Study on collecting information on substances with the view to analyse health, socio-economic and environmental impacts in connection with possible amendments of Directive 98/24/EC (Chemical Agents) and Directive 2009/148/EC (Asbestos)

Study overview and key findings

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1. Introduction

This report summarises the key findings from four reports written within the framework of a study commissioned by the European Commission, Directorate-General for Employment, Social Affairs and Inclusion (DG EMPL) by a consortium comprising RPA (Risk & Policy Analysts) (United Kingdom), COWI A/S (Denmark), FoBiG (Forschungs- und Beratungsinstitut Gefahrstoffe) (Germany), and EPRD (Office for Economic Policy and Regional Development) (Poland). The four reports are:

- Report for lead and its compounds;
- Report for asbestos;
- Report for diisocyanates; and
- Methodological note.

Ensuring a safe and healthy work environment for over 200 million workers in the EU is an ongoing strategic goal for the European Commission according to the Communications from the Commission on the EU Strategic Framework on Health and Safety at Work 2014 – 2020[1] and 2021 - 2027[2].

Cancer and other work-related health problems caused by exposure to carcinogenic and other hazardous chemical substances at the workplace leads to suffering of workers and their caring families. It reduces the length, quality, and productivity of the working lives of European workers.

It is important to ensure that risks to workers' health that arise from exposure to carcinogenic and other hazardous chemicals at the workplace are effectively controlled including, where appropriate, by the use of limit values.

1.1 Substances assessed and key health effects

1.1.1 Lead

Lead and its compounds are key occupational reprotoxicants[3]. Reprotoxic chemicals can cause two groups of ill-health: effects on sexual function and fertility and effects on development of the foetus or offspring (developmental toxicity). Other health ill-effects caused by exposure to lead include brain cancer, neurotoxicity, haematotoxicity, nephrotoxicity and cardiovascular effects.

1.1.2 Asbestos

Asbestos has long been recognised as a key occupational carcinogen. Airborne fibres are very resistant when inhaled and can lead to asbestosis, mesothelioma, cancers of the lung, larynx, and ovary and other non-malignant lung and pleural disorders, including pleural plaques, pleural thickening, and benign pleural effusions. Whilst asbestos is no longer used there is a significant amount of legacy asbestos in older buildings and elsewhere, such as in ships and trains. The management of asbestos in buildings and its safe removal is currently an important topic not only under EU action on prevention and protection of workers but also due to the need for Europe to improve the thermal insulation of its built environment and enable energy savings. This is in line with the ambition of the EU set in the European

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1 Available at: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52014DC0332&from=EN

2 Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021DC0323&qid=1626089672913#PP1Contents

3 Available at: https://ec.europa.eu/social/main.jsp?catId=738&langId=en&pubId=8220&furtherPubs=yes

Green Deal to become the first climate-neutral continent by 2050 and requires full consideration of health and safety at work aspects.

1.1.3 Diisocyanates

Di-isocyanates are respiratory sensitisers, also called asthmagens, potentially causing occupational asthma, which is an allergic reaction that can occur in some workers when they are exposed to such substances. They can cause a change in people's airways, known as the 'hypersensitive state'. Not everyone who becomes sensitised goes on to develop asthma. But once the lungs become hypersensitive, further exposure to the substance, even at quite low levels, may trigger an attack.

1.2 Objective

The objective of the study was to provide the Commission with the most recent, updated and robust information on exposure to lead and its compounds, asbestos and diisocyanates with the view to support the European Commission in future work to revise or introduce occupational exposure limit values (OELs), short term exposure limit values (STELs) and biological limit values (BLVs) under the scope of the Chemical Agents Directive (98/24/EC) or CAD and the Asbestos At Work Directive (2009/148/EC) or AWD.

1.3 Steering group and meetings

1.3.1 Steering group members

The steering group comprised members from both the European Commission and the Working Party on Chemicals:

- European Commission
  - DG Employment, Social Affairs and Inclusion (EMPL);
  - DG Environment (ENV);
  - DG Internal Market, Industry, Entrepreneurship and SMEs (GROW); and
  - Secretary General (SG).
- Working Party on Chemicals (WPC)
  - Workers interest group (WIG);
  - Employers interest group (EIG); and
  - Government interest group (GIG).

1.3.2 Steering group meetings

The steering group met five times on following dates/meetings:

- November 2020 – kick-off meeting;
- December 2020 – inception meeting: agreed the policy options and the requirements for the stakeholder consultation questionnaires;
- April 2021 – interim meeting;
- May 2021 – progress meeting; and
- July 2021 – draft final report meeting.

In addition, the study team presented a progress report to the WPC in June 2021.

1.4 Stakeholders consulted

A wide range of organisations were consulted about all three substances, primarily through several on-line questionnaires, interviews, email exchanges and site visits. The online surveys were open from mid-January 2021 until the end of March 2021. The numbers of each type of consultation conducted are as follows:

- Survey: companies – 419;
- Interviews (trade associations & companies) – 97;
- Site visits – 7 (2 for lead under previous study in 2019);
- Survey: Member State Authorities – 16; and
- Survey: occupational health & safety professionals – 13.

2. Study overview

2.1 Substances assessed

2.1.1 Lead and its compounds

Lead and lead compounds are used for many applications. In addition, workers may be exposed to lead at significant levels from historic applications of lead in activities such as renovation, waste collection, recycling, and remediation. The main sectors for industrial production and use of lead and lead compounds are primary and secondary lead production (incl. battery recycling); battery, lead sheet and ammunition production; production of lead oxides and frits; lead glass and ceramics production. Other industrial applications are: foundries and production of articles of alloys with lead; and production and use of pigments for paint and plastics. Besides these applications, exposure may take place further downstream in the product chain and when the articles and materials become waste or during the waste recovery of recycled materials. Examples of downstream activities are: applications of paints; shooting; work with lead metal; demolition, repair and scrap management; other waste management and soil remediation; work in laboratories; and work activities in other sectors.

The study estimates that approximately 50,000 to 150,000 workers are exposed to lead and its compounds. If no further action is taken, approximately 300 cases of ill-health will occur each year over the next 40 years due to exposure during this period.

Under Annex I of the Chemicals Agents Directive (Directive 98/24/EC) or CAD 'binding occupational exposure limit values' are established, while under Annex II 'binding biological limit values and health surveillance measures' are established. To date, one binding occupational exposure limit value (OEL) and one binding biological limit value (BLV) have been set under the CAD for 'inorganic lead and its compounds'. The current values are set at 0.15 mg/m^3 (equivalent to 150 µg /m^3) and 70 µg Pb/100 ml blood (equivalent to 700 µg /L), respectively.

On the 11th June 2020, the Committee for Risk Assessment (RAC) proposed an OEL of 4 µg /m^3 and a BLV of 150 µg /L blood for lead and its inorganic compounds.

For lead, the specific objective of the study was to assess the impacts of lowering the OEL and BLV in the CAD.

2.1.2 Asbestos

Asbestos is a key occupational carcinogen. Asbestos was used worldwide in building and other materials in many areas of our daily life. It is no longer used in general manufacture and placing on the market or use in the EU is prohibited. There is, however, a substantial legacy problem since it is still present in many older buildings, ships, trains and other installations that are likely to be renovated, adapted or demolished over the coming years. These works present a potential risk of workers being exposed to asbestos and it is important that it is carried out in a controlled way by suitably trained workers and managed under supervision of responsible employers. The management of asbestos in buildings and its safe removal is an important topic and this becomes more important due to the need for the EU to improve the thermal insulation of its built environment to meet the energy saving objectives of the Green Deal.

The study estimates that approximately 4.1 - 7.3 million workers are exposed to asbestos. If no further action is taken, approximately 22 cases of cancer will occur each year over the next 40 years due to exposure during this period.

For asbestos, the specific objective of the study was to assess the impacts of lowering the OEL in the AWD. The OEL is currently 0.1 fibres/cm^3.

At the start of the study, there was no Committee for Risk Assessment (RAC) opinion available. On the 13th July 2021, the RAC published its opinion on the scientific evaluation of occupational exposure limits for asbestos. This took the form of a set of excess risks for a range of 8-hour time weighted average OELs between 0.001 and 0.1 fibres/cm^3.

2.1.3 Diisocyanates

Diisocyanates are widely used in manufacture of polyurethane as both solids and foams, plastics, coatings, varnishes, two-pack paints and adhesives. Workers in companies manufacturing these materials are exposed to diisocyanates, and workers using adhesives, sealants, paints and coatings containing diisocyanates are also exposed. These products are widely used in construction, vehicle repairs, general repairs, textiles, furniture, and the manufacture of motor vehicles, other transport, domestic appliances, machinery, and computers.

The study estimates that approximately 4.2 million workers are exposed to diisocyanates (excluding those who already have asthma). If no further action is taken, approximately 3,000 cases of ill-health will occur each year over the next 40 years due to exposure during this period. The estimated number of cases takes into consideration the anticipated effect of the REACH Restriction, which was introduced in 2020 and comes into effect in 2023. The REACH Restriction introduces specific training requirements for workers using diisocyanates. These requirements complement the general training requirements under EU OSH legislation.

On the 11th June 2020, the RAC published its opinion on the scientific evaluation of occupational exposure limits for diisocyanates. This took the form of a set of excess risks for a range of 8-hour time weighted average OELs between 0.025 and 0.67 µg NCO/m^3, see footnote[4]. The RAC also stated that the value of STEL should be no more than twice that of the OEL and the STEL value should not exceed 6 µg NCO/m^3.

[4] NCO – an isocyanate chemical group, which refers to the nitrogen, carbon, and oxygen atom of the isocyanate group. The mechanistic link between the NCO Groups in diisocyanates and their toxicology is well established. Several expert committees concluded that a joint assessment for all diisocyanates based on NCO concentration is adequate. RAC proposes this approach as well, but also states that there is not enough data to assess potency differences for individual diisocyanates. Some other panels derived limit values for individual diisocyanates based on substance specific data, for example, the German MAK commission.

For diisocyanates, the specific objective of the study was to assess the impacts of introducing an OEL and a short-term exposure limit value (STEL) under the scope of the CAD.

2.2 Policy options

2.2.1 Lead and its compounds

The study aimed to provide a comparison of the costs and benefits for a range of potential OELs and BLVs. The ranges start at the values proposed by the RAC, encompass the values in the Scientific Committee on Occupational Exposure Limits (SCOEL) opinion and end at the current limit values.

Specific values, however, had been established for the purposes of the stakeholder consultation. The specific values functioned as reference points to the consultees who may otherwise have found it impossible to provide data on the costs of the measures being considered.

To alleviate the burden of participation in the surveys for the stakeholders, the BLV options of 200 and 100 µg/L and the OEL option of 100 µg/m³ were omitted in the survey. The detailed analysis of costs concerned lowering the BLV to 700, 300, 150 and 45 µg/L, whereas the costs of lowering the level to 200 and 100 µg/L were interpolated from the costs estimates for the four previous mentioned BLV levels. The OEL options were evaluated in relationship to the BLV options.

Table 2-1 OEL options for lead and its compounds

Level, µg/m³	Level, mg/m³	Reason for inclusion
150	0.15	Existing EU level in the Chemical Agents Directive
100	0.10	Intermediate level of current OELs in EU Member States as agreed by the steering group of this study.
50	0.05	Lowest OEL in EU Member States (Bulgaria, Czech Republic, Denmark, Estonia, Latvia, Poland, Sweden)
20	0.02	Intermediate level between lowest national OEL and the level proposed by RAC as agreed by the steering group of this study.
4	0.004	OEL at the level proposed by RAC

Table 2-2 BLV options for lead and its compounds

Level, µg/L	Level, µg/100 mL	Reason for inclusion
700	70	Existing EU level in the Chemical Agents Directive
300	30	Intermediate level of BLV in EU Member States
200	20	Lowest national BLV in EU Member States for all workers (Denmark). Voluntary target of International Lead Association.
150	15	BLV at the level proposed by RAC
100	10	The ILA voluntary programme recommendation for females of reproductive capacity (defined as ≤45 years of age or as agreed by the

Level, µg/L	Level, µg/100 mL	Reason for inclusion
		company medical advisor) based on DNEL set under REACH. Included as agreed by the steering group of this study.
45	4.5	Biological guidance value related to background exposure of the general population. Applies to women of child-bearing age (under 50 years of age). Included following the agreement of the steering group of this study

2.2.2 Asbestos

At the start of the study, no RAC opinion was available which could inspire the choice of OEL options.

However, based on dialogue with the ECHA OEL secretariat and discussion with the steering group, the OEL options 0.01 and 0.001 fibres/cm^3 were agreed to be included in the stakeholder questionnaires during the December 2020 inception meeting. The option of 0.002 fibres/cm^3 was added in agreement with the steering group at the May 2021 progress meeting.

It was assumed that the scope of the directive will remain unchanged, and it will continue to include fibres with a diameter in the range of 0.2 - 3.0 µm. Consequently, it was assumed that lowering the OEL from 0.1 to 0.01 fibres/cm^3 corresponds to lowering the exposure concentrations of fibres in the workplace by a factor of ten.

The AWD does not define a lower limit for the diameter, but this is in practice set by the prescribed analytical method (optical, phase-contrast microscopy (PCM) or any other method giving equivalent results). If the current OEL is lowered to any of the OEL options under consideration in this study, the electron microscopy methods appear to be the more appropriate analytical method. With the transmission electron microscopy (TEM) method, in practice, fibres with diameters down to 0.01 µm can be measured. A decrease from 0.1 fibres/cm^3 measured by PCM to a concentration of 0.01 fibres/cm^3 measured by TEM, unless a minimum diameter is defined, would require a decrease by more than a factor of ten in exposure concentrations; possibly a factor of 20.

Table 2.3 OEL options for asbestos

Level	Reason for inclusion
0.1 fibres/cm^3 (100 fibres/L, 100,000 fibres/m^3)	Current EU OEL
0.01 fibres/cm^3 (10 fibres/L, 10,000 fibres/m^3)	Equal to the OEL in France* and "acceptance level" in Germany
0.002 fibres/cm^3 (20 fibres/L, 20,000 fibres/m^3)	Equal to the OEL in the Netherlands, the lowest in Member States **
0.001 fibres/cm^3 (1 fibres/L, 1,000 fibres/m^3)	Half of the current Dutch OEL

** The OEL in France differs in practice from the current EU OEL as it is defined that the concentration should be analysed using TEM and thereby in practice addresses both the fibres within the scope of the AWD (with the defined analytical technique in practice fibres with diameter in the range of 0.2-3.0 µm) and 'thin asbestos fibres' (TAF, with diameters of 0.01 - 0.2 µm). Studies indicated that the number of fibres when the TAF are included would typically be a factor of two to three times higher than the number than if the TAF are excluded. As a*

consequence, the OEL in France corresponds to at least a two times lower value than if only the fibres addressed by the AWD are counted.
*** According to the Dutch legislation, asbestos fibres of the chrysotile type and amphibolic asbestos fibres, respectively, should not exceed this value. For exposure to a mixture of the two types, the OEL corresponds to a slightly higher OEL value than if the OEL addresses all asbestos fibre in common as is the situation for the EU OEL.*

It could be argued that an even lower OEL might be considered. The main arguments for not including policy options below 0.001 fibres/cm^3 are that:

- A lower limit seems not to be feasible given the current thinking among experts about the limit of detection. Already the feasibility of measuring at the 0.001 fibres/cm^3 level is challenged by several Steering Committee members and experts; and
- The lowest level suggested is already half of the lowest national OEL.

In the RAC scientific evaluation and opinion on asbestos published on 13th July 2021, no STEL was proposed for asbestos.

Although different fibre types of asbestos vary in toxicological potency, the most common approach by Member States is to set a single OEL covering all fibre types and not to set different OELs for different types of fibres. The OEL in the Netherlands, however, has a specification of different fibres as it is specified that the concentration of chrysotile-type asbestos fibres should not exceed the limit value of 0.002 fibres/cm^3 and the concentration of the amphibole asbestos fibres actinolite, amosite, anthophyllite, tremolite and crocidolite should not collectively exceed the limit value (in practice this means that the total asbestos concentration could exceed the limit value). Also, in Belgium, OELs are established for chrysotile-type asbestos and other asbestos fibres, respectively.

2.2.3 Diisocyanates

The study compared the costs and benefits of a range of OEL and STEL options.

However, specific values were established for the consultation to provide reference points to respondents who would have found it difficult to provide data on all considered options.

Throughout the analysis of benefits and costs, eight reference levels each were taken for OELs and STELs, these are shown in the tables below.

As there is no current EU-wide OEL of STEL for diisocyanates, the baseline is taken to be the median level of the national OELs for diisocyanates, which is 17.5 NCO µg/m^3 and similarly 35 NCO µg/m^3 for STELs.

Table 2-4 OEL options for NCO diisocyanate

Level	Reason for inclusion
17.5 µg/m^3	The median level for a national OEL
10 µg/m^3	Intermediate level
6 µg/m^3	Intermediate level that some companies are achieving
3 µg/m^3	This is half of the maximum STEL recommended by RAC and RAC also recommend that the STEL is at most two times the OEL
1 µg/m^3	This is the lowest OEL in a Member State
0.5 µg/m^3	Intermediate level

Level	Reason for inclusion
0.1 µg/m^3	Intermediate level
0.025 µg/m^3	This value represents the lowest excess risk given by RAC (0.1%)

Table 2-5 STEL options for NCO diisocyanate

Level	Reason for inclusion
35 µg/m^3	The median level for a national STEL
20 µg/m^3	Intermediate level
12 µg/m^3	Two times intermediate level
6 µg/m^3	The maximum STEL recommended by RAC
2 µg/m^3	Two times the lowest OEL in a Member State
1 µg/m^3	Intermediate level
0.2 µg/m^3	Intermediate level
0.05 µg/m^3	Two times the lowest excess risk given by RAC (0.1%)

2.3 Methodology

For each OEL/STEL/BLV option, the information and analysis that supported the impact assessment considered the following:

- cost savings (benefits) from reduced ill health;
- costs for companies of additional risk management measures (RMMs);
- transposition and enforcement costs for public authorities; and
- other types of impacts, such as the availability of a suitable method for measuring the required exposure concentrations.

In addition, market impacts, distributional effects and impacts on the environment are considered. A detailed explanation of these approaches is provided in the methodological note.

2.3.1 Benefits (cost savings)

The cost savings from reduced disease burden were assessed in a model that estimates and monetises ill health under the baseline and policy options.

The number of cases of ill health was estimated by combining Exposure-Risk Relationships (ERRs) for cancer effects or Dose-Response Relationships (DRRs) for non-cancer effects with the number of workers at different exposure concentrations.

Two estimates of the cost savings were developed which relied on two different monetisation approaches (Method 1 and Method 2). Both approaches monetised the same number of avoided cases of ill health and used identical methods for the monetisation of direct (healthcare, informal care, disruption costs to employers) and indirect (productivity, lost earnings[5]) impacts.

However, Method 1 and Method 2 relied on different approaches to the monetisation of intangible benefits: Method 1 used Willingness-to-Pay data to estimate the monetary value of an avoided case of a specific effect/condition, whilst Method 2 relied on disability weights for the different effects to estimate the avoided Disability-Adjusted Life Years (DALYs) and subsequently monetised these using a generic value for a single DALY.

Methods 1 and 2 are not only different approaches but their use in this study relied on different data sources. These two approaches are usually not used in parallel in policy making. The results of both approaches should thus be considered together as indicative of the order of magnitude of the relevant impacts – they are not intended to produce the same estimate or provide a lower and upper bound of a potential range.

2.3.2 Costs

The costs of the different OEL/STEL/BLV options for businesses were estimated in two spreadsheet models (one for di-isocyanates and lead, and another one for asbestos) and sense-checked against consultation responses (and adjusted where necessary). The estimation models were developed because most companies are unable to estimate the specific RMMs that would be required, and their cost.

The starting point for both cost models was the current exposure concentrations and RMMs in place. The model for di-isocyanates and lead made assumptions about the effectiveness and suitability of different RMMs enabling it to select all the RMMs that are suitable to the relevant activities and effective enough to reduce exposure to levels that comply with the OEL/STEL/BLV option. If several RMMs were suitable and effective enough, the model selected the cheapest. The analysis in the model differentiated between different industry sectors and company sizes (small, medium, large).

In the asbestos cost model, companies were divided into five exposure groups according to the Respiratory Protective Equipment (RPE) currently used. For all companies that need to reduce exposure to comply with an OEL option, the model shifted these companies and workers into one of the groups with more effective RPE and calculated the cost difference.

2.3.3 Other impacts

Building on the estimates of the costs for companies, the study considered market effects (single market, innovation and growth, competitiveness of EU businesses, employment), and distributional effects (businesses, SMEs[6], workers, consumers, taxpayers/public authorities, specific Member States/regions).

Environmental impacts were assessed by screening the relevant substances for persistent, bio-accumulative, and toxic properties, reviewing current exposures of the environment, analysing waste management and disposal activities and considering the impact of introducing new RMMs on emissions into the environment.

5 With the exception of cases where lost earnings are already taken into account in some willingness to pay estimates – where these include both intangible and productivity effects, no additional lost earnings are estimated.

6 Small and medium-sized enterprises

3. Cost benefit ratios and key findings

The cost benefit ratios provide a direct comparison of the costs and benefits for each substance. The costs and benefits include all impacts over 40 years and are additional to the baseline. Additionally, certain issues with special relevance for the future decision making are listed for each of the substance groups.

In determining the cost-benefit ratios, a large number of factors including underlying assumptions are taken into consideration. Therefore, the ratios presented should not be used on their own for decision making without a good understanding of the methodologies and associated calculations.

3.1 Lead and its compounds

Table 3-1 Cost-benefit ratios of the BLV options for lead

Impact	BLV options (µg/L)					
	45	100	150	200	300	700
Total benefits M1	€ 320 million	€ 300 million	€ 260 million	€ 210 million	€ 80 million	€ 0
Total benefits M2	€ 440 million	€ 420 million	€ 360 million	€ 300 million	€ 120 million	€ 0
Total costs	€ 6,300 million	€ 1,800 million	€ 750 million	€ 350 million	€ 130 million	€ 0
Cost benefit ratio M1	20	6.0	2.9	1.7	1.6	0
Cost benefit ratio M2	14	4.3	2.1	1.2	1.08	0

Relationship between levels of lead in air (PbA) and blood (PbB)

Blood lead concentrations are recognized as the main exposure metric in assessing occupational exposures in lead. The study includes a complete assessment of the impacts of all BLV options. The assessment of the OEL options could not be performed in a corresponding manner due to missing and uncertain data regarding health effects related to airborne exposures.

PbB and PbA relationships depend on various factors within an occupational setting and unambiguous correlation methods are not available. The recognized best available method for estimating PbB based on PbA shows to have limited value for the calculation of ill health cases in this study, as the validated conversion range and conversion values do not reflect relevant PbB and PbA concentrations of current occupational settings. For that reason, the steering group agreed that the study needed to evaluate the BLV quantitatively and the OEL qualitatively in relation to the BLV options. Most companies focus on PbB management and found it challenging to provide data on PbA management. The qualitative cost assessment of the OEL options did not result in unambiguous conclusions but indicated the OEL option of 50 µg/m³ as an achievable level.

Groups at Extra Risk

RAC recognises the increased susceptibility to lead toxicity to women of childbearing capacity: "*Considering the workplace, women of childbearing capacity and pregnant women* *require specific considerations. Neither the proposed BLV of 150 µg/L blood nor the proposed air limit value of 4 µg/m³ for lead and its inorganic compounds protects from developmental toxicity. No threshold* […] *can be identified at present. The exposure of fertile women to lead should therefore be avoided or minimised.*" This study did not discuss the relationship between setting protective limit values and gender equality. Data on adverse health effects of lead in women of childbearing age, exposure concentrations and numbers of female employees of childbearing age have been included in the study, as well as information on how exposure of women is currently managed in industry. It was not within the scope of the study to provide conclusions on how/if limit values for women of childbearing capacity should be addressed in the CAD.

Development of future exposure concentrations

Data on exposure concentration trends from various sources show that blood lead levels have reduced drastically during the past decades but appear to have stagnated in recent years. Continuous efforts within the main lead producing and processing sectors indicate that further reductions are likely, however, these are not reflected in the exposure concentration trend data of the most recent years.

Available information does not suggest exposure concentration reduction in other sectors than the main lead producing and processing sectors for the recent years. Since May 2021, companies in Germany must comply with the German BLV of 150 µg/L. No data are yet available to show the extent to which the newly introduced German BLV impacts the baseline and the benefits estimation. Technical risk management measures to control airborne concentrations become effective as soon as there are in operation. Reducing blood lead levels takes longer time, minimum two to three months, depending on previous levels, effectiveness of measures and biological parameters. Possible changes in future exposure concentrations were therefore included as a variable in the sensitivity analysis.

Level of compliance costs

The output data of the cost model should be interpreted with caution as the calculation is based on a number of assumptions and simplifications as outlined in the substance report and the methodological note. Nonetheless, the data give an indication of magnitude. Compared to companies' turnover, compliance costs are generally of limited significance for most companies in most sectors for the BLV options ≥ 150 µg/L. This reflects the fact that the current EU BLV is regarded as outdated, and most companies comply with lower national BLVs and/or voluntary industry targets. This also means that many measures for compliance with limit values below the current 700 µg/L are already in place, meaning the cost of implementing additional measures is limited.

A significant part of the compliance cost at the BLV options ≤ 100 µg/L is caused by discontinuations. Discontinuation costs have to be interpreted with care, as the cost model offers limited opportunities to predict a company's alternative opportunities of reacting to lowered limit values other than discontinuing in the case that costs for additionally required RMMs exceed profits. The cost of discontinuation may lead to an overestimation of the total compliance cost.

3.2 Asbestos

Table 3.2 Cost-benefit ratios of the OEL options for asbestos

Impact	OEL options (fibres/cm^3)			
	0.001 fibres/cm^3	0.002 fibres/cm^3	0.01 fibres/cm^3	0.1 fibres/cm^3 (baseline)
Total benefits M1	€ 420 million	€ 410 million	€ 330 million	€0 million
Total benefits M2	€ 220 million	€ 210 million	€ 170 million	€0 million
Total costs	€ 94,000 million	€ 76,000 million	€ 24,000 million	€0 million
Cost benefit ratio M1	220	190	70	0
Cost benefit ratio M2	430	360	140	0

Due to the large number of uncertainties surrounding the estimates, final decisions about the OEL should consider factors beyond a simple comparison of the costs and the benefits that have been monetised in this study. These factors include:

- Although the costs are estimated to significantly outweigh the benefits for all of the policy options considered, it should be noted that the actual exposure concentrations, when RPE has been taken into account, are uncertain. This is because the available data mainly concern the workplace concentrations, and the use of RPE had to be modelled as part of this study. It is therefore possible that the cost savings from reduced ill health modelled in this study are underestimated and the cost-benefit ratio is thus overestimated.
- It should be noted that the total workforce exposed to asbestos is expected to increase over the coming decade.
- Companies in three Member States (France, Germany[7] and the Netherlands who collectively account for 37% of the EU-27 population) work to a limit that is lower than the current OEL in the AWD.
- A key uncertainty relates to the implications for workers with passive exposure in buildings at the option of 0.001 fibres/cm^3. The costs and benefits for this group are highly uncertain and the costs for this group could significantly increase the total costs estimated in this study at this option, because employees may need to take action to reduce passive exposure in buildings.
- It is expected that a large proportion of enterprises where exposure is subject to Article 3 (3) waiver[8] and incidental exposure will opt to no longer accept asbestos related contracts and specialised asbestos removal companies will see their business increase. These income losses or gains can thus be seen as transfer costs with a low net impact overall, although some impacts may occur due to specialised asbestos removal companies benefiting from greater economies of scale.

[7] The current binding OEL in Germany is 0.1 fibres/cm^3 while the 'acceptance level' is 0.01 fibres/cm^3. The mandatory guidelines require measures that are considered in practice to bring the exposure concentration below the 'acceptance level'.

[8] Article 3 (3) of the AWD includes a possibility that some requirements concerning notification of the competent authorities, registering and health surveillance may be waived under certain circumstances

- When the costs of specialised asbestos removal companies in the construction sector increase, they are likely to pass them on to their clients without suffering any losses themselves (this is due to the relatively inelastic demand for asbestos removal). Whilst this may not always be the case where asbestos is contained in movable objects such as trains and ships, it is also unlikely that train refurbishment activities will shift outside the EU because of a lower OEL. It cannot, however, be ruled out that significant price increases would result in clients delaying or abandoning plans to remove asbestos thus resulting in a reduction in asbestos removal revenues and delays in removing passive exposure to asbestos.
- In the current Directive, the likelihood of not exceeding the OEL is a key criterion for the waiver in Article 3(3) to apply. The waiver in Article 3(3) has the potential to reduce the costs of notification estimated in this study.
- Major concern has been raised about the applicability of the existing electron microscopy methods for compliance monitoring at the two lowest OEL options in settings with high dust levels and small asbestos fibre to dust ratios, e.g. by working with building materials with low asbestos concentrations or by exposure to naturally occurring asbestos.
- Monitoring compliance with the current OEL is complex and the requirements for monitoring will depend on the initial risk assessments undertaken. If the OEL is lowered, more often it will be uncertain if the exposure concentration is below the OEL, and more measurements will be needed to confirm the results of the risk assessment or to adjust the working procedures. However, the estimated increase in monitoring costs is highly uncertain.

3.3 Diisocyanates

Table 3-3 Cost-benefit ratios of the OEL options

Impact	OEL options (µg NCO/m³)							
	0.025	0.1	0.5	1	3	6	10	17.5
Total benefits M1	€3,400 million	€2,600 million	€320 million	€93 million	€2 million	-	-	-
Total benefits M2	€6,300 million	€4,700 million	€590 million	€170 million	€4 million	-	-	-
Total costs	€340,000 million	€110,000 million	€35,000 million	€30,000 million	€15,000 million	€14,000 million	€5,600 million	€5,600 million
Cost benefit ratio M1	99	43	109	329	7,221	∞	∞	∞
Cost benefit ratio M2	54	24	60	183	4,036	∞	∞	∞

Notes: ∞ or infinity is given because the costs are high, and the benefits are zero

The most important issue is the degree of uncertainty particularly regarding the benefits, but also regarding the costs. There are five factors contributing to this uncertainty surrounding the benefits:

- **STEL modelling** – The impact of introducing a STEL upon the cases/benefits could not be modelled. This probably means that cases at the higher OEL options are missing and therefore that there should be benefits as the OEL options reduce to 10 or 6 µg NCO/m^3.
- **Limit of quantification (LOQ) –** Many exposure measurements are below the limit of quantification (LOQ) and with agreement of the steering group, are set to default to half the LOQ for all exposures below the LOQ. This probably means that the exposure levels are higher at the lower percentiles than they should be, which implies that the number of cases and the potential benefits at the lower OEL options are overestimated. This issue was addressed in the sensitivity analysis.
- **REACH Restriction** – The impact of the REACH Restriction on exposure concentrations is unknown. ECHA estimated a reduction in the number of cases of between 50 and 70% but this appears to be based on little evidence. To run the cost model, the exposure concentrations after the REACH Restriction had to be estimated, and the assumption of a 50% reduction to all levels agreed between the study team and the steering group could be incorrect. In addition, some reduction in cases is likely to be related to reduced dermal contact, but the likely proportion of the reduction is unknown. This issue was addressed in the sensitivity analysis.
- **DRRs relevance to all diisocyanates uses –** The RAC opinion and the derivation of the DRRs for asthma are based upon two reports: one based entirely on a TDI production facility (Collins *et al.*, 2017) and another report based entirely on HDI used in spray painting (Pronk *et al.*, 2009). TDI is known to be more hazardous than the other diisocyanates and spray painting is a hazardous use because, by definition, the diisocyanate is in aerosol form and thus more likely to be inhaled. Therefore, it seems possible that the DRR may overestimate the risk in sectors using other diisocyanates like MDI, particularly the construction sectors and G45.2 vehicle repair, and/or those sectors not involved in spray painting. However, the study team has no evidence that the data in these two reports is not representative of all diisocyanates and sought to consider all possible reasons for the apparent discrepancy between the expected and modelled number of cases occurring at low exposure levels.
- **Member States with OELs** – The benefits are overestimated by approximately 10% because the effect of the Member States that have already implemented OELs or STELs has not been taken into consideration.

The uncertainty regarding the costs is primarily due to three factors:

- **Cost of compliance with STELs –** The impact of introducing a STEL upon the costs could not be modelled, and the costs associated with achieving STELs at higher exposure values cannot be estimated. Therefore, the costs are an underestimate.
- **Risk management costs** – These may be underestimated as estimates from several other sources (studies, trade associations and consultation survey) tend to be higher.
- **Member States with OELs** – The benefits are overestimated by approximately 10% because the effect of the Member States that have already implemented OELs or STELs has not been taken into consideration.

Further issues relating to the EU strategic goals and EU Green Deal:

- **Non-EU competition** – In nearly all EU's major competitors, the OELs for diisocyanates are 17 µg NCO/m^3 or higher (China has 15 µg NCO/m^3 for HDI, but 48 µg NCO/m^3 for TDI). In many sectors, particularly textiles, apparel, rigid foams, flexible foams, chemicals and furniture, the products are price sensitive and competition from nearby countries such as Turkey, Belarus, UK, Ukraine and Russia is fierce. Saudi Arabia, China, Japan and South Korea are also competitive countries that manufacture products using diisocyanates in many sectors.
- **Small and medium sized companies** – The cost of compliance consisting of risk management measures, monitoring and administrative burden falls relatively heavily on small and medium sized companies at all OEL options. There is a cost of compliance at all options due to the cost of monitoring and administrative burden: the cost per company steps up considerably as the OEL reduces to 6 µg NCO/m^3 and increases again as the OEL reduces to 1 µg NCO/m^3.
- **EU Green Deal** – Several sectors play a significant role in achieving the EU's Green Deal. All construction sectors and C16 Wood are important because considerable renovation of buildings is anticipated: wood is a favoured material due to its sustainability. Energy efficient insulation and an extensive range of building techniques depend upon polyurethane, adhesives, sealants and coatings that use diisocyanates. In addition, in C29 Motor vehicles, manufacturers of electric vehicles are increasingly considering replacing heavier materials in cars with polyurethane to offset the weight of batteries. Finally, sophisticated polyurethane coatings are used in many applications including the rotor surfaces of wind turbines.

Technical and regulatory issues affecting companies implementing an OEL or STEL are:

- **Lowest limit of quantification** – The ISO 17734-1 sampling and analysis method is defined in literature as having an LOQ as low as 0.005 ng/m^3, which appears to be incorrect following conversations with the International Organization for Standardization (ISO). The lowest achievable LOQ is more likely to be 0.3 µg NCO/m^3 for STELs and 0.02 µg NCO/m^3 for OELs. This implies that the lowest STEL that could currently be monitored is 3 µg NCO/m^3 and the lowest OEL is 0.2 µg NCO/m^3.
- **Continuous monitoring** – This is important for identifying peaks quickly and evacuating, if necessary, but there are limits of detection of about 1ppb or about 3.5 µg NCO/m^3. Companies tend to set the warning at 1ppb and evacuation at 5ppb or about 17.5 µg NCO/m^3 or the OEL of many Member States. There are concerns that an OEL below 10 µg NCO/m^3 could lead some companies to remove continuous monitoring, which is expensive, because the warnings cannot be set sufficiently lower than the OEL.
- **Alternatives** – These are often more toxic than diisocyanates. Formaldehyde users in several sectors are waiting for details of a new REACH Restriction which, if it requires a new low limit, may cause them to switch to MDI. Epoxy resins are another alternative that are known to be able to cause skin sensitisation. The alternatives often have a lower performance with issues ranging from being more reactive, not as strong, requiring much greater volumes, and taking longer to install. There are also issues with the market availability of some alternatives.
- **Other regulations being considered** – Polyurethane manufacturers are particularly concerned about two potential changes in next year's REACH revision: Mixture Assessment Factor (MAF) and REACH registration of polymers.

Other issues for DG EMPL and the Working Party on Chemicals to consider are:

- **Standard identification and recording of asthma caused by diisocyanates** – It is difficult to identify cases of occupational asthma caused by diisocyanates accurately as there are many causes of asthma, and there is no consistency in registering cases in the EU. Ideally, there would be a common EU approach to defining and registering cases.

- **Approach to analysing occupational asthmagens** – Sensitising substances present specific challenges as it is hard to model how sensitisation and occupational asthma occurs. Further consideration of the best approach to use when analysing occupational asthmagens is required.
- **Medical surveillance** – According to several stakeholders, industry had expected medical surveillance for workers to be introduced as part of the REACH Restriction. In addition to limit values, the CAD contains provisions for appropriate medical surveillance of workers at a national level. Medical surveillance can also be mandated at an EU level under the CAD: it is already mandated for lead. Further work is beyond the scope of this study, but it is an option that could be considered.

3.4 Find out more

For more detail about the findings of the study for each substance, see the executive summaries and full reports for each substance.

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