European Commission

# Third study on collecting most recent information for a certain number of substances with the view to analyse the health, socio-economic and environmental impacts in connection with possible amendments of Directive 2004/37/EC

(Ref: VC/2017/0011)

## Methodological note

FoBiG Forschungs- und Beratungsinstitut Gefahrstoffe GmbH

RPA Risk & Policy Analysts

COWI

EPRD Policy & Development

*February – 2018*

Social Europe

Luxembourg: Publications Office of the European Union, 2019

PDF 978-92-76-07995-8 doi:10.2767/48915 KE-02-19-403-EN-N

# Third study on collecting most recent information for a certain number of substances with the 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

## Methodological note accompanying the six substance-specific reports under Contract VC/2017/0011

**February 2018**

**Final Report**

| Quality Assurance | |
|---|---|
| **Project reference / title** | J967/DGEmp OELVs 3 |
| **Report status** | Final Report |
| **Main Authors** | Daniel Vencovsky (RPA), Dr Fritz Kalberlah, Meg Postle (RPA), Jan Oltmanns (FoBiG) |
| **Approved for issue by** | Meg Postle (RPA) |
| **Date of issue** | 8 February 2018 |

| Document Change Record | | | |
|---|---|---|---|
| **Report** | **Version** | **Date** | **Change details** |
| Draft Final Report | 1.0 | 3 January 2018 | |
| Final Report | 2.0 | 8 February 2018 | |

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**Acknowledgement**

*This study has received financial support from the European Union Programme for Employment and Social Innovation "EaSI" (2014-2020). For further information please consult: http://ec.europa.eu/social/easi*

This project is funded by
the European Union

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# 1 Introduction

## 1.1 Background

The Carcinogens and Mutagens Directive (Directive 2004/37/EC), hereinafter the CMD, aims to protect workers against health and safety risks from exposure to carcinogens or mutagens at work. To this end, it sets out the minimum requirements for protecting workers that are exposed to carcinogens and mutagens, including the so-called Binding Occupational Exposure Limit Values (OELVs)[1]. For each OELV, Member States are required to establish a corresponding national limit value (OEL), from which they can only deviate to a lower but not to a higher value.

## 1.2 Objectives

This report is one of eight 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.

## 1.3 Structure of the report

The report is organised as follows:

- Section 2 describes how the ERRs and DRRs were derived;
- Section 3 sets out the model used to monetise the savings from avoided ill health;
- Section 4 sets out the key features of the model for the assessment of the costs;
- Section 5 summarises the methods used for the review of the environmental impacts;
- Section 6 describes the consultation activities undertaken within the framework of this study;
- Section 7 summarises the review of the REACH Chemical Safety Reports (CSRs); and
- Section 8 provides a comparison of this study and a report recently completed by RPA & FoBiG for ETUI (2017).

Annex I presents examples of the questionnaires and interview questions.

[1] See http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=URISERV:c11137

# 2 Derivation of the ERRs and DRRs

## 2.1 Introduction

In this project, we provide criteria to select an occupational exposure limit (OEL) for specific substances, which considers the estimated *health impact to workers*. Therefore, we need a methodology for this estimation of "health impact", where this term may be defined as the number of persons ("cases"), either suffering from cancer and/or experiencing some other noncancer health effects due to this occupational exposure.

This methodology section deals with the principles of this estimation procedure. We associate a specific excess cancer risk and a specific threat for noncancer effects to each of potential alternative OELs. From this and knowing the actual/predicted exposure for each substance and each exposure scenario, a cost/ benefit analysis can be based on quantitative information on health impact for any finally selected OEL.

The resulting information to be used for health impact analysis at different potential OELs is defined as:

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

The respective methodology to derive ERRs (or to apply given ERRs) und to derive DRRs is outlined below.

The following restrictions should be borne in mind.

Existing toxicological and epidemiological data in regulatory toxicology usually have not been generated and prepared to provide impact information for multiple health effects for *any* exposure level simulataneously. Very 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 is set and no "cases" of health impairment are assumed, if the OEL is observed.

More precisely, some dose response data or exposure risk relationship data are, in fact, considered by the respective assessors, but those are usually only provided for a different exposure scenario (not current workplace exposure scenarios) and, quite often, only exist for experimental animal study data. In the course of extrapolating to the relevant occupational worker's scenario, such existing dose response data are usually not equally transformed and adapted to the target scenario. If only the derived OEL is safe, the assessor achieved the requested result and he rarely discusses, what is happening at levels well above that OEL. For example, if the toxicologist finds respiratory irritation in an animal study as the critical (lowest) adverse effect and he also finds neurotoxicity and immunological impairments at an, e.g., ten times higher level of exposure in that study, he will only work with the respiratory irritation effects further on to derive the OEL, with only qualitative consideration of the neurotoxic and immunological effects "somewhere" above. The dose response curve for the animal experiment for respiratory irritation is not systematically transformed in a DRR for the sensitive worker at exposure levels beyond the established OEL.

Because of these restrictions, the methodology below does not strive to quantify the aggregated health impact for all cancer risks at all potential cancer sites and for all noncancer effects with may occur simultaneously at different exposure levels. Instead, because of the limited quantitative information and limited scientific consensus on adequate dose response input data, we rather restrict to a proxy calculation, which has to acklowledged to deviate from the "true" health impact.

In conclusion:

- we only apply the ERR on the most critical cancer site, which is given by the assessment of SCOEL (or ECHA/RAC) and only comment qualitatively on further cancer sites, which may be linked to exposure to the respective substance;
- we only refer to the most critical non-cancer effect quantitatively to derive a DRR, usually, the effect, which is also regarded as critical by SCOEL and only comment qualitatively on further non-cancer effects, which may be linked to exposure to the respective substance; and
- as there is even less scientific consensus on the increase of effect severety 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.

It may be easily seen from these restrictions that the calculated health impact (e.g., in terms of "number of estimated cases with health impairments") is not identical to the "real" health impact, but is just an approximation, which often may underestimate the full impact of the occupational exposure to the respective substances. However, as shown in the sensitivity analyses, there are also uncertainties leading to overestimates. In addition, there exist systematic problems to calculate correct "number of cases" for multiple health effects, as there may be many individuals, which will suffer from more of one health effect due to occupational exposure simulataneously; therefore, an additivity assumption for the number of cases would not be correct (significant overestimate). It is assumed that the resulting figures do not lead to a systematic bias for the final selection of a higher or lower OELV.

## 2.2 Methods to derive the ERR

In this project, the starting point for a cancer risk impact assessment assessment is the OEL and the most recent substance evaluation by SCOEL. However,

- For (genotoxic) carcinogens with associated stochastically cancer risk, SCOEL does not fix an OEL (based on excess cancer risk), but only reports cancer risk estimates. In some assessments, SCOEL evaluates the various existing cancer risk estimates and selects the most qualified estimate for further consideration, but again, without fixing a specific risk level to set an OEL;

- For non-genotoxic carcinogens or substances with a health based threshold, SCOEL derives an IOEL as a point estimate, but usually provides no information on the slope of the ERR "above threshold";

- For an impact analysis on health consequences of elevated exposure, it is necessary:

    - to describe the exposure risk relationship (ERR) for (non genotoxic) carcinogens above threshold;

    - to select the most suitable ERR for genotoxic carcinogens, if not provided by SCOEL.

### 2.2.1 General approaches

For carcinogens, frequently no OELs are derived if the carcinogen is regarded a genotoxic compound without a threshold for carcinogenicity. In this case, usually the classification as a carcinogen (according to CLP, IARC, or national cancer classification system) is reported. For some substances, SCOEL also reports excess risk levels, linked to various potential exposure levels (e.g., 1:1000; 1:10,000; 1:100,000 or 4:1000 to 4:100,000).

Three situations can be discriminated:

1. SCOEL presents a clear recommendation on the excess risk at various exposure levels, e.g. as a "unit risk", i.e. excess risk per µg/m³ for a realistic range of potential exposure levels;
2. SCOEL presents various excess risk quantifications, without deciding which one to use for further impact analysis; and
3. SCOEL does not provide information on excess cancer risk at different exposure levels.

Situation 1 is the simplest one: in this project the excess risk estimate by SCOEL is adopted without change and is used as ERR further on. Possibly, a range of exposures has to be additionally documented, for which this ERR is applicable (with possible non-linearities outside of this range).

In Situation 2 (various risk quantifications by SCOEL) it is first determined whether ECHA/RAC assessed the same substance and selected a specific excess risk quantification as the most suitable one. In this case, the ECHA/RAC selection is adopted and used for ERR, again, with a possible specification of an exposure applicability domain. If no priority for a specific ERR can be derived from either SCOEL or ECHA/RAC, assessments of European member states on this substance would be next in priority and, thus, would be adopted based on the assessment best in accordance to the SCOEL opinion and based on the most recent data background. This procedure is also followed, if no SCOEL excess cancer risk data are provided (Sitation 3).

Some European member states (but also, e.g., Japan) use ERRs to derive OELs based on acceptability. In this case, a certain excess risk level, e.g., 4:1000, is associated with national "acceptability" agreements, e.g., the "tolerable risk level" in Germany is set at 4:1000 excess risk. However, this "acceptability criterion" is not adopted in this methodology, but the ERR used can be selected. As an example, Germany provides a methodology to approximate a sublinear exposure risk relationship as ERR (AGS 2008[2] & AGS 2013[3])(AGS, 2013)(AGS, 2008; 2013)(AGS, 2008; 2013)(AGS, 2008; 2013), which could be considered, if no ERR is available from SCOEL and if compatible with the respective mode of action.

Priority (First option: SCOEL; ECHA/RAC; Second option: member state) can be changed, if epidemiological data have been reported by SCOEL for ERR quantification in case a substance which is classified Carc. Cat. 1B (i.e. usually based on animal data with insufficient evidence from

[2] AGS, Ausschuss für Gefahrstoffe (2008): Leitfaden zur Quantifizierung von Krebsrisikozahlen bei Exposition gegenüber krebserzeugenden Gefahrstoffen für die Grenzwertsetzung am Arbeitsplatz, Arbeitskreis Risikoableitung im Unterausschuss „Gefahrstoffbewertung" (UA III) des Ausschusses für Gefahrstoffe (AGS). Bundesanstalt für Arbeitsschutz und Arbeitsmedizin, Dortmund/Berlin/Dresden. http://www.baua.de/de/Publikationen/Fachbeitraege/Gd34.pdf?__blob=publicationFile&v=5

[3] AGS, Ausschuss für Gefahrstoffe (2013): Leitfaden zur Quantifizierung stoffspezifischer Expositions-Risiko-Beziehungen und von Risikokonzentrationen bei Exposition gegenüber krebserzeugenden Gefahrstoffen am Arbeitsplatz, (Anlage 3 zu TRGS 910). Version N10, Stand: 15.09.2013, Ausarbeitung durch den Arbeitskreis Risikoableitung im UA III des AGS. http://www.baua.de/de/Themen-von-A-Z/Gefahrstoffe/TRGS/TRGS-910.html

epidemiological data). In such a case, risk quantifications would be preferred, which fit to the classification (generally, for Carc.Cat 1B: animal data; for Carc.Cat. 1A: human data). However, the selection has to be justified.

These considerations can be supplemented by using other excess risk quantifications, if the range, for which the ERR is given by RAC/SCOEL/MS, does not cover realistic exposure concentrations to be addressed below or above this range. Justification for such "extensions" of a defined area of validity has to be provided.

Within the framework of this project it is avoided to calculate excess cancer risk directly from "Odds Ratios" (OR) or "Standard Mortality Rates" (SMR) or similar figures from an epidemiological study or directly from animal cancer incidence data.

If the ERR is not already provided for a working lifetime exposure scenario, the respective transformation has to be calculated: working life time is assumed to be 40 years, with work day exposure for 8 hours/day, 5 day/week in 48 weeks of a year. It is a conservative estimate based on the most critical cancer site (cancer risk associated with highest risk). Usually only one cancer site is considered. For discussion of associated uncertainties, see Section 2.1.

### 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 – sometimes even after 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. as this information is rarely available with sufficient details (e.g., distribution data of latency within population are usually not available),.

However, it should be noted that time to tumour and latency influences the point in time in future, when reductions of exposure will be effective in reducing 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 OELV is set this year or later in future, may need some assumptions about latency. These latency assumptions are more general defaults, not covered by the ERR/DRR methodology.

For simplicity it is assumed that tumour induction is linearily linked to exposure duration, which is, in reality only true for carcionogens with strictly accumulating risks. Even then, no strict linearity will be observed: some very short exposure duration may not be sufficient to developd tumours at all. In the other hand, few exposure years may already be decisive to result in an identical excess tumour risk as if one is exposed all over his occupational lifetime. However, correlation of exposure duration with tumour risk is substance specific and not further considered within this project due to the complexity of assumptions neseccary for subsequent impact calculations.

### 2.2.3 ERR for threshold- carcinogens

For carcinogens with a "practical threshold" (Bolt and Huici-Montagud, 2008)[4] SCOEL usually does not provide data on the "exposure risk relationship" or the "excess risk" to be assumed above threshold. If this information is not available unambiguously from the SCOEL recommendation or opinion document, the procedure presented above for carcinogens (Section 2.2.1) is followed, but limited to the range above the (practical) threshold (with zero excess risk at or below this cancer threshold). Note that in a recent discussion from ECHA/RAC and SCOEL, there may be changes in the interpretation of the "practical threshold" in terms of risk quantification (ECHA/RAC-SCOEL, 2017) (ECHA/RAC-SCOEL, 2017)[5].DRR

Existing OELs for non-cancer endpoints or for threshold-type carcinogens are usually adopted from SCOEL. However, exposure at national workplaces in Europe may be above this OEL (e.g., if the national OEL is higher than the values by SCOEL). Therefore, a DRR is decribed for a broader range of potential exposure levels. Note that the terminology is not precise for this description of a function: in fact, a "concentration response relationship" is derived with exposure given as a concentration in air (mg/m³). However, the term DRR is maintained as a convention.

For threshold-carcinogens we maintain the terminology of "exposure risk relationship" (ERR) above threshold, even though the stochastic events in genesis of cancer may not be the key mode of action.

To derive a DRR, usually the non-cancer endpoint regarded the most critical by SCOEL, is selected. Data from original toxicological studies, referenced by SCOEL, ECHA/RAC or national committees as being qualified and demonstrating a dose-response, are selected and searched for effect levels linked to a different 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. However,

- different levels of "severity" are not discriminated for reasons of feasibility,
- a change of the critical effect at higher exposure levels (with a potential different slope in dose response) is not considered, and similarly,
- multiple effects occurring in parallel are not considered.

Therefore, the DRR does not cover all potential adverse effects above threshold (and, thus, systematically underestimates impact at high exposure levels). However, increases in severity, potential multiple effects or the change of the leading critical toxicity endpoint at such high exposure levels are described qualitatively.

With these restrictions in mind, the default approach is applied as follows:

- The selected OEL (mostly from SCOEL) is used to define a zero response, i.e., 0 % of the exposed are assumed to suffer from the respective health effect, if exposed for all of their working life time to this OEL-air-concentration.

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[4] Bolt & Huici-Montagud (2008): Strategy of the scientific committee on occupational exposure limits (SCOEL) in the derivation of occupational exposure limits for carcinogens and mutagens, Archives of Toxicology, 82, 61-64

[5] ECHA/RAC-SCOEL (2017): ECHA/RAC-SCOEL Joint Task Force Report. Scientific aspects and methodologies related to the exposure of chemicals at the workplace. Final Version – 28 February 2017 https://echa.europa.eu/documents/10162/13579/rac_joint_scoel_opinion_en.pdf/58265b74-7177-caf7-2937-c7c520768216

- A three times higher concentration (3 x OEL) is usually assumed to correspond to a 10% incidence. This factor 3 is taken from the usual "LOAEC to NOAEC" – default and the corresponding increased incidence of affected persons.
- Further extrapolations to higher concentrations are avoided, if not supported by substance specific data.

Again, before study incidence and exposure data are used to derive a DRR, those have to be adapted to the standard workplace, if used for the impact assessment. Starting from animal data and no transformation available from SCOEL or national committees, such extrapolations are performed according to ECHA- procedural guidance (ECHA 2012[6]) and according to the methodology by SCOEL. The scenario usually is transformed accordingly (i.e. chronic exposure for 8hrs/day, 5 days/week, elevated activity compared to the resting animal).

Substance specific data are preferred to default approaches.

As the threshold for non-cancer effects can be higher or lower than the OEL derived for cancer effects, the starting point for the DRR may be different from the starting point for ERR. Depending on data availability the range, for which a DRR is defined may differ from the range for ERR. As the focus of the impact assessment in this project is on carcinogenicity, the DRR and respective impact on non-cancer effects is regarded as supplemental information. (Bolt und Huici-Montagud, 2008)

[6] ECHA, European Chemicals Agency (2012): Guidance on Information Requirements and Chemical Safety Assessment. Chapter R.8: Characterisation of dose [concentration]-response for human health. Version 2.1, November 2012, http://echa.europa.eu/documents/10162/17224/information_requirements_r8_en.pdf

# 3 Monetisation of the Health Impacts

## 3.1 Introduction

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

The ERRs and DRRs;

- The numbers of workers exposed;
- The exposure concentrations (the average concentrations [Arithmetic Mean or Geometric Mean] are taken as the basis for calculations); and
- Trends in the exposed workforce and exposure concentrations.

For some chemical agents, two scenarios were estimated:

- A: actual exposure concentrations – data on exposure concentrations collected, estimated, etc.; and
- O: exposure concentrations estimated on the basis of existing OELs – this scenario typically assumes that companies have achieved concentrations at 50% of the national OEL.

For some chemical agents, there are sufficient data to show that companies have achieved substantially lower exposure concentrations than demanded by the OELs and, consequently, the O scenario has not been modelled.

### 3.1.1 Cost categories considered

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

**Table 3-1: BR Toolbox on social impacts**

| Aspect | Guidance |
|---|---|
| Health impacts | Direct impacts<br>Indirect impacts: does the option influence the socio-economic environment that can determine health status?<br>*To assess direct and indirect health impacts monetary and non-monetary methodologies can be used.*<br>Non-monetary approaches: QALYs, DALYs, HLYs,<br>Monetary approaches: preference-based approaches (WTP, 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) |

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, that arise directly as a result of cancer, for example those related with care and the costs to employers. Healthcare costs are those associated with the treatment and services patients receive, including the cost of hospitalisation, surgery, physician visits, radiation therapy and chemotherapy/ immunotherapy. Depending on the structure of national

health care provision, these costs may be borne fully or partially by the government (tax payers). Direct medical costs associated with cancer vary significantly by cancer type and also vary over time. Indeed, it has been noted that cancer costs are highest in the initial period following diagnosis and, among patients who die from their disease, at the end of life; they are lowest in the period between the initial and end of life periods, following a "u-shaped" curve (Yaboriff et al., 2012)[7]. 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. Employers might also bear costs indirectly through *inter alia* loss of output; payments related to sick leave; administrative costs related to a worker's absence; additional recruitment costs; loss of experience/expertise; overtime working; compensation payments (although this may be covered by some form of employer's liability insurance); and insurance premiums. 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.

In economic impact terms, the total social costs[8] of ill health are the measured by the costs borne for health care provision, together with lost output (including productivity losses), gross wage and non-wage labour costs of absent workers (such as loss of experience), administrative costs and the intangible costs. These represent the direct and indirect resource costs and the non-market 'external' costs of illness. The other costs listed above (e.g. insurance premiums) relate to what are commonly referred to as 'transfer payments', which do not give rise to net welfare effects. As a result, they are not considered in economic analyses, even though they may be important in financial terms to an individual worker or an employer.

### 3.1.2 The model

The endpoints for which the benefits (i.e. changes in the costs caused by ill health) have been estimated are summarised in the table overleaf.

[7] Yabroff KR et al. (2012): Economic burden of cancer in the US: Estimates, projections and future research, Cancer Epidemiology Biomarkers & Prevention, 20 (20) pp 2006-2014, available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3191884/

[8] From a welfare economic perspective.

| Table 3-2: Relevant endpoints | | |
|---|---|---|
| **Chemical agent** | **Cancer endpoint** | **Non-cancer endpoint** |
| As | Lung cancer | Peripheral neuropathy |
| Be | Lung cancer (but no workers above threshold) | Chronic Beryllium Disease (CBD) |
| Cd | Lung cancer | Increased proteinurea |
| Cr(VI) | Lung cancer | - |
| CH2O | Nasopharyngeal cancer | Sensory irritation |
| MOCA | Lung cancer | - |

The key model inputs are summarised below. The inputs are those parameters whose variation changes the results and for which the model is run multiple times to derive a benefits curve.

| Table 3-3: Key model inputs | |
|---|---|
| **Parameter** | **Explanation** |
| **Rx: Estimate of the risk or fraction of workers affected** | Exposure-Risk Relationship (ERR) or Dose-Response Relationship (DRR) |
| **ExW: Exposed workforce** | Number of workers exposed at different points in time |
| **Cx: Exposure concentration** | 8-hr TWA that the workers are exposed to (real concentration, i.e. if PPE is currently worn, the measured concentrations are adjusted to take into account PPE where possible) |

In addition to the inputs, the model is underpinned by a range of default assumptions regarding the onset of the disease and its effects. These assumptions differ by chemical agent but do not change depending on the variations in the input data. Some of these assumptions are a simplification of complex real life scenarios or best estimates (where authoritative evidence could not be identified from readily available literature).

The key areas in which assumptions had to be made to enable the calculations are set out below.

| Table 3-4: Key assumptions and their consequences for the sensitivity analysis | |
|---|---|
| **Parameter** | **Explanation** |
| ***Onset of the disease*** | |
| **MinEx** | The minimum exposure duration required to develop the endpoint |
| **MaxEx** | The time required for all workers at risk to develop the endpoint |
| **ModEx** | The modelled exposure duration (the ERRs and DRRs are for a 40 year period) |
| **Lat** | The latency with which the effect is demonstrated |
| **Dist** | The distribution of cases over the period between MinEx and 40 years |
| ***The effects of the disease*** | |
| **Mortality** | Mortality rate as a result of the relevant condition |
| **Value of a case** | Monetary value of a case taking into account the direct, indirect, and intangible costs |

The model provides a good 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 60 year assessment period;
- The Present Value (PV) of the direct, indirect, and intangible costs of each case.

## 3.2 Inputs

### 3.2.1 Rx: estimate of the risk or fraction of workers affected

The estimate of the risk or fraction of workers affected:

- For cancer: Exposure-Risk-Relationship (ERR) i.e. excess risk of developing cancer due to lifetime occupational exposure to a chemical agent (taken here to mean 40 years); and
- 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.

### 3.2.2 ExW: exposed workforce

Several scenarios are modelled for the exposed workforce. It is possible to take into account all the complexities of real life workforce changes within the framework of this study and these scenarios are theoretical constructs/simplifications which are designed to provide order of magnitude estimates without the need to construct a very large number of scenarios to cover all the types of workforce dynamics.

Two distinct issues are covered under the term 'turnover'. Primarily, turnover refers to the natural turnover rate resulting from workers leaving their employer and new workers joining. In addition, it can refer to the turnover triggered by those that absent from work due to illness and replaced by others.

The scenarios are:

- **ExW-Constant:** workforce remains unchanged over 40 years (the same individuals, no replacement of workers afflicted by ill health), the whole workforce is replaced in year 41 with these individuals remaining in the exposed workforce over the next 40 years. This scenario does not take into account either the natural turnover of workers changing jobs or the turnover due to the ill health caused by exposure to the relevant chemical agents.

  Assuming a no changing workforce has no impact on the results on the assumption that a reduction in exposure time does not? decrease cancer risk (e.g. the risk for 36 years of exposure is 36/40 x the risk for 40 years) and any exposure (even very short exposures of 2 or 4 years) does not? leads to a proportional cancer risk (quantifiable by linear transformation, e.g. risk for 40 years x 4/40 for 4 years) since risk x 40 years = 36/40 + 4/40 = 1. In other words, it means that the estimated number of cases will be the same whether a given workforce is ex-posed over 40 years to two groups of workers are exposed each for 20 years. Although this may not be the case in reality, it is used here as the most direct approximation of the exposed workforce.

- **ExW-Turnover**: This assumes that there is a turnover of 5% per year (although this is lower than the turnover ratios in the published literature and Eurostat, which are typically derived at the level of individual companies rather than sectors, 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). This means that the whole workforce is replaced every 20 years and no worker is exposed for the full 40 year period (this is modelled here as a group of workers being exposed for a 20 year period, followed by another group of workers exposed over the subsequent 20 years). This increases the number of cases for non-cancer endpoints. The turnover caused by treatment or early retirement due to the conditions considered in this report has not been modelled.

The two scenarios (ExW-Constant and Ex-Turnover) are summarised below. As it can be seen, it results in two bounds, a lower bound linked to the ExW Constant and an upper bound linked to ExW Turnover.

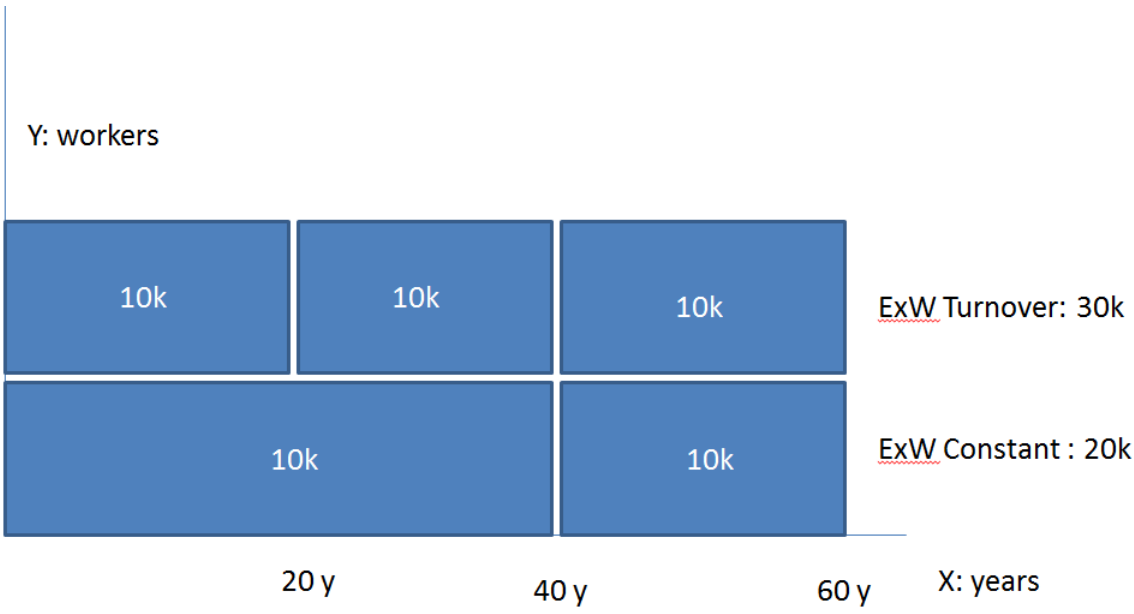


**Figure 3-1: ExW-Constant and Ex-Turnover**

A third ExW scenario is modelled within the framework of the sensitivity analysis which assumes standard turnover rates based on Eurostat resulting in an increase in the exposed workforce and, consequently, ill health by a factor of 4.6.

### 3.2.3 Exposure concentrations

Two scenarios have been modelled:

- ACTUAL (A) with data sourced from literature and consultation – this is the core scenario for cost-benefit calculations; and
- OEL (O) where exposure concentrations are assumed to be 50% of the national OEL – this is used as a check of the order of magnitude of scenario (A).

## 3.3 Assumptions

### 3.3.1 Onset of the disease

***MinEx & MaxEx The minimum & maximum exposure duration required to develop the endpoint***

The model assumes that no cases arise until the minimum exposure duration required to develop the endpoint (MinEx) has expired, see table below. The default MinEx is two years for cancer, a standard assumption for a chronic condition, and 0 years for non-cancer endpoints. Although data on minimum exposure periods are lacking and the data in the table below are generic estimates, a short MinEx has been chosen wherever appropriate. The minimum exposure periods in table below have been derived using a precautionary approach that maximises worker protection. The MaxEx reflect the time required for all workers at risk to develop the endpoint.

| Table 3-5: Minimum & maximum exposure duration to develop a condition (MinEx & MaxEx) | | |
|---|---|---|
| **Endpoint** | **MinEx (years)** | **MaxEx (years)** |
| Cancer | 2 | 40 |
| Non-cancer endpoint default | 1 | 2 |
| Renal disease | 1 | 20 |
| Chronic beryllium disease (CBD) | 1 | 2 |
| Sensory irritation | 1 day | 1 day |
| Peripheral neuropathy | 1 | 2 |

The ERRs and DRRs are for a 40 year period. This is not to say that there is a need for 40 years of exposure to get cancer, in some cases it may be sufficient to be exposed for two years to some agents whilst in other cases 40 years of exposure would be needed.

***Dist The distribution of cases between start of exposure and Year 40***

Valuing the cost of occupational illness involves applying discounted costs to future cases which requires that the estimated cases over a 40 year period are assigned to specific years. However, the ERRs and DRRs developed under this study are for 40 years of exposure.

'Dist' refers to the distribution of cases between start of exposure and Year 40, also taking MinEx into account. This differs between endpoints. The main difference is between cancer and non-cancer endpoints; more information is provided below for each health endpoint.

Cancer

For reasons of simplicity, the following approach is used to distribute the total 40-year cancer **risk** (i.e. not incidence but risk since incidence is delayed due to latency) over the 40 year period:

> It is assumed that no risk arises until MinEx has expired. It is assumed that, subsequently, the distribution is linear, i.e. 0% of the excess risk arises in year 2 and 100% of the excess risk arises by year 40.

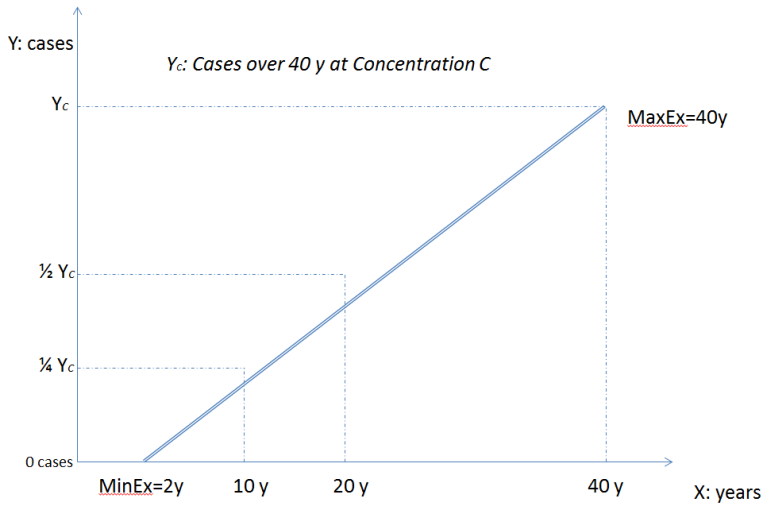


**Figure 3-2: Lung cancer risk – distribution over time**

Default for non-cancer endpoints including CBD

Typically, the fraction affected achieves that predicted by the DRR as soon as MaxEx expires and remains constant over the 40 year period (although the certainty of the 'fraction' estimated on the basis of the DRR increases towards the end of the period). As a default assumption, two years has been chosen as a conservative MaxEx and it is assumed that there will not be further increases of non-cancer effects from longer duration after MaxEx. The fraction affected that is calculated on the basis of the DRR is the same between 2 years and 40 years and increases in a linear manner between Year 0 and Year 2.

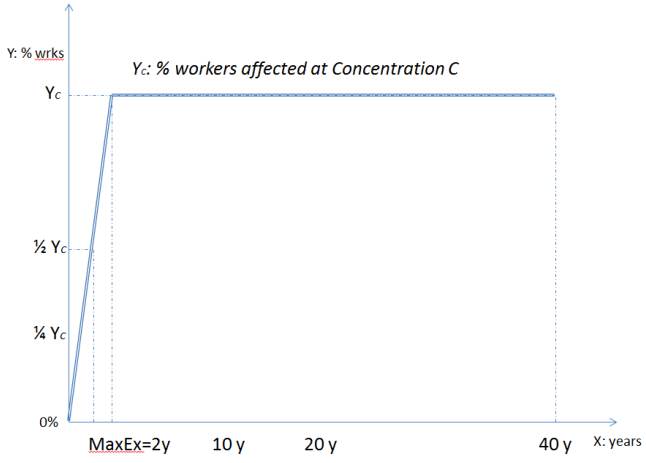


**Figure 3-3: Non-cancer endpoints – fraction affected over time**

$CH_2O$: Sensory irritation

An example is provided below for sensory irritation ($CH_2O$). The DRR only tells us that the fraction affected = 2% (1 day), 2% (1 year), 2% 20 years, 2% (40 years). Workers may be affected after a few hours.

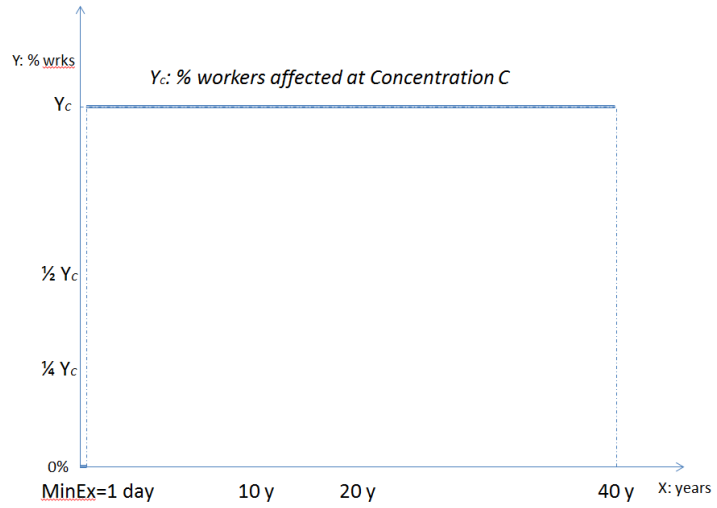


**Figure 3-4: $CH_2O$ & sensory irritation**

Cd: kidney disease

Although the default for non-cancer effects is 2 years and then a constant fraction of workers affected until Year 40, the time typically needed for renal damage is longer than 2 years, e.g. 20 years. The distribution is expected to be largely linear [affected fraction (for 10 years of exposure) = affected fraction (for 40 years of exposure) x (10/ 20)].

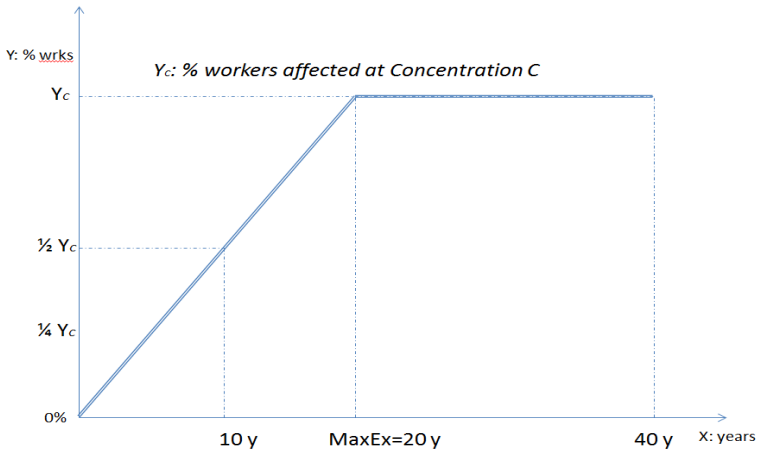


**Figure 3-5: Kidney damage – fraction affected over time**

***Lat Latency***

**MinEx and Dist are then combined with Lat to estimate the specific year of diagnosis of a case.**

Cancer

By way of simplification, a single latency value is used for the calculation of the core scenario. 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.

40 years of exposure and 30 years of latency would translate into a 70 year assessment period. However, in order for the assessment to be protective to workers (longer latency reduces the benefits since they are discounted at lower factors) and to ensure consistency with previous Impact Assessments for the first and the second wave of new OELs under the CMD[9] which relied on an assessment period of 60 years, a latency period of 10 years is used in this study.

A 10 year assessment period means that all cases of cancer that develop on the basis of the risk over the 40 year period will be diagnosed and treated[10] within the assessment period of 60 years. This is shown graphically below.

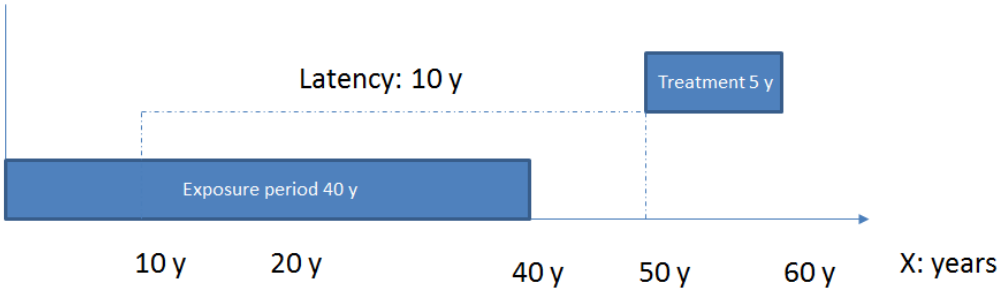


**Figure 3-6: The assessment period**

Non-cancer endpoints

The estimated latency period for the non-cancer endpoints in this study is either 0 years or 2 years. There is very 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 3-6: Latency (Lat)**

| Endpoint | Lat (years) |
|---|---|
| Renal disease | 0 |
| Chronic beryllium disease (CBD) | 2 |
| Sensory irritation | 0 |
| Peripheral neuropathy | 0 |

***ModEx The modelled exposure duration***

The ERRs and DRRs are for a 40 year period. The modelled exposure duration is thus 40 years under the ExW-Constant scenario and 20 years under the ExW-Turnover scenario.

[9] These relied on a 60 year assessment period. http://ec.europa.eu/transparency/regdoc/rep/10102/2016/EN/SWD-2016-152-F1-EN-MAIN-PART-1.PDF, p. 20 and http://ec.europa.eu/transparency/regdoc/rep/10102/2017/EN/SWD-2017-7-F1-EN-MAIN-PART-1.PDF, p. 30

[10] The treatment period for cancer used in the model is five years.

Whilst it is unlikely that a single worker is exposed to a chemical agent at a constant concentration throughout their whole working life, the 40 year period has been chosen in order to be protective to workers by assuming a worst-case scenario. In addition, the evidence used for the development of the ERR means that the greatest certainty about the ERR is at lifetime exposure, i.e. 40 years.

It is highly likely that the real exposure duration is shorter than ModEx (the modelled exposure duration). This could have the following consequences:

- For cancer endpoints, it is expected that the impact on the model results is limited since the relationship between risk and exposure is linear after MinEx

- For non-cancer endpoints, this is expected to result in an underestimation of the number of workers affected (where staff turnover is not taken into account). This underestimation could, theoretically, be most severe in the case of formaldehyde (MinEx=1 day) but the monetary value for sensory irritation chosen for this study negates this underestimation by monetising each case as a long-lasting effect.

### 3.3.2 The effects of the disease

***Mortality rate (MoR)***

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.

**Table 3-7: Mortality rate (MoR)**

| Endpoint | MoR (years) |
|---|---|
| Cancer - lung | 80% |
| Cancer - nasopharynx | 47% |
| End-stage renal disease | 40%[11] |
| Chronic beryllium disease (CBD) | 10% |
| Sensory irritation | 0% |
| Peripheral neuropathy | 0%[12] |

***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.

[11] Average for dialysis and transplant patients, see http://www.lkdn.org/dialysis_life_expectency/KidneyDialysisLifeExpectancy.pdf

[12] Very few forms of peripheral neuropathy are fatal, see https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Peripheral-Neuropathy-Fact-Sheet

| Table 3-8: Treatment period | |
|---|---|
| **Endpoint** | **Treatment period (years)** |
| Cancer | 5 |
| Non-cancer endpoint default | 30 |
| Renal disease | 30 |
| Chronic beryllium disease (CBD) | 30 |
| Sensory irritation | No treatment required in most cases but where treatment required modelled as 1 year |
| Peripheral neuropathy | 30 |

***Monetary value of the relevant endpoint***

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

| Table 3-9: Benefits framework | | |
|---|---|---|
| **Category** | **Cost** | **Notes** |
| Direct | Healthcare | Cost of medical treatment, including hospitalisation, surgery, consultations, radiation therapy, chemotherapy/immunotherapy, etc. |
| | Informal care[13] | 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 (e.g. liability insurance) | 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 | |

If all of these costs were summed up, these would be some double-counting, e.g. healthcare is partly financed by employers' insurance contributions and some elements of 'lost working days' could be included in the WTP for morbidity, etc.

However, all 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.

- Approach 1: Application of a single WTP value to each case; and
- Approach 2: Use of DALYs (Disability-Adjusted Life Year) and their monetisation.

[13] 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 benefits as generated by this study.

*Benefits to workers & 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's 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.

Approach 1 is summarised below.

**Table 3-10: Approach 1 & cancer**

***WTP for avoided mortality and morbidity (VSL and VCM)***

**Value of statistical life:** With regard to the value of a statistical life, the figure adopted is **€4,100,000**. This is consistent with the approach that was applied in the first two OELV studies for DG Employment, and will ensure consistency with the assessments carried out for those studies. In this respect, it is important to note that these figures are assumed to reflect not only an individual's willingness to pay to avoid the risk of death by cancer, but also the value of their lost income/lost output. It does not, however, capture the costs of medical treatment.

**Non-fatal cancers:** Not all cancers will lead to death and it will therefore be important to also include the willingness to pay of individuals' to avoid a case of non-fatal cancer. In this case, willingness to pay will reflect an individual's value to avoid the pain and suffering experienced from the illness; it is less clear, and may vary on a case by case basis, whether such valuations also capture the value of lost income/lost output. The available literature offers a broad range of estimates for the willingness to pay to avoid a non-fatal cancer. Again, value of **€420,000** (2016 figures) has been adopted as the willingness to pay to avoid a non-fatal case of cancer based on the BR Toolbox 2017 tool #31, and to be consistent with the previous two OELV studies for DG Employment.

**Non-cancer endpoints:**

No WTP values have been identified in the literature for the non-cancer endpoints considered in this study and proxies or study team estimates have been used, e.g. elevated proteinurea: €2,000 per non-fatal case, see Cadmium report for details.

Approach 2 is summarised below.

| Table 3-11: Approach 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.<br><br>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.<br><br>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:<br><br>$$DALY = YLD + YLL$$<br><br>YLD, which stands for Years Lived with Disability, is calculated as follows:<br><br>$$YLD = Number\ of\ cases * Average\ disease\ duration * Disability\ weight$$<br><br>YLL, which stand for Years of Life Lost due to premature death, is calculated as:<br><br>$$YLL = Number\ of\ deaths * Life\ expectancy\ at\ age\ of\ death\ in\ years$$ |

Average life expectancy at age of death

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.

Average disease duration (AvDiDu)

The average disease duration (AvDiDu) is given below.

**Table 3-12: Average disease duration**

| Endpoint | Disease duration (years) |
|---|---|
| Cancer | 5 |
| Non-cancer endpoint default | 30 |
| Renal damage | 30 |
| Chronic beryllium disease | 30 |
| Sensory irritation | 30* |
| Peripheral neuropathy | 30 |
| Note: * This is not the disease duration but it used as the basis for cost calculations | |

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[14]. This study builds on the GBD study with the aim of developing a set of weights specific to Europe.

[14] 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

For this study, the disability weights derived in the EBD are used for cancer as these are most relevant to the European population. Disability weights have been collated for eleven different types of cancer but no weight is available for NFC. Different weights have been attributed to different stages of the cancer in the study: operable; inoperable; primary; disseminated; terminal; and hormone refractory cancer.

| Table 3-13: Disability weights collated in European Burden of Disease study (2015) | | |
|---|---|---|
| **Type of cancer** | **Stage of disease** | **Disability Weight** |
| Lung | Operable | 0.265 |
| | Inoperable | 0.358 |
| | Disseminated | 0.515 |
| CBD (COPD[15]) | - | 0.2[16] |
| Elevated proteinuria | - | 0.15[17] |
| Sensory irritation | - | 0.1[18] |
| Peripheral neuropathy | | 0.01 to 0.05* |
| Source: 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<br>* Estimated using data from above source. | | |

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 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.

| Table 3-14: Valuing a DALY |
|---|
| ***Valuing a DALY*** |

[15] As data for CBD are rare, useful proxies are sarcoidosis and chronic obstructive pulmonary disease (COPD). COPD is largely caused by smoking and is characterised by progressive, partially reversible airflow obstruction, systemic manifestations (skeletal muscle dysfunction, depression, and secondary polycythaemia), and increasing frequency and severity of exacerbations. The main symptoms—usually insidious in onset and progressive—are shortness of breath and inability to tolerate physical activity (McIvor, 2007). McIvor A, Little P. (2007) Chronic Obstructive Pulmonary Disease. BMJ 334; 798

[16] Estimated from utility values for severe and very severe COPD (mean utility value 0.7). Estimated disability weight for a severe case of CBD is 0.3, adjusted down to 0.2 to reflect a range of severities captured in this report. Source of utility values: NICE (2016). Single technology appraisal: Roflumilast for treating chronic obstructive pulmonary disease (review of technology appraisal guidance 244) Committee papers. https://www.nice.org.uk/guidance/ta461/documents/committee-papers

[17] Estimated from the average of all utility values reported in NICE TA418 for complications relating to diabetes, including nephropathy and kidney failure (includes proteinuria and microalbuminuria. Source: NICE (2016). Single technology appraisal. Dapagliflozin in triple therapy regimens for treating type 2 diabetes. Committee papers. https://www.nice.org.uk/guidance/ta418/documents/committee-papers

[18] A disability weight of 0.1 has been used in the calculations. This is a conservative estimate based on conditions that may be reflective of more severe espisodes of sensory irritation, as defined in the European Burden of Disease Report (Haagsma, 2015): COPD and other chronic respiratory problems, mild: 0.025, COPD and other chronic respiratory problems, moderate: 0.284.

| Table 3-14: 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).<br><br>From the brief review conducted, there are several valuations for DALYs presented in the literature. For example, Stassen et al. (2007)[19] estimate that the cost of a DALY for severe morbidity health effects is €87,000. According to a website about persistent organic pollutants[20], 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)[21] 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. |

**The value of a DALY used in this study is €100,000 in €2017.**

*Benefits to employers*

The benefits of introducing OELVs have obvious benefits for workers, namely in terms of their health but also, indirectly, on their earnings. Employers will also reap benefits from their employees being less at risk of occupational illness. Such benefits include:

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

A study commissioned by DG Employment (2011)[22] considers the socio-economic costs of accidents and ill-health relating to work and the benefits 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 **€11,660**. 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

[19] 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

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

[21] 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

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

and the chemical sector, though the numbers of cases linked to the latter were limited and this should be borne in mind when applying this estimate to the benefits of introducing OELVs.

Another reason for caution in interpreting this result is that 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 occupational cancer.

HSE (2016) was able to develop estimates of the costs borne by employers.[23] For the UK, they estimated that around 3% of total costs to society were borne by employers, with this equating to a cost of roughly €17 per worker per annum. Multiplying it across the EU-28 worker population (aged 15 to 64) gives a total figure of €4.13 billion in costs to employers associated with the costs of production disturbance, sickness payments due to worker absence and legal obligations with regard to employers' liability insurance. This figure does of course reflect requirements in the UK which may be more or less onerous than those that apply in other Member States. However, it provides an indication of significance of these costs.

Many cancers have latency periods of between 10 and 50 years. As a result, most individuals diagnosed with occupational exposure-related cancer (estimated at over 70%) will have left work by the time they are diagnosed, or may have changed jobs. The relevant employer during the period of exposure is therefore unlikely to bear the costs of disruption from sickness absence, paying sick pay, etc. As noted by the UK HSE, this estimate is also an under-estimate as it fails to capture some costs to employers that may be significant, such as those associated with the loss of expertise, and reductions in productivity of those returning to work after successful cancer treatment. Reputational damage (which can impact on sales and recruitment) is also not included.

*Benefits to 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 for treatment as well as days off due to illness. Luengo-Fernandez et al (2013) 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 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 (i.e. €4 million and €400,000 respectively) 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.

Given the magnitude of the WTP value adopted here for cancer mortality, €4.1m, the decision has been taken not to include an additional element for lost income for mortality effects. However, due to uncertainty as to what may be captured by the value adopted here for cancer morbidity, lost income due to lost working days is considered within this analysis.

This inclusion may result in an overestimation of the economic costs associated with cancer morbidity. However, the exclusion of lost output for cancer mortalities may also lead to an underestimation if

[23] UK HSE (2016): Costs to Britain of Work Related Cancer, Research Report 1074, available at: http://www.hse.gov.uk/research/rrhtm/rr1074.htm

these are not fully accounted for within the value of a statistical life figure used here to reflect the intangible or human costs of a cancer.

*Benefits to 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 €2017 as approximately €7,000).

| Table 3-15: Estimates of the annual healthcare costs per cancer patient | |
|---|---|
| **Cancer** | **Healthcare costs (€)** |
| Prostate | €4,027 |
| Lung | €6,952 |
| Breast | €4,378 |
| Colorectal | €5,037 |
| All cancers | €6,047 |
| Source: Luengo-Fernandez, R. et al (2013): Economic burden of cancer across the European Union: a population-based cost analysis; Lancet Oncology; 14: 1165–74, published online October 14: http://dx.doi.org/10.1016/S1470-2045(13)70442-X | |

Chronic Beryllium Disease (CBD)

Chronic beryllium disease (CBD) predominantly affects the lungs and can lead to severe disability or death (Harber, 2009)[24]. As data for CBD are scarce, a useful proxy may be sarcoidosis (which has very similar presentation to CBD) or chronic obstructive pulmonary disease (COPD). COPD is largely caused by smoking and is characterised by progressive, partially reversible airflow obstruction, systemic manifestations (skeletal muscle dysfunction, depression, and secondary polycythaemia), and increasing frequency and severity of exacerbations. The main symptoms—usually insidious in onset and progressive—are shortness of breath and inability to tolerate physical activity (McIvor, 2007)[25].

First-line therapy for CBD is usually oral corticosteroids, with other agents, such as methotrexate, used as steroid sparing therapy. Corticosteroids have numerous side-effects, but improve symptoms, chest radiographs and lung function. Some patients respond initially, while others worsen.

Treatment for CBD is the same as that for sarcoidosis (UCSF Medical Center, not dated[26]):

- Prednisone is the immunosuppressive drug most commonly prescribed for CBD
- Oxygen therapy – used as disease progresses
- Lung transplant – in severe cases

The following sources were reviewed for cost data on sarcoidosis/granulomatous disease:

- UK NHS Reference costs 2015/16
- Unit costs of health and social care

[24] Harber P, Bansal S, Balmes, J (2009). Progression from Beryllium Exposure to Chronic Beryllium Disease: An Analytic Model. Environ Health Perspect 117; 970–4

[25] McIvor A, Little P. (2007) Chronic Obstructive Pulmonary Disease. BMJ 334; 798

[26] UCSF Medical Center. Chronic Beryllium Disease treatment. https://www.ucsfhealth.org/conditions/chronic_beryllium_disease/treatment.html

Reference costs are used to set prices for NHS-funded services in England. They give the national average unit costs derived from the average unit costs of NHS provider in a given financial year. Providers cost reference costs on a full absorption basis, which means that all the running costs of providing these services are included within the submission. Each reported unit cost includes (DoH, 2016[27]):

- Direct costs - relating directly to the delivery of patient care, e.g. medical staffing costs;
- Indirect costs - indirectly related to the delivery of care, but cannot always be specifically identified to individual patients, e.g. catering and linen; and
- Overhead costs - costs of support services that contribute to the effective running of the organisation, and that cannot be easily attributed to patients, e.g. payroll services.

As such, the UK NHS Reference costs 2015/16 can provide a comprehensive estimate of the costs associated with the treatment of the different conditions.

| Table 3-16: NHS UK reference costs for sarcoidosis/granulomatous disease | |
|---|---|
| **Description** | **Unit cost** |
| Granulomatous, Allergic Alveolitis or Autoimmune Lung Disease, with Interventions | €5,100 |
| Granulomatous, Allergic Alveolitis or Autoimmune Lung Disease, without Interventions, with CC Score 5+ | €2,300 |
| Granulomatous, Allergic Alveolitis or Autoimmune Lung Disease, without Interventions, with CC Score 2-4 | €1,100 |
| Granulomatous, Allergic Alveolitis or Autoimmune Lung Disease, without Interventions, with CC Score 0-1 | €700 |
| Lung Transplant | €36,900 |
| ***Average*** | ***€9,000*** |
| ***Average excl. lung transplant*** | ***€1,000**** |
| *Source: UK NHS Reference costs 2015/16* (UK Department of Health , 2016)<br>*Notes: * It is recognised that some of the costs included in the average of unit treatment costs for sarcoidosis/granulomatous disease are one-off costs (lung transplant). A value of €1,000 is taken reflecting the fact that both lung transplants and severe cases of chronic beryllium are rare.* | |

Chronic Kidney Disease (CKD)

The UK NHS Reference costs 2015/16 for CKD are summarised below.

| Table 3-17: NHS UK reference costs for CKD | |
|---|---|
| **Description** | **Unit cost** |
| Chronic Kidney Disease with Interventions, with CC Score 6+ | €8,239 |
| Chronic Kidney Disease with Interventions, with CC Score 3-5 | €5,626 |
| Chronic Kidney Disease with Interventions, with CC Score 0-2 | €4,338 |
| Chronic Kidney Disease without Interventions, with CC Score 11+ | €3,766 |
| Chronic Kidney Disease without Interventions, with CC Score 8-10 | €3,183 |
| Chronic Kidney Disease without Interventions, with CC Score 5-7 | €2,444 |
| Chronic Kidney Disease without Interventions, with CC Score 3-4 | €1,814 |
| Chronic Kidney Disease without Interventions, with CC Score 0-2 | €1,202 |
| General Renal Disorders with Interventions, with CC Score 6+ | €7,294 |
| General Renal Disorders with Interventions, with CC Score 3-5 | €5,012 |
| General Renal Disorders with Interventions, with CC Score 0-2 | €3,534 |
| General Renal Disorders without Interventions, with CC Score 9+ | €3,242 |

[27] Department of Health (2016). Reference costs 2016. https://www.gov.uk/government/publications/nhs-reference-costs-2015-to-2016

| Table 3-17: NHS UK reference costs for CKD | |
|---|---|
| **Description** | **Unit cost** |
| General Renal Disorders without Interventions, with CC Score 6-8 | €2,436 |
| General Renal Disorders without Interventions, with CC Score 3-5 | €1,670 |
| General Renal Disorders without Interventions, with CC Score 0-2 | €937 |
| ***Average*** | ***€3,600*** |

Sensory irritation

No data are available and €100 per year has been used as an order of magnitude estimate for an average case, taking into account that many cases estimated in this study will require no treatment.

### 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 3-18: Unit costs**

| | Cost | Lung cancer | Nasopharyngeal cancer | CBD | Elevated proteinurea | Sensory irritation | Peripheral neuropathy |
|---|---|---|---|---|---|---|---|
| Direct | Healthcare | €7,000 /year | | € 1,000 /year | CKD: €3,600 /year | €200 /year | €100 /year €1,000 per case |
| | Informal care | €3,000 /year | | €3,000 /year* | €1,500 /year* | €100 /year* | No direct cost estimated |
| | Cost for employers | €12,000 /case | | | | €0 | No direct cost estimated |
| Indirect | Mortality – productivity loss | €5,000 /year | | | | | No effect |
| | Morbidity – lost working days | €1,000 /year | | € 300 /year** | € 500 /year** | € 100 /year** | €1,000 /year** |
| Intangible | Approach 1 WTP: Mortality | €4,100,000 /case | | | | | |
| | Approach 1 WTP: Morbidity | €420,000 /case | | €20,000 /case | €2,000 /case | €500 /case | €3,600 /year |
| | Approach 2 DALY: Morbidity | Value of a DALY: €100,000 | | | | | |

* Estimated as proportional to healthcare costs: 3/7 ratio based on cancer healthcare and informal care costs.
** Estimated as proportional to healthcare costs: 1/7 ratio based on the costs of cancer healthcare and lost working days.

## 3.4 Summary of assumptions – core scenario

### 3.4.1 Cancer effects

***Lung cancer***

| Table 3-19: Lung cancer | |
|---|---|
| **Parameter** | **Core scenario - assumptions** |
| Risk estimate or fraction affected | ERR – number of cases |
| MinEx | 2 |
| MaxEx | 40 |
| ModEx | 40 |
| Lat | 10 |
| Dist | Linear between MinEx and MaxEx |
| Mortality | 80% |
| Duration of a chronic case/treatment | 5 |

***Nasopharyngeal cancer (NFC)***

| Table 3-20: NFC | |
|---|---|
| **Parameter** | **Core scenario - assumptions** |
| Risk estimate or fraction affected | ERR – number of cases |
| MinEx | 2 |
| MaxEx | 40 |
| ModEx | 40 |
| Lat | 10 |
| Dist | Linear between MinEx and MaxEx |
| Mortality | 47% |
| Duration of a chronic case/treatment | 5 |

### 3.4.2 Non-cancer endpoints

***Chronic beryllium disease***

| Table 3-21: CBD | |
|---|---|
| **Parameter** | **Core scenario - assumptions** |
| Risk estimate or fraction affected | DRR – fraction affected |
| MinEx | 1 |
| MaxEx | 2 |
| ModEx | 40 |
| Lat | 2 |
| Dist | Linear between MinEx and MaxEx |
| Mortality | 10% |
| Duration of a chronic case/treatment | 30 |

***Elevated proteinurea***

| Table 3-22: Elevated proteinurea | |
|---|---|
| **Parameter** | **Core scenario - assumptions** |
| Risk estimate or fraction affected | DRR – fraction affected |
| MinEx | 2 |
| MaxEx | 2 |
| ModEx | 40 |
| Lat | 2 |
| Dist | Linear between MinEx and MaxEx |
| Mortality | 2.5% |
| Duration of a chronic case/treatment | 30 |

***Sensory irritation***

There is no typical case of sensory irritation – this endpoint covers a range of effects, the data presented here are just for the purposes of monetisation in this study.

| Table 3-23: Sensory irritation | |
|---|---|
| **Parameter** | **Core scenario - assumptions** |
| Risk estimate or fraction affected | DRR – fraction affected |
| MinEx | 1 day |
| MaxEx | 1 day |
| ModEx | 40 |
| Lat | 0 |
| Dist | Constant throughout ModEx |
| Mortality | 0% |
| Duration of a chronic case/treatment | Unknown but modelled here as 40 years to account for recurring cases |

***Peripheral neuropathy***

| Table 3-24: Peripheral neuropathy | |
|---|---|
| **Parameter** | **Core scenario - assumptions** |
| Risk estimate or fraction affected | DRR – fraction affected |
| MinEx | 0 |
| MaxEx | 20 |
| ModEx | 40 |
| Lat | 0 |
| Dist | Linear between MinEx and MaxEx |
| Mortality | 0% |
| Duration of a chronic case | 30 |

## 3.5 Bringing it all together

The benefits that have been estimated for each chemical agent are summarised below.

| Table 3-25: Costs considered | | |
|---|---|---|
| **Category** | **Code** | **Cost** |
| 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 |

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

*Method 1: Ctotal= Ch+Ci+Cp+Cvsl+Cvsm*

*Method 2: Ctotal= Ch+Ci+Cp+Cl+Cdaly*

*Ce* is not considered in the totals under both Method 1 and 2 to avoid double-counting. *Cl* is not considered under Method 1 since *Cvsl* may already include these costs.

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

| Table 3-26: 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+Cl+Cdaly* |
| Governments | Ch, part of Cp (loss of tax revenue), part of Cl (loss of tax revenue) | *CtotalGov=Ch+0.2(Cp+Cl)*[28] |
| Employers | Ce, Cp | *CtotalEmployer=Ce+0.8*Cp* |

[28] Assumes 20% tax.

# 4 The Cost Model

## 4.1 Introduction

The spreadsheet model calculates the cost of reducing exposure from one level to another, with the resulting sums being used to plot a cost curve. The model t calculates the costs for a group of similar companies incurred in reducing air exposure to a target OEL based on an assumed sequence of RMM implementation which is determined by suitability, effectiveness, and cost. The model is run several times to construct a continuous cost curve.

## 4.2 Key model inputs and assumptions

### 4.2.1 95$^{th}$ percentile

All costs are calculated on the basis of compliance as the 95$^{th}$ percentile of the exposure concentrations. This reflects the fact that it is expected that companies may be asked to demonstrate compliance on this basis rather than on the basis of the average of the samples taken.

### 4.2.2 Discount rate

The static discount rate is 4%: this is taken over the 60 year period. A dynamic discount rate is taken in the sensitivity analysis. The dynamic rates start at 4% for the first 20 years; it then decreases to 3% for the remaining 40 years.

### 4.2.3 Affected workers and workstations

Each company size was assumed to have an average number of workers affected and associated workstations requiring adjustment, shown on Table 5-7.

**Table 4-1: Number of workers and workstations**

| Size of company | Number of workers affected by beryllium | Number of workstation |
|---|---|---|
| Small | 2 | 1 |
| Medium | 7 | 4 |
| Large | 30 | 16 |

Three different costs, all present values for 60 years, are calculated: TOTAL, (CAPEX + OPEX) CAPEX, and OPEX.

### 4.2.4 RMMs considered

The model considers following types of RMMs:

- 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: RMM levels | |
|---|---|
| DI | Discontinuation |
| SU | Substitution |
| RWK | Rework/redesign of the production process |
| LEV3 | Full enclosure |
| LEV2 | Partial enclosure |
| LEV1 | Open hood |
| LEV0 | No LEV |
| WE2 | Pressurised or sealed worker enclosure |
| WE1 | Simple enclosed cabin |
| WE0 | No worker enclosure |
| RPE3 | Breathing apparatus |
| RPE2 | HEPA filter |
| RPE1 | Simple mask |
| RPE0 | No mask |
| OH1 | Organisational & hygiene measures |
| OH0 | No organisational & hygiene measures |
| GDV1 | General dilution ventilation |
| GDV0 | No general ventilation |

### 4.2.5 RMM effectiveness

Every RMM has a different level of effectiveness in reducing the workers exposure to beryllium. 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 RMM | |
|---|---|
| **Type of RMM** | **% reduction in exposure** |
| Discontinuation & Substitution | 100% |
| Rework | 50% |
| Full enclosure | 99.5% |
| Partial enclosure | 90% |
| Open hood | 80% |
| No LEV | 0% |
| Pressurised or sealed | 99.5% |
| Simple enclosed cab | 80% |
| No enclosure | 0% |
| Breathing apparatus | 99.5% |
| HEPA filter | 95% |
| Simple mask | 60% |
| No mask | 0% |
| Organisational measures | 30% |
| No organisational measures | 0% |
| General dilution ventilation | 30% |
| No general ventilation | 0% |

### 4.2.6 RMM costs

Costs have been estimated by company size band.

**Table 4-4: RMM unit costs**

| RMM | CAPEX | OPEX | 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) (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) (most likely electricity, maintenance & repairs, compensation air, heating) | |
| WE2: Pressurised or sealed cabin | Assumed the same as LEV 2 | Assumed the same as LEV2 | Assumed the same as LEV2 |
| 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 CAPEX | Assumed 2 years |
| RPE 2: Mask with HEPA filters | 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>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 CAPEX | Mask: 1 month, Filter: 30 hours |
| RPE 1: Simple mask | 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 CAPEX 2017 incurred every year | |
| OH1: Organisational & hygienic measures | Some data provided through consultation for Cd (ICdA), also consistent with IOM (2012) | Some data provided through consultation for Cd (ICdA) | Only incurred once |

| Table 4-4: RMM unit costs | | | |
|---|---|---|---|
| **RMM** | **CAPEX** | **OPEX** | **Lifespan** |
| | A large range of measures with different costs<br><br>Assumed €1,000 per worker | Zeynep et al (2008): Training annual instructor cost €540<br><br>A large range of measures with different costs<br><br>Assumed 50% | |
| GDV1: General dilution ventilation | Hakimian et al (2015): €22 per cfm 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: Sm: 300 cfm, Me: 2,000 cfm, La: 5,000 cfm | Hakimian (2015): Approx. 30% of CAPEX<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 machines in the different size bands.

| 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 | CAPEX 2017 | Lifespan years | OPEX (% of CAPEX) | CAPEX 2017 | Lifespan years | OPEX (% of CAPEX) | CAPEX 2017 | Lifespan years | OPEX (% of CAPEX) |
| 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 | 10% | 90,000 | 20 | 10% | 260,000 | 20 | 10% |
| RPE 3: Breathing apparatus | 2,600 | 2 | 1,000% | 35,000 | 2 | 1,000% | 100,000 | 2 | 1,000% |
| RPE2: HEPA filter | 300 | Mask: 1 month, Filter: 1 month | 50% | 4,000 | Mask: 1 month, Filter: 1 month | 50% | 11,000 | Mask: 1 month, Filter: 1 month | 50% |
| RPE 1: Simple mask | 500 | Not relevant, 1 per day | Not relevant but CAPEX 2017 incurred every year | 7,000 | Not relevant, 1 per day | Not relevant but CAPEX 2017 incurred every year | 20,000 | Not relevant, 1 per day | Not relevant but CAPEX 2017 incurred every year |
| OH 1: Organisational measures | 2,000 | | 50% | 27,000 | | 50% | 75,000 | | 50% |
| GDV 1: General dilution ventilation | 6,000 | 20 | 30% | 40,000 | 20 | 30% | 100,000 | 20 | 30% |
| *Source: RPA* | | | | | | | | | |

### 4.2.7 Sectoral characteristics that determine suitability of RMMs

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 chemical agent. 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 cause exposure to workers beyond the area where the substance is being worked. This means that administrators, managers and sales staff may be exposed.

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 amount of exposure, form of the substance and extent of spread**

| Type of RMM | <1h | >1h | Dust | Gas | Local | Diffuse | Peripheral |
|---|---|---|---|---|---|---|---|
| Discontinuation & 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 |
| Open hood | Y | Y | Y | Y | Y | Y | Y |
| No LEV | Y | Y | Y | Y | Y | Y | Y |
| Pressurised or sealed | N | Y | Y | Y | N | Y | Y |
| Simple enclosed cab | N | Y | Y | Y | N | Y | Y |
| No enclosure | Y | Y | Y | Y | Y | Y | Y |
| Breathing apparatus | Y | N | Y | Y | Y | Y | Y |
| HEPA filter | Y | N | Y | Y | Y | Y | Y |
| Simple mask | Y | N | Y | Y | Y | Y | Y |
| No mask | Y | Y | Y | Y | Y | Y | Y |
| Organisational measures | Y | Y | Y | N | Y | Y | Y |
| No organisational measures | Y | Y | Y | Y | Y | Y | Y |
| General dilution ventilation | N | Y | N | Y | N | Y | Y |

| Table 4-6: Suitability of various RMMs to amount of exposure, form of the substance and extent of spread | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Type of RMM** | **<1h** | **>1h** | **Dust** | **Gas** | **Local** | **Diffuse** | **Peripheral** |
| No general ventilation | Y | Y | Y | Y | Y | Y | Y |

## 4.3 How does the 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 total cost of reduction is then calculated as a sum of all company-level decisions.

## 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 on the basis of data for several Member States.

| Table 4-7: Cost of sampling and analysis - Denmark | | | |
|---|---|---|---|
| **Unit costs of analysis** | | | |
| | Cost analysis, EUR (Denmark) included Sample media | Standard | **Type** |
| Arsenic | 185 | ISO 15202 | Metal |
| Beryllium | 185 | ISO 15202 | Metal |
| Cadmium | 185 | ISO 15202 | Metal |
| Chromium (VI) | 185 | ISO 16740 | Metal |
| Formaldehyde | 217 | ISO 16000-3 | Fume |
| MOCA | 560 | Eurofins, Internally developed method | Dust |

| **Units costs of planning, sampling and reporting** | | | |
|---|---|---|---|
| | **Number** | **Unit** | |
| **Planning** (independent of number of workplaces) | 6 | man-hours | |
| **Sampling:** | | | |
| Sampling basic costs per day incl. first workplace | 9 | man-hours | |
| Time per workplaces in addition to first workplace the same day | 1 | man-hours | |
| Number of workplaces one person can sample a day | 5 | man-hours | |
| **Reporting:** | | | |
| Reporting independent of number of workplaces | 5 | man-hours | |

**Table 4-7: Cost of sampling and analysis - Denmark**

| | | | |
|---|---|---|---|
| Additional reporting per workplace | 0.25 | man-hours | |
| **Salary** | 120 | EUR/man-hour | Denmark |
| **Rent of pump:** | | | |
| Rent of pump first day | 80 | EUR/workplace | Denmark |
| Rent of pump subsequent days | 40 | EUR/workplace | Denmark |

| **Planned programme** | | | |
|---|---|---|---|
| Substance | Formaldehyde | | |
| Number of workplaces | 17 | | |
| Activity | Units | Unit costs, EUR | Total costs, EUR |
| Planning, man-hours | 6 | 120 | 720 |
| Execution, man-hours | 49 | 120 | 5,880 |
| Reporting, man-hours | 9.3 | 120 | 1,110 |
| Rent of equipment, first day | 5 | 80 | 400 |
| Rent of equipment, subsequent days | 12 | 40 | 480 |
| Analysis | 17 | 217 | 3,689 |
| Total costs | | | 12,279 |
| | **Analysis in percentage of total costs** | | **30%** |

**Table 4-8: Cost of sampling and analysis - UK**

| **Unit costs of analysis** | | | |
|---|---|---|---|
| | Cost analysis, GBP (UK) included Sample media | Standard | **Type** |
| Arsenic | 185.0 | ISO 15202 | Metal |
| Beryllium | 185.0 | ISO 15202 | Metal |
| Cadmium | 185.0 | ISO 15202 | Metal |
| Chromium (VI) | 185.0 | ISO 16740 | Metal |
| Formaldehyde | 217.0 | ISO 16000-3 | Fume |
| MOCA | 560.0 | | Dust |

| **Units costs of planning, sampling and reporting** | | | |
|---|---|---|---|
| | **Number** | **Unit** | |
| **Planning** (independent of number of workplaces) | 8 | man-hours | |
| **Sampling:** | | | |

**Table 4-8: Cost of sampling and analysis - UK**

| | | | |
|---|---|---|---|
| Sampling basic costs per day incl. first workplace | 9 | man-hours | |
| Time per workplaces in addition to first workplace the same day | 1 | man-hours | |
| Number of workplaces one person can sample a day | 5 | man-hours | |
| **Reporting:** | | | |
| Reporting independent of number of workplaces | 5 | man-hours | |
| Additional reporting per workplace | 0.25 | man-hours | |
| **Salary** | 103.7 | GBP/man-hour | UK |
| **Rent of pump:** | | | |
| Rent of pump first day | 0 | GBP/workplace | Included in cost of hiring consultant |
| Rent of pump subsequent days | 0 | GBP/workplace | Included in cost of hiring consultant |

| **Planned programme** | | | |
|---|---|---|---|
| Substance | Arsenic | | |
| Number of workplaces | 17 | | |
| Activity | Units | Unit costs, GBP | Total costs, GBP |
| Planning, man-hours | 8 | 103.7 | 830 |
| Execution, man-hours | 49 | 103.7 | 5,082 |
| Reporting, man-hours | 9.3 | 103.7 | 959 |
| Rent of equipment, first day | 5 | 0 | - |
| Rent of equipment, subsequent days | 12 | 0 | - |
| Analysis | 17 | 185 | 3,145 |
| Total costs | | | 10,016 |
| | **Analysis in percentage of total costs** | | **31%** |

**Table 4-9: Cost of sampling and analysis - Greece**

| **Unit costs of analysis** | | | |
|---|---|---|---|
| | Cost analysis, EUR (EL) included Sample media | Standard | **Type** |
| Arsenic | 185 | ISO 15202 | Metal |
| Beryllium | 185 | ISO 15202 | Metal |
| Cadmium | 185 | ISO 15202 | Metal |
| Chromium (VI) | 185 | ISO 16740 | Metal |
| Formaldehyde | 217 | ISO 16000-3 | Fume |
| MOCA | 560 | | Dust |

| **Units costs of planning, sampling and reporting** | | | |
|---|---|---|---|
| | **Number** | **Unit** | |

**Table 4-9: Cost of sampling and analysis - Greece**

| | | | |
|---|---|---|---|
| **Planning** (independent of number of workplaces) | 8 | man-hours | |
| **Sampling:** | | | |
| Sampling basic costs per day incl. first workplace | 9 | man-hours | |
| Time per workplaces in addition to first workplace the same day | 1 | man-hours | |
| Number of workplaces one person can sample a day | 5 | man-hours | |
| **Reporting:** | | | |
| Reporting independent of number of workplaces | 5 | man-hours | |
| Additional reporting per workplace | 0.25 | man-hours | |
| **Salary** | 39.0 | EUR/man-hour | |
| **Rent of pump:** | | | |
| Rent of pump first day | 0 | EUR/work place | Included in cost of hiring consultant |
| Rent of pump subsequent days | 0 | EUR/work place | Included in cost of hiring consultant |

| **Planned programme** | | | |
|---|---|---|---|
| Substance | Arsenic | | |
| Number of workplaces | 17 | | |
| Activity | Units | Unit costs, EUR | Total costs, EUR |
| Planning, man-hours | 8 | 39.0 | 312 |
| Execution, man-hours | 49 | 39.0 | 1,911 |
| Reporting, man-hours | 9.3 | 39.0 | 361 |
| Rent of equipment, first day | 5 | 0 | - |
| Rent of equipment, subsequent days | 12 | 0 | - |
| Analysis | 17 | 185 | 3,145 |
| Total costs | | | 5,729 |
| | **Analysis in percentage of total costs** | | **55%** |

**Table 4-10: Cost of sampling and analysis - Lithuania**

| **Unit costs of analysis** | | | |
|---|---|---|---|
| | Cost analysis, EUR (LT) included Sample media | Standard | **Type** |
| Arsenic | 185 | ISO 15202 | Metal |
| Beryllium | 185 | ISO 15202 | Metal |
| Cadmium | 185 | ISO 15202 | Metal |
| Chromium (VI) | 185 | ISO 16740 | Metal |
| Formaldehyde | 217 | ISO 16000-3 | Fume |
| MOCA | 560 | | Dust |

**Table 4-10: Cost of sampling and analysis - Lithuania**

| **Units costs of planning, sampling and reporting** | | | |
|---|---|---|---|
| | **Number** | **Unit** | |
| **Planning** (independent of number of workplaces) | 8 | man-hours | |
| **Sampling:** | | | |
| Sampling basic costs per day incl. first workplace | 9 | man-hours | |
| Time per workplaces in addition to first workplace the same day | 1 | man-hours | |
| Number of workplaces one person can sample a day | 5 | man-hours | |
| **Reporting:** | | | |
| Reporting independent of number of workplaces | 5 | man-hours | |
| Additional reporting per workplace | 0.25 | man-hours | |
| **Salary** | 17.0 | EUR/man-hour | |
| **Rent of pump:** | | | |
| Rent of pump first day | 0 | EUR/work place | Included in cost of hiring consultant |
| Rent of pump subsequent days | 0 | EUR/work place | Included in cost of hiring consultant |

| **Planned programme** | | | |
|---|---|---|---|
| Substance | Arsenic | | |
| Number of workplaces | 17 | | |
| Activity | Units | Unit costs, EUR | Total costs, EUR |
| Planning, man-hours | 8 | 17.0 | 136 |
| Execution, man-hours | 49 | 17.0 | 833 |
| Reporting, man-hours | 9.3 | 17.0 | 157 |
| Rent of equipment, first day | 5 | 0 | - |
| Rent of equipment, subsequent days | 12 | 0 | - |
| Analysis | 17 | 185 | 3,145 |
| Total costs | | | 4,271 |
| | **Analysis in percentage of total costs** | | **74%** |

**Table 4-11: Cost of sampling and analysis - Poland**

| **Unit costs of analysis** | | | |
|---|---|---|---|
| | Cost analysis, EUR (PL) included Sample media | Standard | **Type** |
| Arsenic | 185 | ISO 15202 | Metal |
| Beryllium | 185 | ISO 15202 | Metal |
| Cadmium | 185 | ISO 15202 | Metal |
| Chromium (VI) | 185 | ISO 16740 | Metal |

**Table 4-11: Cost of sampling and analysis - Poland**

| | | | |
|---|---|---|---|
| Formaldehyde | 217 | ISO 16000-3 | Fume |
| MOCA | 560 | | Dust |

| **Units costs of planning, sampling and reporting** | | | |
|---|---|---|---|
| | **Number** | **Unit** | |
| **Planning** (independent of number of workplaces) | 8 | man-hours | |
| **Sampling:** | | | |
| Sampling basic costs per day incl. first workplace | 9 | man-hours | |
| Time per workplaces in addition to first workplace the same day | 1 | man-hours | |
| Number of workplaces one person can sample a day | 5 | man-hours | |
| **Reporting:** | | | |
| Reporting independent of number of workplaces | 5 | man-hours | |
| Additional reporting per workplace | 0.25 | man-hours | |
| **Salary** | 25.0 | EUR/man-hour | |
| **Rent of pump:** | | | |
| Rent of pump first day | 0 | EUR/work place | Included in cost of hiring consultant |
| Rent of pump subsequent days | 0 | EUR/work place | Included in cost of hiring consultant |

| **Planned programme** | | | |
|---|---|---|---|
| Substance | Arsenic | | |
| Number of workplaces | 17 | | |
| Activity | Units | Unit costs, EUR | Total costs, EUR |
| Planning, man-hours | 8 | 25.0 | 200 |
| Execution, man-hours | 49 | 25.0 | 1,225 |
| Reporting, man-hours | 9.3 | 25.0 | 231 |
| Rent of equipment, first day | 5 | 0 | - |
| Rent of equipment, subsequent days | 12 | 0 | - |
| Analysis | 17 | 185 | 3,145 |
| Total costs | | | 4,801 |
| | **Analysis in percentage of total costs** | | **66%** |

**Table 4-12: Cost of sampling and analysis - Slovenia**

| **Unit costs of analysis** | | | |
|---|---|---|---|
| | Cost analysis, EUR (SI) included Sample media | Standard | **Type** |
| Arsenic | 185 | ISO 15202 | Metal |

**Table 4-12: Cost of sampling and analysis - Slovenia**

| | | | |
|---|---|---|---|
| Beryllium | 185 | ISO 15202 | Metal |
| Cadmium | 185 | ISO 15202 | Metal |
| Chromium (VI) | 185 | ISO 16740 | Metal |
| Formaldehyde | 217 | ISO 16000-3 | Fume |
| MOCA | 560 | | Dust |

| **Units costs of planning, sampling and reporting** | | | |
|---|---|---|---|
| | **Number** | **Unit** | |
| **Planning** (independent of number of workplaces) | 8 | man-hours | |
| **Sampling:** | | | |
| Sampling basic costs per day incl. first workplace | 9 | man-hours | |
| Time per workplaces in addition to first workplace the same day | 1 | man-hours | |
| Number of workplaces one person can sample a day | 5 | man-hours | |
| **Reporting:** | | | |
| Reporting independent of number of workplaces | 5 | man-hours | |
| Additional reporting per workplace | 0.25 | man-hours | |
| **Salary** | 41.0 | EUR/man-hour | |
| **Rent of pump:** | | | |
| Rent of pump first day | 0 | EUR/work place | Included in cost of hiring consultant |
| Rent of pump subsequent days | 0 | EUR/work place | Included in cost of hiring consultant |

| **Planned programme** | | | |
|---|---|---|---|
| Substance | Arsenic | | |
| Number of workplaces | 17 | | |
| Activity | Units | Unit costs, EUR | Total costs, EUR |
| Planning, man-hours | 8 | 41.0 | 328 |
| Execution, man-hours | 49 | 41.0 | 2,009 |
| Reporting, man-hours | 9.3 | 41.0 | 379 |
| Rent of equipment, first day | 5 | 0 | - |
| Rent of equipment, subsequent days | 12 | 0 | - |
| Analysis | 17 | 185 | 3,145 |
| Total costs | | | 5,861 |
| | **Analysis in percentage of total costs** | | **54%** |

# 5 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. Many assumptions, which may or may not be realistic, would have to be included in an analysis of this environmental impact:

- Is the reduction of OELs mainly achieved by increased emissions from ventilation/ exhaust increase?
- Is air emission controlled and reduced, e.g., by filter systems?
- Is removed air integrated into secondary cycles with additional precipitation devices?
- Are filters subsequently disposed or treated (e.g., waste incineration)?
- Are there water screens established to collect and dispose aerosols from workplace?
- What is the link between water screens and effluent water to sewage systems?
- What is the current exact exposure scenario and the status of exposure reduction measures in place?

Because of these heterogeneous parameters, no general and realistic calculation on an environmental impact is possible. Qualitatively, it is assumed that changes in OEL will have limited consequences on environmental exposure and therefore there is only a low-priority need for quantitative consideration within the overall impact assessment.

However, it is suggested to acknowledge the "starting point" for each of the substances: do the substances in question represent currently a major environmental problem, *independently* from any potential additional emission from industrial processes considered to change due to OEL changes? We conclude that any emissions into the environment should be carefully analysed, if the current status of environmental impact is highly relevant.

Therefore, below, we briefly describe environmental impact profiles for all of the six substances, independently from changes due to OEL changes. We selected four indices to characterise the current environmental status:

1. PBT-profile. Persistency, bioaccumulation and toxicity (PBT) are defined parameters under various regulations and are an important criterion for "substances of very high concern" (SVHC) under REACH. Therefore, we analysed whether the substances in question would be categorised as PBT.
2. The "predicted no effect concentration" (PNEC) is an environmental hazard indicator. A currently already existing relevant risk for the environment can be deduced, if prevailing environmental exposure is close to the PNEC or even exceeds the PNEC. Therefore, we screened information on the ratio: "environmental exposure/ PNEC", where ratios close to 1 would substantiate environmental concern (we did not discriminate the aquatic or soil compartment in detail for the purpose of this screening).
3. Additional air emissions may be of primary concern as an entry pathway into the environment from industrial pathways, where workplace exposure is via aerosols/ dust or gases. Therefore we looked for indicators in respect to the degree emissions into environment from industrial processes contribute to the overall environmental burden (e.g., from power stations, traffic, natural sources, etc.).
4. Finally, we considered the exposure pathway: "humans via the environment". If current environmental concentrations already indicate / cause a health problem to humans (e.g., via

food or drinking water exposure) without consideration of additional emissions from OEL changes, this should be acknowledged. However, no formal assessment of "humans via the environment" as would be required according to REACH guidance was performed, because of the input variables would be highly speculative.

From these four criteria we derive an attributed overall environmental weighting of the respective substance, with:

- "low" relevance, where most of the criteria above do not indicate concern;
- "moderate" relevance, where some of the criteria indicate relevant concern, but others do not;
- "significant" relevance, if most of the criteria indicate relevant concern; and
- "substantial" relevance, where any changes in environmental concentrations should be carefully observed, because the current status of the environmental impact by that substance already indicates the need for exposure reduction, as manifest from all four criteria.

# 6 Summary of the Consultation Exercise

## 6.1 Overview

The aim of the consultation activities was to collect more detailed information on the potential impacts of modifications to the CMD that is not available in published literature and internet searches. Although some information on OELs is available, limited information is available on concrete measures already in place and that would need to be implemented should limits be modified. The information sought via consultation therefore included sizes of companies, sectors and processes that would be affected, number of workers exposed, current air concentrations of chemical agents concerned (both 8 hour time weighted averages and 15 minute reference periods), risk management measures currently in place, as well as risk management measures that would need to be implemented should the OELs be modified and associated costs.

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

- questionnaires
- telephone interviews
- site visits.

Mixed methods were adopted to ensure that a large number of organisations and individuals were able to provide their views within the time constraints and resource limits. Using mixed methods also enabled the study team to gather varying details of information and to explore information further where the need arose.

Both national experts and chemical agent experts involved in inviting stakeholders to participate in the questionnaires, interviews and site visits were regularly updated, by means of an online hub, with regard to one another's' activities to limit any overlap. The national experts, with significant experience in data collection, were able to translate questions into the native languages of the stakeholders and to pose specific relevant questions. The use of national experts not only ensured that a larger number of stakeholders were able to respond, but also ensured that they were able to respond in more detail in a language that they were comfortable with. The chemical agent experts were able to provide significant input to the process by ensuring that more specific and relevant questions were asked, based on any information already obtained.

Consultation and desk-research guides were compiled 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.

***Targeted Online Questionnaires***

Stakeholders were initially contacted via email with an overview of the study and a link to the questionnaires. If the stakeholders preferred to answer the questionnaire in a Word document (so that it could be shared among several colleagues, for example), it was also possible to obtain these upon request.

Four separate questionnaires were drawn up, each one created to gather information from different stakeholder groups:

- Questionnaire 1 was aimed at companies whose workers were exposed to cadmium and its organic compounds, beryllium and its inorganic compounds, inorganic arsenic compounds, formaldehyde and 4,4'-Methylene-bis(2-chloroaniline) (MOCA);
- Questionnaire 2 for companies whose workers are exposed to Cr(VI) compounds from welding, plasma cutting and similar processes that generate fumes;
- Questionnaire 3 for occupational health and safety experts; and
- Questionnaire 4 for Member State authorities.

The questions aimed to collect information on processes during which worker exposure to the chemical agents 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 limits. It was important to focus the questionnaires in risk management measures in particular, as little information is available in the literature on the particular measures used.

A large number of the questions were closed, enabling stakeholders to respond more efficiently and responses to be analysed more efficiently. Where needed open questions were used to obtain more detail. Logic was also used on the online survey programme, thereby limiting the questions to the most relevant for that particular stakeholder, based on their answers to the initial few questions.

Questionnaires 1, 2 and 3 were all translated into English, German, French, Spanish, Italian and Polish. Questionnaire 4 was provided in English only as it was felt that Member State Authorities are likely to be sufficiently proficient in English.

At the end of the questionnaires respondents were given the opportunity to provide contact details so that we could review their responses over the phone, and they were furthermore asked to indicate whether they would be willing to host a site visit. Any of those who indicated that they were willing to have an interview or host a site visit were followed up by a relevant expert.

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.

***Telephone interviews***

Both national experts and chemical agent experts were utilised for the purposes of the telephone interviews. Telephone interviews were requested both in the online questionnaires and via direct email and phone contact undertaken by the experts.

The purpose of the telephone interviews was to gain more insight into the answers provided in response to the questionnaires. It enabled more detailed information on processes to be collected, pinpointing exactly where exposure is likely to occur, what kinds of risk management measures are already in place and how effective they are, and what risk management measures would be required should limits be lowered and other potential ramifications for the company.

The experts were provided with detailed instructions (in the form of a consultation guide) in relation to the information that was to be collected and included email templates that were to be translated into the relevant national languages. Interviews were based on responses to the questionnaires (in cases where a response had already been received) which enabled more detailed information to be collected in addition to the responses already received. National experts were available for all 28 Member States and the chemical agent experts provided input into the questions to be asked (based on information already obtained).

***Site visits***

Companies whose activities are likely to be affected by the potential modifications to the CMD were also asked whether they would be willing to welcome members of the study team for a site visit. These companies were asked both within the online questionnaire and within the telephone interviews.

The purpose of the site visits was to a gain a more concrete understanding of the risk management measures currently in place to protect against exposure to the chemical agents concerned, as well as of the risk management measures that would need to be implemented should the CMD be modified.

Staff attending the site visits were selected for their language capabilities and their knowledge of the chemical agent concerned, enabling more detailed information to be collected.

Detailed notes from each site visit were drafted and sent back to the company visited to ensure that they were satisfied with the information recorded. This also enabled the company to add more detail and information to the study, where possible, and to confirm the level of confidentiality afforded to the information.

## 6.2 Results of consultation

### 6.2.1 Questionnaires

As can be seen from the summary tables below, 2,961 stakeholders were invited directly to respond to the online questionnaires. However, a much larger number of stakeholders were reached indirectly. In addition to contacting stakeholders directly, associations within sectors relevant to the chemical agents in question were also approached and asked to forward the questionnaires to their members, thereby efficiently providing a large number of stakeholders with the opportunity to respond. Stakeholders were selected from each of the sectors identified as being relevant for each of the chemical agents.

Reminders were sent to those who had already been contacted but who had not responded. Any responses received were recorded in an excel spreadsheet, so that those who had responded could be removed from the reminder mailing lists. In cases where the second reminder did not result in a response, follow-up phone calls were carried out. The follow-up phone call could either result in a teleconference arranged for a later date, or responses to the questionnaire could be provided then and there, over the phone.

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

| Table 6-1: Summary of numbers of stakeholders contacted and outcomes | |
|---|---|
| **Stakeholder type** | **Total number contacted** |
| Academia | 6 |
| Member State authorities | 28 |
| Manufacturer/user | 1,635 |
| National industry association | 409 |
| Trade union | 185 |
| EU Association | 199 |
| Independent expert | 7 |
| Urban wastewater treatment plants | 174 |
| Ventilation providers | 317 |
| Third country authority | 1 |
| **Total** | **2,961** |

The next table provides an overview of the number of responses received to the questionnaire among those contacted.

| Table 6-2: Breakdown of questionnaire responses per stakeholder type | |
|---|---|
| **Stakeholder type** | **Questionnaire responses** |
| EU Association | 2 |
| International Association | N/A |
| Manufacturer/user | 63 |
| Member State Authorities | 23 |
| National industry association | N/A |
| Occupational Health & Safety Professionals | 16 |
| **Total** | **104** |

A larger proportion of the responses were received directly from manufacturers/users. This is due to the fact that associations were asked to encourage their members to respond directly to the questionnaire, and due to the fact that a higher number of manufacturer/users were contacted than any other stakeholder group.

Trade Unions were not provided with an online questionnaire, but were instead emailed with a set of questions relevant to them. Consultation with trade unions is explained in further detail in the section entitled 'Other Consultation'.

The following table provides a breakdown of the questionnaire responses per chemical agent.

| Table 6-3: Breakdown of questionnaire responses per chemical agent | |
|---|---|
| **Chemical agent** | **Questionnaire responses** |
| Arsenic | 22 |
| Beryllium | 3 |
| Cadmium | 11 |
| Chromium VI | 18 |
| Formaldehyde | 32 |
| MOCA | 2 |
| General response (not specific to any one chemical agent) | 7 |

A relatively large number of responses were received in relation to the most widely used chemical agents (i.e. formaldehyde, arsenic, chromium VI and cadmium). It is thought that relatively fewer responses were received in relation to the other chemical agents (i.e. beryllium and MOCA) due to their relatively limited use.

The following table provides a breakdown of questionnaire responses per company size.

| Table 6-4: Breakdown of questionnaire responses per company size | |
|---|---|
| **Company size** | **Questionnaire responses** |
| Small enterprise (10-49 persons employed) | 9 |
| Medium-sized enterprise (50-249 persons employed) | 19 |
| Large enterprise (250 or more persons employed) | 35 |
| **Total** | **63** |

A relatively larger number of 'large companies' responded to the questionnaires than the other company sizes. This is thought to be due to the fact that large companies have more resources available to participate in such studies and are therefore more likely to be able to dedicate staff and time for these purposes.

### 6.2.2 Interviews

Both the national experts and the chemical agent specific experts carried out interviews with relevant stakeholders in order to obtain more detailed information based on the responses to the questionnaire. Minutes were taken during the interview and the level of confidentiality afforded to them was confirmed by those interviewed.

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

| Table 6-5: Breakdown of interviews per stakeholder type | |
|---|---|
| **Stakeholder type** | **Interviews** |
| EU Association | 13 |
| International Association | 1 |
| Manufacturer/user | 38 |
| National industry association | 19 |
| Occupational Health & Safety Professionals | 12 |
| Trade Union | 5 |
| Member State Authorities | 5 |
| Third country authority | 1 |
| **Total** | **93** |

A relatively larger number of interviews were carried out with manufacturer/users. This is due to the fact that both directly and indirectly a larger number of manufacturer/users were invited to respond to the questionnaires than any other group, and each questionnaire asked whether these manufacturer/users would be willing to participate in a telephone interview. Furthermore, a larger number of manufacturer/users exist than any other of the stakeholder groups. A relatively small number of trade unions were interviewed. This is believed to be due to the fact that many of the trade unions do not have information specific to the chemical agents concerned.

| Table 6-6: Breakdown of interviews per company size | |
|---|---|
| **Company size** | **Interviews** |
| Small enterprise (10-49 persons employed) | 6 |
| Medium-sized enterprise (50-249 persons employed) | 12 |
| Large enterprise (250 or more persons employed) | 20 |
| **Total** | **38** |

A relatively larger number of interviews were carried out with large enterprises. As mentioned previously, this is likely to be due to the fact that larger companies are in a better position to set aside resources that enable them to participate in such a study.

| Table 6-7: Breakdown of interviews per chemical agent | |
|---|---|
| **Chemical agent** | **Interviews** |
| Arsenic | 18 |
| Beryllium | 4 |
| Cadmium | 10 |
| Chromium VI | 12 |
| Formaldehyde | 30 |
| MOCA | 1 |
| General response (not specific to any one chemical agent) | 26 |

It is important to note that some of the interviews were relevant for more than one chemical agent and so the total in this case is larger than the total number of interviews carried out overall.

As can be seen from the table above, a relatively large number of interviews were carried out in relation to the most widely used chemical agents (i.e. formaldehyde, arsenic, chromium VI and cadmium). It is thought that relatively fewer interviews were arranged in relation to the other chemical agents (i.e. beryllium and MOCA) due to their relatively limited and niche uses.

### 6.2.3 Site visits

In addition to being interviewed, stakeholders were also asked whether they would be willing to host a site visit. The aim of this site visit was to obtain a more concrete understanding of the risk management measures that have already been implemented to protect workers from exposure to the relevant chemical agents, as well as of the risk management measures that would need to be implemented and their associated costs should the occupational exposure limits be reduced. It also enabled additional contextual information to be obtained, such as likelihood of being able to substitute a chemical agent, whether there are specific site characteristics that make implementation of new equipment difficult, specifically how often workers are likely to be exposed (their work patterns), etc.

Those attending the site visits were provided with site visit guides, detailing the information that was to be obtained and based on information that had already been obtained via the questionnaires and/or interviews.

A total of **18** site visits were carried out.

The following table provides a breakdown of the number of site visits relevant to each chemical. It is important to note that some of the site visits were relevant to more than one chemical agent.

| Table 6-8: Number of site visits per chemical agent (all arranged site visits, including those planned but not carried out yet) | |
|---|---|
| **Chemical agent** | **Number of site visits relevant to chemical agent** |
| Arsenic | 5 |
| Beryllium | 3 |
| Cadmium | 3 |
| Chromium VI | 5 |
| Formaldehyde | 5 |
| MOCA | 0 |

The following table provides a breakdown of the number of site visits carried out in each Member State.

| Table 6-9: Number of site visits per Member State (all arranged site visits, including those planned but not carried out yet) | |
|---|---|
| **Member State** | **Number of site visits** |
| Austria | 1 |
| Belgium | 1 |
| Denmark | 2 |
| Estonia | 1 |
| Finland | 3 |
| France | 2 |
| Germany | 3 |
| Netherlands | 2 |
| Portugal | 1 |
| Spain | 1 |
| UK | 1 |
| **Grand Total** | **18** |

The number of site visits carried out in each Member State depended on which companies indicated they were willing to host a site visit.

### 6.2.4 Other consultation

***Trade unions***

184 trade unions were contacted in order to inform them of the study and provide the opportunity to contribute information. Questionnaires with specific questions were not drafted for trade unions as the information readily available to them is likely to vary from trade union to trade union. For this reason a set of basic questions were provided either via email or asked over the phone, and the experts carrying out the interview were able to ask more detailed questions in relation to the responses.

Six written responses were received in response to the requests. Trade unions predominantly provided information at a more general level (i.e. not particular to a specific chemical agent), with occasionally more specific data relating to a particular substance.

The trade unions viewed the Commission's efforts to expand the CMD positively, but were concerned that reprotoxic substances should also be included.

Information was provided by trade unions on the risks arising from exposure to carcinogens and mutagens at work. It was stated, for example, that the risks arising from exposure to carcinogens and mutagens at work are not immediately visible, and that inconsistencies exist within data with regard to cancers recognised as occupational diseases and the number of cancers attributable to occupational exposure, for example. More generally, it was underlined by the trade unions that the quality of the data on occupational cancers is rather low, with EU data on cancer containing little information on patients' occupations. The point was also raised that, due to the long latency period of some of the associated cancers, companies where exposure has taken place are unlikely to be burdened by the periods of absence associated with cancer.

With regard to the setting of OELs, it was indicated by the trade unions that clear criteria are needed in order to ensure greater transparency and consistency within the legislation.

***Face-to-face meetings and additional conference calls***

Two face to face meetings were held with the International Cadmium Association (ICdA); one in Paris and one in London. More than 10 conference calls have also been carried out with the ICdA.

Two face-to-face meetings were carried out with the Beryllium Science and Technology Association (BeST). During these meetings information was provided on the different uses, processes, and relevant sectors. Furthermore, opinions were provided on whether or not an STEL would be appropriate for beryllium.

There was also a telephone call meeting with key members of US-OSHA, including the project manager responsible for the recommendation from US-OSHA to set the USA PEL at 0.2µg/$m^3$ (total particulate) for beryllium.

***Laboratories***

36 laboratories were also contacted to obtain sample quotes of monitoring costs for the chemical agents in question. Ten responded, with four able to provide beneficial information.

## 6.3 Data processing

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

The information obtained from consultation (in conjunction with information obtained via desk-based research) was used for the purposes of defining in which sectors the chemical agents were used, in which processes (with, in some cases, extremely detailed lists and descriptions of specific processes provided), how often samples are taken to measure concentrations in the air, whether they are taken at a time that concentrations are likely to be at their highest/lowest, etc. Information was also obtained that helped to confirm whether OELs set at a national level are expressed in inhalable, respirable or thoracic fraction. Furthermore, more detailed information was obtained on whether or not samples are taken by external accredited laboratories, whether the equipment used by the laboratories can detect the lower levels proposed, specific PPE used for specific processes, etc.

All of this data, quantitative and qualitative, was beneficial in enabling the expert to come to some conclusions with regard to impacts. It would not have been possible to obtain this level of detail

without continued questioning from both the national (in native languages) and chemical-agent specific experts via consultation.

## 6.4 Conclusions

A large amount of information was collected via consultation through means of the tailored online questionnaires, telephone interviews and site visits. Efforts were made to contact a variety of relevant stakeholders in all of the Member States, for each of the relevant chemical agents, from companies of varying sizes.

The information collected via consultation has enabled the study team to gain a more nuanced understanding of the likely concrete 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, site visits and face-to-face meetings 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 CMD.

The initial use of questionnaires enabled information to be obtained at a broader level. Information on the sizes of companies likely to be affected, their processes and some of the risk management measures implemented. The information obtained via the questionnaires could then act as a basis and be explored further via both interviews and site visits. The information obtained via the interviews and site visits gave the experts a greater understanding of the issues that could arise, should the proposed measures be implemented.

In addition to the use of questionnaires, interviews and site visits, face-to-face meetings were also carried out with key associations relevant to beryllium and cadmium. These face-to-face meetings allowed a large amount of information to be obtained and analysed in relation to two of the chemical agents.

It is important to note that Information was however more readily available for some chemical agents than for others. The lack of information received in relation to MOCA, for example, is thought to be due to its limited use. Similarly, a relatively smaller amount of information was obtained with respect to beryllium. Once again this is thought to be due to its limited use, and due to more specific, niche uses that stakeholders were not aware of or had little information on. Furthermore, there exist only a small number of importers of beryllium (approximately four) within the EU – most/all of which were consulted via their association.

The following tables provide complete overviews of questionnaire responses, interviews and site visits per stakeholder type, company size, and chemical agent.

| Table 6-20: Breakdown of questionnaire responses, interviews and site visits per stakeholder type | | | |
|---|---|---|---|
| **Stakeholder type** | **Questionnaire responses** | **Interviews** | **Site visits** |
| EU Association | 2 | 13 | N/A |
| International Association | N/A | 1 | N/A |
| Manufacturer/user | 63 | 38 | 18 |
| National industry association | N/A | 19 | N/A |
| Occupational Health & Safety Professionals | 16 | 12 | N/A |
| Trade Union | N/A | 5 | N/A |
| Member State Authorities | 23 | 5 | N/A |
| Third country authority | 0 | 1 | |
| **Total** | **104** | **93** | **18** |

| Table 6-31: Breakdown of questionnaire responses, interviews and site visits per company size | | | |
|---|---|---|---|
| **Company size** | **Questionnaire responses** | **Interviews** | **Site visits** |
| Small enterprise (10-49 persons employed) | 9 | 6 | 4 |
| Medium-sized enterprise (50-249 persons employed) | 19 | 12 | 7 |
| Large enterprise (250 or more persons employed) | 35 | 20 | 7 |

| Table 6-42: Breakdown of questionnaire responses, interviews and site visits per chemical agent | | | |
|---|---|---|---|
| **Chemical agent** | **Questionnaire responses** | **Interviews** | **Site visits** |
| Arsenic | 22 | 18 | 5 |
| Beryllium | 3 | 4 | 3 |
| Cadmium | 11 | 10 | 3 |
| Chromium VI | 18 | 12 | 5 |
| Formaldehyde | 32 | 30 | 5 |
| MOCA | 2 | 1 | 0 |
| General response (not specific to any one chemical agent) | 7 | 26 | N/A |

# 7 Review of the REACH CSRs

## 7.1 Identification of the relevant CSRs

In an attempt to gain further insight in current risk management measures and actual exposure levels at workplaces, chemical safety reports (CSRs) submitted under Regulation (EC) No 1907/2006 were assessed. Since CSRs are confidential, ECHA was requested to extract CSRs from registration dossiers for a limited number of 19 chemical agents belonging to the six (groups of) chemicals subject to this report (see ). Upon this request ECHA extracted all files attached in section 13 of the IUCLID datasets of all registrations for these 19 chemical agents. In some cases, these attachments did not represent complete CSRs, but rather other attachments (e.g. files intended to document strictly controlled intermediates for chemical agents registered as intermediates or only part A of the CSR, which typically only contains a statement that RMMs are implemented and communicated).
lists the chemical agents for which such attachments were extracted and the groups to which they belong.

**Table 7-1: List of chemical agents for which CSRs were requested from ECHA**

| Chemical agent | CAS No. | Group |
|---|---|---|
| 4,4'-methylenebis[2-chloroaniline] | 101-14-4 | 4,4'-methylenebis[2-chloroaniline] (MOCA) |
| Beryllium oxide | 1304-56-9 | Beryllium and inorganic beryllium compounds |
| Beryllium | 7440-41-7 | Beryllium and inorganic beryllium compounds |
| Cadmium carbonate | 513-78-0 | Cadmium and inorganic cadmium compounds |
| Cadmium oxide | 1306-19-0 | Cadmium and inorganic cadmium compounds |
| Cadmium sulphide | 1306-23-6 | Cadmium and inorganic cadmium compounds |
| Cadmium | 7440-43-9 | Cadmium and inorganic cadmium compounds |
| Cadmium chloride | 10108-64-2 | Cadmium and inorganic cadmium compounds |
| Cadmium nitrate | 10325-94-7 | Cadmium and inorganic cadmium compounds |
| Cadmium hydroxide | 21041-95-2 | Cadmium and inorganic cadmium compounds |
| Lead, bullion | 97808-88-3 | Cadmium and inorganic cadmium compounds |
| Chromium trioxide | 1308-38-9 | Chromium (VI) compounds |
| Formaldehyde | 50-00-0 | Formaldehyde |
| Gallium arsenide | 1303-00-0 | Inorganic arsenic compounds including arsenic acid and its salts |
| Diarsenic triselenide | 1303-36-2 | Inorganic arsenic compounds including arsenic acid and its salts |
| Diarsenic trioxide | 1327-53-3 | Inorganic arsenic compounds including arsenic acid and its salts |
| Arsenic acid | 7778-39-4 | Inorganic arsenic compounds including arsenic acid and its salts |
| Lead, antimonial, dross | 69029-51-2 | Inorganic arsenic compounds including arsenic acid and its salts |
| Flue dust, lead-refining | 69029-67-0 | Inorganic arsenic compounds including arsenic acid and its salts |

Data were extracted in September 2017. All files received from ECHA were evaluated in a secure IT environment.

Under the REACH Regulation, substances can be registered with a full registration (FULL) or an intermediate registration (INT), if the substance is exclusively handled under strictly controlled conditions. In addition, registrations are often submitted by consortia of companies with a single lead

company (LEAD) generally submitting the complete CSR and all the members of such a joint submission (MEMBER) often only attaching Part A of the CSR (see above).

The following table summarises the registrations available per substance differentiated by the registration (FULL; INT) and submission type (LEAD, MEMBER).

| Table 7-2: Available REACH registrations | | | | | | |
|---|---|---|---|---|---|---|
| Chemical agent | CAS No. | Number of registrations | | | | |
| | | Total | FULL LEAD | FULL MEMBER | INT LEAD | INT MEMBER |
| 4,4'-methylenebis[2-chloroaniline] | 101-14-4 | *Potentially confidential* | | | | |
| Beryllium oxide | 1304-56-9 | | | | | |
| Beryllium | 7440-41-7 | | | | | |
| Cadmium carbonate | 513-78-0 | | | | | |
| Cadmium oxide | 1306-19-0 | | | | | |
| Cadmium sulphide | 1306-23-6 | | | | | |
| Cadmium | 7440-43-9 | | | | | |
| Cadmium chloride | 10108-64-2 | | | | | |
| Cadmium nitrate | 10325-94-7 | | | | | |
| Cadmium hydroxide | 21041-95-2 | | | | | |
| Lead, bullion | 97808-88-3 | | | | | |
| Chromium trioxide | 1308-38-9 | | | | | |
| Formaldehyde | 50-00-0 | | | | | |
| Gallium arsenide | 1303-00-0 | | | | | |
| Diarsenic triselenide | 1303-36-2 | | | | | |
| Diarsenic trioxide | 1327-53-3 | | | | | |
| Arsenic acid | 7778-39-4 | | | | | |
| Lead, antimonial, dross | 69029-51-2 | | | | | |
| Flue dust, lead-refining | 69029-67-0 | | | | | |
| **Total** | | **392** | **18** | **321** | **1** | **52** |

With the exception of cadmium carbonate, a single FULL LEAD registration and up to 204 FULL MEMBER registrations are available per substance. This is in agreement with expectation since there is only a single lead company per consortium, but multiple member companies. In the case of cadmium carbonate, a company registering the substance as an intermediate under strictly controlled conditions acted as the lead company, while all members of the joint submission registered the substance with a full registration (potentially because they or their downstream users use the substance in other applications than an intermediate under strictly controlled conditions). Formaldehyde represents a special case, since registrations for this substance account for more than half of all registrations evaluated for all 19 chemical agents (207/392, 53 %).

Among the 392 registrations, there are some registrations that are currently not active: 1 annulled 4 revoked and 27 inactive registrations.

## 7.2 Evaluation of CSRs

While all 19 chemical agents are registered, a registration may or may not contain a complete CSR (as discussed above). Therefore, the attachments extracted by ECHA were further analysed to establish whether these constituted complete CSRs or other files. While the LEAD FULL registration is generally expected to contain the complete CSR, members of a joint submission can chose to submit an

additional CSR, e.g. with uses specific to their company or its downstream users that are not covered by the CSR of the lead company.

Further evaluation of the extracted information also suggested that there are some cases, where the LEAD FULL registration did not contain a CSR, while MEMBER FULL registrations did. This was e.g. the case when the registration of the lead company was 'inactive' (see above). Other cases appeared to suggest that responsibilities are changing (e.g. a former member taking over as the lead company in a joint submission). As a result of these considerations, CSRs of lead and members were evaluated, whenever possible. However, the sheer number of CSRs submitted prevented such evaluations for a few chemical agents, most notably formaldehyde. In such cases, the CSR from the LEAD FULL registration was given preference. In some cases, different versions of almost identical CSRs were submitted by different companies. These appeared to reflect a different update status of the registrations and the most recent version of the CSR was evaluated. In a single case, the entire CSR was claimed confidential by the lead company and could not be evaluated. In this case, available member CSRs were evaluated.

This evaluation also showed that exposure of workers to formaldehyde was based on a separate report annexed to the CSR. This annex was not only submitted by the lead company, but also by many members of the joint submission. This annex formed the basis of the evaluations in the case of formaldehyde. As a consequence, the impossibility to evaluate all attachments submitted for formaldehyde is considered a minor issue.

The following table summarises the information on CSRs available for evaluation.

**Table 7-3: Availability of CSRs for evaluation**

| Chemical agent | CAS No. | CSR availability (justification) |
|---|---|---|
| 4,4'-methylenebis[2-chloroaniline] | 101-14-4 | 2 CSRs |
| Beryllium oxide | 1304-56-9 | No CSR (≤ 10 tonnes per annum) |
| Beryllium | 7440-41-7 | No CSR (≤ 10 tonnes per annum) |
| Cadmium carbonate | 513-78-0 | 2 CSRs |
| Cadmium oxide | 1306-19-0 | 1 CSR |
| Cadmium sulphide | 1306-23-6 | 1 CSR |
| Cadmium | 7440-43-9 | 1 CSR |
| Cadmium chloride | 10108-64-2 | 2 CSRs |
| Cadmium nitrate | 10325-94-7 | 1 CSR |
| Cadmium hydroxide | 21041-95-2 | 1 CSR |
| Lead, bullion | 97808-88-3 | 1 CSR – not evaluated |
| Chromium trioxide | 1308-38-9 | 2 CSRs (checked only for information on welding and associated operations) |
| Formaldehyde | 50-00-0 | Many CSRs (evaluation based on Annex on worker exposure) |
| Gallium arsenide | 1303-00-0 | 2 CSRs |
| Diarsenic triselenide | 1303-36-2 | No CSR (≤ 10 tonnes per annum) |
| Diarsenic trioxide | 1327-53-3 | 2 CSRs (checked for uses exempted from authorisation) |
| Arsenic acid | 7778-39-4 | 1 CSR |
| Lead, antimonial, dross | 69029-51-2 | 1 CSR – not evaluated |
| Flue dust, lead-refining | 69029-67-0 | 1 CSR – not evaluated |

There are some special cases that require further discussion:

- Beryllium and beryllium oxide are registered only at a volume ≤ 10 tonnes per annum, which does not require a chemical safety assessment. CSRs were therefore not available for these chemical agents.
- The same applies to diarsenic triselinide.
- The CSRs for all cadmium compounds are largely based on the CSRs for cadmium and cadmium oxide (including identical exposure estimates). Data were therefore extracted from the CSRs for these two compounds. However, CSRs for all other cadmium compounds listed were checked to identify any additional uses (only one additional use identified).
- 'Lead, bullion', 'Lead, antimonial, dross' and 'Flue dust, lead-refining': the evaluation showed that these chemical agents consist of many different metals (e.g. antimony, arsenic, cadmium, chromium and nickel) and cannot be meaningfully assigned to one of the six (groups of) chemical agents (despite the assignment shown in ).
- Diarsenic trioxide is included in Annex XIV of the REACH Regulation, i.e. it is subject to authorisation. Since this substance is therefore prohibited from being used in the EU in many applications unless an application for authorisation has been submitted, the registration CSRs were only evaluated with respect to uses exempted from authorisation, i.e. manufacture and the use as an intermediate. CSRs submitted in the context of an application for authorisation were evaluated separately.

Available CSRs were evaluated in detail for uses of the substance, occupational exposure associated with these uses as well as risk management measures and operational conditions. These data were used in the assessments of the chemicals agents documented in separate reports.

# 8 Differences Between this Study and RPA & FoBiG (2017)

In 2017, RPA & FoBiG completed a study for ETUI on the Economic Costs of Occupational Cancer.[29] Although this study considered some of the chemical agents also considered in this study, the results from the ETUI study and this study are not compatible as the methodological approaches and side conditions of the two assessments differed fundamentally.

***Cancer risk quantification and cancer site***

In this study, exposure risk relationship (ERR) calculations have been used which need exposure concentrations to be transformed to excess cancer risk and cancer cases. For the ETUI study exposure concentration was not directly included as standard mortality rates or odds ratios were directly transformed into attributable fractions. The specifications in this study are to focus on one cancer site as usually there exists one ERR for the most sensitive cancer site (confirmed by SCOEL or RAC). In the ETUI study, various cancer sites were addressed in parallel for one chemical agent.

***Key studies***

In this study, cancer risk quantification is only based on key studies which were regarded optimal by SCOEL or RAC. In the ETUI study, it was expected to refer to various cancer risk quantifications, and to develop own cancer estimates to calculate alternative risk quantifications.

***Substances included***

The ETUI study did not differentiate between the classification of substance groups under one heading and was also not linked to the CMD definitions of compounds. In this study, subsets of compounds to be assessed were defined, with substances included or excluded according to CMD. This influenced the number of exposed persons and the number of cancer cases.

***Exposure duration and quantification***

The attributable fraction (fraction of the total number of cancer cases reported in annual incidence statistics) used in the ETUI study is a key figure for the cancer case quantification. The ERR refers to a unit risk, based on 40 years occupational exposure. Transformation to a statistical incidence figure for a certain year needs many assumptions and leads to different results than for attributable fractions. Results on cancer cases referring to the incidence in a certain calendar year are not comparable to a quantification of cancer risk assuming 40 years of exposure (ERR), which is derived from earlier exposures and taken as a figure independent from the time of exposure. Exposure concentrations are usually not identical to those values measured or estimated as shift-time weighted average over a day, week, or longer. For some exposure scenarios, it was taken into account that exposure is only part-time or occurs occasionally. This leads to significant changes in average exposure concentrations compared to full shift exposures (not addressed in the ETUI study).

***Number of exposed workers***

The number of exposed workers to carcinogens is a highly uncertain figure. In the ETUI study, certain assumptions were used and deviated from the assumptions used for this study. The uncertainties for

[29] See https://www.etui.org/content/download/33168/307556/file/J907%2BFinal%2BReport%2B9%2BNov%2B2017-2.pdf

both studies were discussed, but uncertainties of estimates were higher within the ETUI project. For example, for a substance used under “closed conditions”, the number of workers in the respective sector may be much higher than the number of exposed persons in this sector. This specific analysis was not performed quantitatively in the ETUI study. The ETUI study also included self-employed workers who are not subject to the CMD.

# Annex 1 Questionnaires and Example Interview and Site Visit Questions

The four questionnaires used, in addition to example sets of interview and site visit questions are provided on the following pages. It is important to note that these questions acted as an initial basis. Once information at a broader level was obtained from stakeholders, this was then used as the basis for more detailed questions drawn-up by the chemical agent experts and where necessary translated into native languages by the national experts.

## A1.1 Questionnaire for companies whose workers are exposed to the relevant chemical agents

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) has been contracted by the European Commission (DG Employment, Social Affairs and Inclusion) to carry out a study to support a possible amendment of Directive 2004/37/EC on the protection of workers from exposure to carcinogens or mutagens at work (hereinafter the Carcinogens and Mutagens Directive or CMD).

The objective of the study is to assess the impacts of establishing **Occupational Exposure Limits (OELs)** and, where relevant, other potential measures such as **Short-term Exposure Limits (STELs)** for the following chemical agents[30]:

- cadmium and its inorganic compounds;
- beryllium and its inorganic compounds;
- inorganic arsenic compounds including arsenic acid and its salts;
- formaldehyde; and
- 4,4'-Methylene-bis(2-chloroaniline) (MOCA)[31].

For each agent, a range of potential limit values is being assessed reaching from the lowest to the highest values resulting from SCOEL recommendations, RAC opinions and OELs established in EU Member States.

The purpose of this questionnaire is to collect data and information that will underpin the assessment. This questionnaire is intended for **all companies that expose their workers to the relevant chemical agents**.

This questionnaire is intended for a **single facility and chemical agent**. If workers are exposed at multiple facilities or they are exposed to more than one of the relevant chemical agents, please complete the questionnaire several times or contact the study team.

The deadline for completion of the questionnaire is **3 November 2017**.

[30] The study is also assessing the impacts of an OEL of 5 µg/m$^3$ for '*chromium (VI) compounds in **welding or plasma cutting processes or similar work processes that generate fume'*** which will enter into force 5 years after the transposition date of the compromise recently reached by Council and the European Parliament on the Commission proposal COM(2016)248 final. These impacts are subject to a separate questionnaire.

[31] For MOCA, also the impacts of establishing a skin notation are being assessed.

All responses to this questionnaire will be treated in the **strictest confidence** and will only be used for the purposes of this study. In preparing our reports for the Commission (which, subsequently, may be published), care will be taken to ensure that specific responses cannot be linked to individual companies.

If you have any questions about this study, please contact Daniel Vencovsky (daniel.vencovsky@rpaltd.co.uk or +44 (0)1508 528 465).

***Definitions and acronyms***

| | |
|---|---|
| CMD | Carcinogens and Mutagens Directive 2004/37/EC |
| MOCA | 4,4'-Methylene-bis(2-chloroaniline) |
| OEL | The term Occupational Exposure Limit Value (OEL) refers to the limit of the time-weighted average (TWA) of the concentration in the air within the breathing zone of a worker, measured or calculated in relation to a reference period of eight hours. |
| PROC | Process category |
| RAC | The Committee for Risk Assessment (RAC) is a scientific committee of ECHA that prepares the opinions related to the risks of substances to human health and the environment. It also assisted DG Employment with the evaluation of MOCA and inorganic arsenic compounds. |
| RMM | Risk Management Measure |
| SCOEL | The Scientific Committee on Occupational Exposure Limits (SCOEL) assists the Commission, in particular, in evaluating scientific data and recommending OELs. |
| SEG | Similar Exposure Group |
| Skin notation | An indication that the dermal route of exposure is scientifically considered to be relevant (in addition to the inhalation route) |
| STEL | A Short-term Exposure Limit (STEL) is a limit of the concentration in the air within the breathing zone of a worker, measured or calculated in relation to a reference period of fifteen minutes. |
| SU | Sector of Use |
| TWA | Time-weighted average |

# A) About your company

A1) Please provide the following details

| Question | Answer |
|---|---|
| Name of contact person | |
| Company | |
| Email address of contact person | |
| Telephone number of contact person | |

A2) What is the size of your company?

*For enterprise size definitions, please refer to [http://ec.europa.eu/growth/smes/business-friendly-environment/sme-definition/index_en.htm](http://ec.europa.eu/growth/smes/business-friendly-environment/sme-definition/index_en.htm)*

| |
|---|
| ☐ *Micro enterprise (less than 10 persons employed)* |
| ☐ *Small enterprise (10-49 persons employed)* |
| ☐ *Medium-sized enterprise (50-249 persons employed)* |
| ☐ *Large enterprise (250 or more persons employed)* |

A3) How many facilities where workers are exposed to one or more of the chemical agents within the scope of this study does your company have?

☐ *1* ☐ *More than 1*

*If more than 1, please complete this questionnaire several times or contact the study team.*

A4) Please define the sector in which your company is active (if possible using a NACE code[32]):

A5) Please give the name and location (incl. country) of the facility for which you are completing the questionnaire.

A6) Please select the chemical agent for which you are completing this questionnaire.

☐ *Cadmium and its inorganic compounds*

☐ *Beryllium and its inorganic compounds*

☐ *Inorganic arsenic compounds including arsenic acid and its salts*

☐ *Formaldehyde*

[32] Statistical Classification of Economic Activities in the European Community, Rev. 2; see http://ec.europa.eu/eurostat/ramon/nomenclatures/index.cfm?TargetUrl=LST_NOM_DTL&StrNom=NACE_REV2&StrLanguageCode=EN&IntPcKey=&StrLayoutCode=HIERARCHIC

☐ *4,4'-Methylene-bis(2-chloroaniline) (MOCA)*

A7) If your workers are exposed to As, Cd, or Be compounds, please specify the specific compounds that they are exposed to (e.g. beryllium metal, beryllium oxide, etc.) See here for a non-exhaustive list (examples) of the relevant compounds.

# B) Current exposure at your facility

B1) How would you like to provide data on worker exposure?

*Please select the reference group for which you have data on worker exposure. One reference group is sufficient, e.g. there is no need for data by both SEGs and REACH descriptors, just one or the other.*

| |
|---|
| ☐ *Similar Exposure Group(s) (SEGs) -> go to Section BA* |
| ☐ *Own categories: process/activity or department/unit or similar -> go to Section BB* |
| ☐ *REACH descriptors (SUs and PROCs) -> go to Section BC* |
| ☐ *We have no data on worker exposure -> go to Section C* |

A **Similar Exposure Group (SEG)** is a group of workers having the same general exposure profile for the chemical agent(s) being studied because of the similarity and frequency of the tasks they perform, the materials and processes with which they work and the similarity of the way they perform those tasks. A SEG can be constituted by one worker.

The use of your **own categories** allows you to specify the category for which you are providing worker exposure data. These could include, for example, a **process** (i.e. a set of operations to produce an output), **activity** (typical activities performed by worker(s) during the working day) or a specific **department/unit** in your plant which has a common exposure source.

The descriptors used under **REACH** include the **Sector of Use** (SU) which describes in which sector of the economy exposure occurs (e.g. rubber manufacturing sector, glass manufacturing sector, etc.) and the **process categories (PROCs)** which describe the tasks, application techniques or process types defined from the occupational perspective.

***BA) SEGs***

B2) How many SEGs are there at your facility?

☐ 1 SEG

☐ 2 SEGs

☐ 3 SEGs

☐ 4 SEGs

☐ 5 SEGs

☐ more than 5 SEGs

***SEG 1***

PLEASE COPY AND PASTE B3-B5 FOR EACH SEG

B3) Please describe **SEG 1**.

| Question | Answer |
|---|---|
| Use(s) | |
| Task(s)/process(es)/exposure source(s) | |
| Number of workers | |

B4) Please provide data for inhalation exposure in **SEG 1**.

| Question | Answer |
|---|---|
| ***8 hr Time Weighted Average (TWA)*** | |
| How is the 8 hr TWA exposure concentration determined? | ☐ Measured ☐ Estimated<br>How estimated (method) or measured (personal or work area sampling)? |
| Air exposure concentration (8 hr TWA) and unit*:<br>If measured, please specify the number of samples and how the **exposure concentration given above** was derived. *See below for an explanation.* | |
| ***Concentration over a 15 minute reference period*** | |
| How is the 15 minute exposure concentration determined? | ☐ Measured ☐ Estimated<br>How estimated (method) or measured (personal or work area sampling)? |
| Air exposure concentration (15 mins) and unit*:<br>If measured, please specify the number of samples and how the **exposure concentration given above** was derived. *See below for an explanation.* | |

*Note: *Please provide data in the format that you use (e.g. to demonstrate compliance with your national OEL or STEL) but, if possible, please also provide the Arithmetic Mean, 90th percentile (if more than ten values are available) and the range (if more than one value is available).*

**Values based on measured samples can be derived using, for example, the following methods:**

- A single sample or several individual samples
- A single value combining all samples:
  - Arithmetic mean
  - Geometric mean
  - Median
  - 95th percentile, 90th percentile, 70th percentile, other percentile (please specify)
  - Mode
- If a lognormal probability density function is estimated and a single value is presented:
  - Highest point (global maximum/mode) of the lognormal probability density function
  - Arithmetic mean
  - Geometric mean/median
  - 95th percentile, 90th percentile, 70th percentile, other percentile (please specify)
- Other, please specify

B5) Which Risk Management Measures (RMMs) are in place to control inhalation exposure in **SEG 1**?

| Measures that seek to | | Yes/No and specify RMMs (e.g. general ventilation, LEV, etc.) |
|---|---|---|
| 1 Substitute/reduce quantities of chemical agents | | |
| 2 Reduce the number of workers exposed (fewer, rotate, etc.) | | |
| 3 Reduce the concentration at the workplace: | 3a. Process-related measures (design of work processes, etc.) | |
| | 3b. Control equipment to enclose, extract, or ventilate, etc. | |
| | 3c. Detect unusual exposures | |

| Measures that seek to | | Yes/No and specify RMMs (e.g. general ventilation, LEV, etc.) |
|---|---|---|
| 4 Reduce worker exposure: | 4a. Collective protection measures to reduce exposure to workers | |
| | 4b. Individual protection measures to reduce exposure to workers | |
| 5 Other measures, please specify | | |

***BB) Process/activity or department/unit or similar***

B6) Please specify the reference group of workers for which you will provide exposure data, e.g. those undertaking a certain process/activity **or** belonging to a department/unit **or** the whole facility.

B7) How many such groups are there at your facility?

☐ 1 Group

☐ 2 Groups

☐ 3 Groups

☐ 4 Groups

☐ 5 Groups

☐ more than 5 Groups

***Group 1***

B8) Please describe **Group 1**.

| Question | Answer |
|---|---|
| Use(s) | |
| Task(s)/process(es)/exposure source(s) | |
| Number of workers | |

B9) Please specify the air exposure concentrations in **Group 1**.

| Question | Answer | |
|---|---|---|
| ***8 hr Time Weighted Average (TWA)*** | | |
| How is the 8 hr TWA exposure concentration determined? | ☐ Measured | ☐ Estimated<br>How estimated (method) or measured (personal or work area sampling)? |
| Air exposure concentration (8 hr TWA) and unit*: | | |
| If measured, please specify the number of samples and how the **exposure concentration given above** was derived. *See below for an explanation.* | | |
| ***Concentration over a 15 minute reference period*** | | |
| | ☐ Measured | ☐ Estimated |

| Question | Answer |
|---|---|
| How is the 15 minute exposure concentration determined?<br><br>Air exposure concentration (15 mins) and unit*:<br>If measured, please specify the number of samples and how the **exposure concentration given above** was derived. *See below for an explanation.* | How estimated (method) or measured (personal or work area sampling)? |

*Note: * Please provide data in the format that you use (e.g. to demonstrate compliance with your national OEL or STEL) but, if possible, please also provide the Arithmetic Mean, 90th percentile (if more than ten values are available) and the range (if more than one value is available).*

**Values based on measured samples can be derived using, for example, the following methods:**

- A single sample or several individual samples
- A single value combining all samples:
  - Arithmetic mean
  - Geometric mean
  - Median
  - 95th percentile, 90th percentile, 70th percentile, other percentile (please specify)
  - Mode
- If a lognormal probability density function is estimated and a single value is presented:
  - Highest point (global maximum/mode) of the lognormal probability density function
  - Arithmetic mean
  - Geometric mean/median
  - 95th percentile, 90th percentile, 70th percentile, other percentile (please specify)
- Other, please specify

B10) Which Risk Management Measures (RMMs) are in place to control inhalation exposure in Group 1?

| Measures that seek to | | Yes/No and specify RMMs (e.g. general ventilation, LEV, etc.) |
|---|---|---|
| 1 Substitute/reduce quantities of chemical agents | | |
| 2 Reduce the number of workers exposed (fewer, rotate, etc.) | | |
| 3 Reduce the concentration at the workplace: | 3a. Process-related measures (design of work processes, etc.) | |
| | 3b. Control equipment to enclose, extract, or ventilate, etc. | |
| | 3c. Detect unusual exposures | |
| 4 Reduce worker exposure: | 4a. Collective protection measures to reduce exposure to workers | |
| | 4b. Individual protection measures to reduce exposure to workers | |
| 5 Other measures, please specify | | |

***BC) REACH descriptors***

B11) Please specify the relevant Sector of Use (SU)[33] in which exposure occurs.

*This questionnaire has space for one use only. If several uses are relevant, please provide responses for the main use and contact the study team.*

B12) For the use during which exposure to the chemical agent in question may occur, in how many process categories (PROCs) are workers exposed?

☐ 1 PROC

☐ 2 PROCs

☐ 3 PROCs

☐ 4 PROCs

☐ 5 PROCs

☐ more than 5 PROCs

***First PROC***

B13) Please describe the **first PROC**.

| Question | Answer |
|---|---|
| PROC code[34] | |
| Number of workers | |

B14) Please specify the extent of inhalation exposure.

| Question | Answer |
|---|---|
| How is the air exposure concentration determined? | ☐ Measured ☐ Estimated<br>How estimated (method) or measured (personal or work area sampling)? |
| Frequency of exposure | |
| Duration of exposure | |
| Exposure concentration (including unit) | |

B15) Which Risk Management Measures (RMMs) are in place to control exposure in this PROC?

| Measures that seek to | Yes/No and specify RMMs (e.g. general ventilation, LEV, etc.) |
|---|---|
| 1 Substitute/reduce quantities of chemical agents | |
| 2 Reduce the number of workers exposed (fewer, rotate, etc.) | |

[33] The sector of use category (SU) describes in which sector of the economy exposure occurs, e.g. rubber manufacturing sector, glass manufacturing sector, agriculture, forestry, fishery. See pp. 43-44 https://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf

[34] See pp49-54 https://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf

| Measures that seek to | | Yes/No and specify RMMs (e.g. general ventilation, LEV, etc.) |
|---|---|---|
| 3 Reduce the concentration at the workplace: | 3a. Process-related measures (design of work processes, etc.) | |
| | 3b. Control equipment to enclose, extract, or ventilate, etc. | |
| | 3c. Detect unusual exposures | |
| 4 Reduce worker exposure: | 4a. Collective protection measures to reduce exposure to workers | |
| | 4b. Individual protection measures to reduce exposure to workers | |
| 5 Other measures, please specify | | |

# C) Compliance with a potential new OEL under the CMD

This section enquires about the Risk Management Measures (RMMs) that would have to be put in place to comply with a new OEL under the CMD.

The term **Occupational Exposure Limit Value (OEL)** refers to the limit of the time-weighted average (TWA) of the concentration in the air within the breathing zone of a worker, measured or calculated in relation to a reference period of eight hours.

Although a wide range of potential OELs is being assessed in this study, the limit values and air concentrations given below are used as reference points for this questionnaire.

***Cadmium and its inorganic compounds***

| | |
|---|---|
| 1 Lowest technically feasible concentration | The term 'technically feasible' refers to the availability of technical means to achieve the relevant air concentration without taking economic viability into account. |
| 2 Lowest economically viable concentration | The term 'economically viable' refers to the lowest 8 hour TWA concentration that can be achieved without your facility discontinuing the relevant activities/production. |
| 3 OEL at the level proposed in SCOEL OPIN 336 | Cd: 1 µg/m$^3$ (inhalable) |
| 4 OEL at the level of the lowest current national OEL in EU Member States | Same as above |
| 5 Mean, median, and mode of national OELs in EU Member States | Cd: 10 µg/m$^3$ (respirable), for the purposes of this questionnaire taken to equal 50 µg/m$^3$ (inhalable) |

C-Cd 1) Which **additional** Risk Management Measures (RMMs) would you have to implement to achieve the lowest **technically feasible** 8 hour TWA air concentration of the relevant chemical agent?

| SEG/Group/PROC | 8 hour TWA air concentration that could potentially be achieved | Additional RMMs required |
|---|---|---|
| SEG/Group/PROC No. 1: | | |

| SEG/Group/PROC | 8 hour TWA air concentration that could potentially be achieved | Additional RMMs required |
|---|---|---|
| SEG/Group/PROC No. 2: | | |
| SEG/Group/PROC No. 3: | | |
| SEG/Group/PROC No. 4: | | |
| SEG/Group/PROC No. 5: | | |

C-Cd 2) Which **additional** RMMs would you have to implement to achieve the lowest **economically viable** 8 hour TWA air concentration of the relevant chemical agent?

| SEG/Group/PROC | 8 hour TWA air concentration that could potentially be achieved | Additional RMMs required |
|---|---|---|
| SEG/Group/PROC No. 1: | | |
| SEG/Group/PROC No. 2: | | |
| SEG/Group/PROC No. 3: | | |
| SEG/Group/PROC No. 4: | | |
| SEG/Group/PROC No. 5: | | |

C-Cd 3) Which RMMs would you have to implement to comply with the OELs given below?

| SEG/Group/PROC | 1 µg/m$^3$ (inhalable) | 10 µg/m3 (respirable), for the purposes of this questionnaire taken to equal 50 µg/m3 (inhalable) |
|---|---|---|
| SEG/Group/PROC No. 1: | | |
| SEG/Group/PROC No. 2: | | |
| SEG/Group/PROC No. 3: | | |
| SEG/Group/PROC No. 4: | | |
| SEG/Group/PROC No. 5: | | |

***Beryllium and its inorganic compounds***

| | |
|---|---|
| 1 Lowest technically feasible concentration | The term 'technically feasible' refers to the availability of technical means to achieve the relevant air concentration without taking economic viability into account. |
| 2 Lowest economically viable concentration | The term 'economically viable' refers to the lowest 8 hour TWA concentration that can be achieved without your facility discontinuing the relevant activities/production. |
| 3 OEL at the level proposed in SCOEL REC 175 | Be: 0.02 µg/m$^3$ (inhalable fraction) |
| 4 OEL at the level of the lowest current national OEL in EU Member States | Be: 0.1 µg/m$^3$ (inhalable) |
| 5 Median and mode of national OELs in EU Member States | Be: 2 µg/m$^3$ (inhalable) |

C-Be 1) Which **additional** Risk Management Measures (RMMs) would you have to implement to achieve the lowest **technically feasible** 8 hour TWA air concentration of the relevant chemical agent?

| SEG/Group/PROC | 8 hour TWA air concentration that could potentially be achieved | Additional RMMs required |
|---|---|---|
| SEG/Group/PROC No. 1: | | |
| SEG/Group/PROC No. 2: | | |
| SEG/Group/PROC No. 3: | | |
| SEG/Group/PROC No. 4: | | |
| SEG/Group/PROC No. 5: | | |

C-Be 2) Which **additional** RMMs would you have to implement to achieve the lowest **economically viable** 8 hour TWA air concentration of the relevant chemical agent?

| SEG/Group/PROC | 8 hour TWA air concentration that could potentially be achieved | Additional RMMs required |
|---|---|---|
| SEG/Group/PROC No. 1: | | |
| SEG/Group/PROC No. 2: | | |
| SEG/Group/PROC No. 3: | | |
| SEG/Group/PROC No. 4: | | |
| SEG/Group/PROC No. 5: | | |

C-Be 3) Which RMMs would you have to implement to comply with the OELs given below?

| SEG/Group/PROC | 2 µg/m$^3$ (inhalable) | 0.1 µg/m$^3$ (inhalable) | 0.02 µg/m$^3$ (inhalable fraction) |
|---|---|---|---|
| SEG/Group/PROC No. 1: | | | |
| SEG/Group/PROC No. 2: | | | |
| SEG/Group/PROC No. 3: | | | |

| SEG/Group/PROC | 2 µg/m³ (inhalable) | 0.1 µg/m³ (inhalable) | 0.02 µg/m³ (inhalable fraction) |
|---|---|---|---|
| SEG/Group/PROC No. 4: | | | |
| SEG/Group/PROC No. 5: | | | |

***Inorganic arsenic compounds including arsenic acid and its salts***

| | |
|---|---|
| 1 Lowest technically feasible concentration | The term 'technically feasible' refers to the availability of technical means to achieve the relevant air concentration without taking economic viability into account. |
| 2 Lowest economically viable concentration | The term 'economically viable' refers to the lowest 8 hour TWA concentration that can be achieved without your facility discontinuing the relevant activities/production. |
| 3 OEL at the level proposed by SCOEL or RAC | No value proposed |
| 4 OEL at the level of the lowest current national OEL in EU Member States | As: 0.01 mg/m³ |
| 5 Median of national OELs in EU Member States | As: 0.225 mg/m³ |

C-As 1) Which **additional** Risk Management Measures (RMMs) would you have to implement to achieve the lowest **technically feasible** 8 hour TWA air concentration of the relevant chemical agent?

| SEG/Group/PROC | 8 hour TWA air concentration that could potentially be achieved | Additional RMMs required |
|---|---|---|
| SEG/Group/PROC No. 1: | | |
| SEG/Group/PROC No. 2: | | |
| SEG/Group/PROC No. 3: | | |
| SEG/Group/PROC No. 4: | | |
| SEG/Group/PROC No. 5: | | |

C-As 2) Which **additional** RMMs would you have to implement to achieve the lowest **economically viable** 8 hour TWA air concentration of the relevant chemical agent?

| SEG/Group/PROC | 8 hour TWA air concentration that could potentially be achieved | Additional RMMs required |
|---|---|---|
| SEG/Group/PROC No. 1: | | |
| SEG/Group/PROC No. 2: | | |
| SEG/Group/PROC No. 3: | | |
| SEG/Group/PROC No. 4: | | |
| SEG/Group/PROC No. 5: | | |

C-As 3) Which RMMs would you have to implement to comply with the OELs given below?

| SEG/Group/PROC | 0.01 mg/m$^3$ | 0.225 mg/m$^3$ |
|---|---|---|
| SEG/Group/PROC No. 1: | | |
| SEG/Group/PROC No. 2: | | |
| SEG/Group/PROC No. 3: | | |
| SEG/Group/PROC No. 4: | | |
| SEG/Group/PROC No. 5: | | |

***Formaldehyde***

| | |
|---|---|
| 1 Lowest technically feasible concentration | The term 'technically feasible' refers to the availability of technical means to achieve the relevant air concentration without taking economic viability into account. |
| 2 Lowest economically viable concentration | The term 'economically viable' refers to the lowest 8 hour TWA concentration that can be achieved without your facility discontinuing the relevant activities/production. |
| 3 OEL at the level proposed in SCOEL REC 125 | Formaldehyde: 0.369 mg/m$^3$=0.3 ppm |
| 4 OEL at the level of the lowest current national OEL in EU Member States | Formaldehyde: 0.15 mg/m$^3$=0.12 ppm |
| 5 Mode of national OELs in EU Member States | Formaldehyde: 0.6 mg/m$^3$=0.49 ppm |

C-FA 1) Which **additional** Risk Management Measures (RMMs) would you have to implement to achieve the lowest **technically feasible** 8 hour TWA air concentration of the relevant chemical agent?

| SEG/Group/PROC | 8 hour TWA air concentration that could potentially be achieved | Additional RMMs required |
|---|---|---|
| SEG/Group/PROC No. 1: | | |
| SEG/Group/PROC No. 2: | | |
| SEG/Group/PROC No. 3: | | |
| SEG/Group/PROC No. 4: | | |
| SEG/Group/PROC No. 5: | | |

C-FA 2) Which **additional** RMMs would you have to implement to achieve the lowest **economically viable** 8 hour TWA air concentration of the relevant chemical agent?

| SEG/Group/PROC | 8 hour TWA air concentration that could potentially be achieved | Additional RMMs required |
|---|---|---|
| SEG/Group/PROC No. 1: | | |
| SEG/Group/PROC No. 2: | | |
| SEG/Group/PROC No. 3: | | |
| SEG/Group/PROC No. 4: | | |
| SEG/Group/PROC No. 5: | | |

C-FA 3) Which RMMs would you have to implement to comply with the OELs given below?

| SEG/Group/PROC | 0.6 mg/m$^3$ = 0.49 ppm | 0.369 mg/m$^3$= 0.3 ppm | 0.15 mg/m$^3$ = 0.12 ppm |
|---|---|---|---|
| SEG/Group/PROC No. 1: | | | |
| SEG/Group/PROC No. 2: | | | |
| SEG/Group/PROC No. 3: | | | |
| SEG/Group/PROC No. 4: | | | |
| SEG/Group/PROC No. 5: | | | |

***MOCA***

| | |
|---|---|
| 1 Lowest technically feasible concentration | The term 'technically feasible' refers to the availability of technical means to achieve the relevant air concentration without taking economic viability into account. |
| 2 Lowest economically viable concentration | The term 'economically viable' refers to the lowest 8 hour TWA concentration that can be achieved without your facility discontinuing the relevant activities/production. |
| 3 OEL at the value proposed by SCOEL or RAC | No value proposed |
| 4 OEL at the level of the lowest current national OEL in EU Member States | MOCA: 0.005 mg/m$^3$ |
| 5 Median and mode of national OELs in EU Member States | MOCA: 0.02 mg/m$^3$ |

C-MOCA 1) Which **additional** Risk Management Measures (RMMs) would you have to implement to achieve the lowest **technically feasible** 8 hour TWA air concentration of the relevant chemical agent?

| SEG/Group/PROC | 8 hour TWA air concentration that could potentially be achieved | Additional RMMs required |
|---|---|---|
| SEG/Group/PROC No. 1: | | |
| SEG/Group/PROC No. 2: | | |
| SEG/Group/PROC No. 3: | | |
| SEG/Group/PROC No. 4: | | |
| SEG/Group/PROC No. 5: | | |

C-MOCA 2) Which **additional** RMMs would you have to implement to achieve the lowest **economically viable** 8 hour TWA air concentration of the relevant chemical agent?

| SEG/Group/PROC | 8 hour TWA air concentration that could potentially be achieved | Additional RMMs required |
|---|---|---|
| SEG/Group/PROC No. 1: | | |
| SEG/Group/PROC No. 2: | | |
| SEG/Group/PROC No. 3: | | |

| SEG/Group/PROC | 8 hour TWA air concentration that could potentially be achieved | Additional RMMs required |
|---|---|---|
| SEG/Group/PROC No. 4: | | |
| SEG/Group/PROC No. 5: | | |

C-MOCA 3) Which RMMs would you have to implement to comply with the OELs given below?

| SEG/Group/PROC | 0.02 mg/m$^3$ | 0.005 mg/m$^3$ |
|---|---|---|
| SEG/Group/PROC No. 1: | | |
| SEG/Group/PROC No. 2: | | |
| SEG/Group/PROC No. 3: | | |
| SEG/Group/PROC No. 4: | | |
| SEG/Group/PROC No. 5: | | |

# D) Compliance with a potential new STEL under the CMD

This section enquires about the Risk Management Measures (RMMs) that would have to be put in place to comply with a new STEL under the CMD.

The term **STEL** refers to the limit of the concentration in the air within the breathing zone of a worker, measured or calculated in relation to a reference period of fifteen minutes.

***Beryllium and its inorganic compounds***

Although a wide range of potential STELs is being assessed in this study, the limit values and air concentrations given below are used as reference points for this questionnaire:

| | |
|---|---|
| 1 Lowest technically feasible concentration | The term 'technically feasible' refers to the availability of technical means to achieve the relevant air concentration without taking economic viability into account. |
| 2 Lowest economically viable concentration | The term 'economically viable' refers to the lowest concentration that can be achieved without your facility discontinuing the relevant activities/production. |
| 3 STEL at the level proposed in SCOEL REC 175 | Be: 0.2 µg/m$^3$ (inhalable fraction) |
| 4 STEL at the level of the current lowest national 15 minute limit | Be: 0.4 µg/m$^3$ (inhalable) |
| 5 Median and mode of national STELs in EU Member States | Be: 8 µg/m$^3$ (inhalable) |

D-Be 1) Which **additional** Risk Management Measures (RMMs) would you have to implement to achieve the lowest **technically feasible** air concentration of the relevant chemical agent **over a reference period of 15 minutes**?

Are these the same as given by you under C1) for the lowest technically feasible OEL?

☐ Yes ☐ No

IF NO, please answer the questions below.

| SEG/Group/PROC | Air concentration over 15 minutes that could potentially be achieved | Additional RMMs required |
|---|---|---|
| SEG/Group/PROC No. 1: | | |
| SEG/Group/PROC No. 2: | | |
| SEG/Group/PROC No. 3: | | |
| SEG/Group/PROC No. 4: | | |
| SEG/Group/PROC No. 5: | | |

D-Be 2) Which **additional** RMMs would you have to implement to achieve the lowest **economically viable** air concentration of the relevant chemical agent **over 15 minutes**?

Are these the same as given by you under C2) for the lowest economically OEL?

☐ Yes ☐ No

IF NO, please answer the questions below.

| SEG/Group/PROC | Air concentration over 15 minutes that could be achieved | Additional RMMs required |
|---|---|---|
| SEG/Group/PROC No. 1: | | |
| SEG/Group/PROC No. 2: | | |
| SEG/Group/PROC No. 3: | | |
| SEG/Group/PROC No. 4: | | |
| SEG/Group/PROC No. 5: | | |

D-Be 3) Which **additional** RMMs would you have to implement to comply with the STELs given below?

| SEG/Group/PROC | 8 µg/m³ (inhalable) | 0.4 µg/m³ (inhalable) | 0.2 µg/m³ (inhalable fraction) |
|---|---|---|---|
| SEG/Group/PROC No. 1: | | | |
| SEG/Group/PROC No. 2: | | | |
| SEG/Group/PROC No. 3: | | | |
| SEG/Group/PROC No. 4: | | | |
| SEG/Group/PROC No. 5: | | | |

***Formaldehyde***

Although a wide range of potential STELs is being assessed in this study, the limit values and air concentrations given below are used as reference points for this questionnaire:

| | |
|---|---|
| 1 Lowest technically feasible concentration | The term 'technically feasible' refers to the availability of technical means to achieve the relevant air concentration without taking economic viability into account. |

| | |
|---|---|
| 2 Lowest economically viable concentration | The term 'economically viable' refers to the lowest concentration that can be achieved without your facility discontinuing the relevant activities/production. |
| 3 STEL at the level proposed in SCOEL REC 125 | Formaldehyde: 0.738 mg/m$^3$=0.6 ppm |
| 4 STEL at the level of the current lowest national 15 minute limit | Formaldehyde: 0.37 mg/m$^3$=0.3 ppm |
| 5 Mode of national STELs in EU Member States | Formaldehyde: 1.2 mg/m$^3$=1.48 ppm |

D-FA 1) Which **additional** Risk Management Measures (RMMs) would you have to implement to achieve the lowest **technically feasible** air concentration of the relevant chemical agent **over a reference period of 15 minutes**?

Are these the same as given by you under C1) for the lowest technically feasible OEL?

☐ Yes ☐ No

IF NO, please answer the questions below.

| SEG/Group/PROC | Air concentration over 15 minutes that could potentially be achieved | Additional RMMs required |
|---|---|---|
| SEG/Group/PROC No. 1: | | |
| SEG/Group/PROC No. 2: | | |
| SEG/Group/PROC No. 3: | | |
| SEG/Group/PROC No. 4: | | |
| SEG/Group/PROC No. 5: | | |

D-FA 2) Which **additional** RMMs would you have to implement to achieve the lowest **economically viable** air concentration of the relevant chemical agent **over 15 minutes**?

Are these the same as given by you under C2) for the lowest economically OEL?

☐ Yes ☐ No

IF NO, please answer the questions below.

| SEG/Group/PROC | Air concentration over 15 minutes that could be achieved | Additional RMMs required |
|---|---|---|
| SEG/Group/PROC No. 1: | | |
| SEG/Group/PROC No. 2: | | |
| SEG/Group/PROC No. 3: | | |
| SEG/Group/PROC No. 4: | | |
| SEG/Group/PROC No. 5: | | |

D-FA 3) Which **additional** RMMs would you have to implement to comply with the STELs given below?

| SEG/Group/PROC | 1.2 mg/m$^3$= 1,4 ppm | 0.738 mg/m$^3$=0.6 ppm | 0.37 mg/m$^3$=0.3 ppm |
|---|---|---|---|
| SEG/Group/PROC No. 1: | | | |
| SEG/Group/PROC No. 2: | | | |
| SEG/Group/PROC No. 3: | | | |
| SEG/Group/PROC No. 4: | | | |
| SEG/Group/PROC No. 5: | | | |

## E) Further communication

E1) **Clarifications:** Please provide an email address or telephone number in case the study team needs clarification of any of your responses to this questionnaire.

E2) **More detailed telephone discussion:** Would you be willing to take part in a follow up interview to discuss the potential impacts of the potential OELs and STELs in more detail?

☐ Yes ☐ No

E3) **Site visit:** Would you be willing to host a site visit enabling the study team to gain a first-hand account of the issues involved with complying with a range of potential OEL and STEL values?

☐ Yes ☐ No

# A1.2 Questionnaire for companies – Cr(VI) compounds from welding, plasma cutting, and similar processes that generate fumes

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) has been contracted by the European Commission (DG Employment, Social Affairs and Inclusion) to carry out a study regarding Directive 2004/37/EC on the protection of workers from exposure to carcinogens or mutagens at work (hereinafter the Carcinogens and Mutagens Directive or CMD).

One of the objectives of the study is to assess the impacts of an OEL of 5 µg/m$^3$ for 'chromium (VI) compounds in welding or plasma cutting processes or similar work processes that generate fume' which will enter into force 5 years after the transposition date of the compromise recently reached by Council and the European Parliament on the Commission proposal COM(2016)248 final.

The purpose of this questionnaire is to collect data and information that will underpin the evaluation. This questionnaire is intended for **companies whose employees are potentially exposed to fumes from welding, plasma cutting and similar processes containing Cr(VI) compounds**.

This questionnaire is intended for a **single facility** only. If workers are exposed at multiple facilities belonging to your company, please fill out one questionnaire for every facility or contact the study team.

The deadline for completion of the questionnaire is **3 November 2017**.

**Where you do not have the information requested in this questionnaire, please provide qualitative estimates.**

All responses to this questionnaire will be treated in the **strictest confidence** and will only be used for the purposes of this study. In preparing our reports for the Commission (which, subsequently, may be published), care will be taken to ensure that specific responses cannot be linked to individual companies.

If you have any questions about this study, please contact Marlies Warming (mrwa@cowi.dk, + 45 5640 4517, COWI Denmark).

| ***Acronyms*** | |
|---|---|
| CMD | Carcinogens and Mutagens Directive 2004/37/EC |
| RMM | Risk Management Measure |
| SEG | Similar Exposure Group |
| TWA | Time-weighted average |

# A) About your company

A1) Please provide the following details

| Question | Answer |
|---|---|
| Name of contact person | |
| Company | |
| Email address of contact person | |
| Telephone number of contact person | |

A2) What is the size[35] of your company?

| |
|---|
| ☐ *Micro enterprise (less than 10 persons employed)* |
| ☐ *Small enterprise (10-49 persons employed)* |
| ☐ *Medium-sized enterprise (50-249 persons employed)* |
| ☐ *Large enterprise (250 or more persons employed)* |

A3) How many facilities, where workers are exposed to Cr(VI) in fumes from welding, cutting, thermal spraying or similar processes, does your company have?

| |
|---|
| ☐ *1* |
| ☐ *More than 1* |

*If more than 1, please complete this questionnaire separately for each facility.*

A4) Please define the sector in which your company is active (if possible using a NACE code[36]):

| |
|---|
| |

[35] For enterprise size definitions, please refer to http://ec.europa.eu/growth/smes/business-friendly-environment/sme-definition/index_en.htm

[36] Statistical Classification of Economic Activities in the European Community, Rev. 2; see http://ec.europa.eu/eurostat/ramon/nomenclatures/index.cfm?TargetUrl=LST_NOM_DTL&StrNom=NACE_REV2&StrLanguageCode=EN&IntPcKey=&StrLayoutCode=HIERARCHIC

## B) Current exposure at your facility

B1) Please indicate the name and location of the facility for which you are completing the questionnaire.

| Question | Answer |
|---|---|
| Name | |
| Location (incl. country) | |

B2) How would you like to provide data on worker exposure?

| |
|---|
| ☐ *Similar Exposure Group(s) (SEGs)* |
| ☐ *Another group of workers (defined by you), such as process/activity or department/unit or similar* |
| ☐ *We have no data on worker exposure -> go to Section C* |

If 'Another (self-defined) group of workers' please specify below:

| |
|---|
| |

A **Similar Exposure Group (SEG)** is a group of workers having the same general exposure profile for the chemical agent(s) being studied because of the similarity and frequency of the tasks they perform, the materials and processes with which they work and the similarity of the way they perform those tasks. A SEG can be constituted by one worker.

For example, a SEG could be:

- A group of welders working full-time with Manual Metal Arc (MMA) welding of stainless steel
- A group of operators cutting steel plates at a cutting table
- A single worker performing thermal spraying task occasionally

The use of your **own categories** allows you to specify the category for which you are providing worker exposure data. These could include, for example, a **process** (i.e. a set of operations to produce an output), **activity** (typical activities performed by worker(s) during the working day) or a specific **department/unit** in your plant which has a common exposure source.

B3) How many "Similar Exposure Groups" (SEGs) or "Groups defined by you" are there at your facility?

*This questionnaire has space for up to **five** groups. If there are more than five groups at your facility, please complete this questionnaire for the five groups with the greatest exposure (number of workers and exposure concentration).*

| |
|---|
| ☐ 1 SEG/Self-defined group |
| ☐ 2 SEGs/Self-defined groups |
| ☐ 3 SEGs/Self-defined groups |
| ☐ 4 SEGs/Self-defined groups |
| ☐ 5 SEGs/Self-defined groups |
| ☐ more than 5 SEGs/Self-defined groups |

***Group 1***

B4) Please describe **Group 1**.

| Question | Answer |
|---|---|
| Please specify the relevant thermal metal work processes (several answers possible). | ☐ Welding. Please indicate which process(es):<br>☐ Thermal cutting. Please indicate which process(es):<br>☐ Thermal spraying. Please indicate which process(es):<br>☐ Other. Please indicate which: |
| Please indicate which materials are worked with (several answers possible).) | ☐ Stainless steel<br>☐ High-alloyed chromium-containing steels<br>☐ Scrap steel<br>☐ Low-alloyed steel<br>☐ Other. Please indicate which: |
| Please specify the number of workers working full-time with the mentioned tasks and processes. | |
| Please specify the number of workers working part-time (estimate hours/day) with the mentioned tasks and processes. | |

B5) Please provide data for air exposure to Cr(VI) in **Group 1.**

| Question | Answer |
|---|---|
| ***1) Exposure concentration value*** | |
| Which kind of exposure concentration value do you have available for this group? | ☐ 8 hr Time Weighted Average (TWA) concentration → 2)<br>☐ Concentration over a 15 minute reference period → 3)<br>☐ Other exposure concentration → 4)<br>☐ None. The work place is established according to industrial safety regulations by the national authority for occupational health. Therefore, the exposure concentrations are expected to be below the national occupational exposure limit.<br>☐ None. The concentration of Cr(VI) compounds at the workplace is not known. In order to evaluate exposure, an occupational exposure value for the process is used (e.g. particles of welding fume in mg/m³).<br>☐ Don't know. |
| ***2) 8 hr Time Weighted Average (TWA)*** | |
| How is the 8 hr TWA exposure concentration determined? | ☐ Measured<br>☐ Estimated. Please indicate how:<br>☐ Don't know. |
| If measured, please specify the number of samples and how the **exposure concentration given below** was derived. See below for an explanation. | |
| Air exposure concentration (8 hr TWA) and unit: | |
| ***3) Concentration over a 15 minute reference period*** | |
| How is the 15 minute exposure concentration determined? | ☐ Measured<br>☐ Estimated. Please indicate how:<br>☐ Don't know. |
| If measured, please specify the number of samples and how the **exposure concentration given below** was derived. See below for an explanation. | |
| Air exposure concentration (15 mins) and unit: | |
| ***4) Other exposure concentration value*** | |
| How is the exposure concentration determined? | ☐ Measured<br>☐ Estimated. Please indicate how:<br>☐ Don't know. |
| If measured, please specify the number of samples and how the **exposure concentration given below** was derived. See below for an explanation. | |
| Air exposure concentration and unit: | |

**Values based on measured samples can be derived using, for example, the following methods:**

- A single sample or several individual samples
- A single value combining all samples:
  - Arithmetic mean
  - Geometric mean
  - Median
  - 95th percentile, 90th percentile, 70th percentile, other percentile (please specify)
  - Mode
- If a lognormal probability density function is estimated and a single value is presented:
  - Highest point (global maximum/mode) of the lognormal probability density function

- Arithmetic mean
- Geometric mean/median
- 95th percentile, 90th percentile, 70th percentile, other percentile (please specify)

- Other, please specify

B6) Which Risk Management Measures (RMMs) are currently in place to control exposure in **Group 1**?

| Measures that seek to | | Answer |
|---|---|---|
| 1. Reduce the number of workers exposed (fewer, rotate, etc.) | | ☐ Rotation of workers<br>☐ Substitution of workers by automatization/ robotic operators<br>☐ Other, please specify: |
| 2. Reduce the concentration at the workplace | General ventilation | ☐ Yes ☐ No |
| | Local exhaust ventilation (LEV) | ☐ Fume hoods<br>☐ Extraction or grinding tables<br>☐ Fume extractor guns (on-torch spot extraction)<br>☐ Low-vacuum spot extraction<br>☐ High-vacuum spot extraction<br>☐ Mobile extraction and filter units<br>☐ Other, please specify: |
| | Modification of working processes (e.g. use of secondary shield gas containing reducing agents in gas metal arc welding) may reduce Cr(VI) exposure) | ☐ Yes ☐ No<br>If yes, please specify: |
| | Substitution of working processes (For some materials, processes generating less fumes and/or less Cr(VI) may be available) | ☐ Yes ☐ No<br>If yes, please specify: |
| | Substitution of materials (e.g. use of electrodes generating less fumes and/or less Cr(IV)) | ☐ Yes ☐ No<br>If yes, please specify: |
| | Detect unusual exposures | ☐ Yes ☐ No<br>If yes, please specify: |
| | Cleaning of base metal surfaces of any coating or paint | ☐ Yes ☐ No ☐ Not relevant |
| 3. Reduce worker exposure: | Information of workers on working with hazardous materials | ☐ Yes ☐ No<br>If yes, please specify: |
| | Personal protection equipment (PPE) to reduce inhalation exposure to workers | ☐ Fresh-air supplying masks<br>☐ Simple filter masks<br>☐ Filter masks with battery-powered filter-ventilation-unit (turbo-unit)<br>☐ Other, please specify: |
| 4. Other measures, please specify | | |

***Group 2***

B7) Please describe **Group 2**.

| Question | Answer |
|---|---|
| Please specify the relevant thermal metal work processes (several answers possible). | ☐ Welding. Please indicate which process(es):<br>☐ Thermal cutting. Please indicate which process(es):<br>☐ Thermal spraying. Please indicate which process(es):<br>☐ Other. Please indicate which: |
| Please indicate which materials are worked with (several answers possible).) | ☐ Stainless steel<br>☐ High-alloyed chromium-containing steels<br>☐ Scrap steel<br>☐ Low-alloyed steel<br>☐ Other. Please indicate which: |
| Please specify the number of workers working full-time with the mentioned tasks and processes. | |
| Please specify the number of workers working part-time (estimate hours/day) with the mentioned tasks and processes. | |

B8) Please provide data for air exposure to Cr(VI) in **Group 2.**

| Question | Answer |
|---|---|
| ***1) Exposure concentration value*** | |
| Which kind of exposure concentration value do you have available for this group? | ☐ 8 hr Time Weighted Average (TWA) concentration → 2)<br>☐ Concentration over a 15 minute reference period → 3)<br>☐ Other exposure concentration → 4)<br>☐ None. The work place is established according to industrial safety regulations by the national authority for occupational health. Therefore, the exposure concentrations are expected to be below the national occupational exposure limit.<br>☐ None. The concentration of Cr(VI) compounds at the workplace is not known. In order to evaluate exposure, an occupational exposure value for the process is used (e.g. particles of welding fume in mg/m³).<br>☐ Don't know. |
| ***2) 8 hr Time Weighted Average (TWA)*** | |
| How is the 8 hr TWA exposure concentration determined? | ☐ Measured<br>☐ Estimated. Please indicate how:<br>☐ Don't know. |
| If measured, please specify the number of samples and how the **exposure concentration given below** was derived. | |
| Air exposure concentration (8 hr TWA) and unit: | |
| ***3) Concentration over a 15 minute reference period*** | |
| How is the 15 minute exposure concentration determined? | ☐ Measured<br>☐ Estimated. Please indicate how:<br>☐ Don't know. |
| If measured, please specify the number of samples and how the **exposure concentration given below** was derived. | |
| Air exposure concentration (15 mins) and unit: | |
| ***4) Other exposure concentration value*** | |
| How is the exposure concentration determined? | ☐ Measured<br>☐ Estimated. Please indicate how:<br>☐ Don't know. |
| If measured, please specify the number of samples and how the **exposure concentration given below** was derived. | |
| Air exposure concentration and unit: | |

B9) Which Risk Management Measures (RMMs) are currently in place to control exposure in **Group 2**?

| Measures that seek to | Answer |
|---|---|
| 1. Reduce the number of workers exposed (fewer, rotate, etc.) | ☐ Rotation of workers<br>☐ Substitution of workers by automatization/ robotic operators<br>☐ Other, please specify: |

| Measures that seek to | | Answer |
|---|---|---|
| 2. Reduce the concentration at the workplace | General ventilation | ☐ Yes ☐ No |
| | Local exhaust ventilation (LEV) | ☐ Fume hoods<br>☐ Extraction or grinding tables<br>☐ Fume extractor guns (on-torch spot extraction)<br>☐ Low-vacuum spot extraction<br>☐ High-vacuum spot extraction<br>☐ Mobile extraction and filter units<br>☐ Other, please specify: |
| | Modification of working processes (e.g. use of secondary shield gas containing reducing agents in gas metal arc welding) may reduce Cr(VI) exposure) | ☐ Yes ☐ No<br>If yes, please specify: |
| | Substitution of working processes (For some materials, processes generating less fumes and/or less Cr(IV) may be available) | ☐ Yes ☐ No<br>If yes, please specify: |
| | Substitution of materials (e.g. use of electrodes generating less fumes and/or less Cr(IV)) | ☐ Yes ☐ No<br>If yes, please specify: |
| | Detect unusual exposures | ☐ Yes ☐ No<br>If yes, please specify: |
| | Cleaning of base metal surfaces of any coating or paint | ☐ Yes ☐ No ☐ Not relevant |
| 3. Reduce worker exposure: | Information of workers on working with hazardous materials | ☐ Yes ☐ No<br>If yes, please specify: |
| | Personal protection equipment (PPE) to reduce inhalation exposure to workers | ☐ Fresh-air supplying masks<br>☐ Simple filter masks<br>☐ Filter masks with battery-powered filter-ventilation-unit (turbo-unit)<br>☐ Other, please specify: |
| 4. Other measures, please specify | | |

***Group 3***

B10) Please describe **Group 3**.

| Question | Answer |
|---|---|
| Please specify the relevant thermal metal work processes (several answers possible). | ☐ Welding. Please indicate which process(es):<br>☐ Thermal cutting. Please indicate which process(es):<br>☐ Thermal spraying. Please indicate which process(es):<br>☐ Other. Please indicate which: |
| Please indicate which materials are worked with (several answers possible).) | ☐ Stainless steel<br>☐ High-alloyed chromium-containing steels<br>☐ Scrap steel<br>☐ Low-alloyed steel |

| Question | Answer |
|---|---|
| | ☐ Other. Please indicate which: |
| Please specify the number of workers working full-time with the mentioned tasks and processes. | |
| Please specify the number of workers working part-time (estimate hours/day) with the mentioned tasks and processes. | |

B11) Please provide data for air exposure to Cr(VI) in **Group 3.**

| Question | Answer |
|---|---|
| ***1) Exposure concentration value*** | |
| Which kind of exposure concentration value do you have available for this group? | ☐ 8 hr Time Weighted Average (TWA) concentration → 2)<br>☐ Concentration over a 15 minute reference period → 3)<br>☐ Other exposure concentration → 4)<br>☐ None. The work place is established according to industrial safety regulations by the national authority for occupational health. Therefore, the exposure concentrations are expected to be below the national occupational exposure limit.<br>☐ None. The concentration of Cr(VI) compounds at the workplace is not known. In order to evaluate exposure, an occupational exposure value for the process is used (e.g. particles of welding fume in mg/m³).<br>☐ Don't know. |
| ***2) 8 hr Time Weighted Average (TWA)*** | |
| How is the 8 hr TWA exposure concentration determined? | ☐ Measured<br>☐ Estimated. Please indicate how:<br>☐ Don't know. |
| If measured, please specify the number of samples and how the **exposure concentration given below** was derived. | |
| Air exposure concentration (8 hr TWA) and unit: | |
| ***3) Concentration over a 15 minute reference period*** | |
| How is the 15 minute exposure concentration determined? | ☐ Measured<br>☐ Estimated. Please indicate how:<br>☐ Don't know. |
| If measured, please specify the number of samples and how the **exposure concentration given below** was derived. | |
| Air exposure concentration (15 mins) and unit: | |
| ***4) Other exposure concentration value*** | |
| How is the exposure concentration determined? | ☐ Measured<br>☐ Estimated. Please indicate how:<br>☐ Don't know. |
| If measured, please specify the number of samples and how the **exposure concentration given below** was derived. | |

| Question | Answer |
|---|---|
| Air exposure concentration and unit: | |

B12) Which Risk Management Measures (RMMs) are currently in place to control exposure in **Group 3**?

| Measures that seek to | | Answer |
|---|---|---|
| 1. Reduce the number of workers exposed (fewer, rotate, etc.) | | ☐ Rotation of workers<br>☐ Substitution of workers by automatization/ robotic operators<br>☐ Other, please specify: |
| 2. Reduce the concentration at the workplace | General ventilation | ☐ Yes ☐ No |
| | Local exhaust ventilation (LEV) | ☐ Fume hoods<br>☐ Extraction or grinding tables<br>☐ Fume extractor guns (on-torch spot extraction)<br>☐ Low-vacuum spot extraction<br>☐ High-vacuum spot extraction<br>☐ Mobile extraction and filter units<br>☐ Other, please specify: |
| | Modification of working processes (e.g. use of secondary shield gas containing reducing agents in gas metal arc welding) may reduce Cr(VI) exposure) | ☐ Yes ☐ No<br>If yes, please specify: |
| | Substitution of working processes (For some materials, processes generating less fumes and/or less Cr(IV) may be available) | ☐ Yes ☐ No<br>If yes, please specify: |
| | Substitution of materials (e.g. use of electrodes generating less fumes and/or less Cr(IV)) | ☐ Yes ☐ No<br>If yes, please specify: |
| | Detect unusual exposures | ☐ Yes ☐ No<br>If yes, please specify: |
| | Cleaning of base metal surfaces of any coating or paint | ☐ Yes ☐ No ☐ Not relevant |
| 3. Reduce worker exposure: | Information of workers on working with hazardous materials | ☐ Yes ☐ No<br>If yes, please specify: |
| | Personal protection equipment (PPE) to reduce inhalation exposure to workers | ☐ Fresh-air supplying masks<br>☐ Simple filter masks<br>☐ Filter masks with battery-powered filter-ventilation-unit (turbo-unit)<br>☐ Other, please specify: |
| 4. Other measures, please specify | | |

***Group 4***

B13) Please describe **Group 4**.

| Question | Answer |
|---|---|
| Please specify the relevant thermal metal work processes (several answers possible). | ☐ Welding. Please indicate which process(es):<br>☐ Thermal cutting. Please indicate which process(es):<br>☐ Thermal spraying. Please indicate which process(es):<br>☐ Other. Please indicate which: |
| Please indicate which materials are worked with (several answers possible).) | ☐ Stainless steel<br>☐ High-alloyed chromium-containing steels<br>☐ Scrap steel<br>☐ Low-alloyed steel<br>☐ Other. Please indicate which: |
| Please specify the number of workers working full-time with the mentioned tasks and processes. | |
| Please specify the number of workers working part-time (estimate hours/day) with the mentioned tasks and processes. | |

B14) Please provide data for air exposure to Cr(VI) in **Group 4.**

| Question | Answer |
|---|---|
| ***1) Exposure concentration value*** | |
| Which kind of exposure concentration value do you have available for this group? | ☐ 8 hr Time Weighted Average (TWA) concentration → 2)<br>☐ Concentration over a 15 minute reference period → 3)<br>☐ Other exposure concentration → 4)<br>☐ None. The work place is established according to industrial safety regulations by the national authority for occupational health. Therefore, the exposure concentrations are expected to be below the national occupational exposure limit.<br>☐ None. The concentration of Cr(VI) compounds at the workplace is not known. In order to evaluate exposure, an occupational exposure value for the process is used (e.g. particles of welding fume in mg/m³).<br>☐ Don't know. |
| ***2) 8 hr Time Weighted Average (TWA)*** | |
| How is the 8 hr TWA exposure concentration determined? | ☐ Measured<br>☐ Estimated. Please indicate how:<br>☐ Don't know. |
| If measured, please specify the number of samples and how the **exposure concentration given below** was derived. | |
| Air exposure concentration (8 hr TWA) and unit: | |
| ***3) Concentration over a 15 minute reference period*** | |
| How is the 15 minute exposure concentration determined? | ☐ Measured<br>☐ Estimated. Please indicate how:<br>☐ Don't know. |
| If measured, please specify the number of samples and how the **exposure** | |

| Question | Answer |
|---|---|
| **concentration given below** was derived. | |
| Air exposure concentration (15 mins) and unit: | |
| ***4) Other exposure concentration value*** | |
| How is the exposure concentration determined? | ☐ Measured<br>☐ Estimated. Please indicate how:<br>☐ Don't know. |
| If measured, please specify the number of samples and how the **exposure concentration given below** was derived. | |
| Air exposure concentration and unit: | |

B15) Which Risk Management Measures (RMMs) are currently in place to control exposure in **Group 4**?

| Measures that seek to | | Answer |
|---|---|---|
| 1. Reduce the number of workers exposed (fewer, rotate, etc.) | | ☐ Rotation of workers<br>☐ Substitution of workers by automatization/ robotic operators<br>☐ Other, please specify: |
| 2. Reduce the concentration at the workplace | General ventilation | ☐ Yes ☐ No |
| | Local exhaust ventilation (LEV) | ☐ Fume hoods<br>☐ Extraction or grinding tables<br>☐ Fume extractor guns (on-torch spot extraction)<br>☐ Low-vacuum spot extraction<br>☐ High-vacuum spot extraction<br>☐ Mobile extraction and filter units<br>☐ Other, please specify: |
| | Modification of working processes (e.g. use of secondary shield gas containing reducing agents in gas metal arc welding) may reduce Cr(VI) exposure) | ☐ Yes ☐ No<br>If yes, please specify: |
| | Substitution of working processes (For some materials, processes generating less fumes and/or less Cr(IV) may be available) | ☐ Yes ☐ No<br>If yes, please specify: |
| | Substitution of materials (e.g. use of electrodes generating less fumes and/or less Cr(IV)) | ☐ Yes ☐ No<br>If yes, please specify: |
| | Detect unusual exposures | ☐ Yes ☐ No<br>If yes, please specify: |
| | Cleaning of base metal surfaces of any coating or paint | ☐ Yes ☐ No ☐ Not relevant |
| 3. Reduce worker exposure: | Information of workers on working with hazardous materials | ☐ Yes ☐ No<br>If yes, please specify: |

| Measures that seek to | | Answer |
|---|---|---|
| | Personal protection equipment (PPE) to reduce inhalation exposure to workers | ☐ Fresh-air supplying masks<br>☐ Simple filter masks<br>☐ Filter masks with battery-powered filter-ventilation-unit (turbo-unit)<br>☐ Other, please specify: |
| 4. Other measures, please specify | | |

***Group 5***

B16) Please describe **Group 5**.

| Question | Answer |
|---|---|
| Please specify the relevant thermal metal work processes (several answers possible). | ☐ Welding. Please indicate which process(es):<br>☐ Thermal cutting. Please indicate which process(es):<br>☐ Thermal spraying. Please indicate which process(es):<br>☐ Other. Please indicate which: |
| Please indicate which materials are worked with (several answers possible).) | ☐ Stainless steel<br>☐ High-alloyed chromium-containing steels<br>☐ Scrap steel<br>☐ Low-alloyed steel<br>☐ Other. Please indicate which: |
| Please specify the number of workers working full-time with the mentioned tasks and processes. | |
| Please specify the number of workers working part-time (estimate hours/day) with the mentioned tasks and processes. | |

B17) Please provide data for air exposure to Cr(VI) in **Group 5.**

| Question | Answer |
|---|---|
| ***1) Exposure concentration value*** | |
| Which kind of exposure concentration value do you have available for this group? | ☐ 8 hr Time Weighted Average (TWA) concentration → 2)<br>☐ Concentration over a 15 minute reference period → 3)<br>☐ Other exposure concentration → 4)<br>☐ None. The work place is established according to industrial safety regulations by the national authority for occupational health. Therefore, the exposure concentrations are expected to be below the national occupational exposure limit.<br>☐ None. The concentration of Cr(VI) compounds at the workplace is not known. In order to evaluate exposure, an occupational exposure value for the process is used (e.g. particles of welding fume in mg/m³).<br>☐ Don't know. |
| ***2) 8 hr Time Weighted Average (TWA)*** | |
| How is the 8 hr TWA exposure concentration determined? | ☐ Measured<br>☐ Estimated. Please indicate how:<br>☐ Don't know. |

| Question | Answer |
|---|---|
| If measured, please specify the number of samples and how the **exposure concentration given below** was derived. | |
| Air exposure concentration (8 hr TWA) and unit: | |
| ***3) Concentration over a 15 minute reference period*** | |
| How is the 15 minute exposure concentration determined? | ☐ Measured<br>☐ Estimated. Please indicate how:<br>☐ Don't know. |
| If measured, please specify the number of samples and how the **exposure concentration given below** was derived. | |
| Air exposure concentration (15 mins) and unit: | |
| ***4) Other exposure concentration value*** | |
| How is the exposure concentration determined? | ☐ Measured<br>☐ Estimated. Please indicate how:<br>☐ Don't know. |
| If measured, please specify the number of samples and how the **exposure concentration given below** was derived. | |
| Air exposure concentration and unit: | |

B18) Which Risk Management Measures (RMMs) are currently in place to control exposure in **Group 5**?

| Measures that seek to | | Answer |
|---|---|---|
| 1. Reduce the number of workers exposed (fewer, rotate, etc.) | | ☐ Rotation of workers<br>☐ Substitution of workers by automatization/ robotic operators<br>☐ Other, please specify: |
| 2. Reduce the concentration at the workplace | General ventilation | ☐ Yes ☐ No |
| | Local exhaust ventilation (LEV) | ☐ Fume hoods<br>☐ Extraction or grinding tables<br>☐ Fume extractor guns (on-torch spot extraction)<br>☐ Low-vacuum spot extraction<br>☐ High-vacuum spot extraction<br>☐ Mobile extraction and filter units<br>☐ Other, please specify: |
| | Modification of working processes (e.g. use of secondary shield gas containing reducing agents in gas metal arc welding) may reduce Cr(VI) exposure) | ☐ Yes ☐ No<br>If yes, please specify: |
| | Substitution of working processes | ☐ Yes ☐ No<br>If yes, please specify: |

| Measures that seek to | | Answer |
|---|---|---|
| | (For some materials, processes generating less fumes and/or less Cr(IV) may be available) | |
| | Substitution of materials (e.g. use of electrodes generating less fumes and/or less Cr(IV)) | ☐ Yes ☐ No<br>If yes, please specify: |
| | Detect unusual exposures | ☐ Yes ☐ No<br>If yes, please specify: |
| | Cleaning of base metal surfaces of any coating or paint | ☐ Yes ☐ No ☐ Not relevant |
| 3. Reduce worker exposure: | Information of workers on working with hazardous materials | ☐ Yes ☐ No<br>If yes, please specify: |
| | Personal protection equipment (PPE) to reduce inhalation exposure to workers | ☐ Fresh-air supplying masks<br>☐ Simple filter masks<br>☐ Filter masks with battery-powered filter-ventilation-unit (turbo-unit)<br>☐ Other, please specify: |
| 4. Other measures, please specify | | |

# C) RMMs required to achieve OELs for Cr(VI) from welding, plasma cutting and similar work processes that generate fumes

This section enquires about the measures that will have to be put in place to comply with the new OEL of 5 µg/m$^3$ for 'chromium (VI) compounds in welding or plasma cutting processes or similar work processes that generate fume' which will enter into force 5 years after the transposition date of the compromise recently reached by Council and the European Parliament on the Commission proposal COM(2016)248 final.

C1) Which Risk Management Measures (RMMs) (if any) will you have to implement to achieve an OEL of 25 µg/m$^3$?

| Similar exposure group | Additional RMMs to comply with an OEL of 25 µg/m³ | Compliance with an OEL of 25 µg/m³ already achieved | Don't know |
|---|---|---|---|
| SEG/Group 1 | Please specify: | ☐ | ☐ |
| SEG/Group 2 | Please specify: | ☐ | ☐ |
| SEG/Group 3 | Please specify: | ☐ | ☐ |
| SEG/Group 4 | Please specify: | ☐ | ☐ |
| SEG/Group 5 | Please specify: | ☐ | ☐ |

C2) Which RMMs (if any) will you have to implement to achieve an OEL of 5 µg/m$^3$?

| Similar exposure group | Additional RMMs to comply with an OEL of 5 µg/m³ | Compliance with an OEL of 5 µg/m³ already achieved | Don't know |
|---|---|---|---|
| SEG/Group 1 | Please specify: | ☐ | ☐ |
| SEG/Group 2 | Please specify: | ☐ | ☐ |
| SEG/Group 3 | Please specify: | ☐ | ☐ |
| SEG/Group 4 | Please specify: | ☐ | ☐ |
| SEG/Group 5 | Please specify: | ☐ | ☐ |

# D) Further communication

D1) **Clarifications:** Please provide an email address or telephone number in case the study team needs clarification of any of your responses to this questionnaire.

| |
|---|
| |

D2) **More detailed telephone discussion:** Would you be willing to take part in a follow up interview to discuss the impacts of the OEL of 5 µg/m$^3$?

| | |
|---|---|
| ☐ Yes | ☐ No |

D3) **Site visit:** Would you be willing to host a site visit enabling the study team to gain a first-hand account of the issues involved with complying with the impacts of the OEL of 5 µg/m$^3$?

| | |
|---|---|
| ☐ Yes | ☐ No |

## A1.3 Questionnaire for occupational health & safety experts

***This questionnaire is for occupational health and safety (OSH) professionals working with companies to reduce workers' exposure to the relevant chemical agents. As an OSH expert, we hope that you will help us to understand the risk management measures required to implement OELs and STELs and thus assess their technical and economic feasibility.***

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) has been contracted by the European Commission (DG Employment, Social Affairs and Inclusion) to carry out a study to support a possible amendment of Directive 2004/37/EC on the protection of workers from exposure to carcinogens or mutagens at work (hereinafter the Carcinogens and Mutagens Directive or CMD).

The objective of the study is to assess the impact of establishing Occupational Exposure Limits (OELs) and, where relevant, Short-term Exposure Limits (STELs) for the following chemical agents[37]:

- cadmium and its inorganic compounds
- beryllium and its inorganic compounds
- inorganic arsenic compounds including arsenic acid and its salts
- formaldehyde
- 4,4'-Methylene-bis(2-chloroaniline) (MOCA) (includes consideration of a skin notation)

For each agent, a range of potential limit values is being assessed reaching from the lowest to the highest values resulting from Scientific Committee on OELs (SCOEL) recommendations, Committee for Risk Assessment (RAC) opinions and OELs established in EU Member States.

The deadline for completion of the questionnaire is **3 November 2017**.

All responses to this questionnaire will be treated in **strict confidence** and will only be used for the purposes of this study. In preparing our reports for the Commission (which, subsequently, may be published), care will be taken to ensure that specific responses cannot be linked to individual companies.

If you have any questions about this study, please contact Daniel Vencovsky (daniel.vencovsky@rpaltd.co.uk or +44 (0)1508 528 465).

| ***Definitions and acronyms*** | |
|---|---|
| CMD | Carcinogens and Mutagens Directive 2004/37/EC |
| MOCA | 4,4'-Methylene-bis(2-chloroaniline) |
| OSH | Occupational Health & Safety |
| RAC | The Committee for Risk Assessment (RAC) is a scientific committee of ECHA that prepares the opinions related to the risks of substances to human health and the environment. It also assisted DG Employment with the evaluation of MOCA and inorganic arsenic compounds. |
| RMM | Risk Management Measure |
| SCOEL | The Scientific Committee on Occupational Exposure Limits (SCOEL) assists the Commission, in particular, in evaluating scientific data and recommending OELs. |
| Skin notation | An indication that the dermal route of exposure is scientifically considered to be relevant (in addition to the inhalation route) |
| STEL | A Short-term Exposure Limit (STEL) is a limit of the concentration in the air within the breathing zone of a worker, measured or calculated in relation to a reference period of fifteen minutes. |
| TWA | Time-weighted average |

# A) About you

Please provide the following details.

| Question | Answer |
|---|---|
| A1 Name | |

[37] The study is also assessing the impacts of an OEL of 5 µg/m$^3$ for '*chromium (VI) compounds in **welding or plasma cutting processes or similar work processes that generate fume'*** which will enter into force 5 years after the transposition date of the compromise recently reached by Council and the European Parliament on the Commission proposal COM(2016)248 final.

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| A2 Company | |
| A3 Country | |
| A4 Email | |
| A5 Telephone | |

## B) Your experience with the chemical agents being assessed

A6) Which chemical agent(s) do you have experience with in terms of evaluating or controlling worker exposure? Tick all that apply.

| |
|---|
| ☐ Cadmium and its inorganic compounds |
| ☐ Beryllium and its inorganic compounds |
| ☐ inorganic arsenic compounds including arsenic acid and its salts |
| ☐ Formaldehyde |
| ☐ 4,4'-Methylene-bis(2-chloroaniline) (MOCA) |
| ☐ None of the above |

Please complete the relevant sections for the chemical agents with which you have experience.

## C-Cd) RMMs for cadmium and its inorganic compounds

Cd 1a) Please list the specific compounds that you have experience of evaluating, proposing measures to control, and/or implementing measures to control. See here for a non-exhaustive list (examples) of the relevant compounds.

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Cd 1b) Please list all the specific applications for which you have experience of evaluating or reducing air concentrations of cadmium and its inorganic compounds in workers' environments?

*For the purposes of this questionnaire, the term 'application' encompasses all activities during which occupational exposure to cadmium and its inorganic compounds may occur, including production and use of the cadmium and its inorganic compounds, research & development, recycling, import, storage and transport.*

Examples of possible applications include: zinc smelting and cadmium refining, speciality chemicals, nickel cadmium batteries, pigments, speciality aerospace connectors and fasteners, surface treatment, photovoltaic cells, and cadmium waste recycling.

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Cd 2) Please indicate all measures that you have recommended to reduce inhalation exposure to cadmium and its inorganic compounds?

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| ☐ 1 Substitute/reduce quantities of chemical agents |
| ☐ 2 Reduce the number of workers exposed (fewer, rotate, etc.) |
| 3 Reduce the concentration at the workplace: |
| ☐ 3a. Process-related measures (design of work processes, etc.) |
| ☐ 3b. Control equipment to enclose, extract, or ventilate, etc. |
| ☐ 3c. Detect unusual exposures |
| 4 Reduce worker exposure: |
| ☐ 4a. Collective protection measures to reduce exposure to workers |
| ☐ 4b. Individual protection measures to reduce exposure to workers (PPE) |
| ☐ 5 Other measures, please give details |

Cd 3) If necessary, please give more details, for example to differentiate between applications.

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## D-Cd) National OEL

Please provide some information about the cadmium **OELs** (limits on air concentration expressed as an 8 hour TWA) for the Member State where you are based.

| Question | Answer |
|---|---|
| Cd 4) OEL (value, unit)<br>Please indicate if respirable, inhalable or total dust) | |
| Cd 5) Is this OEL? | ☐ Binding<br>☐ Indicative |
| Cd 6) Please define the scope of OEL. Does it include cadmium and all its inorganic compounds? | |
| Cd 7) How is the compliance of the OEL determined? | ☐ Estimated<br>☐ Measured |
| Cd 8) If measured:<br>How many samples and how often are they taken?<br>How is compliance with the OEL determined?<br>See below for an explanation. | |
| Cd 9) Any other comments about the OEL | |

**To determine compliance, values based on measured samples can be derived using, for example, the following methods:**

- A single sample or several individual samples
- A single value combining all samples:
  - Arithmetic mean
  - Geometric mean
  - Median
  - 95th percentile, 90th percentile, 70th percentile, other percentile (please specify)
  - Mode
- If a lognormal probability density function is estimated and a single value is presented:
  - Highest point (global maximum/mode) of the lognormal probability density function
  - Arithmetic mean
  - Geometric mean/median
  - 95th percentile, 90th percentile, 70th percentile, other percentile (please specify)
- Other, please specify

## E-Cd) Potential new OEL under the CMD

This section looks at the potential to reduce air concentrations of cadmium and its inorganic compounds, measured or calculated as a time-weighted average over eight hours, establishing new Occupational Exposure Limit Values (OELs) for cadmium and its inorganic compounds under the CMD.

Cd 16) What is the lowest 8 hour TWA air concentration of cadmium that you have achieved?

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Cd 17) Which application did this apply to?

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Cd 18) Which measures were used to achieve this exposure value for cadmium?

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Cd 19) In your opinion, is it feasible to reduce air concentrations of cadmium in the application you specified in Cd 17) to a level below your response to Cd 16)?

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| ☐ Yes | ☐ No |

Cd 20) If YES to Cd 19), please indicate the three measures that you think are the most effective way of achieving this?

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| ☐ (a) limiting the quantities of cadmium at the place of work |
| ☐ (b) minimising the number of workers exposed or likely to be exposed |
| ☐ (c) designing work processes and engineering control measures to avoid or minimise the release of cadmium into the place of work |
| ☐ (d) evacuating cadmium at source, using a local extraction system or general ventilation, (whilst protecting public health and the environment) |
| ☐ (e) using existing appropriate procedures to measure cadmium, in particular for the early detection of abnormal exposures resulting from an unforeseeable event or an accident |
| ☐ (f) application of suitable working procedures and methods |
| ☐ (g) collective protection measures and/or, where exposure cannot be avoided by other means, individual protection measures |
| ☐ (h) hygiene measures, in particular regular cleaning of floors, walls and other surfaces |
| ☐ (i) information for workers |
| ☐ (j) demarcation of risk areas and use of adequate warning and safety signs including 'no smoking' signs in areas where workers are exposed or likely to be exposed to carcinogens or mutagens |
| ☐ (k) drawing up plans to deal with emergencies likely to result in abnormally high exposure |
| ☐ (l) means for safe storage, handling and transportation, in particular by using sealed and clearly and visibly labelled containers |
| ☐ (m) other measures, please give details |

## C-Be) RMMs for beryllium and its inorganic compounds

Be 1a) Please list the specific compounds that you have experience of evaluating, proposing measures to control, and/or implementing measures to control. See here for a non-exhaustive list (examples) of the relevant compounds.

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Be 1b) Please list all the specific applications for which you have experience of evaluating or reducing air concentrations of beryllium and its inorganic compounds in workers' environments?

*For the purposes of this questionnaire, the term 'application' encompasses all activities during which occupational exposure to beryllium and its inorganic compounds may occur, including production and use of the beryllium and its inorganic compounds, research & development, recycling, import, storage and transport.*

Examples of possible applications include: foundries – melting and alloy casting, manufacture of injection moulds, stamping, recycling & scrap, laboratories, transportation, ICT, medical devices, defence & security, fire-fighting & rescue, oil, gas & electricity, space & research, glass & glass products, concrete and concrete product manufacturers, construction, fertiliser manufacturers, construction material manufacturers and farming

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Be2) Please indicate all measures that you have recommended to reduce inhalation exposure to beryllium and its inorganic compounds?

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|---|
| ☐ 1 Substitute/reduce quantities of chemical agents |
| ☐ 2 Reduce the number of workers exposed (fewer, rotate, etc.) |
| 3 Reduce the concentration at the workplace: |
| ☐ 3a. Process-related measures (design of work processes, etc.) |
| ☐ 3b. Control equipment to enclose, extract, or ventilate, etc. |
| ☐ 3c. Detect unusual exposures |
| 4 Reduce worker exposure: |
| ☐ 4a. Collective protection measures to reduce exposure to workers |
| ☐ 4b. Individual protection measures to reduce exposure to workers (PPE) |
| ☐ 5 Other measures, please give details |

Be3) If necessary, please give more details, for example to differentiate between applications.

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## D-Be) National OEL and STEL

Please provide some information about the beryllium **OELs** (limits on air concentration expressed as an 8 hour TWA) for the Member State where you are based.

| Question | Answer |
|---|---|
| Be 4) OEL (value, unit)<br>Please indicate if respirable, inhalable or total dust) | |
| Be 5) Is this OEL? | ☐ Binding<br>☐ Indicative |
| Be 6) Please define the scope of OEL. Does it include beryllium and all its inorganic compounds? | |
| Be 7) How is the compliance of the OEL determined? | ☐ Estimated<br>☐ Measured |
| Be 8) If measured:<br>How many samples and how often are they taken?<br>How is compliance with the OEL determined?<br>See below for an explanation. | |
| Be 9) Any other comments about the OEL | |

**To determine compliance, values based on measured samples can be derived using, for example, the following methods:**

- A single sample or several individual samples
- A single value combining all samples:
  - Arithmetic mean
  - Geometric mean
  - Median
  - 95th percentile, 90th percentile, 70th percentile, other percentile (please specify)
  - Mode
- If a lognormal probability density function is estimated and a single value is presented:
  - Highest point (global maximum/mode) of the lognormal probability density function

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| - Arithmetic mean<br>- Geometric mean/median<br>- 95th percentile, 90th percentile, 70th percentile, other percentile (please specify)<br>• Other, please specify |

Please provide some information about the beryllium **STELs** (limits on air concentration during a reference period of 15 minutes) for the Member State where you are based.

| Question | Answer |
|---|---|
| Be 10) STEL (value & unit)<br>Please indicate if respirable, inhalable or total dust) | |
| Be 11) Is the STEL? | ☐ Binding<br>☐ Indicative |
| Be 12) Please define the the scope of STEL. Does it include beryllium and all its inorganic compounds? | |
| Be 13) How is compliance with the STEL determined? | ☐ Estimated<br>☐ Measured |
| Be 14) If measured:<br>How many samples and how often are they taken?<br>How is compliance with the STEL determined?<br>See above for an explanation. | |
| Be 15) Any other comments about the STEL | |

## E-Be) Potential new OEL under the CMD

This section looks at the potential to reduce air concentrations of beryllium and its inorganic compounds, measured or calculated as a time-weighted average over eight hours, establishing new Occupational Exposure Limit Values (OELs) for beryllium and its inorganic compounds under the CMD.

Be 16) What is the lowest 8 hour TWA air concentration of beryllium that you have achieved?

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Be 17) Which application did this apply to?

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Be 18) Which measures were used to achieve this exposure value for beryllium?

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Be 19) In your opinion, is it feasible to reduce air concentrations of beryllium in the application you specified in Be 17) to a level below your response to Be 16)?

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|---|---|
| ☐ Yes | ☐ No |

Be 20) If YES to Be 19), please indicate the three measures that you think are the most effective way of achieving this?

| |
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| ☐ (a) limiting the quantities of beryllium at the place of work |
| ☐ (b) minimising the number of workers exposed or likely to be exposed |
| ☐ (c) designing work processes and engineering control measures to avoid or minimise the release of beryllium into the place of work |

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| ☐ (d) evacuating beryllium at source, using a local extraction system or general ventilation, (whilst protecting public health and the environment) |
| ☐ (e) using existing appropriate procedures to measure beryllium, in particular for the early detection of abnormal exposures resulting from an unforeseeable event or an accident |
| ☐ (f) application of suitable working procedures and methods |
| ☐ (g) collective protection measures and/or, where exposure cannot be avoided by other means, individual protection measures |
| ☐ (h) hygiene measures, in particular regular cleaning of floors, walls and other surfaces |
| ☐ (i) information for workers |
| ☐ (j) demarcation of risk areas and use of adequate warning and safety signs including 'no smoking' signs in areas where workers are exposed or likely to be exposed to carcinogens or mutagens |
| ☐ (k) drawing up plans to deal with emergencies likely to result in abnormally high exposure |
| ☐ (l) means for safe storage, handling and transportation, in particular by using sealed and clearly and visibly labelled containers |
| ☐ (m) other measures, please give details |

## F-Be) Potential new STEL under the CMD

This section looks at the potential to reduce air concentrations of beryllium and its inorganic compounds, measured or calculated as a time-weighted average over 15 minutes, establishing new Short-term Exposure Limits (STELs) under the CMD for beryllium and its inorganic compounds.

Be 21) What is the lowest 15 minute TWA beryllium concentration in the air that you have achieved?

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Be 22) Which application did this apply to?

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| |

Be 23) Which measures were used to achieve this exposure value for beryllium?

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Be 24) In your view, is it feasible to reduce air concentrations of beryllium in the application you specified in Be 22) to a level below your response to Be 21)?

| | |
|---|---|
| ☐ Yes | ☐ No |

Be 25) If YES to Be 24), which three measures do you think are the most effective way of achieving this?

| |
|---|
| ☐ (a) limiting the quantities of beryllium at the place of work |
| ☐ (b) minimising the number of workers exposed or likely to be exposed |
| ☐ (c) designing work processes and engineering control measures to avoid or minimise the release of beryllium into the place of work |
| ☐ (d) evacuating beryllium at source, using a local extraction system or general ventilation, (whilst protecting public health and the environment) |
| ☐ (e) using existing appropriate procedures to measure beryllium, in particular for the early detection of abnormal exposures resulting from an unforeseeable event or an accident |
| ☐ (f) application of suitable working procedures and methods |
| ☐ (g) collective protection measures and/or, where exposure cannot be avoided by other means, individual protection measures |
| ☐ (h) hygiene measures, in particular regular cleaning of floors, walls and other surfaces |
| ☐ (i) information for workers |
| ☐ (j) demarcation of risk areas and use of adequate warning and safety signs including 'no smoking' signs in areas where workers are exposed or likely to be exposed to carcinogens or mutagens |
| ☐ (k) drawing up plans to deal with emergencies likely to result in abnormally high exposure |
| ☐ (l) means for safe storage, handling and transportation, in particular by using sealed and clearly and visibly labelled containers |
| ☐ (m) other measures, please give details |

## C-As) RMMs for inorganic arsenic compounds including arsenic acid and its salts

As 1a) Please list the specific compounds that you have experience of evaluating, proposing measures to control, and/or implementing measures to control. See here for a non-exhaustive list (examples) of the relevant compounds.

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As 1b) Please list all the specific applications for which you have experience of evaluating or reducing air concentrations of inorganic arsenic compounds including arsenic acid and its salts in workers' environments?

*For the purposes of this questionnaire, the term 'application' encompasses all activities during which occupational exposure to inorganic arsenic compounds may occur, including production and use of the inorganic arsenic compounds, research & development, recycling, import, storage and transport.*

Examples of possible applications include: smelting of non-ferrous metal, coal-fired power plants, battery assembly, preparation of or work with pressure-treated wood, glass-manufacturing, electronics, manufacture of pesticides and fireworks, production and use of alloys, coatings for photocopier drums, microelectronics (often as a waste residue) and producing gallium arsenide.

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| |

As 2) Please indicate all measures that you have recommended to reduce inhalation exposure to inorganic arsenic compounds?

| |
|---|
| ☐ 1 Substitute/reduce quantities of chemical agents |
| ☐ 2 Reduce the number of workers exposed (fewer, rotate, etc.) |
| 3 Reduce the concentration at the workplace: |
| ☐ 3a. Process-related measures (design of work processes, etc.) |
| ☐ 3b. Control equipment to enclose, extract, or ventilate, etc. |
| ☐ 3c. Detect unusual exposures |
| 4 Reduce worker exposure: |
| ☐ 4a. Collective protection measures to reduce exposure to workers |
| ☐ 4b. Individual protection measures to reduce exposure to workers (PPE) |
| ☐ 5 Other measures, please give details |

As 3) If necessary, please give more details, for example to differentiate between applications.

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## D-As) National OEL

Please provide some information about the arsenic **OELs** (limits on air concentration expressed as an 8 hour TWA) for the Member State where you are based.

| Question | Answer |
|---|---|
| As 4) OEL (value, unit)<br>Please indicate if respirable, inhalable or total dust) | |
| As 5) Is this OEL? | ☐ Binding<br>☐ Indicative |
| As 6) Please define the scope of OEL. Does it include inorganic arsenic compounds? | |

| Question | Answer |
|---|---|
| As 7) How is the compliance of the OEL determined? | ☐ Estimated<br>☐ Measured |
| As 8) If measured:<br>How many samples and how often are they taken?<br>How is compliance with the OEL determined?<br>See below for an explanation. | |
| As 9) Any other comments about the OEL | |

**To determine compliance, values based on measured samples can be derived using, for example, the following methods:**

- A single sample or several individual samples
- A single value combining all samples:
  - Arithmetic mean
  - Geometric mean
  - Median
  - 95th percentile, 90th percentile, 70th percentile, other percentile (please specify)
  - Mode
- If a lognormal probability density function is estimated and a single value is presented:
  - Highest point (global maximum/mode) of the lognormal probability density function
  - Arithmetic mean
  - Geometric mean/median
  - 95th percentile, 90th percentile, 70th percentile, other percentile (please specify)
- Other, please specify

## E-As) Potential new OEL under the CMD

This section looks at the potential to reduce air concentrations of arsenic and its inorganic compounds, measured or calculated as a time-weighted average over eight hours, establishing new Occupational Exposure Limit Values (OELs) for arsenic and its inorganic compounds under the CMD.

As 16) What is the lowest 8 hour TWA air concentration of arsenic that you have achieved?

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| |

As 17) Which application did this apply to?

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|---|
| |

As 18) Which measures were used to achieve this exposure value for arsenic?

| |
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| |

As 19) In your opinion, is it feasible to reduce air concentrations of arsenic in the application you specified in As 17) to a level below your response to As 16)?

| | |
|---|---|
| ☐ Yes | ☐ No |

As 20) If YES to As 19), please indicate the three measures that you think are the most effective way of achieving this?

| |
|---|
| ☐ (a) limiting the quantities of arsenic at the place of work |
| ☐ (b) minimising the number of workers exposed or likely to be exposed |

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| ☐ (c) designing work processes and engineering control measures to avoid or minimise the release of arsenic into the place of work |
| ☐ (d) evacuating arsenic at source, using a local extraction system or general ventilation, (whilst protecting public health and the environment) |
| ☐ (e) using existing appropriate procedures to measure arsenic, in particular for the early detection of abnormal exposures resulting from an unforeseeable event or an accident |
| ☐ (f) application of suitable working procedures and methods |
| ☐ (g) collective protection measures and/or, where exposure cannot be avoided by other means, individual protection measures |
| ☐ (h) hygiene measures, in particular regular cleaning of floors, walls and other surfaces |
| ☐ (i) information for workers |
| ☐ (j) demarcation of risk areas and use of adequate warning and safety signs including 'no smoking' signs in areas where workers are exposed or likely to be exposed to carcinogens or mutagens |
| ☐ (k) drawing up plans to deal with emergencies likely to result in abnormally high exposure |
| ☐ (l) means for safe storage, handling and transportation, in particular by using sealed and clearly and visibly labelled containers |
| ☐ (m) other measures, please give details |

## C-FA) RMMs for formaldehyde

FA 1) Please list all the specific applications for which you have experience of evaluating or reducing air concentrations of formaldehyde?

*For the purposes of this questionnaire, the term 'application' encompasses all activities during which occupational exposure to the relevant compounds may occur, including production and use of the inorganic arsenic compounds, research & development, recycling, import, storage and transport.*

Examples of possible applications include: resins; inactivating agent in vaccines, medicines, dental surgery products, medical textiles, tissue preservation; biocide for sterilising; pesticides, fungicides, herbicides; animal feed and fish vaccines; shower gels, shampoos, deodorants, nail hardeners; foam resin for cleaning products; metal remover fluids; binding agent in paintings, polishes, and varnishes; "glue resin" in wood panels and furniture; paper products, kitchen rolls, napkins, sack papers, labels, currency, maps and filter papers; crease-proof agent for clothes and household linen products; tanneries; electrical/electronic appliances; safety belt components, fuel system components, engine components; photographic materials.

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FA 2) Please indicate all measures that you have recommended to reduce inhalation exposure to formaldehyde?

| |
|---|
| ☐ 1 Substitute/reduce quantities of chemical agents |
| ☐ 2 Reduce the number of workers exposed (fewer, rotate, etc.) |
| 3 Reduce the concentration at the workplace: |
| ☐ 3a. Process-related measures (design of work processes, etc.) |
| ☐ 3b. Control equipment to enclose, extract, or ventilate, etc. |
| ☐ 3c. Detect unusual exposures |
| 4 Reduce worker exposure: |
| ☐ 4a. Collective protection measures to reduce exposure to workers |
| ☐ 4b. Individual protection measures to reduce exposure to workers (PPE) |

| |
|---|
| ☐ 5 Other measures, please give details |

FA 3) If necessary, please give more details, for example to differentiate between applications.

| |
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| |

## D-FA) National OEL and STEL

Please provide some information about the formaldehyde **OELs** (limits on air concentration expressed as an 8 hour TWA) for the Member State where you are based.

| Question | Answer |
|---|---|
| FA 4) OEL (value, unit) | |
| FA 5) Is this OEL? | ☐ Binding<br>☐ Indicative |
| FA 6+7) How is the compliance of the OEL determined? | ☐ Estimated<br>☐ Measured |
| FA 8) If measured:<br>How many samples and how often are they taken?<br>How is compliance with the OEL determined?<br>See below for an explanation. | |
| FA 9) Any other comments about the OEL | |

**To determine compliance, values based on measured samples can be derived using, for example, the following methods:**

- A single sample or several individual samples
- A single value combining all samples:
  - Arithmetic mean
  - Geometric mean
  - Median
  - 95th percentile, 90th percentile, 70th percentile, other percentile (please specify)
  - Mode
- If a lognormal probability density function is estimated and a single value is presented:
  - Highest point (global maximum/mode) of the lognormal probability density function
  - Arithmetic mean
  - Geometric mean/median
  - 95th percentile, 90th percentile, 70th percentile, other percentile (please specify)
- Other, please specify

Please provide some information about the arsenic **TELs** (limits on air concentration during a reference period of 15 minutes) for the Member State where you are based.

| Question | Answer |
|---|---|
| FA 10) STEL (value & unit)<br>Please indicate if respirable, inhalable or total dust) | |
| FA 11) Is the STEL? | ☐ Binding<br>☐ Indicative |

| Question | Answer |
|---|---|
| FA 12-13) How is compliance with the STEL determined? | ☐ Estimated<br>☐ Measured |
| FA 14) If measured:<br>How many samples and how often are they taken?<br>How is compliance with the STEL determined?<br>See above for an explanation. | |
| FA 15) Any other comments about the STEL | |

## E-FA) Potential new OEL under the CMD

This section looks at the potential to reduce air concentrations of formaldehyde, measured or calculated as a time-weighted average over eight hours, establishing new Occupational Exposure Limit Values (OELs) for formaldehyde under the CMD.

F 16) What is the lowest 8 hour TWA air concentration of formaldehyde that you have achieved?

| |
|---|
| |

FA 17) Which application did this apply to?

| |
|---|
| |

FA 18) Which measures were used to achieve this exposure value for arsenic?

| |
|---|
| |

FA 19) In your opinion, is it feasible to reduce air concentrations of formaldehyde in the application you specified in F 17) to a level below your response to F 16)?

| | |
|---|---|
| ☐ Yes | ☐ No |

FA 20) If YES to F 19), please indicate the three measures that you think are the most effective way of achieving this?

| |
|---|
| ☐ (a) limiting the quantities of formaldehyde at the place of work |
| ☐ (b) minimising the number of workers exposed or likely to be exposed |
| ☐ (c) designing work processes and engineering control measures to avoid or minimise the release of formaldehyde into the place of work |
| ☐ (d) evacuating formaldehyde at source, using a local extraction system or general ventilation, (whilst protecting public health and the environment) |
| ☐ (e) using existing appropriate procedures to measure formaldehyde, in particular for the early detection of abnormal exposures resulting from an unforeseeable event or an accident |
| ☐ (f) application of suitable working procedures and methods |
| ☐ (g) collective protection measures and/or, where exposure cannot be avoided by other means, individual protection measures |
| ☐ (h) hygiene measures, in particular regular cleaning of floors, walls and other surfaces |
| ☐ (i) information for workers |
| ☐ (j) demarcation of risk areas and use of adequate warning and safety signs including ‘no smoking’ signs in areas where workers are exposed or likely to be exposed to carcinogens or mutagens |
| ☐ (k) drawing up plans to deal with emergencies likely to result in abnormally high exposure |
| ☐ (l) means for safe storage, handling and transportation, in particular by using sealed and clearly and visibly labelled containers |

| |
|---|
| ☐ (m) other measures, please give details |

## F-FA) Potential new STEL under the CMD

This section looks at the potential to reduce air concentrations of formaldehyde, measured or calculated as a time-weighted average over 15 minutes, establishing new Short-term Exposure Limits (STELs) under the CMD for formaldehyde.

FA 21) What is the lowest 15 minute TWA formaldehyde concentration in the air that you have achieved?

| |
|---|
| |

FA 22) Which application did this apply to?

| |
|---|
| |

FA 23) Which measures were used to achieve this exposure value for formaldehyde?

| |
|---|
| |

FA 24) In your view, is it feasible to reduce air concentrations of formaldehyde in the application you specified in F 22) to a level below your response to F 21)?

| | |
|---|---|
| ☐ Yes | ☐ No |

FA 25) If YES to FA24), which three measures do you think are the most effective way of achieving this?

| |
|---|
| ☐ (a) limiting the quantities of formaldehyde at the place of work |
| ☐ (b) minimising the number of workers exposed or likely to be exposed |
| ☐ (c) designing work processes and engineering control measures to avoid or minimise the release of formaldehyde into the place of work |
| ☐ (d) evacuating formaldehyde at source, using a local extraction system or general ventilation, (whilst protecting public health and the environment) |
| ☐ (e) using existing appropriate procedures to measure formaldehyde, in particular for the early detection of abnormal exposures resulting from an unforeseeable event or an accident |
| ☐ (f) application of suitable working procedures and methods |
| ☐ (g) collective protection measures and/or, where exposure cannot be avoided by other means, individual protection measures |
| ☐ (h) hygiene measures, in particular regular cleaning of floors, walls and other surfaces |
| ☐ (i) information for workers |
| ☐ (j) demarcation of risk areas and use of adequate warning and safety signs including 'no smoking' signs in areas where workers are exposed or likely to be exposed to carcinogens or mutagens |
| ☐ (k) drawing up plans to deal with emergencies likely to result in abnormally high exposure |
| ☐ (l) means for safe storage, handling and transportation, in particular by using sealed and clearly and visibly labelled containers |
| ☐ (m) other measures, please give details |

## C-MOCA) RMMs for MOCA

M 1) Please list all the specific applications for which you have experience of evaluating or reducing air concentrations of MOCA?

*For the purposes of this questionnaire, the term 'application' encompasses all activities during which occupational exposure to the relevant compounds may occur, including production and use of the inorganic arsenic compounds, research & development, recycling, import, storage and transport.*

Examples of possible applications include: cast polyurethane elastomer production, production of polyurethane pre-polymers/polymers, suppliers for the polyurethane sector, moulders casting polyurethane formulations.

| |
|---|
| |

M 2) Please indicate all measures that you have recommended to reduce inhalation exposure to MOCA?

| |
|---|
| ☐ 1 Substitute/reduce quantities of chemical agents |
| ☐ 2 Reduce the number of workers exposed (fewer, rotate, etc.) |
| 3 Reduce the concentration at the workplace: |
| ☐ 3a. Process-related measures (design of work processes, etc.) |
| ☐ 3b. Control equipment to enclose, extract, or ventilate, etc. |
| ☐ 3c. Detect unusual exposures |
| 4 Reduce worker exposure: |
| ☐ 4a. Collective protection measures to reduce exposure to workers |
| ☐ 4b. Individual protection measures to reduce exposure to workers (PPE) |
| ☐ 5 Other measures, please give details |

M 3) If necessary, please give more details, for example to differentiate between applications.

| |
|---|
| |

## D-MOCA) National OEL

Please provide some information about the MOCA **OELs** (limits on air concentration expressed as an 8 hour TWA) for the Member State where you are based.

| Question | Answer |
|---|---|
| M 4) OEL (value, unit) | |
| M5) Is this OEL? | ☐ Binding<br>☐ Indicative |

| Question | Answer |
|---|---|
| M 6+7) How is the compliance of the OEL determined? | ☐ Estimated<br>☐ Measured |
| M 8) If measured:<br>How many samples and how often are they taken?<br>How is compliance with the OEL determined?<br>See below for an explanation. | |
| M 9) Any other comments about the OEL | |

**To determine compliance, values based on measured samples can be derived using, for example, the following methods:**

- A single sample or several individual samples
- A single value combining all samples:
  - Arithmetic mean
  - Geometric mean
  - Median
  - 95th percentile, 90th percentile, 70th percentile, other percentile (please specify)
  - Mode
- If a lognormal probability density function is estimated and a single value is presented:
  - Highest point (global maximum/mode) of the lognormal probability density function
  - Arithmetic mean
  - Geometric mean/median
  - 95th percentile, 90th percentile, 70th percentile, other percentile (please specify)
- Other, please specify

# E-MOCA) Potential new OEL under the CMD

This section looks at the potential to reduce air concentrations of MOCA, measured or calculated as a time-weighted average over eight hours, establishing new Occupational Exposure Limit Values (OELs) for MOCA under the CMD.

M 16) What is the lowest 8 hour TWA air concentration of MOCA that you have achieved?

| |
|---|
| |

M 17) Which application did this apply to?

| |
|---|
| |

M 18) Which measures were used to achieve this exposure value for MOCA?

| |
|---|
| |

M 19) In your opinion, is it feasible to reduce air concentrations of MOCA in the application you specified in M 17) to a level below your response to M 16)?

| | |
|---|---|
| ☐ Yes | ☐ No |

M 20) If YES to M 19), please indicate the three measures that you think are the most effective way of achieving this?

| |
|---|
| ☐ (a) limiting the quantities of MOCA at the place of work |
| ☐ (b) minimising the number of workers exposed or likely to be exposed |

| |
|---|
| ☐ (c) designing work processes and engineering control measures to avoid or minimise the release of MOCA into the place of work |
| ☐ (d) evacuating MOCA at source, using a local extraction system or general ventilation, (whilst protecting public health and the environment) |
| ☐ (e) using existing appropriate procedures to measure MOCA, in particular for the early detection of abnormal exposures resulting from an unforeseeable event or an accident |
| ☐ (f) application of suitable working procedures and methods |
| ☐ (g) collective protection measures and/or, where exposure cannot be avoided by other means, individual protection measures |
| ☐ (h) hygiene measures, in particular regular cleaning of floors, walls and other surfaces |
| ☐ (i) information for workers |
| ☐ (j) demarcation of risk areas and use of adequate warning and safety signs including 'no smoking' signs in areas where workers are exposed or likely to be exposed to carcinogens or mutagens |
| ☐ (k) drawing up plans to deal with emergencies likely to result in abnormally high exposure |
| ☐ (l) means for safe storage, handling and transportation, in particular by using sealed and clearly and visibly labelled containers |
| ☐ (m) other measures, please give details |

## G-MOCA) Potential new skin notation under the CMD

This section looks at the potential impact of establishing a skin notation for MOCA.

M 21) In your view, is it feasible to reduce dermal uptake of MOCA in the application(s) with which you have experience?

| | |
|---|---|
| ☐ Yes | ☐ No |

M 22) If YES to M 21), which three measures do you think are the most effective way of achieving this?

| |
|---|
| ☐ (a) limiting the quantities of MOCA at the place of work |
| ☐ (b) minimising the number of workers exposed or likely to be exposed |
| ☐ (c) designing work processes and engineering control measures to avoid or minimise the release of MOCA into the place of work |
| ☐ (d) evacuating MOCA at source, using a local extraction system or general ventilation, (whilst protecting public health and the environment) |
| ☐ (e) using existing appropriate procedures to measure MOCA, in particular for the early detection of abnormal exposures resulting from an unforeseeable event or an accident |
| ☐ (f) application of suitable working procedures and methods |
| ☐ (g) collective protection measures and/or, where exposure cannot be avoided by other means, individual protection measures |
| ☐ (h) hygiene measures, in particular regular cleaning of floors, walls and other surfaces |
| ☐ (i) information for workers |
| ☐ (j) demarcation of risk areas and use of adequate warning and safety signs including 'no smoking' signs in areas where workers are exposed or likely to be exposed to carcinogens or mutagens |
| ☐ (k) drawing up plans to deal with emergencies likely to result in abnormally high exposure |
| ☐ (l) means for safe storage, handling and transportation, in particular by using sealed and clearly and visibly labelled containers |
| ☐ (m) other measures, please give details |

## H) Further communication

Q8 Please provide an email address or telephone number in case the study teams needs to clarify any of your responses.

| |
|---|
| |

Q9 Are you willing to take part in a follow up interview to discuss the potential impacts of the new OELVs, STELs and of the skin notation for MOCA in more detail?

| | |
|---|---|
| ☐ Yes | ☐ No |

# A1.4 Questionnaire for Member State authorities

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) has been contracted by the European Commission (DG Employment, Social Affairs and Inclusion) to carry out a study to support a possible amendment of Directive 2004/37/EC on the protection of workers from exposure to carcinogens or mutagens at work (hereinafter the Carcinogens and Mutagens Directive or CMD).

The objectives of the study are:

a) to assess the impacts of establishing Occupational Exposure Limit Values (OELs) and, where relevant, other potential measures such as Short-term Exposure Limits (STELs) for the following chemical agents[38]:
   - cadmium and its inorganic compounds*;
   - beryllium and its inorganic compounds*;
   - inorganic arsenic compounds including arsenic acid and its salts*;
   - formaldehyde; and
   - 4,4'-Methylene-bis(2-chloroaniline) (MOCA) (includes the consideration of a skin notation).

   **As far as under the scope of the CMD*

   For each agent, a range of potential limit values is being assessed reaching from the lowest to the highest values resulting from SCOEL recommendations, RAC opinions and OELs established in EU Member States.

b) to describe and assess the OEL-deriving systems in EU Member States and selected competitor countries.

The purpose of this questionnaire is to collect data and information that will underpin the assessment. This questionnaire is intended for **Member State authorities** that are responsible for setting and/or

[38] The study is also assessing the impacts of an OEL of 5 µg/m$^3$ for '*chromium (VI) compounds in **welding or plasma cutting processes or similar work processes that generate fume'*** which will enter into force 5 years after the transposition date of the compromise recently reached by Council and the European Parliament on the Commission proposal COM(2016)248 final.

enforcing national OELs and/or would be able to provide any information, views, and data on the likely impacts of new OELs, STELs and skin notations under the CMD.

The questionnaire consists of six parts:

- Part A: National systems for setting OELs, STELs and skin notations.
- Part B: Enforcement of existing OELs and STELs
- Part C: Current OELs, STELs and skin notations for the five chemical agents
- Part D: The impacts of potential new OELs for the five chemical agents (and STELs for Be and formaldehyde and skin notation for MOCA)
- Part E: Cr(VI) from welding, plasma cutting, and similar work processes that generate fumes
- Part F: Further communication

The deadline for completion of the questionnaire is **3 November 2017**.

If you have any questions about this study, please contact Daniel Vencovsky (daniel.vencovsky@rpaltd.co.uk or +44 (0)1508 528 465).

| ***Definitions and acronyms*** | |
|---|---|
| CMD | Carcinogens and Mutagens Directive 2004/37/EC |
| MOCA | 4,4'-Methylene-bis(2-chloroaniline) |
| OEL | The term Occupational Exposure Limit Value (OEL) refers to the limit of the time-weighted average (TWA) of the concentration in the air within the breathing zone of a worker, measured or calculated in relation to a reference period of eight hours. |
| RAC | The Committee for Risk Assessment (RAC) is a scientific committee of ECHA that prepares the opinions related to the risks of substances to human health and the environment. It also assisted DG Employment with the evaluation of MOCA and inorganic arsenic compounds. |
| RMM | Risk Management Measure |
| SCOEL | The Scientific Committee on Occupational Exposure Limits (SCOEL) assists the Commission, in particular, in evaluating scientific data and recommending OELs. |
| Skin notation | An indication that the dermal route of exposure is scientifically considered to be relevant (in addition to the inhalation route) |
| STEL | A Short-term Exposure Limit (STEL) is a limit of the concentration in the air within the breathing zone of a worker, measured or calculated in relation to a reference period of fifteen minutes. |
| TWA | Time-weighted average |

# Part A: Setting national exposure limits

***OELs***

A1) Does your country have a list of OELs?

| |
|---|
| ☐ *Yes* |
| ☐ *No, but a list from another country/organisation is used* |
| ☐ *No* |

If available, please provide a link to an up-to-date list or attach as a separate document:

| |
|---|
| |

A2) Has your country specified a methodology for setting OELs?

| |
|---|
| ☐ *Yes* |
| ☐ *No, but a methodology from another country/organisation is used* |
| ☐ *No, generally applicable methodology does not exist* |
| ☐ *Other, please specify:* |

If available, please provide a link to an explanatory document or attach as a separate file:

| |
|---|
| |

A3) How often is the list of OELs updated?

| |
|---|
| ☐ *Yearly* |
| ☐ *Regularly but less often than every year:* |
| ☐ *As and when need arises* |
| ☐ *Other, please specify:* |

A4) Please briefly describe the procedure for setting exposure limit values, e.g. the Committee(s) involved, stakeholder consultation, legislative process, etc.

| |
|---|
| |

A5) Please provide name(s) and contact details of **scientific** expert(s) that could provide more information on the methodology for setting national limit values, i.e. someone who can explain the scientific background of national OELs or methodology.

| |
|---|
| |

A6) Please provide name(s) and contact details of **administrative** expert(s) that could explain the role of national OELs, i.e. explain the legal integration of OELs into worker protection regulation.

| |
|---|
| |

A7) Have OELs been derived for carcinogenic or non-carcinogenic properties?

| |
|---|
| ☐ *Carcinogenic* |
| ☐ *Non-carcinogenic* |
| ☐ *Both or depends on the chemical agent* |
| ☐ *Other, please specify:* |

A8) Are the OELs in your Member State…

| |
|---|
| ☐ *Health-based* |
| ☐ *Risk-based* |
| ☐ *Based on socioeconomic and/or technical and/or health considerations (aggregate assessment)* |
| ☐ *Depends on the chemical agent (some health-based, some risk-based, etc.)* |
| ☐ *Other, please specify:* |

A9) Are the OELs in your Member State…

| |
|---|
| ☐ *Binding* |
| ☐ *Indicative* |
| ☐ *Some are binding, some are indicative* |
| ☐ *Other, please specify:* |

A10) Does the procedure for setting OELs involve co-operation with other countries or international organisations, e.g. use of OELs from another country with national validation, etc.?

| |
|---|
| |

***STELs***

A11) Does your country have a list of STELs?

| |
|---|
| ☐ *Yes* |
| ☐ *No, but a list from another country/organisation is used* |
| ☐ *No* |

If available, please provide a link to an up-to-date list or attach as a separate document:

| |
|---|
| |

A12) Has your country specified a methodology for setting STELs?

| |
|---|
| ☐ *Yes* |
| ☐ *No, but a methodology from another country/organisation is used* |
| ☐ *No, a generally applicable methodology does not exist* |
| ☐ *Other, please specify:* |

If available, please provide a link to an explanatory document or attach as a separate file:

| |
|---|
| |

***Skin notations***

A13) Does the legislation in your Member State include a skin notation for any chemical agent?

| |
|---|
| A **skin notation** is an indication that the dermal route of exposure is scientifically considered to be relevant (in addition to the inhalation route). |

| |
|---|
| ☐ *Yes* |
| ☐ *No, but a list from another country/organisation is used* |
| ☐ *No* |
| ☐ *Other* |

If available, please provide a link to an up-to-date list or attach as a separate document:

| |
|---|
| |

# Part B: Enforcing national exposure limits

B1) Please summarise how compliance with **binding OELs** needs to be demonstrated in your Member State.

| Question | Answer |
|---|---|
| How is the air exposure concentration determined? | ☐ Measured<br>☐ Estimated |
| If **estimated**, please specify how: | |
| If **measured**, how many samples and how often do they need to be taken to demonstrate compliance? | |
| If **measured**, are there any rules on whether sampling has to be personal or for the work area? | |
| If **measured**, does air sampling have to be carried out by an external contractor? | ☐ Yes<br>☐ No |

| Question | Answer |
|---|---|
| If measured, how is compliance with the OEL determined? See below for an explanation. | |

**Values based on measured samples can be derived using, for example, the following methods:**

- A single sample or several individual samples
- A single value combining all samples:
  - Arithmetic mean
  - Geometric mean
  - Median
  - 95th percentile, 90th percentile, 70th percentile, other percentile (please specify)
  - Mode
- If a lognormal probability density function is estimated and a single value is presented:
  - Highest point (global maximum/mode) of the lognormal probability density function
  - Arithmetic mean
  - Geometric mean/median
  - 95th percentile, 90th percentile, 70th percentile, other percentile (please specify)
- Other, please specify

B2) Please summarise how compliance with **binding STELs** needs to be demonstrated in your Member State.

| Question | Answer |
|---|---|
| How is the air exposure concentration determined? | ☐ Measured<br>☐ Estimated |
| If **estimated**, please specify how: | |
| If **measured**, how many samples and how often do they need to be taken to demonstrate compliance? | |
| If **measured**, are there any rules on whether sampling has to be personal or for the work area? | |
| If **measured**, does air sampling have to be carried out by an external contractor? | ☐ Yes<br>☐ No |
| If measured, how is compliance with the OEL determined? See below for an explanation. | |

**Values based on measured samples can be derived using, for example, the following methods:**

- A single sample or several individual samples
- A single value combining all samples:
  - Arithmetic mean
  - Geometric mean
  - Median
  - 95th percentile, 90th percentile, 70th percentile, other percentile (please specify)
  - Mode
- If a lognormal probability density function is estimated and a single value is presented:
  - Highest point (global maximum/mode) of the lognormal probability density function
  - Arithmetic mean
  - Geometric mean/median
  - 95th percentile, 90th percentile, 70th percentile, other percentile (please specify)
- Other, please specify

B3) If relevant, please specify the obligations for companies that are triggered by a skin notation.

| |
|---|
| |

# Part C: OELs, STELs and skin notations for the five chemical agents

C1) For which of the following chemical agents does your Member State have a binding OELs, STELs or skin notation, either binding or indicative? Please tick all that apply. *See here for a non-exhaustive list (examples) of the relevant cadmium, beryllium, and arsenic compounds.*

| |
|---|
| ☐ cadmium and its inorganic compounds |
| ☐ beryllium and its inorganic compounds |
| ☐ inorganic arsenic compounds including arsenic acid and its salts |
| ☐ formaldehyde |
| ☐ 4,4'-Methylene-bis(2-chloroaniline) (MOCA) |

C2) Please provide the following information for **cadmium and its inorganic compounds**.

*See here for a non-exhaustive list (examples) of the relevant cadmium compounds.*

| Question | Answer |
|---|---|
| *Please provide information about **OEL(s)** for cadmium and its inorganic compounds* | |
| Cd 1) OEL or OELs (value, unit)<br>Please define the scope* of the OEL(s)<br>Please indicate if respirable, inhalable or total dust<br>Please give details about all OELs if more than one | |
| Cd 2) Is the OEL? | ☐ Binding<br>☐ Indicative |
| Cd 3) Any other comments about the OEL | |
| *Please provide information about **STEL(s)** for cadmium and its inorganic compounds* | |
| Cd 4) STEL or STELs (value, unit)<br>Please define the scope* of the STEL(s)<br>Please indicate if respirable, inhalable or total dust<br>Please give details about all STELs if more than one | |
| Cd 5) Is the STEL? | ☐ Binding<br>☐ Indicative |
| Cd 6) Any other comments about the STEL | |
| *Please provide information about the a **skin notation** for your Member State* | |
| Cd 7) Does legislation cover skin notation | ☐ Yes<br>☐ No |
| Cd 8) If yes, please give details | |
| *Please provide information about further sources of information* | |
| Cd 9) Is there a background document on how the OEL in your country was derived. If possible, provide an English translation. | ☐ Yes, attached or link supplied<br>☐ Yes, but not publicly available<br>☐ No |
| Cd 10) If a link, please insert | |
| Cd 11) Are there further national data/ assessment documents on this chemical agent? If possible, provide an English translation. | ☐ Yes, attached or link supplied<br>☐ Yes, but not publicly available<br>☐ No |
| Cd 12) If a link, please insert | |
| Cd 13) Is there a national expert available to explain background and details of national regulations for this chemical agent | ☐ Yes, contact details provided<br>☐ No |
| Cd 14) If yes, please give contact details | |
| ** Does it include cadmium and all its inorganic compounds and all occupations in which exposure occurs?* | |

C3) Please provide the following information for **beryllium and its inorganic compounds**.

*See here for a non-exhaustive list (examples) of the relevant beryllium compounds.*

| Question | Answer |
|---|---|
| *Please provide information about **OEL(s)** for beryllium and its inorganic compounds* | |
| Be 1) OEL or OELs (value, unit)<br>Please define the scope* of the OEL(s)<br>Please indicate if respirable, inhalable or total dust<br>Please give details about all OELs if more than one | |
| Be 2) Is the OEL? | ☐ Binding<br>☐ Indicative |
| Be 3) Any other comments about the OEL | |
| *Please provide information about **STEL(s)** for beryllium and its inorganic compounds* | |
| Be 4) STEL or STELs (value, unit)<br>Please define the scope* of the STEL(s)<br>Please indicate if respirable, inhalable or total dust<br>Please give details about all STELs if more than one | |
| Be 5) Is the STEL? | ☐ Binding<br>☐ Indicative |
| Be 6) Any other comments about the STEL | |
| *Please provide information about a **skin notation** for your Member State* | |
| Be 7) Does legislation cover skin notation | ☐ Yes<br>☐ No |
| Be 8) If yes, please give details | |
| *Please provide information about further sources of information* | |
| Be 9) Is there a background document on how the OEL in your country was derived. If possible, provide an English translation. | ☐ Yes, attached or link supplied<br>☐ Yes, but not publicly available<br>☐ No |
| Be 10) If a link, please insert | |
| Be 11) Are there further national data/ assessment documents on this chemical agent? If possible, provide an English translation. | ☐ Yes, attached or link supplied<br>☐ Yes, but not publicly available<br>☐ No |
| Be 12) If a link, please insert | |
| Be 13) Is there a national expert available to explain background and details of national regulations for this chemical agent | ☐ Yes, contact details provided<br>☐ No |
| Be 14) If yes, please give contact details | |
| ** Does it include beryllium and all its inorganic compounds and all occupations in which exposure occurs?* | |

C4) Please provide the following information for **inorganic arsenic compounds including arsenic acid and its salts**.

*See here for a non-exhaustive list (examples) of the relevant beryllium compounds.*

| Question | Answer |
|---|---|
| *Please provide information about **OEL(s)** for inorganic arsenic compounds including arsenic acid and its salts* | |
| As 1) OEL or OELs (value, unit)<br>Please define the scope* of the OEL(s)<br>Please indicate if respirable, inhalable or total dust<br>Please give details about all OELs if more than one | |
| As 2) Is the OEL? | ☐ Binding<br>☐ Indicative |
| As 3) Any other comments about the OEL | |
| *Please provide information about **STEL(s)** for inorganic arsenic compounds including arsenic acid and its salts* | |
| As 4) STEL or STELs (value, unit)<br>Please define the scope* of the STEL(s)<br>Please indicate if respirable, inhalable or total dust<br>Please give details about all STELs if more than one | |
| As 5) Is the STEL? | ☐ Binding<br>☐ Indicative |
| As 6) Any other comments about the STEL | |
| *Please provide information about a **skin notation** for your Member State* | |
| As 7) Does legislation cover skin notation | ☐ Yes<br>☐ No |
| As 8) If yes, please give details | |
| *Please provide information about further sources of information* | |
| As 9) Is there a background document on how the OEL in your country was derived. If possible, provide an English translation. | ☐ Yes, attached or link supplied<br>☐ Yes, but not publicly available<br>☐ No |
| As 10) If a link, please insert | |
| As 11) Are there further national data/ assessment documents on this chemical agent? If possible, provide an English translation. | ☐ Yes, attached or link supplied<br>☐ Yes, but not publicly available<br>☐ No |
| As 12) If a link, please insert | |
| As 13) Is there a national expert available to explain background and details of national regulations for this chemical agent | ☐ Yes, contact details provided<br>☐ No |
| As 14) If yes, please give contact details | |
| ** Does it include all inorganic arsenic compounds including arsenic acid and its salts and all occupations in which exposure occurs?* | |

C5) Please provide the following information for **formaldehyde**.

| Question | Answer |
|---|---|
| *Please provide information about **OEL(s)** for formaldehyde* | |
| F1) OEL or OELs (value, unit)<br>Please define the scope* of the OEL(s)<br>Please give details about all OELs if more than one | |
| F2) Is the OEL? | ☐ Binding<br>☐ Indicative |
| F 3) Any other comments about the OEL | |
| *Please provide information about **STEL(s)** for formaldehyde* | |
| F4) STEL or STELs (value, unit)<br>Please define the scope* of the STEL(s)<br>Please give details about all STELs if more than one | |
| F5) Is the STEL? | ☐ Binding<br>☐ Indicative |
| F6) Any other comments about the STEL | |
| *Please provide information about a **skin notation** for your Member State* | |
| F7) Does legislation cover skin notation | ☐ Yes<br>☐ No |
| F8) If yes, please give details | |
| *Please provide information about further sources of information* | |
| F9) Is there a background document on how the OEL in your country was derived. If possible, provide an English translation. | ☐ Yes, attached or link supplied<br>☐ Yes, but not publicly available<br>☐ No |
| F10) If a link, please insert | |
| F11) Are there further national data/ assessment documents on this chemical agent? If possible, provide an English translation. | ☐ Yes, attached or link supplied<br>☐ Yes, but not publicly available<br>☐ No |
| F12) If a link, please insert | |
| F13) Is there a national expert available to explain background and details of national regulations for this chemical agent | ☐ Yes, contact details provided<br>☐ No |
| F14) If yes, please give contact details | |
| ** Does it include all occupations in which exposure occurs?* | |

C6) Please provide the following information for **MOCA**.

| Question | Answer |
|---|---|
| *Please provide information about **OEL(s)** for MOCA* | |
| M1) OEL or OELs (value, unit)<br>Please define the scope* of the OEL(s)<br>Please give details about all OELs if more than one | |
| M2) Is the OEL? | ☐ Binding<br>☐ Indicative |
| M3) Any other comments about the OEL | |
| *Please provide information about **STEL(s)** for MOCA* | |
| M4) STEL or STELs (value, unit)<br>Please define the scope* of the STEL(s)<br>Please give details about all STELs if more than one | |
| M5) Is the STEL? | ☐ Binding<br>☐ Indicative |
| M6) Any other comments about the STEL | |
| *Please provide information about a **skin notation** for your Member State* | |
| M7) Does legislation cover skin notation | ☐ Yes<br>☐ No |
| M8) If yes, please give details | |
| *Please provide information about further sources of information* | |
| M9) Is there a background document on how the OEL in your country was derived. If possible, provide an English translation. | ☐ Yes, attached or link supplied<br>☐ Yes, but not publicly available<br>☐ No |
| M10) If a link, please insert | |
| M11) Are there further national data/ assessment documents on this chemical agent? If possible, provide an English translation. | ☐ Yes, attached or link supplied<br>☐ Yes, but not publicly available<br>☐ No |
| M12) If a link, please insert | |
| M13) Is there a national expert available to explain background and details of national regulations for this chemical agent | ☐ Yes, contact details provided<br>☐ No |
| M14) If yes, please give contact details | |
| ** Does it include all occupations in which exposure occurs?* | |

# Part D: The impacts of potential new OELs for the five chemical agents (and STELs for Be and formaldehyde and skin notation for MOCA)

*The purpose of the questions in this section is to assist the consultants in identifying key impact categories. Any issues identified in this manner will be subject to a detailed assessment during the remainder of the study. You may be contacted for a more detailed discussion of the impacts that you have identified as significant.*

*When differentiating between significant and moderate impacts, please consider the proportion of the relevant stakeholders that would be affected, the magnitude of the expected impacts and their duration. For example, an increase in cost affecting most companies in a significant way over the long-term is a 'significant negative impact.'*

***Cadmium and its inorganic compounds***

*See here for a non-exhaustive list (examples) of the relevant cadmium compounds.*

Although a wide range of potential OELs is being assessed in this study, the limit values given below are used as reference points for this questionnaire:

| | |
|---|---|
| 1 OEL at the level proposed in SCOEL OPIN 336 | Cd: 1 µg/m$^3$ (inhalable) |
| 2 OEL at the level of the lowest current national OEL in EU Member States | Same as above |
| 3 Mean, median, and mode of national OELs in EU Member States | Cd: 10 µg/m$^3$ (respirable), for the purposes of this questionnaire taken to equal 50 µg/m$^3$ (inhalable) |

D1) What would be the impact of the following OELs for cadmium and its inorganic compounds?

**For the purposes of this questionnaire taken to equal 50 µg/m$^3$ (inhalable)*

| Impact | OEL | Significant negative impact | Moderate negative impact | No impact | Moderate positive impact | Significant positive impact |
|---|---|---|---|---|---|---|
| Costs for companies | 1 µg/m$^3$ (inhalable) | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 10 µg/m$^3$ (respirable) * | ☐ | ☐ | ☐ | ☐ | ☐ |
| Costs for public authorities | 1 µg/m$^3$ (inhalable) | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 10 µg/m$^3$ (respirable) * | ☐ | ☐ | ☐ | ☐ | ☐ |
| Competitiveness | 1 µg/m$^3$ (inhalable) | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 10 µg/m$^3$ (respirable) * | ☐ | ☐ | ☐ | ☐ | ☐ |
| SMEs | 1 µg/m$^3$ (inhalable) | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 10 µg/m$^3$ (respirable) * | ☐ | ☐ | ☐ | ☐ | ☐ |

| Impact | OEL | Significant negative impact | Moderate negative impact | No impact | Moderate positive impact | Significant positive impact |
|---|---|---|---|---|---|---|
| Occupational health | 1 µg/m³ (inhalable) | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 10 µg/m³ (respirable) * | ☐ | ☐ | ☐ | ☐ | ☐ |
| Environment | 1 µg/m³ (inhalable) | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 10 µg/m³ (respirable) * | ☐ | ☐ | ☐ | ☐ | ☐ |

***Beryllium and its inorganic compounds***

*See here for a non-exhaustive list (examples) of the relevant beryllium compounds.*

D2) What would be the impact of the following **OELs** for beryllium and its inorganic compounds?

Although a wide range of potential OELs is being assessed in this study, the limit values given below are used as reference points for this questionnaire:

| | |
|---|---|
| 1 OEL at the level proposed in SCOEL REC 175 | Be: 0.02 µg/m³ (inhalable fraction) |
| 2 OEL at the level of the lowest current national OEL in EU Member States | Be: 0.1 µg/m³ (inhalable) |
| 3 Median and mode of national OELs in EU Member States | Be: 2 µg/m³ (inhalable) |

| Impact | OEL | Significant negative impact | Moderate negative impact | No impact | Moderate positive impact | Significant positive impact |
|---|---|---|---|---|---|---|
| Costs for companies | 0.02 µg/m³ (inhalable) | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 0.2 µg/m³ (inhalable) | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 2 µg/m³ (inhalable) | ☐ | ☐ | ☐ | ☐ | ☐ |
| Costs for public authorities | 0.02 µg/m³ (inhalable) | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 0.2 µg/m³ (inhalable) | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 2 µg/m³ (inhalable) | ☐ | ☐ | ☐ | ☐ | ☐ |
| Competitiveness | 0.02 µg/m³ (inhalable) | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 0.2 µg/m³ (inhalable) | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 2 µg/m³ (inhalable) | ☐ | ☐ | ☐ | ☐ | ☐ |
| SMEs | 0.02 µg/m³ (inhalable) | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 0.2 µg/m³ (inhalable) | ☐ | ☐ | ☐ | ☐ | ☐ |

| Impact | OEL | Significant negative impact | Moderate negative impact | No impact | Moderate positive impact | Significant positive impact |
|---|---|---|---|---|---|---|
| | 2 µg/m³ (inhalable) | ☐ | ☐ | ☐ | ☐ | ☐ |
| Occupational health | 0.02 µg/m³ (inhalable) | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 0.2 µg/m³ (inhalable) | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 2 µg/m³ (inhalable) | ☐ | ☐ | ☐ | ☐ | ☐ |
| Environment | 0.02 µg/m³ (inhalable) | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 0.2 µg/m³ (inhalable) | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 2 µg/m³ (inhalable) | ☐ | ☐ | ☐ | ☐ | ☐ |

D3) What would be the impact of the following **STELs** for beryllium and its inorganic compounds?

Although a wide range of potential STELs is being assessed in this study, the limit values given below are used as reference points for this questionnaire:

| | |
|---|---|
| 1 STEL at the level proposed in SCOEL REC 175 | Be: 0.2 µg/m³ (inhalable fraction) |
| 2 STEL at the level of the current lowest national 15 minute limit | Be: 0.4 µg/m³ (inhalable) |
| 3 Median and mode of national STELs in EU Member States | Be: 8 µg/m³ (inhalable) |

| Impact | STEL | Significant negative impact | Moderate negative impact | No impact | Moderate positive impact | Significant positive impact |
|---|---|---|---|---|---|---|
| Costs for companies | 0.2 µg/m³ (inhalable) | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 0.4 µg/m³ (inhalable) | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 8 µg/m³ (inhalable) | ☐ | ☐ | ☐ | ☐ | ☐ |
| Costs for public authorities | 0.2 µg/m³ (inhalable) | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 0.4 µg/m³ (inhalable) | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 8 µg/m³ (inhalable) | ☐ | ☐ | ☐ | ☐ | ☐ |
| Competitiveness | 0.2 µg/m³ (inhalable) | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 0.4 µg/m³ (inhalable) | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 8 µg/m³ (inhalable) | ☐ | ☐ | ☐ | ☐ | ☐ |
| SMEs | 0.2 µg/m³ (inhalable) | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 0.4 µg/m³ (inhalable) | ☐ | ☐ | ☐ | ☐ | ☐ |

| Impact | STEL | Significant negative impact | Moderate negative impact | No impact | Moderate positive impact | Significant positive impact |
|---|---|---|---|---|---|---|
| | 8 µg/m$^3$ (inhalable) | ☐ | ☐ | ☐ | ☐ | ☐ |
| Occupational health | 0.2 µg/m$^3$ (inhalable) | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 0.4 µg/m$^3$ (inhalable) | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 8 µg/m$^3$ (inhalable) | ☐ | ☐ | ☐ | ☐ | ☐ |
| Environment | 0.2 µg/m$^3$ (inhalable) | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 0.4 µg/m$^3$ (inhalable) | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 8 µg/m$^3$ (inhalable) | ☐ | ☐ | ☐ | ☐ | ☐ |

***Inorganic arsenic compounds including arsenic acid and its salts***

*See here for a non-exhaustive list (examples) of the relevant arsenic compounds.*

Although a wide range of potential OELs is being assessed in this study, the limit values given below are used as reference points for this questionnaire:

| | |
|---|---|
| 1 OEL at the level of the lowest current national OEL in EU Member States | As: 0.01 mg/m$^3$ |
| 2 OEL at the value recommended by SCOEL or RAC | No value recommended |
| 3 Median of national OELs in EU Member States | As: 0.225 mg/m$^3$ |

D4) What would be the impact of the following OELs for inorganic arsenic compounds including arsenic acid and its salts?

| Impact | OEL | Significant negative impact | Moderate negative impact | No impact | Moderate positive impact | Significant positive impact |
|---|---|---|---|---|---|---|
| Costs for companies | 0.01 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 0.225 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Costs for public authorities | 0.01 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 0.225 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Competitiveness | 0.01 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 0.225 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| SMEs | 0.01 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 0.225 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Occupational health | 0.01 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 0.225 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Environment | 0.01 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 0.225 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |

***Formaldehyde***

D5) What would be the impact of the following **OELs** for formaldehyde?

Although a wide range of potential OELs is being assessed in this study, the limit values and air concentrations given below are used as reference points for this questionnaire:

| | |
|---|---|
| 1 OEL at the level proposed in SCOEL REC 125 | Formaldehyde: 0.369 mg/m$^3$=0.3 ppm |
| 2 OEL at the level of the lowest current national OEL in EU Member States | Formaldehyde: 0.15 mg/m$^3$ |
| 3 Mode of national OELs in EU Member States | Formaldehyde: 0.6 mg/m$^3$ |

| Impact | OEL | Significant negative impact | Moderate negative impact | No impact | Moderate positive impact | Significant positive impact |
|---|---|---|---|---|---|---|
| Costs for companies | 0.15 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 0.369 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 0.6 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Costs for public authorities | 0.15 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 0.369 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 0.6 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Competitiveness | 0.15 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 0.369 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 0.6 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| SMEs | 0.15 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 0.369 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 0.6 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 0.15 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |

| Impact | OEL | Significant negative impact | Moderate negative impact | No impact | Moderate positive impact | Significant positive impact |
|---|---|---|---|---|---|---|
| Occupational health | 0.369 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 0.6 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Environment | 0.15 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 0.369 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 0.6 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |

D6) What would be the impact of the following **STELs** for formaldehyde?

Although a wide range of potential STELs is being assessed in this study, the limit values and air concentrations given below are used as reference points for this questionnaire:

| | |
|---|---|
| 1 STEL at the level proposed in SCOEL REC 125 | Formaldehyde: 0.738 mg/m$^3$=0.6 ppm |
| 2 STEL at the level of the current lowest national 15 minute limit | Formaldehyde: 0.37 mg/m$^3$=0.3 ppm |
| 3 Mode of national STELs in EU Member States | Formaldehyde: 1.2 mg/m$^3$ |

| Impact | STEL | Significant negative impact | Moderate negative impact | No impact | Moderate positive impact | Significant positive impact |
|---|---|---|---|---|---|---|
| Costs for companies | 0.37 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 0.738 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 1.2 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Costs for public authorities | 0.37 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 0.738 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 1.2 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Competitiveness | 0.37 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 0.738 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 1.2 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| SMEs | 0.37 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 0.738 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 1.2 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Occupational health | 0.37 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 0.738 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 1.2 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Environment | 0.37 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 0.738 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 1.2 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |

***MOCA***

D7) What would be the impact of the following **OELs** for MOCA?

Although a wide range of potential OELs is being assessed in this study, the limit values and air concentrations given below are used as reference points for this questionnaire:

| | |
|---|---|
| 1 OEL at the level of the lowest current national OEL in EU Member States | MOCA: 0.005 mg/m$^3$ |
| 2 OEL at the value recommended by SCOEL or RAC | No value recommended |
| 3 Median and mode of national OELs in EU Member States | MOCA: 0.02 mg/m$^3$ |

| Impact | OEL | Significant negative impact | Moderate negative impact | No impact | Moderate positive impact | Significant positive impact |
|---|---|---|---|---|---|---|
| Costs for companies | 0.005 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 0.02 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Costs for public authorities | 0.005 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 0.02 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Competitiveness | 0.005 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 0.02 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| SMEs | 0.005 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 0.02 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Occupational health | 0.005 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 0.02 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Environment | 0.005 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |
| | 0.02 mg/m$^3$ | ☐ | ☐ | ☐ | ☐ | ☐ |

D8) What would be the impact of a **skin notation** for MOCA?

| Impact | Significant negative impact | Moderate negative impact | No impact | Moderate positive impact | Significant positive impact |
|---|---|---|---|---|---|
| Costs for companies | ☐ | ☐ | ☐ | ☐ | ☐ |
| Costs for public authorities | ☐ | ☐ | ☐ | ☐ | ☐ |
| Competitiveness | ☐ | ☐ | ☐ | ☐ | ☐ |
| SMEs | ☐ | ☐ | ☐ | ☐ | ☐ |
| Occupational health | ☐ | ☐ | ☐ | ☐ | ☐ |
| Environment | ☐ | ☐ | ☐ | ☐ | ☐ |

# Part E: Cr(VI) from welding, plasma cutting, and similar work processes that generate fumes

E1) What impacts do you expect to occur in the affected industry located in your Member State as a result of an OEL of 5 µg/m$^3$ for *chromium (VI) compounds in* ***welding or plasma cutting processes or similar work processes that generate fume*** which will enter into force after 5 years after the transition date of the compromise recently reached by Council and the European Parliament on the Commission proposal COM(2016)248 final.

*Note: For the purposes of this study, it is assumed that the OEL of 5 µg/m³ will become effective from 2024, i.e. it is assumed that the latest transposition date will be 2019.*

| Impact | Significant negative impact | Moderate negative impact | No impact | Moderate positive impact | Significant positive impact |
|---|---|---|---|---|---|
| Costs for companies | ☐ | ☐ | ☐ | ☐ | ☐ |
| Costs for public authorities | ☐ | ☐ | ☐ | ☐ | ☐ |
| Competitiveness | ☐ | ☐ | ☐ | ☐ | ☐ |
| SMEs | ☐ | ☐ | ☐ | ☐ | ☐ |
| Occupational health | ☐ | ☐ | ☐ | ☐ | ☐ |
| Environment | ☐ | ☐ | ☐ | ☐ | ☐ |

E2) Please provide additional information on the impacts expected to arise at the end of the transition period for Cr(VI) from welding, plasma cutting, and similar work processes that generate fumes.

| |
|---|
| |

## Part F: Further communication

F1) Please specify the contact persons for further communication.

| Part | Contact person | Email | Telephone number |
|---|---|---|---|
| Part A: Setting national limit values | | | |
| Part B: Enforcing national limit values | | | |
| Part C: Existing limit values for the six chemical agents | | | |
| Part D: Impacts of new OELs, STELs, and skin notations | | | |

## A1.5 Example interview questions

1) In which sectors/uses does occupational exposure to the relevant chemical agents occur?
2) In what processes does occupational exposure to the relevant chemical agents occur?
3) In how many companies does exposure to the relevant chemical agents occur?
4) What proportion of these companies are SMEs?
5) How many workers are exposed to the relevant chemical agents (total and per company)?
6) What Risk Reduction Measures (RMMs) do they already have in place? See the questionnaire for companies for categories of RMMs.
7) Would CMD OELVs for the relevant chemical agents result in significant costs for your members?
8) At what level would the OELs have to be set to result in such costs?
9) Would Short-term Exposure Limits (STELs) in the CMD for beryllium and its inorganic compounds and formaldehyde entail significant costs?
10) At what level would the STELs have to be set to result in such costs?
11) Would a skin notation for MOCA entail significant costs in your Member State?
12) Any other impacts?

## A1.6 Example site visit questions

| **General information** | **Value / information** | **Comments** |
|---|---|---|
| Process or Similar Exposure Group (SEG) | | |
| Task | | *Brief description, e.g. filling big bags, surface treatment, sampling* |
| No. of potentially exposed workers per task per shift | | *For example: 1 operator and 1 supervisor, 5 operators* |
| Frequency of use | | *For example: daily, 1/week, 1/month etc.* |
| Duration of use | | *For example: full shift, <4h/shift,< 1h/shift etc.* |
| Other tasks in same workroom | | *Relate to other SEGs/PROCs of the same use* |
| **Chemical agent / Product** | **Value / information (circle/delete)** | |
| Physical state of chemical agent handled | Liquid / Solid / Solid in liquid | Please delete all, if not applicable |
| Physical state of product handled | Liquid / Solid / Solid in liquid | Please delete all, if not applicable |
| Concentration | | Concentration of chemical agent in product during this task |
| Dustiness of product (if solid) | Firm granules, flakes or pellets | e.g., firm polymer, granules, granules covered wax |
| | Granules, flakes or pellets | visible dust; e.g., fertilizer, garden peat animal pellets |
| | Coarse dust | dust cloud settles quickly: e.g. sand |
| | Fine dust | e.g., talcum powder, carbon black |
| | Extremely fine and light powder | e.g. magnesium stearate |
| **Workroom characteristics** | | |

| | | |
|---|---|---|
| Size of workroom | 30 / 100 / 300 / 1000 / 3000 m3 | Or provide exact number or estimate floor area and height |
| Type of ventilation | Natural / mechanical | |
| ACH (air changes per hour) | 0.3 / 1 / 3 / 10 / 30 | 1/h, or alternatively/in addition (next row) |
| Ventilation system | m3/h | *Provide air circulation (in m3/h) and other information (e.g. balanced ventilation, overpressure suppression)* |
| Functioning of mechanical ventilation system checked regularly? | Yes / No | *Provide details, e.g. annually by external service provider; quantitatively/qualitatively* |
| **Task / conditions of use and RMMs** | | |
| Use/consumption rate of the product | | L/min or kg/min, OR simply **volume/amount** handled per shift (compare with duration above); '2000 kg transferred in bag bags in 4h' |
| Level of automation | | Manual or automated or semi-automated or a combination (provide details if possible) |
| Containment | | Ask for efficiency and how this is assessed and checked |
| Type of process | | Open/closed; also ask for other technical measures that are aimed at reducing exposure (for Cr(VI): specifics for welding process) |
| Process temperature | | Any hot processes involved? |
| Level of agitation | | If process is open / not fully contained; e.g. stirring, scrubbing etc. |
| Work direction | | Upward, level, downward (applies to tasks such as brushing, rolling, spraying) |
| Local exhaust ventilation including type | Completely enclosed / half open / open | |
| Efficiency (%) | | Also ask how this is assessed |
| Segregation of worker from the source? | | E.g. in control room, in separate cabin |

| | | |
|---|---|---|
| Tools used during manual tasks | | E.g. brush, roller, spraying device (handle length) |
| Worker - source distance | < 30 cm, < 1m, > 1m, > 4m | Consider impact of tools in increasing the distance |
| Contamination of tools | High / Medium / Low | Visual impression |
| Airflow direction | | Away from the worker or not (for spraying) |
| Other | | *Ask staff member what other technical RMMs are in place* |
| **Exposure / contact** | | |
| Exposure data available? | Yes / No | Ask specifically for air monitoring and biomonitoring (MOCA and Cd at least)<br>Ask also for dermal exposure measurements (but quite unlikely to be available) |
| If yes, key values for **shift average**? | | AM and P90 at least (if possible); ranges; Please note whether exposure covers this tasks only of several tasks (i.e. different processes); if biomonitoring values are not provided for confidentiality reasons, ask for qualitative information |
| If yes, key values for **short-term exposure** (for this process or SEG)? | | AM and P90 at least (if possible); ranges; Please note whether exposure covers this tasks only of several tasks (i.e. different processes) |
| If high short-term exposure, additional RMMs? | | Ask if and what additional measures are taken to reduce short-term exposure. |
| Frequency and duration of contact | | Differentiate inhalation/dermal, if required; may be qualitative; may be different from frequency of the entire tasks, e.g. if process is contained, but samples are taken |
| Kind of contact | | Qualitative, e.g. dusty work, significant aerosol generation, intensive skin contact |
| Generation of aerosols or splashes | Yes / No | Qualitatively as an option: sometimes, rarely, often etc. |
| Body parts in contact with chemical agent/product | | For example: hands only, hands and forearms, hands and upper part of the body, potentially entire body |
| **PPE** | | |

| | | |
|---|---|---|
| Gloves | Yes / No | Please note specific type (specific name of the glove and manufacturer of the glove) |
| Respiratory protection | Yes / No | If yes, note exact filter type and type of mask (e.g. half or full face mask) or breathing apparatus |
| Other PPE | Yes / No | Specify; e.g. apron, protective suit and try to note specific type (Manufacturer and name of PPE) |
| **Possible changes** | | |
| **Substitution** | | |
| Principal options | | Ask, whether this has already been looked at; how many alternatives are there etc.; follow-up from questionnaire |
| Feasibility, costs | | May be qualitative, e.g.: requires completely new plant, requires new piece of equipment, can be used in same plant etc.; factors preventing implementation<br>If costs cannot be quantified, try to get an order of magnitude (e.g. 10-50 k€, millions of €) |
| **Technical RMMs** | | |
| Principal options | | Ask e.g. for containment, mechanical ventilation (instead of natural), additional local exhaust ventilation, better local exhaust ventilation |
| Feasibility, costs | | May be qualitative, e.g.: requires new piece of equipment, requires low cost adaptations etc.; factors preventing implementation<br>If costs cannot be quantified, try to get an order of magnitude (e.g. 10-50 k€, millions of €) |
| **Organisational RMMs /conditions of use** | | |
| Principal options | | Ask e.g. for job rotation, reduction in the number of samples, reduced amount of chemical agent used, reduced concentrations, other factors potentially reducing exposure etc.; factors preventing implementation |
| Feasibility, costs | | If costs cannot be quantified, try to get an order of magnitude (e.g. 10-50 k€, millions of €) |

| | |
|---|---|
| **Achieving OELs** | We particularly want to know what RMMs they need to use to achieve lower OELs, and are trying to establish the OEL tipping points where further RMMs and therefore costs will be required.<br><br>If the person has knowledge or opinions about this, probe further. |
| **Potential substitutes?** | Has the company considered this? What would be the impacts? |
| **Free text notes** | |

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