# 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)

Methodological note and data collection synopsis

Final Report

Written by Sophie Garrett, Daniel Vencovsky, Hannah Collins

September 2021

**EUROPEAN COMMISSION**

Directorate-General for Employment Social Affairs and Inclusion

Directorate Employment

Unit Health and Safety

*Contact:* Charlotte Grevfors Ernoult

E-mail: charlotte.grevfors-ernoult@ec.europa.eu

European Commission
B-1049 Brussels

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Manuscript completed in September 2021



PDF ISBN 978-92-76-41926-6 doi: 10.2767/734383 KE-01-21-291-EN-N

Luxembourg: Publications Office of the European Union, 2021

# Table of Contents

# List of abbreviations and acronyms

| | |
|---|---|
| AWD | Asbestos at Work Directive |
| BAT | Best Available Technique |
| BLV | Biological Limit Value |
| CAREX | Carcinogen Exposure |
| CAD | Chemical Agents Directive |
| CAS | Chemicals Abstracts Service |
| CBA | Cost Benefit Analysis |
| CEA | Cost Effectiveness Analysis |
| CEN | European Committee of Standardization |
| CLH | Harmonised Classification and Labelling |
| C&L | Classification and Labelling Inventory |
| CMD | The Carcinogens and Mutagens Directive |
| CSR | Chemical Safety Report |
| DALY | Disability Adjusted Life Years |
| DG | Directorate General |
| DRR | Dose Response Relationship |
| EC | European Commission |
| ECHA | European Chemicals Agency |
| ERR | Exposure Risk Relationship |
| EU | European Union |
| FoBiG | Forschungs und Beratungsinstitut Gefahrstoffe |
| IA | Impact Assessment |
| IARC | International Agency for Research of Cancer |
| LEV | Local Exhaust Ventilation |

| | |
|---|---|
| LOD | Limit of Detection |
| MCA | Multi-Criteria Analysis |
| NACE | Nomenclature statistique des activités économiques dans la Communauté européenne" or the Statistical Classification of Economic Activities in the European Community |
| OEL | Occupational Exposure Limit |
| OEL | Occupational Exposure Limit Value |
| OSH | Occupational Safety and Health |
| PPE | Personal Protective Equipment |
| QALY | Quality-Adjusted Life Year |
| REACH | Registration, Evaluation, Authorisation and Restriction of Chemicals |
| RMM | Risk Management Measure |
| RPA | Risk & Policy Analysts |
| RPE | Respiratory Protective Equipment |
| SME | Small and Medium-sized Enterprise |
| STEL | Short-Term Exposure Limits |
| TWA | Time Weighted Average |
| VCM | Value of Cancer Morbidity |
| VSL | Value of Statistical Life |
| WPC | Working Party on Chemicals |

# 1. Introduction

## 1.1 This methodological note and data collection synopsis

This methodological note and data collection synopsis summarises the methods used and data collected in the project '*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)*.

This note builds on similar documents developed in the framework of two previous OEL studies[1] undertaken for DG Employment, Social Affairs and Inclusion by RPA Risk & Policy Analysts, COWI, FoBiG Forschungs- und Beratungsinstitut Gefahrstoffe, and EPRD. Parts of the text are direct reuse of the text from reports previously published by RPA, COWI and FoBiG.

However, the methods used for previous studies have been further developed to reflect the experiences obtained in past projects carried out by the same team and accommodate the specificities of the substances subject to this study, in particular with regard to the costs of an asbestos OEL and the health effects from reduced exposure to di-isocyanates and lead.

This document complements the three substance-specific reports produced under the same contract for:

- Asbestos
- Lead and its compounds
- Di-isocyanates

This note should be read in conjunction with the substance-specific reports – for some aspects, a more detailed description of the relevant methods is provided in the substance-specific reports; for other aspects, a more detailed account of the methods, data, and assumptions is provided in this report.

## 1.2 Objectives

This report is one of four reports elaborated within the framework of a study undertaken for the European Commission by a consortium comprising RPA Risk & Policy Analysts (United Kingdom), FoBiG Forschungs- und Beratungsinstitut Gefahrstoffe (Germany), COWI (Denmark), and EPRD Office for Economic Policy and Regional Development (Poland).

The specific objective of this report is to set out the methods that underpin the assessment in the substance-specific reports, and to summarise the consultation exercise.

[1] Socio-economic analysis collecting most recent information for a certain number of substances with a view to analyse the health, socio-economic and environmental impacts in connection with possible amendments of Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work", CMD 3 (2017-18) and CMD4 (2019-2020).

## 1.3 Structure of the report

The report is organised as follows:

- Chapter 2 describes how the Exposure-Risk Relationships (ERRs) and Dose Response Relationships (DRRs) for estimating health impacts on workers were derived;
- Chapter 3 sets out the model used to estimate the incidence of ill health under the different scenarios and monetise the savings from avoided ill health (the assessment of the "benefits");
- Chapter 4 sets out the key features of the model for the assessment of the costs of OELs for di-isocyanates and lead;
- Chapter 5 sets out the key features of the model used for the estimation of the costs of OELs for asbestos;
- Chapter 6 summarises the approach to the review of the environmental impacts; and
- Chapter 7 describes the consultation activities undertaken within the framework of this study.

# 2. Derivation of the ERRs and the DRRs

## 2.1 Introduction

One of the criteria for the selection of a limit value (OEL or BLV) for a specific substance is the estimated impact on occupational health. Therefore, a method for the estimation of the 'health impact' is required, where this term is defined as the number of people ("cases") either suffering from cancer and/or non-cancer health effects due to occupational exposure to the relevant substance.

This section deals with the principles of this estimation procedure. A detailed explanation of how the specific inputs such as the dose-response relationships were derived is given in each of the substance-specific reports in the sections:

- 2.2. Summary of epidemiological and experimental data, and
- 2.3 Deriving an Exposure Risk Relationship (ERR) for carcinogenic effects and a Dose Response Relationship (DRR) for non-carcinogenic effects.

The excess health risk at the different potential OEL or BLV levels is based on:

- Exposure-Risk Relationship (ERR) for cancer risk, and
- Dose Response Relationship (DRR) for noncancer effects.

A specific excess risk of ill health is then estimated for specific OEL or BLV values based on the ERR/DRR and the actual/predicted exposure for each exposure scenario. The health effects are subsequently monetised for the purposes of a Cost-Benefit Analysis (CBA).

The respective methodologies to derive (and to apply) the ERRs and DRRs are summarised in this section.

The following restrictions should be borne in mind:

Existing toxicological and epidemiological data in regulatory toxicology have usually not been generated and prepared to enable researchers to estimate impacts for a range of exposure levels across multiple health effects. Often, the focus of the analysis of toxicological data is to provide only one point estimate for a *safe* (or *low risk*) level of exposure based on one critical health effect. Usually, at this level the national OEL or BLV is set and no "cases" of health impairment are assumed to occur if the limit is observed.

Some dose-response or exposure-risk relationship data are, in fact, considered by the respective assessors, but those are usually only provided for a single scenario and often can only be derived from experimental animal study data. In the course of extrapolating to the relevant occupational exposure scenario, such existing dose response data are usually not transformed and adapted to a range of target scenarios. Once a 'safe' OEL/BLV has been determined, the effects at levels well above that OEL/BLV are rarely discussed. For example, if a toxicologist finds respiratory irritation in an animal study as the critical (lowest) adverse effect and they also find neurotoxicity and immunological impairments at an, e.g., ten times higher level of exposure, they would typically focus on the safe level for respiratory irritation effects to quantitatively determine the most appropriate OEL and complement this with a qualitative discussion of the neurotoxic and immunological effects at higher exposure

levels. In addition, the dose response curve for respiratory irritation from experimental animal data is typically not systematically transformed into a DRR for a worker at exposure levels above the 'safe level' OEL.

Because of these limitations, this study (and the previous OEL studies carried out for DG Employment, Social Affairs and Inclusion by this consortium) had to develop methods to estimate health impact for a range of health effects identified by RAC as relevant ones – this includes both cancer (one or several cancer sites) and non-cancer effects, including dose-response relationships for the relevant exposure range above a threshold for effects. It should be noted that due to the limited quantitative dose response input data in many cases, these should be treated as indicate of the "true" health impact rather than as precise estimates.

In conclusion:

- we apply the ERR on the most critical cancer sites, which are given by the assessment of the European Chemicals Agency / Committee for Risk Assessment (ECHA/RAC), and only comment qualitatively on further cancer sites, which may be linked to exposure to the respective substance, but are expected to contribute less to the overall excess cancer risk from this substance;
- we refer to the most critical non-cancer effects quantitatively to derive DRRs; for this, the effects, which were regarded as the most critical ones by RAC in the relevant range of workplace exposures are selected and we only comment qualitatively on further non-cancer effects, which may be linked to exposure to the respective substance at higher exposure levels only or which might be of unclear health significance; and
- as there is even less scientific consensus on the increase of effect severity with increasing exposure concentration and the respective data are often not adapted to the workplace exposure scenario, we focus on the *fraction of workers affected* at the different exposure levels when we establish a DRR, without taking into account the increase of severity of effects. The potential severity of these effects is subsequently taken into account in the process of monetisation of their incidence estimated on the basis of the DRR.

These limitations suggest that the health impacts estimated in this study are only an approximation of the 'real' health impacts which may underestimate the full impact of the occupational exposure to the respective substances. However, as shown in the sensitivity analyses, there are also uncertainties that may result in overestimation of these impacts. In addition, a further complication is the 'number of cases' for multiple health effects, as there may be many individuals, which will suffer from more than one health effect due to occupational exposure simultaneously. Therefore, an additivity assumption for the number of cases would not be correct (significant overestimate).

Despite these limitations, it is expected that the health impacts estimated in this study do not lead to a systematic bias in the final selection of an OEL or BLV.

## 2.2 Methods to derive the ERRs and DRRs

### 2.2.1 Data bases and approaches used

In this project, the starting point for a cancer risk impact assessment is the OEL proposed by RAC (or, in the case of diisocyanates, the DRR proposed) and the respective RAC opinion, together with the annexed background report. For asbestos, the RAC opinion is not yet available and ECHA's "Scientific report for evaluation of limit values for asbestos at the workplace", published for public consultation in 2021, and the ERR presented there were used as starting point.

With the di-isocyanates for the first time RAC developed a DRR (without a proposal for an OEL) for a non-cancer health endpoint, i.e. asthma. In the case of lead, non-cancer endpoints are in the focus of the OEL derivation by RAC. However, despite a limited database, in addition cancer risks in humans are given attention in this report.

For asbestos there is a general agreement to derive ERRs for carcinogenic risks using a linear extrapolation approach. T his approach is also proposed in ECHA's Scientific report.

For non-cancer endpoints, the RAC opinions as well as other recent evaluations and literature reports, have been reviewed to identify the most relevant endpoints for humans. Relevance means that existing information makes it likely that effects might occur in humans at exposure levels relevant to the policy options considered in this study. Human data are preferred over experimental animal data both in the case of lead and di-isocyanates. Experimental data are used as supportive information only where sufficient human dose-response information is available to derive a DRR.

Data from original toxicological and epidemiological studies, referenced by RAC or national committees as being qualified and demonstrating a dose-response, have been examined for effect levels linked to a specific fraction of the exposed humans (or animals). If not contradicted by the overall weight of evidence, this slope reported in such a study is adopted for the DRR. If effects are reported on a continuous scale, this needs to be transformed to quantal data (i.e., the incidence of effects in the exposed population), which often requires certain assumptions.

As the threshold for non-cancer effects can be different to that for cancer effects, the starting point for the DRR may be different from the starting point for ERR.

The scientific basis for the substance-specific ERRs and DRRs, and reference to ERRs and DRRs derived by various scientific bodies, are described in detail in each of the substance-specific reports in section 2.3, "Deriving an Exposure Risk Relationship (carcinogenic effects) and a Dose Response Relationship (non-carcinogenic effects)"

### 2.2.2 Time to tumour and latency

The slope of the ERR presented may implicitly be influenced by latency. However, there is no explicit "risk/time to tumour-relationship" considered in the toxicological part of this project. Some tumours may occur already early within the exposure period of a worker or may occur late – even some time after the potential 40 years of employment (i.e. after retirement). Latency depends on the target organ, exposure concentration and the mode of action. If available, latency information is documented in the respective substance report, but note that this information is rarely available in sufficient detail (e.g., distribution data of latency within the population are usually not available).

However, it should be noted that time to tumour and latency influences the point in time in future when reduction in exposure resulting from a new OEL/BLV/STEL translates into a reduction in excess cancer risk (at population risk level). Therefore, separately from the toxicological input, the calculated baseline (number of cases presently) and assumptions on the return of benefits and costs in future time, if an OEL, BLV or STEL is set this year or later in future, may need some assumptions about latency. Unless stated otherwise in the relevant substance report, these latency assumptions are general default values also used in the previous OEL studies carried out by the same consortium (e.g. 10-50 years for solid tumours, average: 30 years).

For simplicity, it is assumed that tumour induction is linearly linked to exposure duration, which is, in reality only true for carcinogens with strictly accumulating risks. Even then, no strict linearity will be observed: some short exposure duration may not be sufficient to develop tumours at all. On the other hand, few exposure years may already be decisive to result in an identical excess tumour risk as if one is exposed over their entire working life. However, correlation of exposure duration with tumour risk is substance-specific and not further considered within this project due to the complexity of assumptions necessary for subsequent impact calculations.

Available information for the estimated latency is for each of the substances described in the substance-specific reports in section 2.3, “Deriving an Exposure Risk Relationship (carcinogenic effects) and a Dose Response Relationship (non-carcinogenic effects)”.

# 3. Estimation and Monetisation of the Health Impacts

## 3.1 Introduction

The current and future cases of ill health (current burden of disease and future burden of disease) have been estimated for both cancer and non-cancer endpoints using the following inputs:

- ERRs and DRRs for the relevant health effects;
- Numbers of workers exposed;
- Exposure concentrations (di-isocyanates) or blood lead levels (lead); and
- Past and future trends in the exposed workforce and exposure concentrations.

This methodology section deals with the principles of this estimation procedure. The specific procedures used for the derivation of the parameters used for each of the substances are described in each of the substance-specific reports.

### 3.1.1 Cost categories considered for the estimation of cost savings from avoided ill health (benefits)

Specific guidance is provided in the Better Regulation (BR) Toolbox for health impacts (BR Tool #31). This is summarised in the table below.

*Table 3-1 BR Toolbox on health impacts*

| Aspect | Guidance |
|---|---|
| Health impacts | Direct impacts<br><br>Indirect impacts: does the option influence the socio-economic environment that can determine health status?<br><br>To assess direct and indirect health impacts monetary and non-monetary methodologies can be used.<br><br>Non-monetary approaches: Quality adjusted life years (QALYs), Disability adjusted life years) (DALYs), Healthy life years (HLYs).<br><br>Monetary approaches: preference-based approaches Willingness to pay (WTP), Willingness to accept (WTA) -> Value of Statistical Life (VOSL), Value of Life-Year (VOLY), accounting-style approaches (cost of illness method=only medical expenses, human capital method=loss of future earnings in case of disability or premature death) |

*Source: Better Regulation (BR) Toolbox for health impacts (BR Tool #31)*

Focusing on the example of cancer, the costs of cancer can be divided into:

- **Direct costs:** These are the costs of healthcare, in other words, the medical costs associated with the treatment of cancer and other costs, including non-medical costs. Other direct costs may be incurred by the patients (say the cost of transport to attend appointments) but also by their family/friends, for example, through providing unpaid care.

- **Indirect costs:** These are the monetary losses associated with the time spent receiving medical care, including productivity losses due to time spent away from work or other usual activities and lost productivity due to premature death. Depending on the national structure of social security provision, the government (tax payers) may also bear the costs of any disability/social security payments and will also suffer losses through foregone tax receipts.

- **Intangible costs:** These include the non-financial 'human' losses associated with cancer, e.g. reduced quality of life, pain, suffering, anxiety and grief.

This note focuses on the methods used to estimate the cost savings (benefits) from reduced ill health. The methods used for the assessment of other types of benefits/cost savings are not summarised in this note and are described in the substance specific reports even where a common approach has been used for the assessment of these benefits. For example, it is expected that a new EU OEL may save individual Member States the cots of developing their own OELs. The study takes €100,000 per Member State as an approximation of the general order of magnitude of the applicable costs of introducing an OEL and STEL for Member States where there is currently no OEL or STEL and €50,000 per Member State where there is an existing OEL or STEL but it is possible that it may be revised.

### 3.1.2 The model

The following table provides a summary of the key endpoints per substance for which quantitative estimations are provided in this study.

*Table 3-2 Carcinogenic and non-carcinogenic endpoints*

| Substance | Carcinogenic endpoints | Non-carcinogenic endpoints |
|---|---|---|
| Di-isocyanates | - | Asthma<br>Irritation |
| Asbestos | Lung cancer and mesothelioma | -* |
| Lead and its compounds | Central Nervous System (CNS Cancer) | Neuropathy<br>Anaemia<br>Chronic kidney disease stage 1<br>Elevated blood pressure<br>Male fertility<br>Pre-eclampsia |

| Substance | Carcinogenic endpoints | Non-carcinogenic endpoints |
|---|---|---|
| | | Developmental toxicity |

*Notes: * Asbestosis (no DRR derived as only expected at concentrations above the current OEL)*

*Source: Analysis by RPA, COWI & FoBiG*

The key model inputs are summarised below. These are used to estimate the number cases of ill health over the relevant period. The exposed workforce is divided into several bands which are characterised by variations in some of these inputs and for which the incidence of ill health is estimated separately and subsequently aggregated into totals for each substance.

*Table 3-3 Key model inputs*

| Parameter | Explanation |
|---|---|
| Exposure-risk/dose-response relationship | Exposure-Risk Relationship (ERR) for cancer effects or Dose-Response Relationship (DRR) for non-cancer effects |
| Exposed workforce | Number of workers exposed |
| Exposure concentration | For OELs: 8-hr TWA (time-weighted average) that the workers are exposed to (real concentration, i.e. if personal protective equipment (PPE) is currently worn, the measured concentrations are adjusted to take into account PPE where possible)<br>For STELs: 15-min peak exposure (real concentration after taking into account PPE)<br>For BLVs: the concentration of the relevant substance or metabolite in the relevant biological media such as blood or urine |
| Trends | Past and future trends in numbers of workers exposed and/or exposure concentrations |

*Source: Analysis by RPA, COWI & FoBiG*

In addition to the key inputs set out above, the model relies on a range of assumptions that determine when the relevant effect occurs or is diagnosed, the nature and severity of its effects, and how long these effects (or their consequences) last. These assumptions differ by substance and health outcome. Some of these assumptions are a simplification of complex real-life scenarios or best estimates (where authoritative evidence could not be identified from available literature).

The key areas in which assumptions had to be made to enable the model to estimate and monetise the incidence of ill-health over the relevant assessment period are set out below.

*Table 3-4 Further assumptions for the estimation of the year of occurrence of the relevant effects and their monetisation*

| Parameter | Explanation |
|---|---|
| **Onset of the disease** | |
| MinEx | The minimum exposure duration required to develop the endpoint |
| MaxEx | The time needed to reach the maximum risk (i.e. after the MaxEx has been reached, the risk does not increase further) |
| Lat | The latency with which the effect is demonstrated |
| Dist | The distribution of cases over the period between MinEx and the MaxEx: the default assumption is a linear accumulation of risk over the relevant period |
| **The effects of the disease** | |
| Mortality | Mortality rate as a result of the relevant condition |
| Severity | The typical severity (mild to severe) of the relevant outcome – where a range of severities is expected, a weighted average has been estimated |
| Value of a case | Monetary value of a case taking into account the direct, indirect, and intangible costs estimated relying either on a) Willingness to Pay (WTP) for a case of mortality or morbidity or b) monetised Disability Adjusted Life Years (DALYs) |

*Source: Analysis by RPA, COWI & FoBiG*

The model provides an approximation of the order of magnitude of the expected impacts and the core calculations are supported by sensitivity analysis. The outputs of the model include:

- The number of new cases for each health endpoint assigned to a specific year in the assessment period;
- The Present Value (PV) of the direct, indirect, and intangible costs of these cases.

## 3.2 Inputs

### 3.2.1 Dose/exposure-risk relationship

The risk of developing the relevant effect is estimated by combining exposure concentrations with:

- For cancer: Exposure-Risk Relationship (ERR), i.e. excess risk of developing cancer due to lifetime occupational exposure to a substance (40 years); or
- For non-cancer endpoints: Dose-Response-Relationship (DRR), i.e. the proportion of workers that will develop an endpoint when exposed to a certain level of exposure. The DRR typically is defined for the health endpoint as it occurred in the underlying

study and does not provide an indication for progression of disease severity. This is taken into account in the course of monetisation of the cases estimated by the model.

### 3.2.2 ExW: exposed workforce

The sources of data and assumptions used to estimate the numbers of workers exposed to the relevant substance are detailed in the substance-specific reports, together with the expected future trends.

As a default value, it is assumed that there is a staff turnover of 5% per year. The 5% per year is lower than the turnover ratios in most of the published literature and Eurostat, which are typically derived at the level of individual companies rather than sectors. However, it is common that, e.g., construction workers would continue to work within construction for a major part of their work life, but it is uncertain to what extent they would continue with a job function with a specific exposure situation.

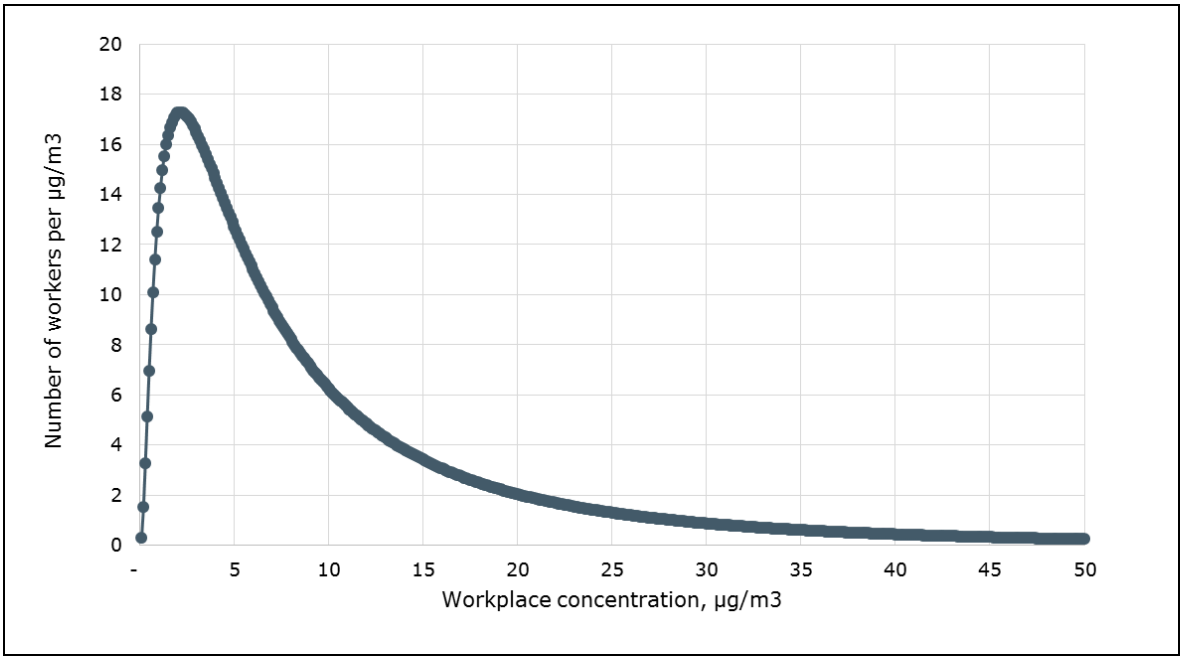
We consider, in accordance with the assumptions in of previous RPA & COWI studies, that a ratio of 5% is deemed appropriate to account for the fact that some workers may continue to work in the same sector and continue to be exposed to the same substances.

### 3.2.3 Exposure concentrations

For each substance, one or more exposure scenarios have been modelled based on data sourced from literature and consultation – these scenarios are used for the estimation of the costs and benefits (cost savings from reduced ill-health) of the OEL and BLV policy options.

The number of workers exposed at levels of relevance for the assessment of establishing an OEL is derived from consultation with relevant companies and industry associations, databases, literature, workers' associations and other sources. For each of the relevant sectors, distributions of workers over exposure levels were established. In general, it is assumed that the exposure concentrations are lognormal distributed, and exposure data collected for this study are fitted to a lognormal distribution for which the key parameters such as the $50^{th}$, $75^{th}$, $90^{th}$ and $95^{th}$ percentiles are estimated (please note that these parameters may differ between substances). An example of a log-normal distribution of exposure concentrations is given below.

*Figure 3-1 Log normal distribution of workplace concentrations fitted to model dataset.*




*Source: Analysis by RPA, COWI & FoBiG*

When the main parameters (different percentiles) of a lognormal distribution have been estimated, the exposed workforce is divided into several (typically five) exposure bands and each of these exposure bands is assigned a representative exposure or biomonitoring concentration. For the band with the lowest exposure, the highest exposure concentration in that band is typically taken as representative. For the highest exposure band, the geometric mean (GM) of the concentrations in that band is taken as representative. For the intervening bands, the arithmetic mean (AM) of each band is taken as representative.

Where such information is available, the study team has tried to establish for all reported data whether these are a result of personal or stationary sampling and whether they reflect exposure with or without wearing personal protective equipment (PPE).

Exposure concentrations estimated based on data from literature or consultation have ben sense-checked against existing OEL and BLVs in EU Member States to ensure that they are representative of present day exposure which is expected to be defined by national legal requirements. Consequently, it has not been necessary to take the existing OELs into account when estimating the effects of introduction of a new OEL/BLV.

### 3.2.4 The effect of introducing an OEL/BLV

The background for the models used is the approach set out in EN 689:2018: “Workplace exposure. Measurement of exposure by inhalation to substances. Strategy for testing compliance with occupational exposure limit values“. This standard is widely relied on when determining compliance with an OEL. A summary of the approach in this standard is provided in Box 3-1.

*Box 3-1 Summary of the approach in EN689*

In the standard, compliance with an OEL is determined by either a screening test or a test of compliance.

**Screening test**

The **screening test** requires three to five exposure measurements on workers belonging to a SEG.

- a) If all results are below:
  - 1) 0.1 * OEL for a set of three exposure measurements or,
  - 2) 0.15 * OEL for a set of four exposure measurements or,
  - 3) 0.2 * OEL for a set of five exposure measurements

  then it is considered that the OEL is respected: **Compliance**.
- b) If one of the results is greater than the OEL, it is considered that the OEL is not respected: **Non-compliance.** In case that the first measurement result is above the OEL, it is not necessary to perform any additional measurements.
- c) If all the results are below the OEL and a result above 0.1 * OEL (set of three results) or 0.15 * OEL (set of four results) or 0.2 * OEL (set of five results) it is not possible to conclude on compliance with the OEL. **No-decision.** In this situation additional exposure measurements shall be carried out in order to apply the test based on the calculation of the confidence interval of the probability of exceeding the OELV, as specified below.

**Test of compliance with the OEL**

According to the standard, the appraiser shall select a statistical test of whether the exposures in a Same Exposure Group (SEG) comply with the OEL. The test shall measure, with at least 70 % confidence, whether less than 5 % of exposures in the SEG exceed the OEL.

*Source: based on EN689*

EN689:2018 requires that “less than 5% of exposures exceed the OEL” - this can be interpreted as meaning that 5% of the measurements may be above the OEL. As a result, compliance in the model developed for this study is taken to mean that the 95$^{th}$ percentile (P95) of the exposure distribution is at or below the OEL or BLV.

Consequently, the effects of lowering an OEL or BLV are modelled in this study as follows:

- The 95$^{th}$ percentile of the current exposure distribution (air or biomonitoring concentrations) is compared with the target OEL/BLV and a reduction factor is estimated to show by how much the 95$^{th}$ percentile of the distribution needs to reduce.
- It is expected that the whole exposure distribution is reduced by this factor and the reduction factor is thus applied to all exposure bands. This reflects the expectation

that there is variability even between measurements carried out for workers in similar exposure situations.

- No health effects are expected to occur when exposure has been reduced below a threshold.

This means that, even when the OEL/BLV has been lowered to a value that is the threshold for the relevant health effects, some ill health can still be expected to occur because some exposure will still exceed the P95(=OEL/BLV) value.

## 3.3 Assumptions

### 3.3.1 Onset of the disease

#### 3.3.1.1 MinEx & MaxEx - The minimum and maximum exposure duration required to develop the endpoint

No cases arise until the minimum exposure duration required to develop the endpoint (MinEx) has been reached (see Table 3-5 below). No further increase in risk is assumed to arise with increasing exposure time after the expiration of the MaxEx.

The basis for estimation of MinEx and MaxEx for each of the substances is described in the substance-specific reports. The default MinEx is two years for cancer, a standard assumption for a chronic condition. However, for practical reasons, the risk of developing cancer is assumed by the model to start in the first year of exposure and accumulate in a linear fashion up to a full risk estimated on the basis of the ERR after 40 years of exposure – this may lead to a slight overestimation of the risk. The minimum exposure (MinEx) periods in the table below have been derived using a precautionary approach that maximises worker protection.

The MaxEx reflects the time needed to reach the maximum risk estimated on the basis of the ERR/DRR and exposure concentration or biomonitoring. MaxEx is either based on the situation in the key studies used to derive the DRR (if workers were exposed for ten years in that study, it has been proposed that MaxEx is ten years because this was the exposure time leading to the effect size used for the DRR) or converted to a full working life (40 years).

*Table 3-5 Minimum and maximum exposure duration to develop a condition (MinEx and MaxEx)*

| Substance | Endpoint (ERR or DRR) | MinEx (years) | MaxEx (years) |
|---|---|---|---|
| Di-isocyanates | Asthma | 1 day (0 years) | 40 |
| | Irritation | 1 day (0 years) | 1 day (0 years) |
| Asbestos | Lung cancer and mesothelioma | 2 (for practical reasons the model assumes 0) | 40 |
| Lead and its compounds | CNS cancer | 2 (for practical reasons the model assumes 0) | 40 |

| Substance | Endpoint (ERR or DRR) | MinEx (years) | MaxEx (years) |
|---|---|---|---|
| | Neuropathy | 1 day (0 years) | 7 |
| | Anaemia | 1 day (0 years) | 10 |
| | Chronic kidney disease | 1 day (0 years) | 5 |
| | Elevated BP | 1 day (0 years) | 10 |
| | Male fertility | 1 day (0 years) | 3 |
| | Pre-eclampsia | 1 day (0 years) | No information available – assumed to be 1 in order to be conservative |
| | Developmental toxicity | 1 day (0 years) | No information available – assumed to be 1 in order to be conservative |

*Source: Analysis by RPA, COWI & FoBiG*

#### 3.3.1.2 Dist - the distribution of cases over time

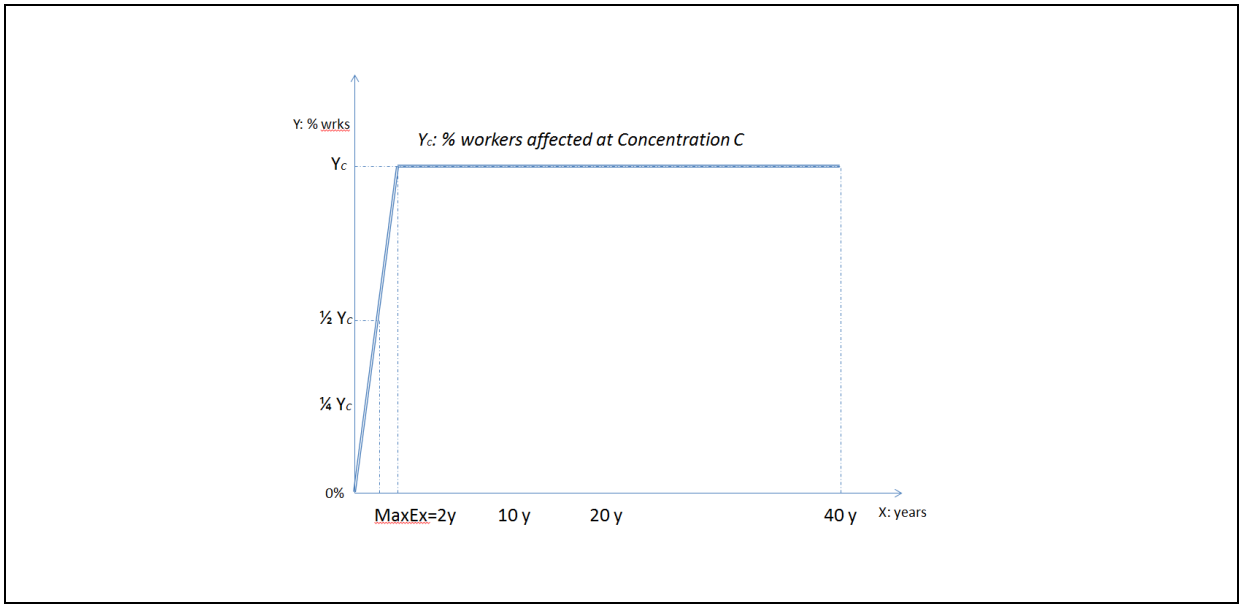
Valuing the cost of occupational illness involves applying discounted costs to future cases which requires that the estimated cases over the period between MinEx and MaxEx are assigned to specific years.

The distribution of cases between start of exposure and the MaxEx is modelled based on the assumption of a linear accumulation of risk over time with the maximum risk being achieved at MaxEx. The risk in a given year thus equals Risk=Risk at MaxEx/(MaxEx-MinEx).

For reasons of simplicity, the following approach is used to distribute the total **risk** (i.e. not incidence since incidence is delayed due to latency) over the 40 period assessed in this study. As noted above, although in theory no risk arises until the MinEx of two years has expired, for practical reasons, the models used for this study adopt a conservative approach and assume that risk arises from Year 1. It is assumed that the distribution is linear, i.e. 1/40 of the excess risk arises in Year 1 and 100% of the excess risk predicted for a specific exposure concentration arises by Year 40.

For cancer endpoints, the MaxEx is typically the full working life, i.e. 40 years. For non-cancer endpoints, the MaxEx can be shorter and the full risk estimated by the DRR can arise sooner than at the end of a person's working life. This is illustrated in the figure below.

*Figure 3-2 Non-cancer endpoints – fraction affected over time - example with a MaxEx of 2 years*




*Source: Analysis by RPA, COWI & FoBiG*

### 3.3.1.3 Latency

The estimated risk is combined with latency to estimate the specific year of diagnosis of a case.

***Cancer endpoints***

By way of simplification, default latency values are used unless more detailed estimates exist for the specific substance. According to Rushton et al. (2012), all solid tumours are expected to have a latency of 10-50 years, meaning that the average latency is 30 years.

Latency periods for the cancer endpoints are shown in the table below. The basis for the estimation of latency for each of the substances is described in section 2.3 of the substance-specific reports.

*Table 3-6 Latency (Lat) periods of cancer endpoints*

| Substance | Endpoint | Lat (years) |
|---|---|---|
| Asbestos | Lung cancer and mesotheli-oma | 30 years (default value for solid tumours in line with previous OELs studies) |
| Lead and its compounds | CNS cancer | 30 (default value for solid tumours in line with previ-ous OELs studies) |

*Source: Analysis by RPA, COWI & FoBiG*

***Non-cancer endpoints***

The estimated latency period for the non-cancer endpoints in this study is 0 years. There is limited evidence for latency of the relevant non-cancer conditions and these are study team assumptions derived for the purposes of the modelling for this study.

*Table 3-7 Latency (Lat) periods of non-cancer endpoints*

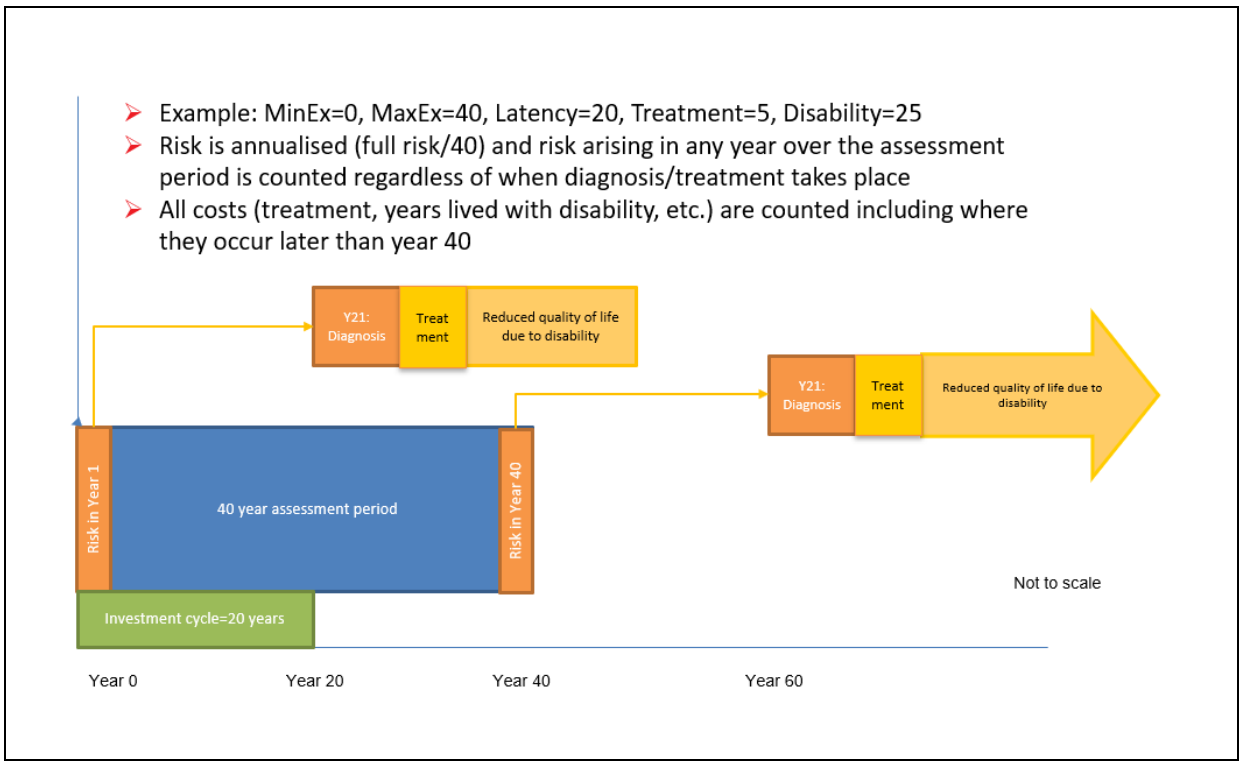
| Substance | Endpoint | Lat (years) |
|---|---|---|
| Di-isocyanates | Asthma | 0 |
| | Irritation | 0 |
| Lead and its compounds | Neuropathy | 0 |
| | Anaemia | 0 |
| | Chronic kidney disease | 0 |
| | Elevated BP | 0 |
| | Male fertility | 0 |
| | Pre-eclampsia | 0 |
| | Developmental toxicity | 0 |

*Source: Analysis by RPA, COWI & FoBiG*

#### 3.3.1.4 Summary

By way of summary, the method used in the model to estimate the incidence of disease and the relevant costs over time is shown graphically below.

*Figure 3-3 Incidence and costs of disease over time*




*Source: Analysis by RPA, COWI & FoBiG*

## 3.3.2 The effects of the disease

### 3.3.2.1 MoR - mortality rate

Mortality rate as a result of the relevant condition is important since different monetary values are applied to mortality and morbidity. The mortality rates used in the model are given below. The basis for the estimation of mortality rate for each of the substances is described in the substance-specific reports.

*Table 3-8 Mortality rate (MoR)*

| Substance | Endpoint | MoR |
|---|---|---|
| Di-isocyanates | Asthma | 0% |
| | Irritation | 0% |
| Asbestos | Lung cancer and mesothelioma | 80% |
| Lead and its compounds | CNS Cancer | 80% |
| | Neuropathy | 0% |
| | Anaemia | 0% |

| Substance | Endpoint | MoR |
|---|---|---|
| | Chronic kidney disease stage 1 | 0% |
| | Elevated blood pressure | 0% |
| | Male fertility | 0% |
| | Pre-eclampsia | 1.5% |
| | Developmental toxicity | 0% |

*Source: Analysis by RPA, COWI & FoBiG*

#### 3.3.2.2 Treatment period

The treatment periods used in the model are given below. The end of the treatment period signifies either a fatal or illness-free outcome. The basis for the estimation of treatment period for each of the substances is described in the substance-specific reports.

*Table 3-9 Treatment period*

| Substance | Endpoint | Treatment period (years) |
|---|---|---|
| Di-isocyanates | Asthma | 1 |
| | Irritation | 1 |
| Asbestos | Lung cancer and mesothelioma | 5 |
| Lead and its compounds | CNS Cancer | 5 |
| | Neuropathy | 20 |
| | Anaemia | 1 |
| | Chronic kidney disease stage 1 | 20 |
| | Elevated blood pressure | 20 |
| | Male fertility | 5 |
| | Pre-eclampsia | 1 |
| | Developmental toxicity | 1 |

*Source: Analysis by RPA, COWI & FoBiG*

#### 3.3.2.3 Monetary value of the relevant endpoint

The approach to the monetisation of ill health effects is based on the following approach.

*Table 3-10 Cost saving framework*

| Category | Cost | Notes |
|---|---|---|
| Direct | Healthcare | Cost of medical treatment, including hospitalisation, surgery, consultations, radiation therapy, chemotherapy/immunotherapy, etc. |
| | Informal care[2] | Opportunity cost of unpaid care (i.e. the monetary value of the working and/or leisure time that relatives or friends provide to those with cancer) |
| | Cost for employers | Cost to employers due to insurance payments and absence from work |
| Indirect | Mortality – productivity loss | The economic loss to society due to premature death |
| | Morbidity – lost working days | Loss of earnings and output due to absence from work due to illness or treatment |
| Intangible | Approach 1 WTP: Mortality | A monetary value of the impact on quality of life of affected workers |
| | Approach 1 WTP: Morbidity | |
| | Approach 2 DALY: Mortality | |
| | Approach 2 DALY: Morbidity | |

*Source: Analysis by RPA, COWI & FoBiG*

All of the costs in the table above have been quantified to ensure that the study can estimate the impacts on individual stakeholder groups. The approach to the derivation of the costs for each of the cost categories above is set our below.

Two approaches to the monetisation of intangibles have been adopted for the purposes of this study:

- Method 1: Application of WTP values to each case (differentiating between mortality and morbidity); and
- Method 2: Use of DALYs (Disability adjusted life year) and their monetisation.

[2] A decision has been taken to include informal care costs in this analysis even though some elements of these costs may also have been included in individuals' willingness to pay values to avoid a future case of ill health. This decision may result in an overestimate of the cost savings (benefits) as generated by this study.

The only difference between Method 1 and Method 2 is the way in which avoided cases of ill health are monetised. Both methods monetise the same number of avoided cases of ill health.

#### 3.3.2.4 Cost savings for workers and families

The direct and indirect resource costs are estimated using market-based information, for example, data on health care costs, and estimates of lost output (i.e. the value of a day of work).

Added to these are the 'human' or intangible costs associated with a case, which are measured in terms of an individual's willingness to pay for the reduction in the risk of mortality or morbidity (Approach 1) or monetised DALYs (Approach 2).

Under Approach 1, the most commonly used means of estimating individuals' WTP for a reduction in the risk of an illness is through the use of experimental markets and survey techniques (e.g. contingent valuation or contingent ranking studies) to directly elicit individuals' WTP for a reduction in the risk of death or morbidity.

The key measures are the value of a statistical life – a VSL – and the value of a case of morbidity (value of cancer morbidity VCM or value of morbidity VM). The VSL is essentially a measure of a change in the risk of fatality, where this is found by determining individuals' willingness to pay for a small change in risk which is then summed across the population at risk.

Method 1 is summarised below.

*Box 3-2 Method 1 and cancer*

WTP for avoided mortality and morbidity (Value of Statistical Life - VSL and Value of Cancer Morbidity - VCM)

**Value of Statistical Life – VSL:** With regard to the value of a statistical life, the figure adopted is **€4,710,000**. This is based on Better Regulation Tool #31. Here, a range from €3.5 to 5 million is suggested. We use the mid-point (€4,250,000), updated from €2012 prices used in Better Regulation Tool #31 using Eurostat's GDP deflator (Dataset: GDP and main components (output, expenditure and income) [namq_10_gdp]) which provides the following result: 2021/2012: 1.108.

**Value of Cancer Morbidity -VCM:** Not all cancers will lead to death and it will therefore be important to also include the willingness of individuals to pay to avoid a case of non-fatal cancer. The available literature offers a broad range of estimates for the willingness to pay to avoid a non-fatal cancer. A value of €410,000 (2012 prices) has been adopted as the willingness to pay to avoid a non-fatal case of cancer based on the BR Tool #31. This figure has been updated to 2021 prices: **€455,000.**

*Source: Analysis by RPA, COWI & FoBiG based on Better Regulation Tool #36*

Method 2 is summarised below.

*Box 3-3 Method 2 - DALYs*

One DALY can be thought of as one lost year of 'healthy life', and the burden of disease can be thought of as a measurement of the gap between current health status and an ideal situation where everyone lives into old age, free of disease and disability.

DALYs were developed to reflect the sum of years of life lost (YLL) due to premature mortality and years lived in disability/disease (YLD). YLLs are calculated as the number of deaths at each age multiplied by the standard life expectancy for each age. YLDs represent the number of disease/disability cases in a period multiplied by the average duration of disease/disability and weighted by a disease/disability factor.

DALYs take into account the number of years of life lost due to either premature mortality or to living in a less than perfect health state, and are calculated as follows:

$$DALY = YLD + YLL$$

YLD, which stands for Years Lived with Disability, is calculated as follows:

$$YLD = Number\ of\ cases * Average\ disease\ duration * Disability\ weight$$

YLL, which stand for Years of Life Lost due to premature death, is calculated as:

$$YLL = Number\ of\ deaths * Life\ expectancy\ at\ age\ of\ death\ in\ years$$

*Source: Analysis by RPA, COWI & FoBiG based on Better Regulation Tool #31 and other sources*

#### 3.3.2.5 Years of life lost due to premature mortality

The average life expectancy used for the calculations in the model is 82 years. In the absence of other information and taking into account the age distribution of cancer deaths, it is assumed that a typical cancer death occurs at the age of 60 and the number of years lost is thus 22.

#### 3.3.2.6 Average disease duration

The average disease duration is given below.

*Table 3-11 Average disease duration*

| Substance | Endpoint | Disease duration (years) |
|---|---|---|
| Di-isocyanates | Asthma | 30 |
| | Irritation | 30 |
| Asbestos | Lung cancer and mesothelioma | 5 |
| Lead and its compounds | CNS Cancer | 5 |
| | Neuropathy | 20 |
| | Anaemia | 1 |
| | Chronic kidney disease stage 1 | 20 |
| | Elevated blood pressure | 20 |
| | Male fertility | 20 |
| | Pre-eclampsia | 1 |

| Substance | Endpoint | Disease duration (years) |
|---|---|---|
| | Developmental toxicity | 1 |

*Source: Analysis by RPA, COWI & FoBiG in the substance-specific reports*

#### 3.3.2.7 Disability weight

There are two main sources of disability weights. The first is taken from the WHO Global Burden of Disease (GBD) study (2013) which was updated in 2015. The second set of weights are taken from the European Disability Weights Project (2015) conducted by the European Centre for Disease Prevention and Control[3].

For this study, the disability weights derived in the EBD are used for cancer as these are most relevant to the European population. For the other effects, disability weights have been estimated in the substance specific reports.

*Table 3-12 Disability weights used in this study*

| Endpoint | During treatment | After treatment |
|---|---|---|
| Asthma | 0.045 | 0.020 |
| Irritation | 0.006 | 0.000 |
| Lung cancer and mesothelioma | 0.265 | 0.515 |
| CNS Cancer | 0.265 | 0.515 |
| Neuropathy | 0.030 | 0.030 |
| Anaemia | 0.045 | 0.004 |
| Chronic kidney disease stage 1 | 0.000 | 0.000 |
| Elevated blood pressure | 0.041 | 0.041 |
| Male fertility | 0.008 | 0.000 |
| Pre-eclampsia | 0.049 | 0.000 |
| Developmental toxicity | 0.000 | 0.000 |

*Source: Analysis by RPA, COWI & FoBiG in the substance-specific reports*

An issue with the use of DALYs is that they measure health loss, rather than welfare loss and so the weights derived through these studies do not necessarily reflect the welfare losses suffered through illness. This may have consequences for their use in this study, as they may underestimate the true welfare losses from an illness for an individual. Haagsma

[3] Haagsma et al. (2015): Assessing disability weights based on the responses of 30,660 people from four European countries. Available at: http://pophealthmetrics.biomedcentral.com/articles/10.1186/s12963-015-0042-4

et al. (2014) also note that valuations can vary significantly across countries, due to clear contextual differences in the ways people perceive health problems and how they affect their lives.

*Box 3-4 Valuing a DALY*

**Valuing a DALY**

To obtain the value of a DALY, the Value of a Statistical Life must be divided by the number of DALYs corresponding to a premature death. This number varies and is a function of the age at which death occurs, which itself depends on the nature of the risk considered (here, chemical exposure health impacts).

From the brief review conducted, there are several valuations for DALYs presented in the literature. For example, Stassen et al. (2007)[4] estimate that the cost of a DALY for severe morbidity health effects is €87,000. According to a website about persistent organic pollutants[5], the value of a DALY in the US is calculated as $120,000 as of 2008. This is equivalent to approximately €76,500 (using 2008 exchange rates). This calculation is based on dividing the Value of a Statistical Life (VSL) by the number of DALYs corresponding to a premature death. A study by Highfill and Bernstein (2014)[6] values a DALY averted as the value of a year of life in full health and sets this as being in the range of $100,000 to $200,000. This is equivalent to a range between €63,500 and €127,000. However, the study recommends the use of the lower estimate.

*Source: Analysis by RPA, COWI & FoBiG and the sources mentioned in the box*

**The value of a DALY used in this study is €100,000.[7]**

### 3.3.2.8 Cost savings for employers

Introducing OELs have obvious cost savings for workers, namely in terms of their health but also, indirectly, on their earnings. Employers will also accrue cost savings from their employees being less at risk of occupational illness. Such cost savings include:

- higher labour productivity resulting from reductions in absenteeism and associated production losses;
- reduced administrative or legal costs relating to employees who are ill;
- reduced insurance premiums;
- reduced reputational risks; and
- reduced sick leave payments.

[4] Stassen et al. (2015): DALYs versus WTP for Environmental Health Priority Setting based on Data of Air Pollution and Noise in Flanders. Available at: https://lirias.kuleuven.be/handle/123456789/407179

[5] http://www.popstoolkit.com/economic/training/overview/benefit+quantification/daly.aspx

[6] Highfill and Bernstein (2014): Using Disability Adjusted Life Years to Value the Treatment of Thirty Chronic Conditions in the U.S. from 1987-2010. Available at: https://www.bea.gov/papers/pdf/highfill_bernstein_2014_dalysall.pdf

[7] Although the same value was also used in previous Impact Assessments of OELs elaborated for DG Employment (starting in 2017/18: https://ec.europa.eu/social/main.jsp?catId=738&langId=en&pubId=8224&furtherPubs=yes), a decision was taken not to adjust this value for inflation since the value used originally was an approximation of the order of magnitude rather than a precise estimated and was already rounded up.

A study commissioned by DG Employment (2011)[8] considers the socio-economic costs of accidents and ill-health relating to work and the cost savings to employers of implementing effective health and safety management policies. The report estimates that the cost to employers for a single case of a high-severity accident or disease is **€11,760**. This figure is based on data pertaining to cost categories such as:

- reduced productivity of the injured employee after re-employment;
- costs of a replacement (difference in salary, reduced productivity);
- overtime of colleagues to compensate;
- rehabilitation costs (those paid by employer);
- medical costs (those paid by employer);
- administrative follow-up;
- reorganising the work; and
- training the replacement (time of the trainer).

The study collected data on these cost categories as well as compiling information about 400 cases of worker accidents and ill health. These cases were from 13 sectors including construction, transport and the chemical sector, though the numbers of cases linked to the latter were limited.

Although there are reasons for caution in interpreting this result[9], this estimate has been updated to €2021[10] resulting in €13,200 being the value to employers of avoiding a single case a single case of a high-severity accident or disease – this value was used in the 'cost saving/benefit' model for all substances. The method of summing up the different cost savings (benefits) is set out in Section 3.4 of this report.

It is recognised that companies may also incur court/PR costs and these may not be fully reflected in the estimate above. However, there are insufficient data to estimate the avoided court costs for compensation due to ill health and/or and cost of bad publicity.

#### 3.3.2.9 Cost savings for employers and workers – lost earnings and productivity losses

Individuals will incur costs associated with their inability to work in terms of a loss of earnings, including losses linked to days of treatment as well as days off due to illness. Luengo-Fernandez et al. (2013)[11] developed estimate of the magnitude of such costs by Member State in terms of an average cost per fatal or non-fatal cancer. These included what are referred to as 'productivity losses' due to early death and then lost working days due to morbidity effects. Across all cancers, an average figure of €5,047 is given for productivity losses and €1,118 for the costs associated with lost working days due to morbidity effects (with these based on lost wages as the measure of lost output).

There are difficulties in including the type of estimates generated by Luengo-Fernandez et al. (2013) for lost working days within the analysis carried out here due to the potential for

[8] See http://ec.europa.eu/social/BlobServlet?docId=7416&langId=en

[9] The study only considered a small sub-set of health endpoints and so the costs estimated may be too generic and are likely to underestimate the costs to the employer of the most severe endpoints such as occupational cancer.

[10] Eurostat's GDP deflator (Dataset: GDP and main components (output, expenditure and income) [namq_10_gdp]) was used to adjust the estimate from 2011 to 2021 prices. The adjustment factor used is 1.122.

[11] See https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(13)70442-X/fulltext

double counting. As discussed above, it is not clear whether the figures adopted in this study to reflect the intangible or human costs of cancer mortality and morbidity also include an element related to the loss of income. If they do, then to include a separate cost item to reflect lost income would result in a double-counting of impacts.

#### 3.3.2.10 Cost savings for the public sector - cost of healthcare

Cancer

Key data from Luengo-Fernandez, et al. (2013) are presented in the table below. For the purposes of calculating the healthcare costs of illness, we will make use of the average 'all cancers' figure of €6,047 per case of cancer (updated to €2021 as approximately €7,200).

*Table 3-13 Estimates of the annual healthcare costs per cancer patient*

| Cancer | Healthcare costs (€) |
|---|---|
| CNS Cancer | €7,200 |
| Lung/mesothelioma | €7,200 |

*Source: Analysis by RPA, COWI & FoBiG in the substance-specific reports*

### 3.3.3 Summary of the monetary values used

The unit costs used for monetisation are summarised below. Please note that some of the costs set out in the preceding sections have been rounded.

*Table 3-14 Unit costs used for monetisation of ill health caused by occupational exposure to di-isocyanates, lead and asbestos*

| Endpoint | Direct costs | | | Indirect costs | | Intangible costs | | |
|---|---|---|---|---|---|---|---|---|
| | Healthcare | Informal care | Costs for employers | Mortality – productivity loss | Morbidity – lost working days | Approach 1 WTP: Mortality | Approach 1 WTP: Morbidity | Approach 2 DALY: Morbidity |
| Asthma | €30,000 | €0 | €12,000 | €0 | €31,106 | €0 | €32,000 | Value of a DALY €100,000 |
| Irritation | €500 | €0 | €500 | €0 | €500 | €0 | €500 | Value of a DALY €100,000 |
| Lung cancer and mesothelioma | €7,200 | €3,000 | €12,900 | €5,050 | €1,100 | €4,710,000 | €455,000 | Value of a DALY €100,000 |
| CNS Cancer | €7,200 | €3,000 | €12,900 | €5,000 | €5,416 | €4,710,000 | €455,000 | Value of a DALY €100,000 |
| Neuropathy | €1,000 | €0 | €0 | €0 | €29,778 | €4,710,000 | €107,201 | Value of a DALY €100,000 |
| Anaemia | €4,000 | €0 | €2,400 | €0 | €1,500 | €4,710,000 | €5,000 | Value of a DALY €100,000 |

| Endpoint | Direct costs | | | Indirect costs | | Intangible costs | | |
|---|---|---|---|---|---|---|---|---|
| | Healthcare | Informal care | Costs for employers | Mortality – productivity loss | Morbidity – lost working days | Approach 1 WTP: Mortality | Approach 1 WTP: Morbidity | Approach 2 DALY: Morbidity |
| Chronic kidney disease stage 1 | €1,400 | €0 | €1,800 | €0 | €29,778 | €4,710,000 | €1,000 | Value of a DALY €100,000 |
| Elevated blood pressure | €800 | €0 | €1,800 | €0 | €148,890 | €4,710,000 | €5,000 | Value of a DALY €100,000 |
| Male fertility | €1,400 | €0 | €0 | €0 | €0 | €4,710,000 | €5,416 | Value of a DALY €100,000 |
| Pre-eclampsia | €7,600 | €900 | €5,500 | €5,000 | €100 | €4,710,000 | €5,000 | Value of a DALY €100,000 |
| Developmental toxicity | €0 | €0 | €0 | €0 | €20,300 | €0 | €9,600 (per lost IQ) | €0 |

*Source: Analysis by RPA, COWI & FoBiG in the substance-specific reports*

## 3.4 Bringing it all together

The cost savings (benefits) that have been estimated for each substance are summarised below.

*Table 3-15 Costs considered*

| Category | Cost | Notes |
|---|---|---|
| Direct | Ch | Healthcare |
| | Ci | Informal care |
| | Ce | Total cost to an employer |
| Indirect | Cp | Productivity loss due to mortality |
| | Cl | Lost earnings due to morbidity |
| Intangible | Cvsl | Value of statistical life |
| | Cvsm | Value of cancer morbidity/value of statistical morbidity |
| | Cdaly | Value of DALYs |
| | Ch | Healthcare |

*Source: Analysis by RPA, COWI & FoBiG*

The total avoided cost of ill health is calculated using the following two methods:

Method 1: $Ctotal = Ch+Ci+Ce+Cp+Cvsl+Cvsm$

Method 2: $Ctotal = Ch+Ci+Ce+Cp+Cl+Cdaly$

*Cl* is not considered under Method 1 since *Cvsm* may already include these costs.

Methods 1 and 2 rely on two different approaches to the monetisation of ill health. Both approaches monetise the same number of avoided cases and use identical methods for the monetisation of direct (healthcare, informal care, disruption costs to employers) and indirect (productivity/lost earnings[12]) impacts. However, they rely on different approaches to assign monetary values to intangible effects such as reduced quality of life, pain, suffering, anxiety and grief. Under Method 1, published or estimated Willingness-to-Pay (WTP)[13] values are used to monetise the intangible benefits. Method 2 relies on published or estimated disability weights[14] for specific diseases to estimate the avoided Disability-Adjusted Life Years (DALYs) and subsequently monetises these using a generic monetary value for a single DALY (€100,000 in this study). Methods 1 and 2 are not only different approaches but their use in this study relies on different sources of data. The two approaches are not intended

[12] This is not the case where lost earnings are already taken into account in the Willingness to Pay estimate in published literature.

[13] Willingness-to-pay (WTP) values measure an individual's willingness to pay to avoid a case of a disease.

[14] Disability weights measure the reduction in quality of life of a person that suffers from a specific disease.

to produce the same estimate or provide a lower and upper bound of a potential range. The results of both approaches should be considered together as indicative of the order of magnitude of the relevant impacts.

As noted above, the two methods rely on different approaches to the estimation of intangible costs of ill health. As a result, they rely on different data inputs and these are not consistently available from the same source, meaning that neither of the two methods consistently results in a greater estimate than the other one. In some instances, the methods result in a very similar estimate but this is a coincidence.

In terms of assigning the cost savings (benefits) to the different stakeholder groups, the table below provides an overview of who bears the costs quantified in this study.

*Table 3-16 Quantified costs and stakeholder groups*

| Stakeholder group | Costs | Method of summation |
|---|---|---|
| Workers/family | Ci, Cl, Cvsl, Cvcm, Cdaly | Method 1: CtotalWorker&Family=Ci+Cvsl+Cvcm<br>Method 2: CtotalWorker&Family=Ci+(0.8*Cl)+Cdaly |
| Governments | Ch, part of Cp (loss of tax revenue), part of Cl (loss of tax revenue) | CtotalGov=Ch+0.2(Cp+Cl)[15] |
| Employers | Ce, Cp | CtotalEmployer=Ce+0.8*Cp[16] |

*Source: Analysis by RPA, COWI & FoBiG*

## 3.5 Estimating the current burden of disease

The current burden of disease (i.e. the number of cases diagnosed in 2021) is estimated on the basis of historical exposure.

The estimates relate to the sectors where exposure to the substances currently occurs and do not represent the total burden of past occupational exposure to substances. The total burden from all past occupational exposure to the substances would require consideration of sectors where occupational exposure no longer takes place and which may not be relevant to the problem definition for this Impact Assessment.

The following parameters are estimated from the data collected through literature review and consultation:

- Past rate of change in the exposed workforce; and
- Past rate of change in exposure concentrations.

The model assumes that the cases diagnosed in 2021 reflect the risk that arose in '2021-latency' so if latency is 30 years then incidence in 2021 reflects the risk that arose in 1991

[15] Assumes 20% tax.

and thus reflects the number of workers exposed in 1991 and the exposure concentrations in 1991.

## 3.6 Estimating the future burden of disease

The future burden of disease also takes into account the following parameters

- Future rate of change in the exposed workforce; and
- Future rate of change in exposure concentrations.

# 4. The Cost Model for Estimating Compliance Costs for Companies (Di-isocyanates and Lead)

The cost framework used for the assessment is described in each of the substance reports. The following description focusses on the general features of model for estimating compliance costs for companies for di-isocyanates and lead.

Please note that a different model has been developed for asbestos for which many relevant sectors rely on Risk Management Measures (RMMs) that are different to the ones used for lead and di-isocyanates. The key features of the model for asbestos are presented in Section 5 of this report.

## 4.1 Introduction

### 4.1.1 Identification and screening of economic impacts

In line with the more general IA requirements of BR Tool #19, the assessment first involves determining which of the potentially relevant impacts are expected to be significant and should thus be subject to a detailed cost assessment. There might be specific issues that are more relevant for one substance than the other.

Taking into account the direct and indirect behavioural changes as well as potential ultimate impacts, the most relevant impacts were selected on the basis of the following factors:

- The relevance of the impact within the intervention logic;
- The absolute magnitude of the expected impacts;
- The relative size of expected impacts for specific stakeholders (such as impacts which may be small in absolute terms but may be particularly significant to specific types of companies, regions, sectors, etc.); and
- The importance of the impacts for the Commission's horizontal objectives and policies.

Table 4-1 below summarises the impact categories that could be significant and that are thus assessed in this report.

*Table 4-1 Assessment of the most significant economic impact categories*

| Impact category | Key impacts |
|---|---|
| Operating costs and conduct of business | • Will it impose additional adjustment, compliance or transaction costs on businesses?<br>• Does it impact on the investment cycle?<br>• Will it entail the withdrawal of certain products from the market?<br>• Will it lead to new or the closing down of businesses?<br>• Are some products or businesses treated differently from others in a comparable situation? |
| Administrative burdens on businesses | • Does it affect the nature of information obligations placed on businesses? |
| Trade and investment flows | • How will the option affect exports and imports out of and into the EU? Will imported products be treated differently to domestic goods?<br>• How will investment flows be affected and the trade in services? |

| Impact category | Key impacts |
|---|---|
| | • Will the option affect regulatory convergence with third countries? Have international standards and common regulatory approaches been considered? |
| Public authorities | • Does the option have budgetary consequences for public authorities at different levels of government (EU own resources, national, regional, local), both immediately and in the long run?<br>• Does it bring additional governmental administrative burden?<br>• Does the option require the creation of new or restructuring of existing public authorities? |
| Consumers and households | • Does the option affect the prices consumers pay for goods and services?<br>• Does it have an impact on the quality or safety of the goods/services consumers receive?<br>• Does it affect consumer choice, trust or protection?<br>• Does it have an impact on the availability or sustainability of consumer goods and services? |
| Specific regions or sectors | • Does the option have significant effects on certain sectors?<br>• Will it have a specific impact on certain regions, for instance in terms of jobs created or lost?<br>• Is there a single Member State, region or sector which is disproportionately affected (so-called “outlier” impact)? |

*Source: Better Regulation (BR) Toolbox (BR Tool #19)*

This note sets out the key features of the models developed to estimate the costs of the OEL/STEL/BLV options incurred by industry due to the need to implement more effective Risk Management Measures (RMMs). Other costs have been considered in the substance specific reports including the costs of monitoring for companies and the costs of transposition for Member State authorities – the methods used for the estimation of these costs are often substance-specific and are not set out in this note.

### 4.1.2 Key features of the compliance cost model

The key impact are the compliance costs for industry. These are estimated by means of a compliance cost model. This is a spreadsheet model that considers the RMMs currently in place and estimates the additional Risk Management Measures (RMMs) needed for reducing the air exposure levels from the actual levels to the target level.

The costs are calculated in a worksheet model. The model calculates the costs for a group of similar companies incurred in reducing exposure to a target limit value based on an assumed sequence of RMM implementation which is determined by suitability, effectiveness, and cost.

The output is the cost of implementing the OEL/BLV split by:

- Sector;
- Company size: small, medium and large; and
- Capital expenditure (one-off) and operating expenditure (recurrent).

This model was used to estimate the costs of compliance with the different target OELs for di-isocyanates and lead.

## 4.2 Key model inputs and assumptions

### 4.2.1 Overview of key inputs

The key model inputs include:

- Current exposure concentrations;
- OEL/BLV options;
- Assumptions about how compliance with the OEL/BLV is determined;
- Number of small, medium and large enterprises at each of the current exposure concentrations;
- Estimated average number of exposed workers and workstations using the substance in a company;
- Discount rates;
- Current RMMs;
- RMM effectiveness;
- Cost of RMMs (one-off and recurring) as well as their average lifespan; and
- Suitability of specific RMM types for each of the sector.

Some of these inputs are explained in the substance specific reports (such as the OEL/BLV options). More generic explanations are provided in this section.

### 4.2.2 Current exposure concentrations

The key input into the model is the distribution of exposure concentrations in each relevant industry sector. This involves dividing exposures into several (typically 5) exposure bands and assigning a representative concentration to each exposure band. For the band with the lowest exposure, the highest exposure concentration in that band is typically taken as representative. For the highest exposure band, the geometric mean (GM) of the concentrations in that band is taken as representative. For the intervening bands, the arithmetic mean (AM) of each band is taken as representative.

### 4.2.3 OEL/BLV options

The OEL/BLV and STEL options are summarised in Section 3 of each of the substance-specific reports.

### 4.2.4 Compliance with an OEL

The procedures for determining compliance with an OEL differs among Member States and may even be different within a Member State.

The methodology for defining compliance with an OEL is described in Section 3.2.4.

### 4.2.5 Number of enterprises in each exposure band

One of the key inputs into the model is the number of enterprises in each exposure band, split by sector and enterprise size (small, medium, large).

The model assumes that companies are distributed over the different exposure bands in the same manner as workers, i.e. for example where 10% of exposure measurements are over a certain level, 10% companies have exposure over that level.

The data sources and methods of estimating the numbers of relevant enterprises are specific to each of the substances – see each of the substance-specific reports.

### 4.2.6 Estimated average number of exposed workers and workstations using the substance per company

The average number of exposed workers and workstations was estimated for small, medium and large companies in each sector.

The methods and data sources used for estimating the average number of exposed workers and workstations in each company are specific to each of the substances – see the substance specific reports.

### 4.2.7 Discount rates

The static discount rate is 4%: this is taken over the 40-year period. A dynamic discount rate is used in the sensitivity analysis. The dynamic rates start at 4% for the first 20 years; it then decreases to 3% for the remaining 20 years.

### 4.2.8 Current RMMs

The breakdown of RMMs currently used by the relevant companies, differentiated by enterprise size and sector was estimated for each substance. The data sources and methods of estimation are described in each of the substance-specific reports.

The following types of RMM are considered:

- Local Exhaust Ventilation (LEV), extraction at source;
- Worker Enclosures (WE), i.e. physical separation of workers in an enclosure or control room;
- Respiratory Protective Equipment (RPE);
- General Dilution Ventilation (GDV);
- Organisational & Hygiene measures (OH).

For each type of RMM, several levels that companies can achieve have been defined. These levels are summarised below.

*Table 4-2 RMMs considered in the model*

| RMM type | Levels |
|---|---|
| Substitution (SUB) | Substitution of the substance |
| Rework (RWK) | Rework/redesign of the production process |
| Local Exhaust Ventilation (LEV) | LEV3 Full enclosure<br>LEV2 Partial enclosure<br>LEV1 Open hood |
| Worker Enclosure (WE) | WE2 Pressurised or sealed worker enclosure<br>WE1 Simple enclosed cabin |

| RMM type | Levels |
|---|---|
| Respiratory Protective Equipment (RPE) | RPE3 Breathing apparatus<br>RPE2 HEPA filter/half or full-face negative pressure respirator or similar<br>RPE1 Simple mask/FFP mask or similar |
| Organisational & Hygiene measures (OH) | Organisational & hygiene measures |
| General dilution ventilation (GDV) | General dilution ventilation |

*Source: Analysis by RPA & COWI*

For each sector, the proportion of companies that use these RMMs as their primary means of controlling exposure is estimated, with a combination of primary RMMs always totalling 100%, e.g. no RMM 0%, RPE1 20%, LEV2 80%.

The model is a simplification of reality and focuses on the primary RMM currently used to control exposure. It is recognised that in reality a combination of RMMs may be used by a single company to control exposure. A further simplification is that current RMMs are defined at sectoral rather than company level – all companies in a certain sector are thus assumed to have the same RMMs in place. Again, it is recognised that this is a simplification which may not be the case in real life.

### 4.2.9 RMM effectiveness

Every RMM has a different level of effectiveness in reducing workers' exposure to the substance in question. The generic estimates of RMM effectiveness are tailored to each substance if required – the generic estimates used for the previous OEL studies carried out by RPA and COWI have thus been tailored to lead and di-isocyanates.

The percentage reduction in exposure due to each type of RMM used in the analysis is shown below.

*Table 4-3 Percentage reduction in exposure achieved with RMMs*

| Type of RMM | % reduction (generic) | % reduction (lead and di-isocyanates) |
|---|---|---|
| Substitution possible | 100% | 100% |
| Substitution not possible | 0% | 0% |
| RWK Rework | 50% | 50% |
| LEV3 Full enclosure | 99.5% | 80% |
| LEV2 Partial enclosure | 90% | 70% |
| LEV1 Open hood | 80% | 50% |
| LEV0 No LEV | 0% | 0% |
| WE2 Pressurised or sealed | 99.5% | 70% |
| WE1 Simple enclosed cab | 80% | 60% |
| WE0 No enclosure | 0% | 0% |
| RPE3 Breathing apparatus | 99.5% | 90% |
| RPE2 Half or full-face negative pressure respirator or similar | 95% | 70% |

| Type of RMM | % reduction (generic) | % reduction (lead and di-iso-cyanates) |
|---|---|---|
| RPE1 FFP mask/ simple mask or similar | 60% | 20% |
| RPE0 No mask | 0% | 0% |
| OH1 Organisational measures | 30% | 90% |
| OH0 No organisational measures | 0% | 0% |
| GDV1 General dilution ventilation | 30% | 30% |
| GDV0 No general ventilation | 0% | 0% |

*Source: Analysis by RPA & COWI*

In cases where the required reduction in exposure cannot be achieved using a single RMM, the model allows for the possibility that organisational and hygiene measures (OH1) or re-work (RWK) are combined with any other RMM to increase their effectiveness. For example, combining LEV3 and OH1 achieves a 98% effectiveness.

Where the required reduction in exposure cannot be achieved using the RMMs in the table above or combining them with OH1 or RWK, it is expected that the company in question would have to substitute the substance, or where this is not possible, the company would have to discontinue the operations that involve exposure to the relevant substance. The costs of discontinuation depend on the size of the company – for more information, see each of the substance-specific reports.

### 4.2.10 RMM costs and lifespan

Costs of RMMs depend on the size of the operations of the relevant company. RMM costs have thus been estimated by company size band.

*Table 4-4 RMM unit costs*

| RMM | One-off costs | Recurrent costs | Lifespan |
|---|---|---|---|
| LEV 3: Full enclosure | Based on IOM (2011) – high end of costs | 10% based on US-OSHA (1992) (most likely electricity, maintenance & repairs) | |
| LEV 2: Partial enclosure | Estimated reported in literature which range from €60,000 to €120,000 per company | 10% based on US-OSHA (1992)<br>(most likely electricity, maintenance & repairs, compensation air, heating) | |
| LEV 1: Open hood or add-on | Estimates reported in published literature which range from €1,700 to €15,500 | 10% based on US-OSHA (1992)<br>(most likely electricity, maintenance & repairs, compensation air, heating) | |
| WE 2: Pressurised or sealed cabin | Assumed the same as LEV 2 | Assumed the same as LEV2 | Assumed the same as LEV2 |

| RMM | One-off costs | Recurrent costs | Lifespan |
|---|---|---|---|
| WE 1 : Simple enclosure | Assumed the same as LEV1 | Significantly lower than LEV 1, assumed 3% | Assumed the same as LEV1 |
| RPE 3: Breathing apparatus | Frontline Safety (undated) cost of a belt and a mask: €1,300<br><br>Assume cylinder is then rented | Boconline (undated): €50 for one hour of work (cylinder rental & refill)<br><br>If used every working day for 1 hour, 1,000% of one-off costs | Assumed 2 years |
| RPE 2: Half or full face negative pressure respirator/ Mask with HEPA filters or similar | Hamikian et al. (2015): €25<br><br>Assumed a new mask has to be purchased every two months due to wear and tear/accidental damage, etc.<br><br>Cost per worker €150 | Hamikian et al. (2015): €9 for a pair of HEPA filters<br><br>Usage time 30 hours (Zeynep et al. 2008)<br><br>Annual cost per worker €75, i.e. 50% of one-off costs | Mask: 1 month, Filter: 30 hours |
| RPE 1: FFP mask/ simple mask or similar | Hakimian et al. (2015): €1 per disposable mask<br><br>Assumed a new mask is required every workday, resulting in an annual cost of €260/worker | Not relevant but one-off costs incurred every year | |
| OH1: Organisational & hygienic measures | Some data provided through consultation for Cd (International Cadmium Association, ICdA) as part of CMD 3, also consistent with IOM (2012)<br><br>A large range of measures with different costs | Some data provided through consultation for Cd (ICdA) for CMD 3<br><br>Zeynep et al. (2008): Training annual instructor cost €540<br><br>A large range of measures with different costs<br><br>Assumed 50% | Only incurred once |

| RMM | One-off costs | Recurrent costs | Lifespan |
|---|---|---|---|
| | Assumed €1,000 per worker | | |
| GDV1: General dilution ventilation | Hakimian et al. (2015): €22 per cfm (cubic feet per minute) required<br><br>Zeynep et al. (2008): €10 per cfm<br><br>Figure used: €20 per cfm<br><br>Assumed 10 Air Changes Per Hour<br><br>Assumed cfm required: Small: 300 cfm, Medium: 2,000 cfm, Large: 5,000 cfm | Hakimian (2015): Approx. 30% of one-off costs<br><br>Zeynep et al. (2008): 30% but this is for 24hr operation<br><br>Figure used: 30% | 20 years |

*Sources: Boconline (undated): Charging for cylinder gas, available at https://www.boconline.co.uk/en/how-to-buy/charges-and-payment/charging-for-cylinder-gas/charging-for-cylinder-gas/charging-for-cylinder-gas.html*
*Burgess et al. (2014), http://healthf.kaums.ac.ir/UploadedFiles/jozveh/motalebi/VENTILATIONFORCONTROLOFTHEWORKENVIRONMENT.pdf*
*CPWR (2014) https://www.cpwr.com/sites/default/files/publications/LEV-Works_Welding-Equip-Results.pdf*
*EPA (late 1990s), https://www3.epa.gov/airtoxics/coat/rein/finalrpt.pdf*
*Frontline Safety (undated): Belt, Mask, available at https://www.frontline-safety.co.uk/drager-pas-micro-escape-with-airline-belt-manifold-en139-en402?gclid=EAIaIQobChMI7rXK7cqf1wIVTo0bCh1jzgNqEAQYASABEgKmVfD_BwE and https://www.frontline-safety.co.uk/drager-panorama-nova-p-pc-full-face-mask*
*Hakimian et al. (2015), http://www.rsc.org/suppdata/c5/en/c5en00078e/c5en00078e1.pdf and http://pubs.rsc.org/en/Content/ArticleHtml/2015/EN/c5en00078e#cit45*
*IOM (2011): SHEcan Report P937/4*
*US-OSHA (1992), https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=PREAMBLES&p_id=822*
*Zeynep et al. (2008), http://onlinelibrary.wiley.com/doi/10.1111/j.1530-9290.2008.00030.x/full*

Where unit costs were only available for one or two company size bands, these were extrapolated to other size bands based on the numbers of exposed workers and work stations in the different size bands.

The costs of implementing each of the RMMs in a specific company depend on the number of exposed workers or workstations using the relevant substance. The costs may thus differ between companies in different sectors for which different average company sizes have been estimated (see Section 4.2.6). Examples of these costs for three theoretical company sizes are given in Table 4-5.

*Table 4-5 Cost of various RMMs in €*

| Size of company | Small<br>2 workers exposed<br>Exposed workers on 1 machine | | | Medium<br>27 workers exposed<br>14 machines | | | Large<br>75 workers<br>40 machines | | |
|---|---|---|---|---|---|---|---|---|---|
| Type of RMM | One-off 2021 | Lifespan years | Recurrent (% of one-off) | One-off 2021 | Lifespan years | Recurrent (% of one-off) | One-off 2021 | Lifespan years | Recurrent (% of one-off)) |
| RWK: Rework | 25,000 | | | 350,000 | | | 1,000,000 | | |
| LEV 3: Full enclosure | 45,000 | 20 | 10% | 440,000 | 20 | 10% | 1,700,000 | 20 | 10% |
| LEV2: Partial enclosure | 30,000 | 20 | 10% | 240,000 | 20 | 10% | 650,000 | 20 | 10% |
| LEV1: Open hood | 7,000 | 20 | 10% | 90,000 | 20 | 10% | 260,000 | 20 | 10% |
| WE 2: Pressurised or sealed | 30,000 | 20 | 10% | 240,000 | 20 | 10% | 650,000 | 20 | 10% |
| WE 1: Simple enclosed cab | 7,000 | 20 | 3% | 90,000 | 20 | 3% | 260,000 | 20 | 3% |
| RPE 3: Breathing apparatus | 2,000 | 2 | 500% | 27,000 | 2 | 500% | 75,000 | 2 | 500% |

| **Size of company** | **Small**<br>**2 workers exposed**<br>**Exposed workers on 1 machine** | | | **Medium**<br>**27 workers exposed**<br>**14 machines** | | | **Large**<br>**75 workers**<br>**40 machines** | | |
|---|---|---|---|---|---|---|---|---|---|
| Type of RMM | One-off 2021 | Lifespan years | Recurrent (% of one-off) | One-off 2021 | Lifespan years | Recurrent (% of one-off) | One-off 2021 | Lifespan years | Recurrent (% of one-off)) |
| RPE2: Half or full face negative pressure respirator | 400 | Mask: 2 months | 17% | 5,400 | Mask: 2 months | 17% | 15,000 | Mask: 2 months | 17% |
| RPE 1: FFP mask/ simple mask | 2 per day | Not relevant, 1 per day | Not relevant | 27 per day | Not relevant, 1 per day | Not relevant | 75 per day | Not relevant, 1 per day | Not relevant |
| OH 1: Organisational measures | 4,000 | | 50% | 54,000 | | 50% | 150,000 | | 50% |
| GDV 1: General dilution ventilation | 6,000 | 20 | 30% | 40,000 | 20 | 30% | 100,000 | 20 | 30% |

*Source: Analysis by RPA & COWI*

### 4.2.11 Suitability of RMMs for each sector

Operational characteristics of the activities in each sector mean that not every RMM is suitable to control exposure in each sector. The model thus considers the suitability of each RMM in each of the relevant industry sectors.

The amount of exposure is split into work where the worker is exposed to the substance for less than an hour a day and for more than an hour a day. This also equates to exposure for more or less than 2.5 days/month. Many production activities only occasionally use the relevant substances. Where the exposure is less than an hour a day, it is acceptable, and often more cost effective, to use personal protective equipment (PPE) such as masks with filters or breathing apparatus.

The form of substance to which workers are exposed varies considerably from dust and fibres to vapour, fumes, gas, mist and aerosol. Again, the form of substance has a direct bearing on the types of RMM that are suitable. For example, general dilution ventilation is not advised for removing dust as it tends to stir it up and spread it around. For this analysis, the substance form is split into two types: dust, which also includes fibres; and gas, which includes all the other types.

The extent of the spread is the final characteristic that affects the choice of RMM and this is split into three types: local, diffuse and peripheral. Local means the dust or gas is created around a specific machine and often means that highly targeted ventilation can effectively remove the chemical. Other processes spread the substance over a wider area and this is known as diffuse. In this case, dilution ventilation, workers enclosures or full enclosures are more suitable, the choice depending upon the decrease in exposure required. Peripheral means that the substance spreads more widely and causes exposure to workers beyond the area where the substance is being worked. This means that administrators, managers and sales staff may be exposed.

The proportion of activities characterised by different duration of exposure, forms of the substance and extents of spread has been estimated for each relevant sector in the substance specific reports.

In the table below, the types of RMM that are suitable or not for each amount of exposure, form of substance and extent of spread are shown. These values were built into the cost model.

*Table 4-6 Suitability of various RMMs to duration of exposure, form of the substance and extent of spread*

| Type of RMM | <1h | >1h | Dust | Gas | Local | Diffuse | Peripheral |
|---|---|---|---|---|---|---|---|
| Substitution | Y | Y | Y | Y | Y | Y | Y |
| Rework | Y | Y | Y | Y | Y | Y | Y |
| Full enclosure | Y | Y | Y | Y | Y | Y | Y |
| Partial enclosure | Y | Y | Y | Y | Y | Y | Y |

| Type of RMM | <1h | >1h | Dust | Gas | Local | Diffuse | Periph-eral |
|---|---|---|---|---|---|---|---|
| Open hood | Y | Y | Y | Y | Y | Y | Y |
| No LEV | Y | Y | Y | Y | Y | Y | Y |
| Pressur-ised or sealed | N | Y | Y | Y | N | Y | Y |
| Simple en-closed cab | N | Y | Y | Y | N | Y | Y |
| No en-closure | Y | Y | Y | Y | Y | Y | Y |
| Breath-ing ap-paratus | Y | N | Y | Y | Y | Y | Y |
| Neg. pressure respira-tor | Y | N | Y | Y | Y | Y | Y |
| FFP mask | Y | N | Y | Y | Y | Y | Y |
| No mask | Y | Y | Y | Y | Y | Y | Y |
| Organi-sational measure s | Y | Y | Y | N | Y | Y | Y |
| No or-ganisa-tional measure s | Y | Y | Y | Y | Y | Y | Y |
| General dilution ventila-tion | N | Y | N | Y | N | Y | Y |

| Type of RMM | <1h | >1h | Dust | Gas | Local | Diffuse | Periph-eral |
|---|---|---|---|---|---|---|---|
| No general ventilation | Y | Y | Y | Y | Y | Y | Y |

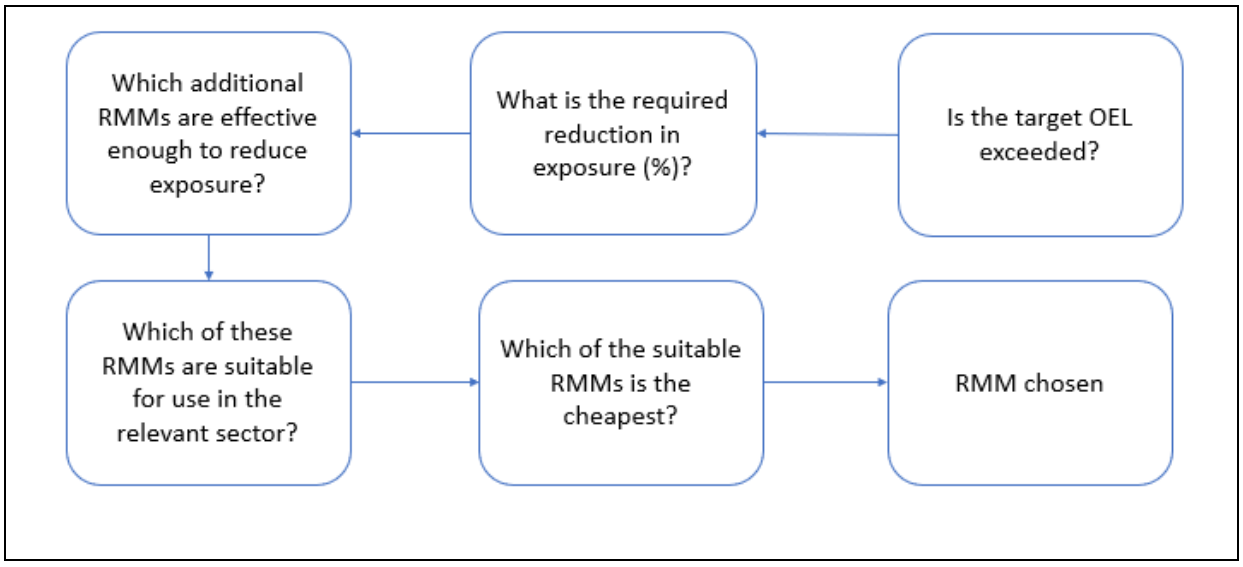
*Source: Analysis by RPA & COWI*

## 4.3 How does the estimation model work?

The assumptions on the effectiveness and suitability individual RMMs are used to determine whether a specific RMM is suitable to reduce exposure in a specific sector by the required degree. If several RMMs are suitable and effective enough, the cheapest one is selected. RMMs that companies already have in place are taken into account and a more effective RMM is chosen.

The logic process underpinning each company level decision is illustrated in the figure below.

*Figure 4-1 Decision making process in the cost estimation model for di-isocyanates and lead (estimated for each company)*




*Source: Analysis by RPA & COWI*

The total cost of reduction is then calculated as a sum of all company-level decisions.

#### 4.3.1.1 Selected issues requiring further explanation

**Discontinuations in the cost model**

Where the RMMs considered in the cost model are not sufficiently effective to achieve the reduction in exposure levels required to comply with an OEL/STEL/BLV option, it is expected that the company in question would have to substitute the substance, or where this is not possible, discontinue the activities that involve exposure to the substance. In a worst-case scenario, the company may have to shut down.

A prediction whether a company would have to discontinue its operations is one of the outcomes considered in the cost model, usually the one associated with the highest cost. Therefore, generally, the model only chooses discontinuation if no RMM (or combination of

RMMs) can achieve the required reduction in exposure. The model assumes that small and medium enterprises discontinuing the operations that involve exposure to the relevant substance would result in the entire company going out of business. The logic behind this is that small and medium organisations are more likely to experience closure if their sole or main operation becomes unfeasible. In contrast, large companies are more likely to discontinue divisions, lines or specific operations which would not result in the full closure of the business but the discontinuation of the line/process using the relevant substance.

If cases where a sector is If the sector is entirely based on the substance, it is possible that 100% of large companies would also be forced to close. In the lead report, the business of the companies in the main sectors (primary and secondary lead producers, lead acid battery manufacturers, lead article manufacture) is entirely based on lead, meaning that, if they could not meet the relevant BLV/OEL option, the relevant companies would shut down. For other sectors with exposure to lead, discontinuation would only apply to certain activities or divisions of the company. For example, a glass manufacturer may discontinue production of lead crystal glass tableware but continue to produce tableware of lead-free glass. In such cases, only the lost profit of the division or activity including lead exposure should be accounted for in the calculation of discontinuation costs. However, such granular data have not been available, and the discontinuation of certain divisions or activities is therefore not accounted for. This leads to an overestimation of the discontinuation costs in the case of lead.

The discontinuation cost is taken as the loss of profit[17] taken over 20 years and the average profit is assumed to be 10% of turnover. The typical profit margins are estimated in the table below based on Eurostat sectoral data on gross operating surplus and turnover.

*Table 4-7 Estimation of typical profit margins based on Eurostat sectoral data*

| Sector NACE code | Sector name | Gross Operating Surplus € million | Turnover € million | Operating Profit Margin |
|---|---|---|---|---|
| A | Agriculture | n/a | n/a | n/a |
| B | Mining & Quarrying | 29,100 | 104,117 | 28% |
| C | Manufacturing | 736,228 | 7,700,014 | 10% |
| D | Electricity, gas, steam and air conditioning supply | 145,064 | 1,448,366 | 10% |
| E | Water supply; sewerage, waste management and remediation activities | 43,500 | 247,000 | 18% |
| F | Construction | 168,400 | 1,576,888 | 11% |
| G | Wholesale and retail trade; repair of | 469,772 | 8,746,671 | 5% |

[17] In RAC/SEAC 2017, on page 30, SEAC states that the "welfare impacts should be measured in terms of the expected profit losses as those correspond to the loss in producer surplus."

| Sector NACE code | Sector name | Gross Operating Surplus € million | Turnover € million | Operating Profit Margin |
|---|---|---|---|---|
| | motor vehicles nad motorcycles | | | |
| H | Transportation and storage | 168,278 | 1,397,368 | 12% |
| I | Accomodation and food service activities | 76,465 | 562,684 | 14% |
| J | Information and communication | 217,282 | 1,215,771 | 18% |
| L | Real estate activities | 193,664 | 470,799 | 41% |
| M | Professional, scientific and technical activities | 216,768 | 1,212,771 | 18% |
| N | Administrative and support service activities | 155,476 | 938,753 | 17% |
| S95 | Repair of computers and personal and household goods | 3,241 | 23,967 | 14% |

*Source: Eurostat, data for EU-27 (excl. UK) in 2018*

The two sectors that are most strongly represented in the substance specific reports are C: Manufacturing (operating profit margin 10%) and F: Construction (operating profit margin 11%). A value of 10% is therefore taken as a typical profit margin in the modelling carried out for this study.

In line with the logic set out above for SMEs shutting down and large companies discontinuing only some activities/lines, the lost profit is assumed to be 10% of annual turnover for 20 years discounted for small and medium sized companies. For large companies, it is assumed to be 1% of annual turnover for 20 years discounted (as noted above, it is estimated that 10% of the companies/operations within a company are likely to discontinue). For large companies in sectors with operations based on the substance, such as refining, the lost profit is assumed to be 10% of annual turnover for 20 years discounted.

The average turnover of small, medium and large companies is estimated taking the Eurostat activity categories (which however, sometimes only partly correspond to the relevant sectors where exposure occurs), stakeholder consultation and Internet searches into account.

Discontinuation costs are estimated per company differentiating by size and sector and subsequently applied to the numbers of companies in the relevant sector; the number of companies in a sector thus has a significant impact on the total cost of all discontinuations.

Comparing the cost of discontinuations with the total compliance costs, it can be seen that they comprise a significant part of the compliance cost for some di-isocyanate and lead OEL/STEL/BLV options. The data should be interpreted with care, as companies may try to find other means for reaching compliance than closing. Also, it is difficult to model the potential to substitute the substance or keep the business alive by reorientating to different products or services. Such other possibilities cannot be reflected in sufficient detail in the cost model.

It should be noted that, although the estimated number of discontinuations is based on a mathematical formula of the cost model which only predicts discontinuation where a sufficiently effective RMM is unavailable, these predictions are checked against consultation responses. For example, the questionnaire included a question on stakeholders' views on the lowest technically possible limit value as well as the one-off and recurring costs of the different OEL/STEL/BLV options.

A different model was used for asbestos and no companies are expected to discontinue operation under the OEL options considered in this study. However, it should be noted that the uncertainty regarding this conclusion increases with decreasing OEL values. The introduction of lower OELs may result in a shift whereby more activities are undertaken by companies specialised in asbestos removal instead of more general service providers. Although this is not expected to lead to discontinuations as working with asbestos containing materials is only a minor and not key activity for 'more general' companies, it cannot be ruled out that some may experience greater impacts under the lowest of the OEL options considered in the asbestos report.

The discontinuations due to the OEL/STEL/BLV options are in addition to the normal rate of bankruptcies. Data on insolvencies suggest that a natural insolvency rate is around 1% per year.[18] However, it may not be appropriate to compare discontinuations resulting from the OEL/STEL/BLV options with the 'natural' bankruptcy rate due to the fact that the nature of these outcomes differs significantly – in cases of natural insolvencies, a company going out of business can be replaced by a competitor or a new market entrant. However, the discontinuations modelled in this study may entail a permanent loss of revenue generating activities in the EU, especially in instances where it is not technically feasible to meet the OEL/STEL/BLV option.

**Negative recurring costs**

The estimated recurrent compliance costs, when compared with the same costs under the baseline, can be both positive or negative. Negative costs (i.e. cost savings) occur, for example, when companies primarily use respiratory protective equipment (RPE), and these companies move to local exhaust ventilation (LEV) such as closed systems or partially closed systems. RPE tends to have a small one-off cost, but a high recurrent cost, whereas LEV has high one-off costs and lower recurrent costs. This negative value shows that in this instance, over 40 years, the cost of operating RPE is higher than installing and running LEV. Although it can be questioned whether relying on RPE is a rational allocation of resources, companies may prefer to pay more over 40 years, rather than face a substantial

[18] Data on insolvencies are available for approximately half of EU Member States from https://www.creditreform.cz/fileadmin/user_upload/CR-International/local_documents/cz/documents/2021-05-20_AY_OE_Analyse_EU-2020_englisch_international.pdf. These data were compared with Eurostat enterprise statistics for 2018. Please note that the insolvency rate given above may overestimate the natural insolvency rate since financial services are not included in the Eurostat dataset for numbers of enterprises used for the calculation presented above.

one-off sum: in particular, small companies may find it difficult to borrow the funds for the investment. It is thus possible that, under the baseline, companies are not always operating the most cost-effective RMM. However, the cost model selects the most appropriate RMM on the basis of the overall cost (PV sum of one-off and recurring costs over 40 years) and thus assumes that companies opt for the RMM with the greatest overall cost-effectiveness regardless of any potential access to finance issues.

In the lead report, some enterprises realise a saving in the recurring cost by changing to more cost-efficient RMMs for different BLVs, for example where exposures can be sufficiently reduced by introducing organisational measures and/or enclosures instead of ventilation, operational expenses for local exhaust ventilation or general workroom ventilation can be saved, and the overall recurring cost may be negative.

Negative values can also occur when a company using closed systems has to discontinue – the cost model treats all discontinuation costs as a one-off cost and, as a result, the overall recurrent costs can appear negative.

**Annual costs estimated from PV40 values**

According to Better Regulation Tool #61, annualisation is a useful method for comparing costs and benefits that have different timeframes. This is study already takes the different timeframes into account in the cost and benefit models and the costs and benefits (cost savings) presented in the substance reports are expressed as PV40 and are directly comparable allowing this study to derive Cost-Benefit Ratios. However, for ease of understanding, the PV40 values in this study are also converted into annual values by dividing the PV40 values by 40.

Annualisation is also used within the framework of ECHA restrictions and authorisations. The ECHA restriction guidance[19], for example, sets out an annualisation formula that relies on both the number of years and discount rates. However, these methods are not used in this study because a) they are often used for a different reason, i.e. to annualise capital investment incurred in year 1 by spreading it over the lifetime of the equipment, and b) since (in the experience of the study team) ECHA's Committee for Socio-economic Analysis (SEAC) appears to be moving towards annualisation by means of simple division by the number of years (at least within the context of Socio-Economic Assessments for REACH authorisations).

## 4.4 Estimation of the costs of sampling and analysis

The costs of monitoring air concentrations (sampling and analysis) are estimated separately to the core model. Please see the substance reports.

[19] https://echa.europa.eu/documents/10162/23036412/sea_restrictions_en.pdf/2d7c8e06-b5dd-40fc-b646-3467b5082a9d

# 5. The Cost Model for Estimating Compliance Costs for Companies (Asbestos)

## 5.1 Introduction

The cost model for the companies' compliance is described below. The cost model takes several inputs and calculates the predicted costs incurred for the target OELs.

The exposure situations for asbestos differs significantly from the general exposure patterns for most other hazardous substances as the activities are not located at specific sites, but the workers are moving from site to site and undertake many different activities, each with its specific exposure characteristics. The work is in this respect more like the work undertaken by maintenance workers for other substances. Even if the RPE in the general hierarchy of the RMMs is the last resort, in practice most workers exposed to asbestos use RPE which in combination with other RMMs to keep the breathing concentration below the OEL. This is recognised in the AWD, Article 12: *"In the case of certain activities such as demolition, asbestos removal work, repairing and maintenance, in respect of which it is foreseeable that the limit value set out in Article 8 will be exceeded despite the use of technical preventive measures for limiting asbestos in air concentrations workers shall be issued with suitable respiratory and other personal protective equipment, which must be worn.'"*

It is expected that the measures taken by each company in response to a new OEL would include a combination of more efficient RPE (for some workers) and more efficient technical/organisational RMMs. In order to reflect this, a specific cost model has been developed for asbestos that relies on asbestos specific packages of measures to control exposure.

Furthermore, the asbestos compliance cost estimation model differs from that for other substances under this study (lead and di-isocyanates) in that the information in the baseline is divided into relevant exposure groups which typically encompass more than one sector with the exception of the construction and demolition sector which is spread across several exposure groups.

## 5.2 Key model inputs and assumptions

### 5.2.1 Key model inputs

The model includes the following types of inputs:

- OEL options;
- Existing OELs in Member States;
- Number of workers exposed by exposure group;
- Sectors in each of the exposure groups and numbers of companies in these sectors at exposure levels at or above 0.002 fibres/cm$^3$;
- Number of small, medium and large enterprises in each of the exposure groups and sectors at exposure levels at or above 0.002 fibres/cm$^3$;
- Estimated breakdown of RPE used;
- Effectiveness of RMMs (in particular RPE);
- Cost of RMMs;

- Discount rates;
- Existing level of compliance with the target OEL (i.e. national OELs in France, Germany and the Netherlands);
- Estimated training needs;
- Costs of analysis for compliance monitoring at the different reference levels; and
- Need for compliance monitoring measurements.

The output is the costs of implementing the OEL split by:

- Exposure group;
- Company size: small, medium and large; and
- Capital expenditure (one-off) and operating expenditure (recurrent) costs.

### 5.2.2 Relevant RMMs

#### 5.2.2.1 RMMs relevant to asbestos

The following RMMs are considered for the assessment of compliance costs for companies:

- Various RPE (need for applying RPE with a higher protection factor).
- Installation of LEV by use of tools.
- Further use of vacuum cleaners.
- Further use of wetting agents and use of wetting agents of higher efficiency.
- Use of various enclosures (part containment, full containment).
- Further training of staff.
- Further need for monitoring.

Furthermore, for activities currently not subject to notification, the following RMMs are included in the cost assessment:

- Health surveillance.
- Registering and notification.

The following costs are estimated by means of the cost assessment model for asbestos:

- RPE; and
- Increased use of vacuum cleaning and dust suppression techniques (referred to as 'RMMs other than RPE' in the model).

The costs of RMMs other than RPE and increased use of vacuum cleaning and dust suppression techniques are estimated outside the cost estimation model – see the asbestos report where the approach to the estimation of each cost component is explained.

### 5.2.2.2 RPE used in the model

**RPE use in the model**

For the estimations of distribution of the current use of RPE, it is assumed that for all workers, the exposure concentration when the RPE is taken into account should be below the OEL (so at a maximum 95% of the workers are exposed at concentrations below the OEL). The distribution of RPE is calculated on the basis of the exposure concentration distributions shown in section 4.3.

It is in the model assumed that RPE with a higher APF would be applied in order to bring the breathing concentration down if the OEL is lowered. It is assumed that the use of more efficient RPE is combined with use of other RMMs, so for some workers the use of more efficient RPE would not on its own bring the concentration sufficiently down. The model assumptions as concern the potential concentrations obtained by use of various RPE are shown in the table below. The costs are calculated on the basis of the exposure concentrations for each exposure group and the differences between the baseline use of RPE and the use of RPE for each reference OEL scenario.

*Table 5.1 Exposure concentration bands and assumed RPE used in Member States with an OEL of 0.1 fibres/cm$^3$*

| Baseline use of RPE a | | | Lowering to 0.01 fibres/cm3 | | Lowering to 0.002 fibres/cm3 | |
|---|---|---|---|---|---|---|
| Exposure concentration, fibre cm$^3$ | AFP | Breathing concentration, fibre cm$^3$ | AFP | Breathing concentration, fibre cm$^3$ | AFP | Breathing concentration, fibre cm$^3$ |
| 0 - 0.001 | 0 | 0 - 0.001 | 0 | 0 - 0.001 | 0 | 0 - 0.001 |
| 0.001 - 0.03 | 0 | 0.001 - 0.03 | 0 - 10 | 0.001 - 0.003 | 0 - 20 | 0.001 - 0.0015 |
| 0.03 - 0.8 | 10 - 20 | 0.003 - 0.04 | 30 - 60 | 0.001 - 0.013 | 250 | 0 - 0.003 |
| 0.8 - 6 | 30 - 60 | 0.03 - 0.1 | 250 - 250 | 0.003 - 0.024 | 250 | 0.003 - 0.024 |
| 6 - 20 | 250 | 0.02 - 0.08 | 250 | 0.003 - 0.01 | 250 | 0.003 - 0.01 |
| 20 - 100 | 2,000 | 0.01 - 0.05 | 2,000 | 0.01 - 0.05 | 2,000 | 0.01 - 0.05 |

*Note: Exposure concentrations are actual concentrations in the workplace taking into account the various RMMs used (except for RPE).*
*Source: Analysis by COWI & RPA*

The model percentage breakdown of RPE currently used by enterprises in Member States with an OEL of 0.1 fibres/cm$^3$ (excl. France, Germany and the Netherlands) is shown below.

*Table 5.2 Percentage breakdown of baseline RPE by enterprises (excl. France, Germany and the Netherlands)*

| Type of RPE/Exposure Group | No mask | Half mask + P2 or P3 filter (AFP 10-20) | Powered hoods/masks and breathing apparatus (APF 30 - 60) | Constant flow breathing apparatus (AFP 250) | Self-contained breathing apparatus (AFP 2000 or more) |
|---|---|---|---|---|---|
| 1) Building and construction - exposure situations subject to notification | 8 | 84 | 8 | 0.1 | 0.02 |
| 2) Building and construction - exposure situations subject to Article 3(3) waiver | 58 | 42 | 0.2 | 0 | 0 |
| 3) Building and construction - passive exposure in buildings | 100 | 0 | 0 | 0 | 0 |
| 4) Exposure to asbestos in articles: Trains, vehicles, vessels, aircraft and other | 8 | 84 | 8 | 0.1 | 0.02 |
| 5) Waste management and land remediation activities | 34 | 66 | 0,4 | 0 | 0 |
| 6) Mining and quarrying - naturally occurring asbestos | 60 | 40 | 0.1 | 0 | 0 |
| 7) Tunnel excavation | 82 | 19 | 0 | 0 | 0 |
| 8) Road construction and maintenance | 90 | 10 | 0 | 0 | 0 |
| 9) Sampling and analysis | 49 | 51 | 0 | 0 | 0 |

*Source: Analysis by COWI & RPA*

The model percentage breakdown of RPE currently used by enterprises in France and Germany are shown below. The percentages are calculated on the basis of the distribution in the Member States with an OEL of 0.1 fibres/cm$^3$ shown above and the assumptions regarding the percentages of the workers in the different exposure bands that step up to an RPE of higher efficiency. The method has been applied in order to use a consistent model even for some of the exposure groups it results in a more diverse use of RPE than has been reported for the stakeholder consultation. For instance, for the group 'Sampling and analysis', it is reported for the stakeholder consultation that a half mask with P2 or P3 filters is in general used, whereas the model assumes that some use less or no RPE and other use more efficient RPE.

Table 5.3 Percentage breakdown of RPE currently used by enterprises (France and Germany)

| Exposure group | No mask | Half mask + P2 or P3 filter (AFP 10-20) | Powered hoods/masks and breathing apparatus (APF 30 - 60) | Constant flow breathing apparatus (AFP 250) | Self-contained breathing apparatus (AFP 2000 or more) |
|---|---|---|---|---|---|
| 1) Building and construction - exposure situations subject to notification | 4 | 67 | 27 | 2 | 0.04 |
| 2) Building and construction - exposure situations subject to Article 3(3) waiver | 28 | 62 | 9 | 0.04 | 0.00 |
| 3) Building and construction - passive exposure in buildings | 98 | 2 | 0 | 0 | 0 |
| 4) Exposure to asbestos in articles: Trains, vehicles, vessels, aircraft and other | 4 | 67 | 27 | 2 | 0.04 |
| 5) Waste management and land remediation activities | 17 | 66 | 17 | 0.01 | 0.00 |
| 6) Mining and quarrying - naturally occurring asbestos | 30 | 60 | 10 | 0.01 | 0.00 |

| Exposure group | No mask | Half mask + P2 or P3 filter (AFP 10-20) | Powered hoods/masks and breathing apparatus (APF 30 - 60) | Constant flow breathing apparatus (AFP 250) | Self-contained breathing apparatus (AFP 2000 or more) |
|---|---|---|---|---|---|
| 7) Tunnel excavation | 42 | 53 | 5 | 0.00 | 0.00 |
| 8) Road construction and maintenance | 48 | 50 | 2 | 0.00 | 0.00 |
| 9) Sampling and analysis | 24 | 62 | 13 | 0.06 | 0.00 |

*Source: Analysis by COWI & RPA*

### 5.2.2.3 RPE used in the model

*Table 5.4 Exposure concentration bands and assumed RPE used in Member States with an OEL of 0.1 fibres/cm$^3$.*

| Baseline use of RPE a | | | Lowering to 0.01 fibres/cm3 | | Lowering to 0.002 fibres/cm3 | |
|---|---|---|---|---|---|---|
| Exposure concentration, fibre cm$^3$ | AFP | Breathing concentration, fibre cm$^3$ | AFP | Breathing concentration, fibre cm$^3$ | AFP | Breathing concentration, fibre cm$^3$ |
| 0 - 0.001 | 0 | 0 - 0.001 | 0 | 0 - 0.001 | 0 | 0 - 0.001 |
| 0.001 - 0.03 | 0 | 0.001 - 0.03 | 0 - 10 | 0.001 - 0.003 | 0 - 20 | 0.001 - 0.0015 |
| 0.03 - 0.8 | 10 - 20 | 0.003 - 0.04 | 30 - 60 | 0.001 - 0.013 | 250 | 0 - 0.003 |
| 0.8 - 6 | 30 - 60 | 0.03 - 0.1 | 250 - 250 | 0.003 - 0.024 | 250 | 0.003 - 0.024 |
| 6 - 20 | 250 | 0.02 - 0.08 | 250 | 0.003 - 0.01 | 250 | 0.003 - 0.01 |
| 20 - 100 | 2,000 | 0.01 - 0.05 | 2,000 | 0.01 - 0.05 | 2,000 | 0.01 - 0.05 |

*Note: Exposure concentrations are actual concentrations in the workplace taking into account the various RMMs used (except for RPE).*
*Source: Analysis by COWI & RPA*

### 5.2.2.4 RMMs other than RPE

The RMMs other than RPE considered in the model is the staff time due to increased increased use of vacuum cleaning and dust suppression techniques.

It is expected that the measures taken by each company in response to a new OEL would include a combination of more efficient RPE (for some workers) and more efficient

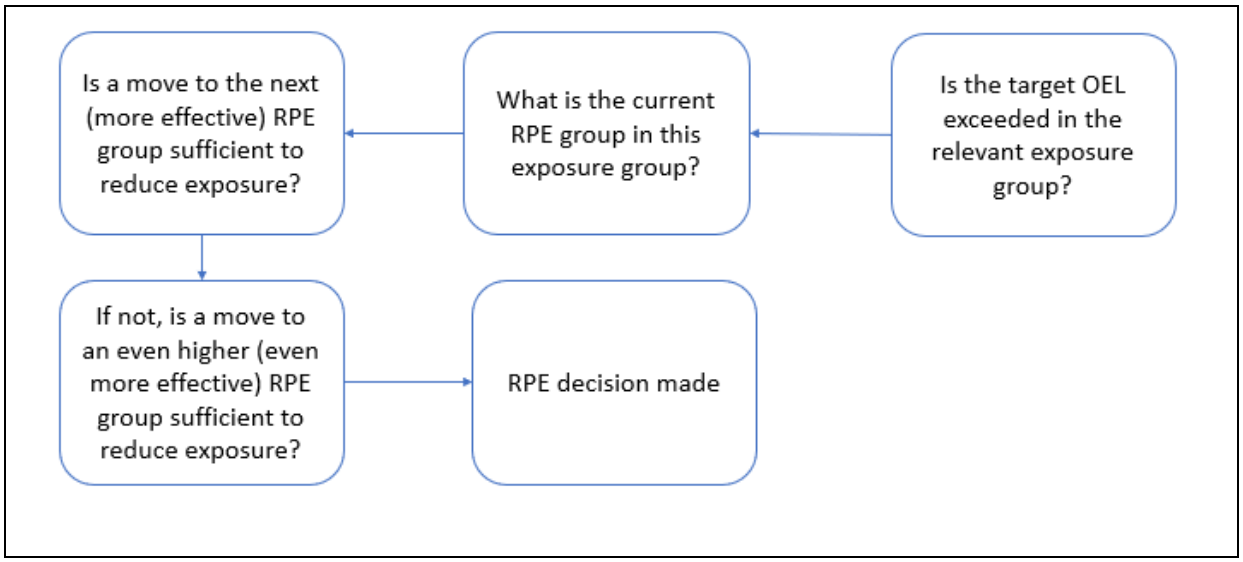
technical/organisational RMMs. More specifically, it is expected that increased costs would be incurred for more extensive use of dust suppression and vacuum cleaning techniques – it is assumed that no new equipment would be needed but staff would have to spend more time using existing vacuum cleaning and dust suppression equipment. These costs are therefore approximated by focusing on the share of staff costs in the total cost of asbestos control. The HSE (2017) data presented in Annex E of the Asbestos Report do not disaggregate between the different RMMs but provide an indication of the relative shares of cash and staff costs in the total cost of control measures. Using these data, it is estimated that staff costs account for around 10% of the total costs. It is therefore expected that the costs of additional RPE account for only around 90% of the total additional costs and the costs of RPE estimated in the preceding section are correspondingly adjusted.

## 5.3 How does the estimation model work?

For the purposes of the model, RPE is divided into four groups. For each exposure group with an exposure concentration that exceeds the target OEL, the model attempts to shift the currently used RPE to an RPE in the next group with higher effectiveness – see section 5.2.2.3. Where this is not sufficient to reduce exposure to the target level, the model estimates that RPE in two groups above the current one is required.

The logic process underpinning the model is illustrated in the figure below.

*Figure 5-1 Decision making process in the asbestos cost estimation model*



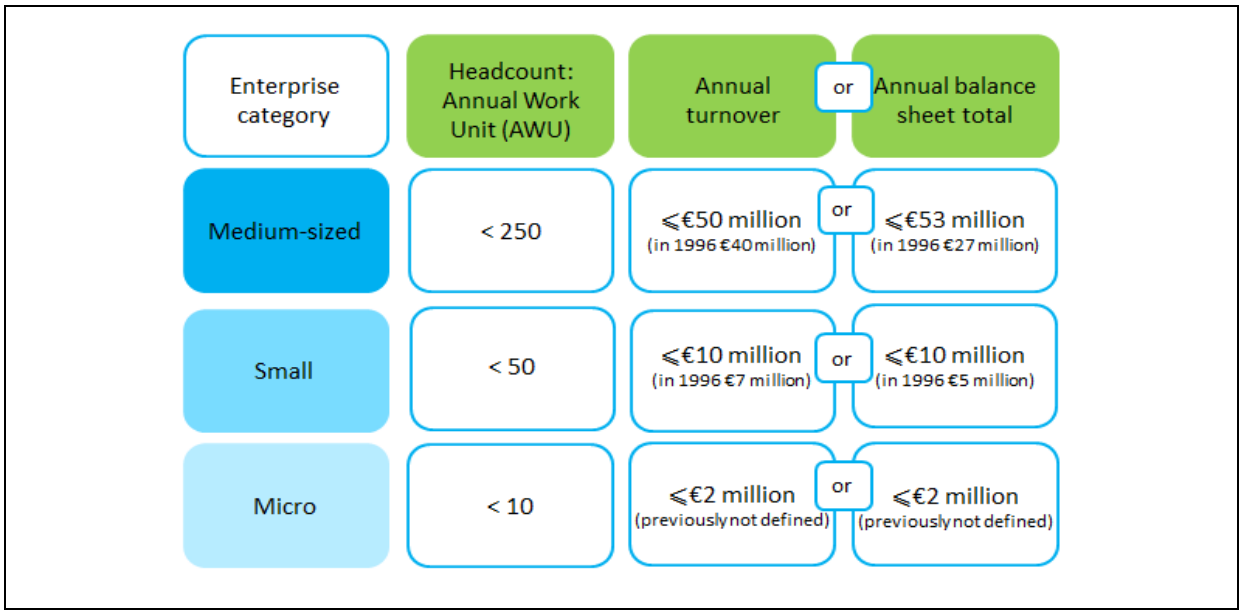

*Source : Analysis by COWI & RPA*

## 5.4 SME test

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

An enterprise is considered to be a medium-sized, small or micro enterprise depending on thresholds that have been outlined by the Commission, see figure below.

*Figure 5-2 Categorisation of SMEs*




The general approach to the assessment of the impacts on SMEs takes into account the steps set out in BR Tool #22 (SME Test). This comprises the following steps:

1) Identification of affected businesses;
2) Consultation of SME stakeholders;
3) Measurement of the impact on SMEs; and
4) Assessment of alternative mechanisms and mitigating measures.

### 5.4.1 Identification of affected businesses

This step focussed on quantifying the presence of SMEs in the key sectors. This relied, to the maximum degree possible, on the use of NACE codes, to facilitate extraction of data on the proportion of SMEs from the Eurostat Structural Business Statistics (SBS) database.

The numbers of small, medium and large enterprises likely to have workers exposed to the relevant substance in the EU is estimated Section 4.12 of the asbestos report, Section 4.15 of the lead report and Section 4.8 in the di-isocyanates reports. These tables show that the vast majority of companies with exposed workers and which are likely be affected by the OEL/STEL/BLV options are SMEs (although this is not the case in some sectors with exposure to lead).

In Section 4.8 of the di-isocyanates report, an overview of each of the sectors includes the consideration of whether the relevant companies are micro-enterprises. This is particularly relevant to di-isocyanates since there is a significant proportion of micro-enterprises in some of the relevant sectors (construction and vehicle repair).

The outcome of this subtask was the identification of the sizes of the businesses in the relevant sectors.

### 5.4.2 Analysis of impacts on SMEs

Having identified the overall costs and benefits, all substance reports contain a dedicated section that considers how the costs are likely to relate to SMEs (Section 8.2 in all substance-specific reports).

The degree of detail in this section corresponds to the importance of the SME aspect to the analysis for the different substances. As a minimum, the identification of the presence of SMEs in the relevant sectors is considered. In the di-isocyanates report, Section 8.2 also provides, for example, the cost per company as a percentage of turnover and discusses the importance of the cost of monitoring and administrative burden for small companies as a proportion of their turnover for the different OEL options.

It should also be noted that the unit costs of RMMs per company in the cost model were also estimated separately for differently sized companies meaning that differences between small, medium and large companies permeate the whole cost assessment in this study (also taking any differences between industry sectors into account).

### 5.4.3 Consultation of SME stakeholders

The consultation exercise for this study paid particular attention to obtaining feedback from SMEs. The number of questionnaire responses by company size is provided in Table 7-4 in Section 7.5.1 of this note. A percentage breakdown of questionnaire responses by company size is also given below.

*Table 5.5 Breakdown of questionnaire responses per company size*

| Company size | Asbestos | Lead and its compounds | Di-isocyanates | Total |
|---|---|---|---|---|
| Small enterprise (10-49 persons employed) | 58% | 11% | 20% | **29%** |
| Medium-sized enterprise (50-249 persons employed) | 31% | 46% | 54% | **46%** |
| Large enterprise (250 or more persons employed) | 11% | 43% | 26% | **24%** |

*Source: estimated based on Section 7 of this report*

The table above shows that most questionnaire responses (approximately 75%) were received from SMEs.

### 5.4.4 Assessment of alternative mechanisms and mitigating measures.

Where relevant, the study team considered the potential for measures that could mitigate the impact on companies – due to the systematic analysis of the presence of SMEs in the relevant sectors, the SME aspect was taken into account in this process. However, it should be noted that alternative mechanisms and mitigating measures were not one of the key tasks of this study which focussed on the assessment of the impacts of the different OEL/STEL/BLV measures within the framework given by the relevant legislation (Chemical

Agents Directive and Asbestos at Work Directive). Nevertheless, examples of relevant aspects that were considered include:

- Asbestos: the potential for a revision of the Article 3(3) waiver in the Asbestos at Work Directive that could reduce some of the burden on companies; and
- Di-isocyanates: although primarily carried out for the purposes of sensitivity analysis, the costs of excluding micro companies from monitoring and administrative burden for construction and G45.2 sectors were considered separately.

# 6. Approach to the Assessment of the Environmental Impacts

Potential changes in OELs for the substances considered in this study may subsequently lead to additional or lower environmental impact.

The approach to the assessment of the environmental impacts includes the following steps:

- **Persistent, bio-accumulative, and toxic (PBT) screening:** this step involves screening for Persistent, Bio-accumulative, and Toxic (PBT) properties. To be classified as PBT, all three criteria must be fulfilled.
- **Current environmental exposure:** this step includes consideration current environmental exposure, including its sources, background exposure levels, environmental (air and water) levels in relation to hazard data; leading to a conclusion on the environmental presence of the relevant substance.
- **Waste management and disposal:** this step first considers the classification of the substance as hazardous waste and its final treatment (disposal or recovery) routes. Subsequently, the potential for releases of the substance and human health risks during waste management and disposal is considered.
- **Impact of introducing new risk management measures (RMMs) on environmental exposure:** this step assesses whether the new RMMs are likely to reduce or increase the overall environmental exposure to the relevant substance?

An analysis of the above-mentioned aspects supports a conclusion on the impact of the additional RMMs on environmental exposure to the relevant substance.

# 7. Summary of the Consultation Exercise

The following section provides a summary of the stakeholder consultation exercise. The section feeds into the Synopsis Report of the Commission's Impact Assessment.

## 7.1 Outline of consultation strategy

The aim of the consultation activities was to collect detailed information on the potential impacts of modifications to the CAD and the AWD that is not available in published literature. Although some information on the impacts of limits such as OELs, STELs, BLVs and notations is available, limited information is available on the specific concrete risk management measures already in place, as well as those that would need to be implemented, should proposed limits be introduced.

Information sought via this consultation included the sectors, processes, as well as size of companies that would be impacted, estimates of numbers of workers exposed currently, current air concentrations of substances concerned (both 8-hour time weighted averages (8-h TWA) and 15-minute reference periods), current biological limit values, and risk management measures in place, as well as risk management measures that would need to be implemented should the limits be introduced and the associated costs.

Consultation carried out for the purposes of this study consisted of the following main activities:

- Questionnaires;
- Email requests (possibly in combination with questionnaires);
- Telephone interviews; and
- Site visits.

Mixed methods (combining, for example, questionnaire responses with telephone interviews and site visits) were adopted to ensure that a large number and a wide variety of organisations and individuals were able to provide data and their views within the time constraints and resource limits. U sing mixed methods also enabled the study team to gather information of varying levels of detail and to explore information further where the need arose.

The following important aspects of the consultation exercise should be mentioned:

- There has been no public consultation as part of this work, although the survey has – through its submission strategy – aimed to reach out widely.
- The consultation has focused on generating *evidence* to directly support the analyses. Views and opinions have also been provided and are presented here as well, but the approach towards this has not been as systematic.
- Much of the evidence gathered is of a confidential nature and is thus not presented here; however, it has been used to support the calculation and assessments that result from the analyses.
- Due to the ongoing COVID-19 pandemic, fewer site visits have been conducted in person than for the previous studies.

The table below summarises by stakeholder group the tools and strategies applied.

*Table 7-1 Consultation tools and strategies*

| Stakeholder type | Main consultation tools | Strategy |
|---|---|---|
| EU Associations and REACH Consortia | Telephone interviews<br>Email requests | Our previous similar work supporting CMD 3 and CMD 4 demonstrated that EU Associations are the best instrument for reaching out to manufacturers/users. Upon our request, the EU associations thus forwarded the questionnaires to national associations and companies. Supplementary information e.g. on number of companies, numbers of workers exposed, market situation, etc. was collected through email requests and telephone interviews with the associations and REACH consortia. |
| Member State Authorities | Questionnaires<br>Telephone interviews | Member State authorities were contacted with a questionnaire and responses were followed up with telephone interviews, where possible. Experience from supporting the CMD 3 and CMD 4 studies demonstrated that this is the most effective way of collecting the specific information across all Member States. |
| Manufacturers/users | Questionnaires<br>Telephone interviews<br>Email requests<br>Site visits (both in person and virtual) | Based on the experience from CMD 3 and CMD 4, questionnaires for manufacturers/users were mainly distributed via EU associations. The EU associations forwarded the questionnaire directly to companies or forwarded it to national industry associations which then forwarded it to their member companies. This strategy was deemed the most sensible as experience from CMD 3 and CMD 4 shows that only a few companies answer the questionnaire unless encouraged to do so by either their relevant EU association or their national industry associations.<br>To increase the number of responses, the questionnaires used for CMD 3 and CMD 4 were shortened, and focused on providing data on existing RMMs as well as RMMs (and costs) needed to comply with the various reference limits (options)<br>Questionnaire responses were, when necessary, followed up by interviews and site visits.<br>Some companies were contacted directly (i.e. not via the associations) by phone by national experts who encouraged and assisted the companies in filling out the questionnaire and/or undertook telephone interviews. This additional approach was selected to ensure that answers were provided by companies situated in as many Member States as possible. |

| Stakeholder type | Main consultation tools | Strategy |
|---|---|---|
| National industry associations | Telephone interviews<br>Email requests | National industry associations were primarily contacted via the EU associations. Some national associations were contacted directly by phone by national experts and interviewed to collect information supplementary to the information from EU associations, and identify relevant national companies to be approached by the national experts. |
| Trade Unions | Telephone interviews<br>Email requests<br>Workshop (with WPC) | Based on previous experience, this study has focused on obtaining a few more targeted telephone interviews and email correspondence, as well as collecting information from worker association representatives of the WPC.<br>To obtain worker's perspectives on the possible measures for establishing/lowering the OELs, site visits will, if possible, include interviews with local health and safety representatives. |
| Occupational Health & Safety Professionals | Questionnaire<br>Telephone interviews | Occupational health and safety professionals were contacted with a questionnaire. This is considered the most efficient way to collect specific information across all Member States. |
| Working Party on Chemicals (WPC) | Participation in workshop | The study team presented draft results to the Working Party on Chemicals in June 2021. This proved to be an effective means of receiving feedback from representatives of industry, employers' associations, workers' organisations and Member State authorities. |
| Laboratories | Telephone interviews<br>Email requests | In the study supporting CMD 3, a large number of laboratories were contacted via email requests. Limited information was obtained, and it was only obtained when the email requests were combined with telephone contact. For previous OELs studies and this study, the approach has been to contact a small number of laboratories by phone and email using direct contacts, and to dedicate efforts to following-up on these, to obtain detailed information on methods applied, standards, limits of quantification and prices. |

*Source: Analysis by RPA and COWI*

Lastly, it is worth mentioning that the consultations were managed by experts on the substances in question, supported by experts in cost-benefit analysis and national experts with a good insight into the conditions specific to each Member State. The survey was implemented by consultation experts. The consultation was carried out by the consortium led by RPA which has worked on all previous four OELs studies.

## 7.2 Consultation activities

The consultation carried out for the purposes of this study consisted of the following main activities. Their use in relation to the specific stakeholder types is explained above. As explained above, it should be noted that the consultation has focused on gathering evidence and has therefore been clearly targeted at specific stakeholders and stakeholder types (explained above) and concentrated on gathering the concrete data needed to inform the baseline and the analysis of options.

- Questionnaire;
- Telephone interviews;
- Email; and
- Site visits.

Both national experts and substance experts (the responsible expert(s) for each substance) of the study team invited stakeholders to participate in the questionnaires, interviews and site visits. Progress made with consultation was logged by the substance experts and consultation coordinator. When requested, questions were translated into native languages of the stakeholders by the national experts. The consortium's substance experts supported the process by ensuring that follow-up consultations focused on the specific and relevant questions, identified on the basis of any information already obtained.

An interview guide was prepared to ensure that the approach to collecting data was thorough and consistent. This guide included information clarifying the objectives of the study, the study approach and provided detailed information on the measures being assessed. It also included information on the role of the national experts and the specific data that needed to be collected via consultation, as well as the need to obtain consent from interviewees in relation to the privacy statement and level of confidentiality afforded to the minutes.

### 7.2.1 Targeted online questionnaires

Stakeholders were initially contacted via email. The e-mail provided an overview of the study and a link to the RPA webpage about the consultation, with links to the questionnaires, privacy statement and introductory letter from the Commission. Stakeholders were also able to download a PDF version of the questionnaire via the website if they preferred (so that it could be shared among several colleagues). Five separate questionnaires were drawn up, targeted at the relevant stakeholder groups (the questionnaires are in Annexes 1 to 5):

- Questionnaire 1 was aimed at companies whose workers were exposed to asbestos;
- Questionnaire 2 was aimed at companies whose workers were exposed to lead and its compounds;
- Questionnaire 3 was aimed at companies whose workers were exposed to di-isocyanates;
- Questionnaire 4 was aimed at occupational health and safety experts; and
- Questionnaire 5 was aimed at Member State authorities.

The questions aimed to collect information on processes during which worker exposure to the substances in question is likely to occur, risk management measures that are already in place, current exposure concentrations, risk management measures that would need to be implemented should the limit be lowered, and any other impacts that could result from the introduction of EU-level limits. As mentioned above, the questionnaires were targeted, focusing on the evidence needed for the analyses. In that regard, particular focus was

placed on risk management measures, as only limited information on these is available in the literature.

Many of the questions were closed, enabling stakeholders to respond efficiently and responses to be analysed efficiently. Where needed, open text questions were used to obtain more detail.

Questionnaires 1-3 were made available in English, French, German, Italian, Polish and Spanish. Stakeholders were also able to request translation into other languages, where necessary.

At the end of the questionnaires, respondents were given the opportunity to provide contact details enabling us to review their responses over the phone.

Although many of the responses provided a significant amount of useful information, many of them were not sufficiently detailed. Other methods of consultation, allowing experts to question and probe answers further (namely telephone interviews and site visits), were therefore required to obtain a more in-depth understanding of the potential impacts.

### 7.2.2 Telephone interviews

Both national experts and substance experts conducted the telephone interviews. Telephone interviews were requested in the online questionnaires as well as via direct email and phone contact.

The majority of telephone interviews were conducted with industry associations, and in some of these cases, members of that association also attended the call via teleconferencing (in one case over 150 members attended the call).

The purpose of the telephone interviews was to gain more insight into the answers provided in response to the questionnaires. It has enabled us to collect more detailed information on processes, to pinpoint exactly where exposure is likely to occur, to investigate what types of risk management measures are already in place and how effective they are, as well as what risk management measures would be required if limits were lowered and other potential ramifications for the company.

The experts conducting the interviews were provided with detailed instructions (in the form of a consultation guide) on the information to be collected, as well as email templates to be translated where necessary into the relevant national languages. Interviews were based on responses to the questionnaires (in cases where a response had already been received) or on more targeted sets of questions drawn up by the consultation coordinator and the substance experts, focusing on any information gaps identified.

### 7.2.3 Email requests

As a supplement to the interviews, various types of information were collected by email requests. Similarly to the questions posed for the telephone interviews, these were drawn up on the basis of information gaps identified by the substance experts.

### 7.2.4 Site visits

Companies whose activities are likely to be affected by the potential modifications to the CAD and AWD were also asked whether they would be willing to offer members of the study team site visits, if these can be held before the study ends within the constraints of COVID-19 or virtual site visits. Potential companies to be visited were identified via the questionnaire or contact was established via EU trade associations.

The purpose of the site visits was to a gain detailed operational understanding of the risk management measures currently in place to protect against exposure to the substances concerned, as well as of the risk management measures that would be needed should the CMD be modified.

Experts attending the site visits were selected for their knowledge of the substance concerned, and where necessary, for their language capabilities, enabling more detailed information to be collected. All site visits were attended by the relevant substance experts who were accompanied, when necessary, by a national expert.

Detailed notes from each site visit were drafted and sent back to the company to ensure that the information recorded was accurate. This process also enabled the company to add more detail and information to the study, where possible, and to confirm the level of confidentiality accorded to the information.

Due to the COVID-19 restrictions in place for the duration of this study, fewer physical site visits took place than for previous studies. Companies were furthermore reluctant to hold virtual site visits due to the confidential nature of the information to be shared.

### 7.2.5 Face-to-face meetings

It has not been possible to conduct face-to-face meetings for this study due to the ongoing COVID-19 pandemic. Greater emphasis has therefore been placed on the collection of information via phone calls and teleconferencing as well as extensive email conversations.

### 7.2.6 Working Party on Chemicals

To collect information and receive feedback, the study team presented to the Working Party on Chemicals as shown below.

*Table 7-2 Working Party on Chemicals presentations*

| Date | Subject, stakeholders and venue |
|---|---|
| 21-22 June 2021 | Working Party on Chemicals, online call |

The study team presented the following information for each of the substances under consideration:

- Limits being proposed.
- The fibres/compounds/substances of relevance
- The cancer and non-cancer endpoints of concern
- The limit options being assessed in the study
- The relevant sectors
- Estimates of numbers of exposed workers per sector
- Estimated current burden of disease
- Estimated future burden of disease
- Estimates of the costs and benefits
- Areas of uncertainty/information gaps.
- Preliminary conclusions.

During this meeting, information/comments were collected by the study team on any limitations identified in relation to the model, impacts on costs and benefits that may have been missed by the study team, as well as any overlap across the substances in terms of impacts.

## 7.3 Stakeholder groups targeted

The following table summarises information on stakeholder groups targeted and the interests represented. The table demonstrates that all relevant stakeholder groups have been approached.

*Table 7-3 Stakeholders targeted and interests represented*

| Stakeholder type | Interests represented |
|---|---|
| EU Associations | Interest of industry |
| Member State Authorities | Interest of Member State authorities |
| Manufacturers/users | Interest of industry |
| National industry associations | Interest of industry |
| Trade Unions | Interest of workers |
| Occupational Health & Safety Professionals | Contacted to obtain scientific information |
| Working Party on Chemicals (WPC) | Interests of industry, workers and Member State authorities |
| Laboratories | Contacted to obtain information on sampling and analysis |

## 7.4 Methodologies and tools to process data

The online questionnaires for this report were gathered using EUSurvey, which is a tool for creating questionnaire-based surveys. EUSurvey allows for control over the creation and design of the questionnaire, as well as having a system in place for the knowledge gathering process. The software allows for the distribution of questionnaires, primarily through email, but also via smartphone, enabling respondents easier and more flexible access to the surveys. The accessibility mode was also activated to enable the format to be adapted for those visually impaired.

A central stakeholder log was also created to allow for a complete overview of consultation activities based on mixed methods. The stakeholder log was used to create different statistics on the stakeholder consultation. The spreadsheet contained contact information, information on contact method, interviews completed, site visits and surveys completion.

The results of the online questionnaires could be downloaded in an Excel spreadsheet format, which allowed the experts to combine the information from the online survey with information obtained through telephone interviews and other means.

Experts responsible for each substance were provided with all the information relevant for their substance (questionnaire responses, interview minutes, site visit reports, position papers, etc.). All information was analysed by the specific substance expert and, where considered robust and relevant, used as the basis for the substance-specific analyses in conjunction with information obtained via desk-based research/literature reviews.

## 7.5 Results of consultation activities

### 7.5.1 Consultation statistics

#### 7.5.1.1 Questionnaires

As can be seen from the summary tables below, around 440 stakeholders were invited directly to respond to the online questionnaires. However, many more were reached indirectly via trade associations in every sector relevant to the specific substances. The key trade associations at EU and national level were identified for each sector and asked to forward the questionnaires to their members, thereby efficiently giving a large number of stakeholders the opportunity to respond.

As described previously, a key lesson learned from the CMD 3 and CMD 4 studies was that most responses came from companies where the questionnaire had been forwarded by trade associations encouraging them to respond. Efforts were therefore made during calls with industry associations to encourage them to forward the questionnaires to their members.

Three reminders were sent to those who had already been contacted but who had not responded. Any response received was recorded in an Excel spreadsheet.

The following tables provide summaries of responses according to stakeholder type and questionnaire.

*Table 7-4 Summary of numbers of stakeholders directly contacted by questionnaire.*

| Stakeholder type | Total number contacted |
|---|---|
| EU associations | 126 |
| National industry associations | 137 |
| International trade associations | 5 |
| Manufacturers/users | 37 |
| Member State authorities | 87 |
| Trade Unions | 1 |
| Occupational health & safety professionals | 38 |
| Total | 440 |

*Note: Questionnaires to manufacturers were mainly distributed via the EU associations and the actual number of companies contacted via the associations is not known.*

The next table provides an overview of the number of responses received to the questionnaire among those contacted. The table includes all questionnaires where the responder submitted their final and complete response. As can be seen, most of the responses were received from companies representing manufacturers/users: the stakeholder group where most requests were also made directly and via associations.

*Table 7-5 Breakdown of questionnaire responses per questionnaire*

| Stakeholder type | Number of full responses |
|---|---|
| Company questionnaire | 390 |
| Member State Authorities | 16 |
| Occupational Health & Safety Professionals | 13 |
| Total | 419 |

The following table provides a breakdown of the questionnaire responses from companies according to the type of substance (responses to the other two questionnaires addressed all three substances).

*Table 7-6 Breakdown of questionnaire responses per substance for the questionnaire for companies*

| Substance | Number of full responses |
|---|---|
| Asbestos | 108 |
| Lead and its compounds | 61 |
| Di-isocyanates | 221 |
| **Total** | **390** |

The following table provides a breakdown of questionnaire responses per company size. A relatively larger number of 'medium-sized' enterprises responded to the questionnaires compared to the other two size groups. A high number of responses for asbestos came from small companies, while a high number of responses for di-isocyanates came from medium-sized companies.

*Table 7-4 Breakdown of questionnaire responses per company size*

| Company size | Asbestos | Lead and its compounds | Di-isocya-nates | Total |
|---|---|---|---|---|
| Small enterprise (10-49 persons employed) | 63 | 7 | 45 | **115** |

| Company size | Asbestos | Lead and its compounds | Di-isocya-nates | Total |
|---|---|---|---|---|
| Medium-sized enter-prise (50-249 persons employed) | 33 | 28 | 119 | **180** |
| Large enterprise (250 or more persons em-ployed) | 12 | 26 | 57 | **95** |

#### 7.5.1.2 Interviews

Both the national experts and the substance-specific experts conducted interviews with relevant stakeholders. Some of the interviews were based on the responses to the questionnaire. The meeting notes were shared with the company after the interview, and that occasion was also used to ensure mutual agreement on the level of confidentiality needed and required. In some instances, the meeting notes consisted of a completed questionnaire.

Summaries of the number of interviews carried out are provided in the tables below.

*Table 7-7 Breakdown of interviews per stakeholder type*

| Stakeholder type | Interviews |
|---|---|
| EU Agency | 1 |
| EU Associations | 29 |
| Member State Authorities | 26 |
| Manufacturers/users | 23 |
| National industry associations | 8 |
| Trade Unions | 7 |
| Laboratories | 3 |
| **Total** | **97** |

*Table 7-8 Breakdown of interviews per substance and stakeholder type*

| Substance | EU Agencies | EU Associations | MS Authorities | Manufacturers/users | National industry associations | Trade unions | laboratories | Total |
|---|---|---|---|---|---|---|---|---|
| Asbestos | 1 | 11 | 22 | 12 | 6 | 6 | 3 | **61** |
| Lead and its compounds | 0 | 9 | 14 | 10 | 4 | 4 | 0 | **41** |
| Di-isocyanates | 0 | 9 | 13 | 3 | 2 | 4 | 0 | **31** |

*Notes: The number of interviews is higher than the total number of interviews presented in the previous table, since one interview might cover more than one substance*.

#### 7.5.1.3 Site visits (real or virtual)

In addition to interviews, stakeholders were also asked whether they would be willing to host a site visit, real or virtual. The aim of the site visit is to obtain a detailed operational understanding of the risk management measures that have already been implemented to protect workers from exposure to the relevant substances, as well as of the risk management measures that would be needed, and their associated costs should the limits be reduced. It also allowed for additional contextual information to be obtained on aspects such as the feasibility and ability of substituting a specific substance, whether specific site characteristics make the implementation of new equipment difficult, and specifics on how often workers are likely to be exposed (their work patterns).

The experts attending the virtual site visits were provided with site visit guides, detailing the information that was to be obtained, as well as information that had already been obtained via the questionnaires and/or interviews. Prior to the virtual site visits relevant questions are sent to the company. In one case, both a physical and a virtual site visit were conducted to obtain further detail from those who were unable to attend due to COVID-19 travel restrictions in place at the time.

A total of five site visits have been conducted as part of this study, plus two site visits conducted for lead and it compounds as part of a previous OELs study.

The following table provides a breakdown of the number of site visits relevant to each substance.

*Table 7-9 Number of site visits conducted per substance*

| Substance | Number of site visits confirmed |
|---|---|
| Asbestos | 1 |
| Lead and its compounds | 2* |
| Di-isocyanates | 4 |

*Note : *site visits for lead and its compounds were conducted under the previous OEL study*

#### 7.5.1.4 Other correspondence

**Asbestos.** For asbestos constructive conversations have been carried out via email with the following stakeholders:

- EDA – European Demolition Association
- Euromines
- Confederation of Danish Industry
- WKO - Wirtschaftskammer Österreich
- EIG (Employer Interest Group, WPC)
- EFBWW - European Federation of Building and Woodworkers
- ETUI
- Chrysotile Information Centre – Pakistan
- FEAD - European Waste Management Association

- Rhodar (asbestos removal company)
- International Environmental Research Foundation (IERF)
- AUVA - Allgemeinen Unfallversicherungsanstalt
- RB Asbestos Consultants
- PTJH Consulting Ltd (aerospace)
- Armco Asbestos Consultants
- TNO (NL)
- INRS (FR)
- STAMI (NO)
- Danish Maritime Authority

**Lead and its compounds**. For lead and its compounds, constructive conversations have been carried out via email with the following stakeholders:

- International Lead Association (ILA)
- ETUI
- European Foundry Association (CAEF)
- Glass alliance Europe
- Copper Alliance Europe
- Federation of European Explosives Manufacturers (FEEM)
- EFBWW - European Federation of Building and Woodworkers
- EDA – European Demolition Association
- Euromines
- Danish Industry
- Romania Health Institute INSP
- AUVA - Allgemeinen Unfallversicherungsanstalt Austria
- BG Bau Germany
- Company, Belgium
- Company, Austria
- Company, Bulgaria
- Company, several facilities within the EU
- Company, Slovenia
- German Non-ferrous metal industry association, VWMetalle

**Diisocyantes**. For di-isocyanates, constructive conversations have been carried out via email with the following stakeholders:

- ISOPA - European Diisocyanate and Polyol Producer`s Association
- ALIPA - European Aliphatic Isocyanates Producers Association
- FEICA - European voice of the adhesive and sealant industry
- CEPE - European Council of the Paint, Printing Ink and Artists‘ Colours Industry
- Europur - European association of flexible polyurethane foam blocks manufacturers
- Euro-moulders - European Association of Manufacturers of Moulded Polyurethane Parts for the Automotive Industry
- Flexible Packaging Europe
- ICOMIA - International Council of Marine Industry Associations
- BG Bau, Germany
- PU Europe - European voice of the polyurethane (PUR / PIR) insulation industry
- European Wood Panel Federation (EPF)
- Company, paints, UK
- Company, chemicals, Germany

#### 7.5.1.5 Summary of consultation statistics

The following tables provide breakdowns of the questionnaire responses, interviews and site visits carried out per stakeholder type, company size, and substance.

The breakdown of questionnaire responses, interviews and site visits stakeholder type are shown below. Most questionnaire responses were received from manufacturers/users, while most interviews were conducted with EU associations, Member State Authorities and manufacturers/users.

*Table 7-10 Breakdown of questionnaire responses, interviews and site visits per stakeholder type*

| Stakeholder type | Questionnaire responses | Interviews | Site visits provisional |
|---|---|---|---|
| EU Agency | | 1 | |
| EU Associations | - | 29 | - |
| Member State Authorities | 16 | 27 | - |
| Manufacturers/users | 390 | 23 | 7* |
| National industry associations | - | 8 | - |
| Trade Unions | - | 6 | - |
| Laboratories | 13 | 3 | - |

| Stakeholder type | Questionnaire responses | Interviews | Site visits provisional |
|---|---|---|---|
| **Total** | **419** | **97** | **7*** |
| **Two of these site visits were conducted under the previous OELs study for lead and its compounds* | | | |

The following table provides a breakdown of questionnaire responses, interviews and site visits conducted by company size. This data shows that most questionnaire responses and interviews were from medium-sized enterprises, while site visits tended to be with large enterprises.

*Table 7-11 Breakdown of questionnaire responses, interviews and site visits per company size (only for consulted companies) [to be completed as regards interviews and site visits]*

| Company size | Questionnaire responses | Interviews | Site visits |
|---|---|---|---|
| Small enterprise (10-49 persons employed) | 115 | 3 | 0 |
| Medium-sized enterprise (50-249 persons employed) | 180 | 11 | 1 |
| Large enterprise (250+ persons employed) | 95 | 9 | 6 |

The breakdown of questionnaire responses, interviews and site visits per substance are provided below. These results show that most questionnaire responses and site visits were provided in relation to diisocyanates, while most interviews were conducted for asbestos (although there is a relatively high response rate across all three substances).

*Table 7-12 Breakdown of questionnaire responses, interviews and site visits per substance (all stakeholders; companies, Member State authorities, trade associations, OSH (Occupational Safety and Health) specialists)*

| Substance | Questionnaire responses | Interviews | Site visits |
|---|---|---|---|
| Asbestos | 130 | 60 | 1 |
| Lead and its compounds | 84 | 41 | 2* |
| Di-isocyanates | 239 | 31 | 4 |

*Notes: *The site visits for lead and its compounds were conducted as part of the previous OELs study*

The breakdown of questionnaire responses, interviews and site visits per Member State are provided below. These results show a high number of questionnaire responses were received from France; many of these responses focused on asbestos and it is thought that the questionnaire had been more easily distributed by the authorities to the companies that have been certified to work with asbestos, due to the stricter certification scheme in France. These responses were not considered a campaign as the answers were deemed to be independent and representing a broad range of sectors and different regions in France.

*Table 7-13 Breakdown of questionnaire responses, interviews and site visits per Member State (all stakeholders; companies, Member State authorities, trade associations, OSH (Occupational Safety and Health) specialists)*

| Country | Questionnaire responses | Interviews | Site visits |
|---|---|---|---|
| **Inside the EU** | | | |
| EU | 1 | 28 | 0 |
| Austria | 5 | 4 | 0 |
| Belgium | 15 | 1 | 0 |
| Bulgaria | 1 | 2 | 0 |
| Croatia | 1 | 1 | 0 |
| Cyprus | 4 | 0 | 0 |
| Czechia | 6 | 2 | 0 |
| Denmark | 3 | 7 | 0 |
| Estonia | 2 | 2 | 0 |
| Finland | 4 | 3 | 0 |
| France | 134 | 6 | 0 |
| Germany | 88 | 5 | 2* |
| Greece | 3 | 0 | 0 |
| Hungary | 10 | 0 | 0 |
| Ireland | 2 | 4 | 0 |
| Italy | 31 | 0 | 0 |
| Latvia | 1 | 2 | 0 |

| Country | Question-naire re-sponses | Interviews | Site visits |
|---|---|---|---|
| Lithuania | 2 | 3 | 0 |
| Luxembourg | 1 | 0 | 0 |
| Malta | 0 | 0 | 0 |
| Netherlands | 14 | 2 | 0 |
| Poland | 15 | 2 | 0 |
| Portugal | 8 | 0 | 0 |
| Romania | 5 | 1 | 0 |
| Slovakia | 1 | 0 | 0 |
| Slovenia | 2 | 6 | 0 |
| Spain | 24 | 2 | 1 |
| Sweden | 8 | 0 | 0 |
| **Outside the EU** | | | 0 |
| Brazil | 2 | 0 | 0 |
| Norway | 1 | 0 | 0 |
| Pakistan | 1 | 0 | 0 |
| Switzerland | 1 | 0 | 0 |
| UK | 20 | 0 | 4 |
| UAE | 1 | 0 | 0 |
| USA | 1 | 0 | 0 |
| **Total** | **419** | **97** | **7** |

***The site visits for lead and its compounds were conducted as part of the previous OELs study*

### 7.5.2 Information on identified campaigns for public consultations

All consultation data was checked for campaigns prior to analysis, no campaigns were identified among the consultation activities.

It is recognised that there was a large number of French companies among respondents to the asbestos questionnaire. However, a detailed examination of the information provided shows differences between these responses and thus suggests that this was not a coordinated campaign.

### 7.5.3 Consultation results by substance

Specific information obtained from the stakeholder consultation on exposure levels, exposed workforce, applied RMMs, costs of compliance with reference OELs, etc. is included in the substance-specific reports.

### 7.5.4 How the information gathered has been taken into account

A large amount of information has been collected via consultation, particularly through means of the tailored online questionnaires, telephone interviews and email correspondence. Efforts have been made to contact a variety of relevant stakeholders in all of the Member States, for each of the relevant substances, from companies of varying sizes.

The information collected to date via consultation has enabled the study team to gain a more nuanced understanding of the likely impacts of modifying or introducing OELs, which could not have been obtained otherwise via desk-based research/literature reviews. Through the combination of desk-based research, questionnaire responses, interviews, and virtual site visits with key associations, it has been possible to compile a significant amount of detailed information in relation to the potential impacts of introducing the proposed measures under the CAD and AWD.

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