohol consumption and additively with viral hepatitis infection.

A follow-up mortality analysis to 2003 carried out on a previous UK study cohort of 1700 male workers exposed to PVC during or prior to 1979 (Graham, 2006) found 6 cases of liver cancer (expected number 2.2) of which 2 were ASL.

1.4.3 Choice of risk estimates to assess health impact

We have selected the same risk estimates for bromoethylene as those selected for vinyl chloride within this research project. As it is not clear how the Kielhorn *et al* (2000) calculated the ‘all studies’ SMR which could be heavily influenced by that reported for the Canadian cohort (SMR = 57.14), we have selected the European cohort (Simonato *et al*, 1991) included in the review by Kielhorn *et al* (2000) as most relevant for comparison with workers in Europe exposed to VCM; histological analysis was performed and 16 of the 24 cases of liver cancer in the study cohort were verified as ASL. The SMR for liver and biliary tract cancer for workers in the European cohort was found to be 2.86 (95% CI, 1.83 – 4.25) and has been used for AF calculation for high exposure to vinyl bromide. Due to the absence of sufficient exposure-response data specific to VCM an RR = 1.89 has been estimated for the low exposure level category for vinyl bromide. This was based on a harmonic mean of the high/low ratios across all other cancer-exposures pairs in the overall project for which data were available.

2 BASELINE SCENARIOS

2.1 PREVALENCE OF BROMOETHYLENE EXPOSURE IN THE EU

Bromoethylene has been available commercially since 1968.

Exposure to bromoethylene was considered by CAREX but it was judged there were no exposed individuals in the EU in 1990-1993 (Kauppinen *et al*, 2000). The Finnish CAREX update for 2009 also indicates there are no individuals exposed in the manufacture of industrial chemicals. The Spanish CAREX (2004) also indicates there are not exposed employees. Other estimates of the number of workers exposed to bromoethylene in Europe are available only from the Finnish Register of Occupational Exposure to Carcinogens which reported one individual who was notified as having been exposed to bromoethylene in 2004 (Saalo *et al*, 2006).

A search in a database[4] for suppliers of chemicals identified three suppliers of bromoethylene in the UK, Germany and Spain. The three sites were indicated as “suppliers”, with the main leading producers being located in China. Therefore, we assumed there are very few people in EU exposed to bromoethylene.

Classification of Industries by Exposure Level

Industries in which bromoethylene exposure may occur have been classified as high, medium or low (historic) exposure based on an evaluation of the peer-reviewed literature and expert judgement. The exposure classification by industry is presented in Table 2.1. The industries, grouped by NACE code, were identified from CAREX and NIOSH published literature.

Table 2.1 Classification of industries by (historic) exposure level

Industry	NACE (rev 1)	Classification
Manufacture of industrial chemicals and chemical products	24	L
Manufacture of rubber and plastic products	25	L
Manufacture of fabricated metal products, except machinery and equipment	28	L
Manufacture of textiles	17	L

2.2 LEVEL OF EXPOSURE TO BROMOETHYLENE

2.2.1 Estimation of exposure levels

Bromoethylene occupational exposures (median 8-hour TWA) calculated for a bromoethylene manufacturing plant in 1980s ranged from 0.4 to 27.5 mg/m^3 (0.1 to 6.3 ppm), depending on the job and the area surveyed. Personal air samples (one-hour) showed that a plant operator was exposed to 0.4 to 1.7 mg/m^3 (0.09 to 0.4 ppm), a laboratory technician to 1.3 to 2.2 mg/m^3 (0.3 to 0.5 ppm), and two loading crewmen to between 5.2 and 27.5 mg/m^3 (1.2 to 6.3 ppm) bromoethylene (Bales, 1978; Oser, 1980 as reported in IARC 1986).

Assuming a 7% reduction in exposure concentrations, which is typical in occupational exposure (Creely *et al*, 2007), current (2010) estimated exposure concentrations will range from 0.15 to 3.12 mg/m^3, which is well below the typical OEL in EU. Only in the Netherlands is the exposure limit lower than these levels.

Exposure concentrations in other industries (NACE codes 25, 28 and 17) are likely to be lower than during manufacturing.

In summary, there are very few employees who may be exposed to bromoethylene in the EU. The estimated exposure levels in the manufacturing industry ranged from 0.15-3.12 mg/m^3. Therefore, exposure levels in all EU countries are likely to be well below the typical OEL (22 mg/m^3).

[4] Available at: http://www.buyersguidechem.com/

2.3 HEALTH IMPACT FROM CURRENT EXPOSURES

Because there are likely to be very few people exposed to this substance and exposure levels are probably much lower than the typical OEL being considered in this report we have not carried out a health impact assessment.

2.4 POSSIBLE COSTS ASSOCIATED WITH NOT MODIFYING THE DIRECTIVE

There is insufficient information available to produce monetised health costs associated with not modifying the directive to include bromoethylene. However, it is likely that any health costs will be very negligible.

3 POLICY OPTIONS

3.1 DESCRIPTION OF MEASURES

Exposure can occur either in facilities that manufacture bromoethylene or in facilities that use this product. Exposure to bromoethylene occurs primarily by inhalation and dermal contact. The following operations may involve bromoethylene and lead to worker exposures to this substance:

- Production of flame-retardant synthetic fibre
- Intermediate in organic synthesis
- Preparation of plastics by polymerization or copolymerization
- Manufacture and transportation of vinyl bromide[5].

Methods that are effective in controlling worker exposures to vinyl bromide, depending on the feasibility of implementation, are as follows:

- Process enclosure
- Local exhaust ventilation
- General ventilation
- Personal protective equipment
- Personal hygiene procedures
- Closed loop / enclosed sampling points
- Dry break coupling systems[6].

As demonstrated by the estimates of exposure levels in section 2.2, it is believed that exposures below the proposed limit of 22 mg/m^3 can be and are achieved by the use of such controls.

[5] Occupational Safety and Health Guideline for Vinyl Bromide. Available online: http://www.osha.gov/SLTC/healthguidelines/vinylbromide/recognition.html
[6] Inchem (2002) Vinyl bromide. Available online: http://www.inchem.org/documents/icsc/icsc/eics0597.htm

3.2 LEVEL OF PROTECTION ACHIEVED (OELS)

The typical OEL in EU is 22 mg/m^3 for 8-hrs TWA. From the data shown in section 2.2 it is likely that most of the manufacturing sites have exposure concentrations below about 3 mg/m^3. Therefore, compliance with the OEL should be straight forward.

The manufacture of bromoethylene is believed to be carried out in closed systems with local exhaust ventilation. Personal protective equipment is also worn. Therefore exposure occurs predominantly during tasks where the system is breached. These tasks, which may give rise to relatively high short-term exposures, include sampling, coupling of delivery lines, and planned and unplanned maintenance. The significance of these exposures depends on how these tasks are carried out and what measures are taken to reduce the exposure. For example, the use of closed loop / enclosed sampling points and dry break coupling systems will reduce exposure. The extent of the use of such systems was not established. It is therefore the extent to which these short-term exposures are controlled that will dictate the significance of the 8-hour TWA exposure.

4 ANALYSIS OF IMPACTS

4.1 HEALTH IMPACTS FROM CHANGES TO THE EU DIRECTIVE

4.1.1 Health information

Because of the uncertainty about the carcinogenicity of 1,2-dibromoethane in humans we have not carried out a health impact assessment. It is likely that the number of people exposed to this substance is less than 8,000 and exposure levels are low. This suggests that any health impact will be small.

4.1.2 Monetised health benefits

In the absence of available data it has not been possible to assess the health impacts of introducing new exposure limits. It has therefore not been possible to produce monetised health benefits. It is estimated that there would be a limited number of employees across the EU exposed to levels of bromoethylene and none would be exposed in excess of the proposed limit value of 22 mg/m^3. Therefore, it is reasonable to assume there would be limited health benefits of introducing an EU-wide OEL at 22 mg/m^3.

4.2 ECONOMIC IMPACTS

4.2.1 Operating costs and conduct of business

Number of Firms Affected

In Section 2.2.1, it is estimated that there would be a limited number of employees across the EU exposed to levels of bromoethylene and none would be exposed in excess of the possible OEL value of 22 mg/m^3 (5 ppm). It is likely that most of the manufacturing sites have exposure concentrations below 3.12 mg/m^3. Exposure concentrations in other industries (NACE codes 25, 28 and 17) are likely to be lower than those experienced during manufacturing.

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 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.

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 22 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 22 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 the possible removal of any competitive disadvantage to those Member States that previously had more stringent national OELs in place (the Netherlands and Spain), although these countries may decide to maintain there existing OELs.

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: ○ 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 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 22 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 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 22 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 22 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 = 22 mg/m^3	
Health Costs	**Health Benefits**	**Health Costs**	**Health Benefits**
There is insufficient information to calculate the health impacts 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 = 22 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 firms where bromoethylene exposure occurs to put 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 22 mg/m^3. Therefore there are not expected to be any significant additional costs of meeting an OEL of 22 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 = 22 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 = 22 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 = 22 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 bromoethylene are estimated to be exposed above the possible EU-wide OEL value of 22 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

We have considered 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) for bromoethylene of 22 mg/m^3 (5 ppm).

Bromoethylene has fairly limited uses, mostly as a flame retardant in the production of acrylic fibres for carpet backing materials, in children's sleepwear and home furnishings. It has been available commercially since 1968.

The number of people that are potentially exposed in Europe is likely to be small, i.e. less than a few hundred, but we have no information to determine the actual extent of exposure. Occupational exposures are currently low, with the highest exposure levels probably about 3 mg/m^3. It has been assumed that exposure levels have been decreasing over recent years by about 7% per annum and so future exposures may continue to decline.

Bromoethylene is an animal carcinogen and although there is no epidemiological data it is assumed it may act similarly to vinyl chloride and cause liver cancer in humans. Based on this analogy we identified a relative risk of 2.86 associated with high exposure and 1.89 for low exposure. However, given the uncertainties around the number of exposed workers we did not undertake a health impact assessment. However, if as we assume the current exposure levels are low and there are a limited number of people exposed then there is unlikely to be any important cancer risk for this substance. There are no estimates of health costs of inaction for this substance.

There are no predicted health benefits from setting an OEL at 22 mg/m^3, although we believe the impact would be relatively small because current exposures are much lower than the proposed OEL. There are no additional costs associated with compliance with a limit of 22 mg/m^3. There are no social or macro-economic costs associated with introducing an OEL. There are also no significant environmental impacts foreseen.

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HEAD OFFICE:

Research Avenue North,
Riccarton,
Edinburgh, EH14 4AP,
United Kingdom
Telephone: +44 (0)131 449 8000
Facsimile: +44 (0)131 449 8084

Tapton Park Innovation Centre,
Brimington Road, Tapton,
Chesterfield, Derbyshire, S41 0TZ,
United Kingdom
Telephone: +44 (0)1246 557866
Facsimile: +44 (0)1246 551212

Research House Business Centre,
Fraser Road,
Perivale, Middlesex, UB6 7AQ,
United Kingdom
Telephone: +44 (0)208 537 3491/2
Facsimile: +44 (0)208 537 3493

Brookside Business Park,
Cold Meece,
Stone, Staffs, ST15 0RZ,
United Kingdom
Telephone: +44 (0)1785 764810
Facsimile: +44 (0)1785 764811

Email: iom@iom-world.org