# Study to collect recent information relevant to modernising EU Occupational Safety and Health chemicals legislation with a particular emphasis on reprotoxic chemicals with the view to analyse the health, socio-economic and environmental impacts in connection with possible amendments of Directive 2004/37/EC and Directive 98/24/EC

**Final Report**
**SUMMARY REPORT**

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# Study to collect recent information relevant to modernising EU Occupational Safety and Health chemicals legislation with a particular emphasis on reprotoxic chemicals with the view to analyse the health, socio-economic and environmental impacts in connection with possible amendments of Directive 2004/37/EC and Directive 98/24/EC on the protection of workers from risks related to exposure to carcinogens, mutagens, reprotoxicants and other chemicals at work

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**Final Report**
**SUMMARY REPORT**

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# Summary Report

## Background to the Study

The EU legislative framework that addresses occupational exposure to Carcinogenic, Mutagenic and Reprotoxic substances includes Directive 98/24/EC (Chemical Agents Directive, CAD) and Directive 2004/37/EC (Carcinogens and Mutagens Directive, CMD).

All reprotoxic substances are currently dealth with in the CAD and those that are also Carcinogenic or Mutagenic (C/M) 1A/1B are also within the scope of the CMD. In accordance with a request[1] from the European Parliament and the Council, this study was launched by the European Commission to assess a number of options for amending the CMD, including the possibility of extending its scope to cover all Reprotoxic (R) 1A/1B substances. This included a number of specific tasks which are set out in the Terms of Reference of this study.[2]

The main objective of this study is to generate the evidence to enable the European Commission to initiate policy discussions regarding the possible future amendment of the CMD in order to include in its scope Reprotoxic 1A and 1B substances and/or, based on a possible merger of the CMD and CAD, additional requirements that would be necessary to address risks from Reprotoxic 1A/1B substances. In addition, several add-on tasks that could be considered as part of a more general revision of the Occupational Safety & Health (OSH) system have been included into the scope of this study, as set out in the Terms of Reference[3].

## EU and National Regulatory Systems

The key features of the regulatory systems seeking to protect workers from risks arising from occupational exposure to Reprotoxic 1A/1B substances at the EU level, in EU Member States, non-EU European Economic Area (EEA) countries (Norway, Iceland and Liechtenstein) and selected third countries that are major EU trading partners are summarised in this report. Based on the comparison of the key features between the CAD and the CMD, the main differences between the two Directives that are relevant to the Impact Assessment part of this study rest upon the following elements:

- The starting points triggering the application of the Directives;
- The level of exposure that signifies risk;
- The circumstances in which substitution should be considered;
- The criteria for deciding on substitutability;
- The Risk Management Measures applicable where substitution is not required; and
- The types of Occupation Exposure Limit values established under the Directives.

When looking at national transposition of the CAD and the CMD, the Member States have broadly selected one of the following approaches to transposition:

- National measures that transpose the two Directives in two separate legal instruments (10 Member States);

[1] Directive (EU) 2017/2398, see https://eur-lex.europa.eu/eli/dir/2017/2398/oj
[2] See https://etendering.ted.europa.eu/document/document-file-download.html?docFileId=36431
[3] See https://etendering.ted.europa.eu/document/document-file-download.html?docFileId=36431

- National measures that transpose the two Directives in one legal instrument (5 Member States); and
- Implementation in a series of national measures (13 Member States).

Eight EU Member States have taken advantage of the fact that the CAD and CMD are 'minimum harmonization' directives and have extended, in part or in full, their national legislation transposing the CMD to cover reprotoxic substances. This is the case in Austria, Belgium, Czech Republic, Finland, France, Germany, Sweden and the United Kingdom. The situation in these countries ranges from the application of all the requirements in the CMD[4] to reprotoxic substances (Belgium) to the extenstion of one or a few of the relevant requirements to reprotoxic substances that are not also C/M 1A/1B substances (examples: substitution and record keeping in the United Kingdom, only substitution in Finland). The requirements on R substances in the remaining 20 Member States generally mirror those in the CAD. There are also differences between the Member States in terms of how many pieces of legislation they have used to transpose the CAD and CMD.

When analysing national transpositions of the CAD and the CMD, this report has looked at the technical manner in which the directives were implemented by the EU Member States, referred to as the 'typology of national measures in the EU', and how such EU Member States regulate reprotoxic substances. To that effect, certain categories were established. However, it must be noted that for certain countries, a clear answer may not always be achievable and, depending on the data and criteria used, alternative classifications of Member States could be possible. In that regard, it is notably not always possible to a draw clear conclusion as to whether some Member States have extended the CMD requirements to Reprotoxic 1A/B substances, and/or the extent thereof.

## Threshold versus Non-threshold Paradigm

One of the issues considered in this report is whether the current paradigm of threshold (T)[5] acting substances addressed by CAD and non-threshold (NT) acting substances addressed by CMD is still relevant, efficient and effective at controlling risks to workers' health.[6] This includes the question of whether, as a default approach (i.e. unless proven otherwise for specific substances), reproductive effects should be presumed to have a threshold. It is, however, recognised that the T vs NT distinction is only one of a number of reasons for the differences between the CAD and CMD approaches, alongside other aspects such as the severe health consequences of C/M substances.

This report concludes that the differentiation between threshold and non-threshold effects is still relevant, effective and efficient for the purposes of EU OSH legislation. However, recent developments in scientific knowledge show that some carcinogens are now assumed to act through a threshold Mode of Action (MoA), which suggests that the determination of the most appropriate approach should be carried out on a substance-by-substance rather than hazard classification basis.

Drawing on a review of scientific literature, this report argues that the T approach continues to be an adequate default approach for reproductive effects, although there may be a small number of

[4] For example, substitution whenever exposure is likely, closed systems, exposure minimisation, keeping certain records for 40 years.

[5] The term 'threshold' means a dose or concentration, below which adverse effects of a substance are not expected to occur.

[6] It should be noted that this is only one of several distinctions between the CAD and CMD, one of the other ones being the severe health consequences that carcinogens can have.

substances for which an NT approach may be more appropriate (this underscores the usefulness of determining which of the two approaches is more suitable on a substance by substance basis). This conclusion takes into account the fact that a small number of reprotoxic substances can act through an endocrine disrupting MoA and, as recognised in the recent Communication from the Commission COM(2018) 734[7], there is an ongoing debate about what should be the most suitable paradigm for risk characterisation of Endocrine Disrupting Chemicals (EDCs). In addition, although the T approach is deemed to be an adequate default approach, the value of the threshold may in some instances be difficult (or impossible) to determine or may be close to (or below) background exposure levels, suggesting that, in these cases, the NT approach to controlling risk may be more appropriate.

As an add-on to the core analysis, the need for the extension of the NT approach to other types of chemical hazards is briefly considered on the example of sensitisers. The majority opinion of the experts and authorities appears to be that, for skin sensitisers, thresholds for induction for sensitisation exist and it is likely that health-based reference values based on the threshold assumption would be determined (despite some methodological difficulties). For respiratory sensitisers, thresholds for adverse effects (induction of sensitisation) exist but are difficult to determine with currently available models and methods, suggesting that the NT approach would be the more practical approach in terms of controlling risks from occupational exposure.

The conclusions in this study reflect what appears to be the prevailing scientific opinion. However, it is recognised that there is a diversity of scientific opinions on some of the relevant issues and there may be a minority scientific opinion that is not in agreement with the findings in this study. In particular, there is a range of opinions regarding whether thresholds exist for adverse effects that occur via the endocrine disruption MoA, as recognised in COM(2018) 734.

## Estimating the Burden of Ill-health

The study adopted two different approaches to estimating the current burden of reproductive ill-health from occupational exposure to Reprotoxic 1A/1B substances that are not also C/M 1A/B[8]:

1. The first method involves adopting a **top-down** approach, drawing on the use of population level incidence and prevalence data for health effects linked to exposures to reprotoxic substances. These prevalence data are adjusted to derive the potential maximal burden of effects that can be attributed to occupation exposure.

2. The second method is based on a **bottom-up** approach. It develops estimates for a set of 30 shortlisted Reprotoxic 1A/1B substances. For these selected substances, dose-response relationships for different effects identified from the toxicological literature have been developed. These have then been combined with data on uses, exposures (including from monitoring data), and numbers of workers likely to be exposed.

Note that for both approaches, we have also quantified the health burden in terms of the associated disability adjusted life years (DALYs) and/or using willingness to pay and cost of illness estimates.

[7] See http://ec.europa.eu/transparency/regdoc/rep/1/2018/EN/COM-2018-734-F1-EN-MAIN-PART-1.PDF

[8] Reprotoxic (R) 1A/1B substances that are not also Carcinogenic or Mutagenic (C/M) 1A/1B are substances that are currently within the scope of the CAD only. R1A/1B substances that are not also C/M 1A/1B are also within the scope of the CMD due to their carcinogenic or mutagenic classification.

***Top down Estimates***

The potential burden of health effects associated with occupational exposures to Reprotoxic 1A/1B substances, as calculated using the top-down approach, can be summarised as follows:

- A wide range of potential effects have been identified as being relevant to Reprotoxic 1A/1B substances, with these including impacts on male and female infertility, neo- and post-natal effects, as well as a range of congenital anomalies in newborn children. Exposures to Reprotoxic 1A/1B substances are not the only risk factors for such effects, however, with other maternal and environmental factors including smoking, obesity and diabetes. In addition, it must be remembered that exposures to reprotoxic substances may not only occur in the workplace.

- Based on a 2010 self-reporting survey (the so-called Sumer survey) carried out on the French labour force:

  - 1.1% of workers self-reported that they were exposed to a selected group of Reprotoxic 1A/1B substances (lead, glycol ethers, phthalates NMP, DMF and DMAC) that are also not classified as carcinogens and mutagens;
  - Although this may represent the population that may be exposed, this does not mean that these workers are exposed at levels which would give rise to effects. Indeed, the data indicate that only a very small percentage of this 1.1% of workers is actually exposed at significant intensities (i.e. above the threshold for effects) and durations to the group of substances; thus, one would expect the potential for impacts to be very low;
  - Extrapolation up from the French data to the EU level and multiplied by two account for other Reprotoxic 1A/1B substances that are also not classified as carcinogens or mutagens leads to estimates that between 22,000 and 61,000 male workers (0.015 – 0.043%) and 3,000 and 8,000 female workers (0.003 - 0.007%)(based on geometric means and with and without welding) are anticipated as being exposed long enough and to levels that may be high enough to give rise to reprotoxic effects (i.e. at levels above the threshold for effects);

- Combining figures on the predicted EU population that may be exposed to Reprotoxic 1A/1B substances at levels that may give rise to effects, as well as adjusting for the percentage of women getting pregnant in any one year, results in the following estimated cases:

  - Fertility effects: between 39 and 1,055 cases of infertility or babies not being carried to term;
  - Developmental effects: between 7 to 219 cases of developmental effects.

There are some important limitations to this top-down assessment. It is based on data for only one country and may therefore not be representative of worker exposures across the EU as a whole. It is also based on only a subset of Reprotoxic 1A and 1B substances not also classified as carcinogens and mutagens although, as discussed in Section B2 below, these include substances that are expected to account for the majority of workplace risks from exposure to Reprotoxic 1A/1B substances. In addition, within the reported data, there are significant numbers of entries which are "not declared" or missing. The reasons for these could range from ignorance to a reluctance to report.

On the other hand, the top-down approach relies on incidence or prevalence rates in the general population and estimates the theoretical maximum number of cases by deducting known non-

occupational causes and applying the resulting incidence rates to the occupationally exposed population. This approach relies on sufficient data being available for non-occupational causes and, as a result, entails a potential for overestimation. Adjustments have also been made to ensure that the population taken into account is of reproductive age; similarly, for developmental effects, it is important to only consider the proportion of births to women within the working population.

All of these adjustments lead to uncertainties. For example, it has not been possible to adjust the data for all known non-occupational causes of infertility and developmental effects, as such an approach would rely on the availability of specific attributable fraction data for those causes; this leads to the potential for overestimation.

***Bottom up Estimates***

The estimates developed for this approach are based on detailed evaluation of 30 substances. Dose-response relationships and thresholds for different reprotoxic effects were developed for each substance and these were combined with data on levels of control in the workplace and the number of workers likely to be exposed.

The potential burden of health effects associated with occupational exposures to Reprotoxic 1A/1B substances that are not also Carcinogens or Mutagens, as calculated using the bottom-up approach, can be summarised as follows:

- At the start of the study (March 2018), a total of 194 substances was identified as Reprotoxic 1A/1B substances registered under REACH. After removing those also classified as Carcinogenic 1A/1B or Mutagenic 1A/1B (43 substances), those already restricted for reasons relevant to occupational exposures or going through Authorisation (12 non-CMR substances) and some self-classified substances, a long list of 52 fully registered/intermediate substances was developed. Substances in this list were prioritised based on consideration of risk (based on tonnages and Derived No Effect Levels), three aprotic solvents were added and a final list of 30 substances was developed;

- These substances may be used in 36 different industry sectors, with individual substances likely to be used in multiple sectors and many of the sectors being likely to use more than one of the substances;

- Data provided by industry (individual companies and associations), collected from CSRs and from the literature indicate that exposure levels are expected to be at levels below the thresholds for effects in most workplaces;

- After applying dose-response relationships and thresholds developed for each of the substances and different health effects (from information provided in the CSRs or SCOEL and RAC opinions), between 24 and 180 cases of reproductive ill health per annum were predicted as arising from exposures to the 30 substances and depending on exposure scenario. When extrapolated to other Reprotoxic 1A/1B substances that are not also Carcinogenic or Mutagenic 1A/1B substances, this figure rises to between 27 and 206 cases of reproductive ill health per annum.

- Finally, it has only been possible to estimate the potential cases of reprotoxic effects that are currently associated with workplace exposures. Exposures to reprotoxic chemicals at levels below the threshold for reprotoxic effects may lead to other health effects not considered

here. Where this is the case, there will be an additional burden of ill health not captured by this study.

The bottom up approach reflects cases for which there is sufficient data and, consequently, it has the potential for underestimation. Dose-response functions can only be developed for the effects for which there are sufficient data in published scientific studies, measured exposure data may suffer from a positive bias, and establishing quantitative correlations between effects analysed in published scientific literature and human reproductive health outcomes is not always possible. This approach thus provides an estimate of the number of cases for which there is sufficient scientific evidence and exposure data. In addition, modelling for all substances (expect for lead) relies on air exposure data and dermal uptake is not modelled. All in all, the consequence is that the bottom-up approach represents an underestimate of the number of cases or reproductive ill health occurring as a result of occupational exposure to the relevant substances.

The bottom-up approach suggests that lead and lead compounds account for a large proportion of the total annual number of cases of reproductive ill health estimated in this study. The implication is that, although this report considers the potential benefits from the inclusion of Reprotoxic 1A/1B substances into the scope of the CMD, a large part of the burden of reproductive ill-health could be eliminated by means of lowering the Biological Limit Value (BLV) and the Binding Occupational Exposure Limit Value (BOELV) for lead under the CAD and ensuring compliance with the revised limit values.

***Valuation of Burden of Ill health under the Baseline***

The economic cost of reproductive ill-health, using the bottom-up calculations, are estimated at between (rounded):

- €460,000 for the 30 substances and €530,000 after extrapolation under the lowest realistic scenario; and
- €2.5 million for the 30 substances and €2.8 million after extrapolation under the highest realistic scenario.

The estimates using the top-down analysis are higher, given the higher number of cases predicted through this method. Based on the use of willingness to pay values, these are estimated at a between €9.1 and €24.3 million per annum for the geometric mean for developmental effects and between €29.7 and €79.5 million per annum for fertility and maternal effects for the geometric mean. At the maximum worst case (Scenario 1 which includes welding and taking the worst-case scenario), the figures rise to €91 million for developmental effects and €290 million for fertility and maternal effects.

Although the numbers of cases calculated under the two approaches are relatively low, the 30 substances are expected to account for around 90% of the overall risk characterisation score for all Reprotoxic 1A/1B substances that are not also Carcinogens or Mutagens 1A/1B. In addition, the top down assessment has a multiplier of 2 built into the estimates to try and account for potential worker exposures above the threshold for effects to other Reprotoxic 1A/1B substances that are not also Carcinogens or Mutagens 1A/1B. In this respect, it is important to remember that the starting point for the assessment was a review of the Classification and Labelling Inventory, which found that there were only 52 fully registered or intermediate substances with harmonised classifications as Reprotoxic 1A/1B substances that were not already Restricted or subject to Authorisation, or held classifications as Carcinogens 1A/1B and, thus, would fall under the CMD for OSH purposes.

Valuation of impacts has drawn on the use of DALYs avoided and direct and indirect cost of illness estimates for the bottom up approach and willingness to pay estimates for the top down approach. It did not prove possible to apply the DALYs approach to the top down estimates due to the number and range of developmental effects that would require consideration. The combined use of the two approaches should ensure that the end estimates are indicative of the range of health impacts.

## Summary of the Policy Options

The Policy Options assessed in this report are:

**Option 1- (baseline without additional guidance):** No changes to EU Occupational Safety and Health (OSH) legislation and no additional OSH guidance;

**Option 1 (baseline including additional guidance):** No changes to EU OSH legislation, additional OSH guidance at EU level;

**Option 2:** Extending the CMD to all Reprotoxic 1A/1B substances;

**Option 3:** Extending the CMD to all Reprotoxic 1A/1B substances but providing derogations from key requirements. These derogations would be revoked for individual substances for which the absence of a threshold for reproductive effects is established by an EU scientific committee;

**Option 3+:** Based on the Cefic[9]/ECEG[10]/ETUC[11]/IndustriAll[12] declaration[13] - extending the CMD to all Reprotoxic 1A/1B substances, always applying requirements on substitution and closed systems, possibility of a derogation from the exposure minimisation requirement in the event of compliance with a health-based BOELV;

**Option 4:** Merging the CAD and CMD into a single piece of legislation and applying CMD-equivalent requirements to all Reprotoxic 1A/1B substances; and

**Option 5:** Merging the CAD and CMD into a single piece of legislation, applying CMD-equivalent requirements to all Reprotoxic 1A/1B substances, updating/modernising OSH terms and requirements, and introducing several add-on elements (including breaking the link between mandatory use of health surveillance and BLVs and applying a non-threshold approach to respiratory and skin sensitisers).

Further details on the Policy Options are provided in Table 1.

**Table 1: Policy Options**

| Option | Details |
|---|---|
| **O1-: Baseline without OSH guidance** | No changes to EU OSH legislation but exposure may change due to other legislation and market developments.<br>No additional guidance provided |

[9] The European Chemical Industry Council
[10] The European Chemical Employers Group
[11] The European Trade Union Confederation
[12] IndustriAll European Trade Union
[13] See https://www.etuc.org/sites/default/files/press-release/file/2018-10/Joint%20Declaration%20Reprotoxics%20signed.pdf

| Table 1: Policy Options | |
|---|---|
| **Option** | **Details** |
| **O1: Baseline (no changes to EU OSH legislation, guidance provided)** | No changes to EU OSH legislation but exposure may change due to other legislation and market developments.<br>Provision of additional guidance on best available techniques and interpretation of the CMD/CAD |
| **O2: R 1A/1B in CMD (no derogations)** | Inclusion of R 1A/1B chemicals into the scope of the CMD with full application of the requirements in the CMD, including:<br>- Substitution: stricter requirement than in the CAD:<br>o mandatory whenever workers 'are or are likely to be exposed'<br>o 'risk > slight risk' not a prerequisite<br>- Closed system: second RMM in the hierarchy under the CMD vs. no explicit reference to closed systems in the CAD (except for intermediates);<br>- Reduction of exposure to as low as technically feasible (minimisation requirement);<br>- IOELVs for R 1A/1B substances would become BOELVs: IOELVs under the CAD for R 1A/1B substances would become BOELVs under the CMD; and<br>- Record keeping: Record keeping for at least 40 years would be required for R 1A/1B substances. |
| **O3: R 1A/1B in CMD with derogations** | Inclusion of R 1A/1B into the scope of the CMD but with derogations from the substitution, closed system, minimisation and record keeping requirements, unless an EU scientific committee confirms the substance has no threshold for reprotoxic effects. CAD IOELVs for R 1A/1B substances become BOELVs under the CMD. |
| **O3+: Cefic/ECEG/ETUC/IndustriAll Declaration: R 1A/1B in CMD with derogations** | Inclusion of R 1A/1B into the scope of the CMD with the following requirements:<br>- A Binding OELV (risk or health based) would be established for Rs;<br>- CMD requirements on prevention (substitution, closed system) would always apply to reprotoxic substances;<br>- If prevention were not possible, then exposure must be reduced to a) a 'safe level' (see below) or b) as low as possible (minimisation requirement);<br>- Safe level: a) the substance has a threshold, b) there is a health-based Binding OELV (including CAD IEOLVs->CMD BOELVs), c) it is proven by exposure measurements that the BOELV is complied with;<br>- Differentiated approach (non-threshold vs safe level) should also be applied to C/M. |
| **O4: Merge CAD & CMD into a single directive but no modernisation** | Merging the CMD and CAD into a single directive, applying CMD-equivalent requirements to R 1A/1B substances but no further changes:<br>- This would effectively be CAD and CMD in parallel but in one document;<br>- Old terminology: language would not be updated or modernised;<br>- CMD-equivalent requirements would apply to CMR 1A/1B substances and CAD requirements would apply to other hazards. |
| **O5: Merge CAD & CMD and modernise** | Merging the CMD and CAD, applying CMD-equivalent requirements to R 1A/1B substances and updating/modernising OSH terms and requirements:<br>- CMD-equivalent requirements apply to CMR 1A/1B substances and CAD-equivalent requirements apply to other types of hazardous substances;<br>- Common terminology for substances subject to CMD-equivalent and CAD-equivalent requirements;<br>- Terminology brought into line with REACH; and<br>- Add on elements: a) skin and respiratory sensitisers would also be subject to CMD-equivalent requirements and b) use of BLVs as part of health surveillance would not be mandatory. |

## Costs of the Policy Options

No additional costs would arise under Option 1-. The guidance developed under Option 1 is expected to result in some additional costs for public authorities and companies. With regard to the inclusion of Reprotoxic 1A/1B substances into the CMD, the more stringent requirements in the CMD have the potential to increase compliance costs for companies in the Member States where these requirements are presently not applied to Reprotoxic 1A/1B substances that are not also C/M 1A/1B. The cost of some of these measures, expressed as an annualised cost, has been estimated between €400 million

and €900 million, as indicated in Table 2.[14] These figures include the costs of considering and documenting the feasibility of substitution and closed systems, as well as implementing closed systems and further measures to minimise exposure.

Due to the large number of uncertainties involved in the estimation of these figures, the range should be seen as illustrative of the general order of magnitude of the potential costs rather than 'definite' estimates. In addition, some relevant compliance costs could not be monetised and, consequently, this range does not represent all the costs that would be incurred. For example, the costs of substitution and compliance with additional Binding Occupational Limit Values (BOELVs) could not be estimated. The costs of substitution are substance specific and a case-by-case examination of all relevant substances and their alternatives in all the relevant sectors/uses has not been possible within the constraints of this study. It is expected that, in some cases, the cost of substitution could be significant. It should, however, be also noted that it is possible that some Member States would take economic feasibility into account when enforcing this provision and that most companies should already be covered by the general substitution requirement in the CAD.

The costs within the range presented above are likely to arise under Options 2, 3+, 4 and 5, all of which involve the extension of the CMD to cover Reprotoxic 1A/1B substances. In the absence of scientific evaluations for all the relevant substances, it is not possible to determine which specific substances would be included into the scope of the CMD requirements under option 3. The costs of Option 3 are likely to be lower than those of Options 2, 3+, 4 and 5 but greater than under Options 1- and 1. In addition, the costs of Option 3 would be staggered as specific non-threshold substances are included into the scope of the relevant requirements over time. Option 3+ can be expected to be the most costly method of extending the CMD to Reprotoxic 1A/1B substances, since it is likely to accelerate the process of adoption of Binding Occupational Exposure Limit Values (BOELVs) for Reprotoxic 1A/1B substances that are not also C/M 1A/1B and would thus involve costs of compliance with these limits, including the need to prove compliance by means of exposure measurements for companies that are already below the thresholds for effects.

The costs of the different policy options are summarised in Table 2.

**Table 2: Costs under the different Policy Options**
***Legend: ++++: very high costs, +++: high costs, ++: medium costs, +: limited costs, 0: no costs***

| Aspect ↓ | | Policy Option → | O1- | O1 | O2 | O3 | O3+ | O4 | O5 |
|---|---|---|---|---|---|---|---|---|---|
| ***Costs for companies (annualised cost)*** | | | | | | | | | |
| Additional OSH guidance | | | 0 | ++ | ++ | ++ | ++ | ++ | ++ |
| Extension of CMD to R 1A/1B | Substitution | Consideration | 0 | 0 | ++ (€10-20m) | + | ++ (€10-20m) | ++ (€10-20m) | ++ (€10-20m) |
| | | Implementation | 0 | 0 | Potentially ++++ | ++ | Potentially ++++ | Potentially ++++ | Potentially ++++ |
| | Closed systems | Consideration | 0 | 0 | +++ (€180-260m) | ++ | +++ (€180-260m) | +++ (€180-260m) | +++ (€180-260m) |
| | | Implementation | 0 | 0 | ++ (€60-240m) | ++ | +++ (€60-240m) | +++ (€60-240m) | +++ (€60-240m) |
| | Exposure minimisation | | 0 | 0 | +++ (€80-250m) | ++ | ++ (less than O2, 4, 5) | +++ (€80-250m) | +++ (€80-250m) |
| | 11 CAD Indicative OELVs -> CMD Binding OELVs | | 0 | 0 | + | + | + | + | + |
| | Record keeping | | 0 | 0 | ++ (€80-140m) | + | Unknown | ++ (€80-140m) | ++ (€80-140m) |

[14] Due to the large number of uncertainties involved in the estimation of the costs, the quantified ranges in Table 2 are illustrative of the magnitude of the potential impacts rather than definite estimates.

| Table 2: Costs under the different Policy Options<br>*Legend: ++++: very high costs, +++: high costs, ++: medium costs, +: limited costs, 0: no costs* | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Aspect ↓** | **Policy Option →** | **O1-** | **O1** | **O2** | **O3** | **O3+** | **O4** | **O5** |
| Additional BOELVs | | + | + | + | + | ++++ | + | + |
| Merging of the two directives | | 0 | 0 | 0 | 0 | 0 | + | + |
| Substance-by-substance threshold vs non-threshold approach | | 0 | 0 | +++ | 0 | ++ | +++ | +++ |
| Modernisation of terms | | + | + | + | + | + | + | Unknown |
| Add-on elements | Health surveillance/ Biological Limit Values | 0 | 0 | 0 | 0 | 0 | 0 | Unknown |
| | Non-threshold approach for sensitisers | 0 | 0 | 0 | 0 | 0 | 0 | Potentially +++ |
| ***Public authorities (total cost in € million)*** | | | | | | | | |
| EU – development of OSH guidance | | 0 | €10m | €10m | €10m | €10m | €10m | €10m |
| Member States – transposition cost | | 0 | 0 | €3m | €3m | €3m | €3m | €3m |

The central assumption of the cost assessment is that that 2% of companies have workers potentially exposed to Reprotoxic 1A/1B substances and would thus incur some costs. This is in line with the approach of the CMD in which exposure signifies risk. The 2% estimate is based on consultation for this study and represents a reasonable worst-case scenario. A sensitivity analysis with 1% and 3% is provided in the report.

The impacts of the extension of the CMD to cover Reprotoxic 1A/1B substances to a large extent depend on the transposition and enforcement decisions taken at the Member State level – these are highly uncertain and the stringency with which the requirements would be interpreted in individual Member States cannot be predicted with any degree of certainty. In addition, the impacts of some of the policy options depend on unknown factors, such as whether a scientific body would deem certain substances to have a threshold for reproductive effects and what would be the value of a health-based BOELV. As a result, estimation of the expected costs and benefits is difficult. Therefore, the analysis in this report should be taken as merely illustrative of the general order of magnitude of the potential costs and benefits. Some of this uncertainty is captured in the ranges presented in this report but there is remaining uncertainty that could not be quantified.

## Benefits of the Policy Options

No reduction in ill-health is expected under Option 1-. Increased uptake of 'best practices' under Option 1 is expected to reduce reproductive ill health but not as much as Options 2, 3, 3+, 4 and 5.

The more stringent requirements in the CMD (differences between the substitution requirements, explicit reference to closed systems and the requirement to minimise exposure, etc.) have a potential to reduce reproductive ill health in the Member States where these requirements are not yet applied to Reprotoxic 1A/1B substances. Due to the large uncertainty, the potential reduction has been estimated to be between 1 and 380 cases of reproductive ill health per year which have a total monetary value between €20,000 and €31 million annually, due to direct, indirect, and intangible costs borne by workers, their families, employers and the public sector.[15] It should be noted that some of the impacts could not be quantified suggesting that these figures are underestimates, although the assumptions adopted for the estimation of ill health reduction resulting from additional exposure prevention/reduction measures mean that the estimated reduction is likely to be an overestimate (see the uncertainty/limitations summary below). These benefits are likely to occur under Options 2, 3+, 4 and 5 which all involve an extension of the CMD to all Reprotoxic 1A/1B substances. Option 3+ is expected to be the most effective option in terms of reducing reproductive ill health since it is likely

[15] Due to the large number of uncertainties involved in their estimation, the benefits estimated in Table 3 are illustrative of the magnitude of the potential impacts rather than definite estimates.

to accelerate the introduction of BOELVs for Reprotoxic 1A/1B substances that are not also C/M 1A/1B. Reductions in ill health under Option 3 are expected to be staggered as non-threshold substances would be included into the scope of the relevant requirements one by one over time. This means that (in the near future as well as when summed up over a longer timeframe) the benefits from Option 3 are likely to be less than those from the options which involve an immediate application of the CMD requirements to Reprotoxic 1A/1B substances.

Although the bulk of the monetised benefits from avoided direct, indirect, and intangible costs of ill health would be accrued by workers and their families, employers would also benefit from reduced absenteeism, administrative simplification, level playing field across the EU, and under those options that differentiate between T and NT on a substance by substance basis also from increased efficiency and trust in the fairness of the OSH system. Public authorities are also likely to benefit from reduced healthcare and social security expenditure – these savings are included in the ranges presented above.

A comparison of the policy options for each impact category is provided in Table 3.

| Table 3: Benefits of the different Policy Options<br>*Key: ++++ substantial benefits, +++ significant benefits, ++ some benefits, + limited benefits, 0 no change.* | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Aspect ↓** | **Policy Option →** | **Relevant stakeholders** | **O1-** | **O1** | **O2** | **O3** | **O3+** | **O4** | **O5** |
| Reduced ill health due to OSH guidance | | Workers & families | 0 | ++ | ++ | ++ | ++ | ++ | ++ |
| Health benefits from extension of the CMD to R 1A/1B substances | Substitution and closed systems | | 0 | 0 | ++<br>1-191 avoided repro cases p.a.<br>€0.02-16m p.a. | ++<br>Not possible to quantify but less than under O2, O3+, O4, and 05 | ++<br>1-191 avoided repro cases p.a.<br>€0.02-16m p.a. | ++<br>1-191 avoided repro cases p.a.<br>€0.02-16m p.a. | ++<br>1-191 avoided repro cases p.a.<br>€0.02-16m p.a. |
| | Exposure minimisation | | 0 | 0 | ++<br>4-191 avoided repro cases p.a.<br>€0.08-16m p.a. | | ++<br>4-191 avoided repro cases p.a.<br>€0.08-16m p.a. | ++<br>4-191 avoided repro cases p.a.<br>€0.08-16m p.a. | ++<br>4-191 avoided repro cases p.a.<br>€0.08-16m p.a. |
| | 40 years of record keeping | Authorities | 0 | 0 | ++ | + | 0 | ++ | ++ |
| | 11 CAD IOELVs -> CMD BOELVs | Workers & families | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Additional OELVs for R 1A/1B substances | | Companies, authorities | ++ | ++ | ++ | ++ | +++ | ++ | ++ |
| Add-on elements (Biological Limit Values and sensitisers) | | Workers and their families | 0 | 0 | 0 | 0 | 0 | 0 | +++ |
| Reduced absenteeism | | Companies | 0 | | | Included in health-related benefits (see above) | | | |
| Reduced healthcare and social sec. expenditure | | Authorities | 0 | | | | | | |
| Administrative simplification | | Companies | 0 | + | ++ | +++ | +++ | +++ | ++++ |
| Administrative simplification – legal coherence | | Authorities | 0 | + | ++ | +++ | +++ | +++ | ++++ |
| Administrative simplification – ease of enforcement | | Authorities | 0 | + | ++ | + | ++ | ++ | +++ |
| Level playing field | | Companies | 0 | + | +++ | ++ | ++++ | +++ | +++ |
| Fundamental rights | | Workers & families | 0 | + | +++ | ++ | +++ | +++ | +++ |
| Modernisation of terms | | Authorities, companies, workers | 0 | 0 | 0 | 0 | 0 | 0 | +++ |
| Individual substance approach (Threshold vs Non-threshold) | | Companies | 0 | 0 | Significant negative impact | ++ | ++ (but +++ if extended to C/M) | Significant negative impact | Significant negative impact |
| ***Overall health benefits for R 1A/1B substances*** | | ***Workers & families, companies, authorities*** | ***0*** | ***+*** | ***+++<br>1-382 avoided repro cases p.a.[1]<br>€0.02-31m p.a.*** | ***++<br>Not quantified but less than under O2, O3+, O4, O5*** | ***+++<br>1-382 avoided repro cases p.a.[1]<br>€0.02-31m p.a.*** | ***+++<br>1-382 avoided repro cases p.a.[1]<br>€0.02-31m p.a.*** | ***+++<br>1-382 avoided repro cases p.a.[1]<br>€0.02-31m p.a.*** |

Notes: p.a.: per annum; IOELV: Indicative Occupational Exposure Limit Value; BOELV: Binding Occupational Exposure Limit Value
1: The low end of the sum of avoided cases does not take into account exposure minimisation since these benefits are highly uncertain

The uncertainties set out above for the cost assessments are also applicable to the benefits estimated in Table 3. In addition, substitution is assumed to eliminate all reproductive ill health in the relevant companies and does not take into account the characteristics of the potential substitutes – the estimates of the reduction in ill health presented in this section could thus be overestimates. Closed systems are assumed to eliminate all exposure and this is also likely to overestimate the benefits since some exposure is likely to remain during maintenance and cleaning. The modelling also assumes that any company that further minimises exposure would eliminate all reproductive ill health – this is unlikely to be the case in reality and thus the estimated reduction represents an overestimation. On the other hand, reduced exposure to the relevant substances is also likely to reduce a range of non-reproductive effects and these reductions are not included in the ranges presented above.

## Market Effects

On the basis of modelled data regarding the numbers of companies that might be affected by different measures included within the policy options, the study concludes that, overall, the costs likely to be incurred represent a relatively low proportion of company turnover. As such, the effects on competitiveness, R&D, the internal market and competition and employment are likely to be limited.

However, in individual circumstances, in particular where companies engage in substitution of Reprotoxic 1A/1B substances, the impacts will be more significant, in particular in the case of SMEs. The relatively high proportion of large companies in the chemicals and other sectors using Reprotoxic 1A/1B substance would suggest that the potential might exist for companies to relocate outside of the EU, with larger companies having greater resources and, in some cases, existing operations in third countries. That being said, the relatively low proportion of turnover that the increased costs would represent under even the most burdensome of the policy options in comparison with the actual investment that might be required to transfer operations would appear to suggest that this will not be an option pursued by most companies (although some individual companies, particularly those which might be required to substitute Reprotoxic 1A/1B substances may opt to relocate).

The absence of detailed information regarding the numbers of companies that actually manufacture and use the different Reprotoxic 1A/1B substances means that it has not been possible to quantify the overall impacts at the sectoral level. As a result, the impacts at sectoral have had to be qualitatively analysed and might be subject to particular uncertainty. It is possible that companies using these substances operate in particular small or niche sub-sectors within the overall sectors analysed, and as such, might represent a more significant part of those particular sub-sectors.

Additionally, it is unknown how individual companies would respond to the changes that would arise under individual options and whilst the policy options clearly have different measures which will need to be adopted under each of the different options, lack of data regarding, for example, the number of companies currently operating at levels below IOELVs means that it is very difficult to establish which companies will undertake specific courses of action.

## Comparison of the Policy Options

Due to the large number of uncertainties involved in the estimation of the costs and benefits, the quantified ranges presented in this report should be seen as illustrative of the magnitude of the potential impacts rather than definite estimates. In addition, some relevant (and potentially significant) costs and benefits could not be monetised, including benefits from reducing other types of health effects. Furthermore, the impacts of the extension of the CMD to cover Reprotoxic 1A/1B

substances to a large extent depend on transposition and enforcement decisions taken at the Member State level, and these cannot be predicted with any degree of certainty.

No change in the current costs and benefits is expected under Option 1-. Although the precise magnitude of the costs and benefits under Option 1 is uncertain (these depend on voluntary uptake of best practice measures), it can be expected that any benefits would be accrued in an efficient manner, i.e. unnecessary compliance costs for companies would be avoided.

Under Options 2, 3+, 4 and 5, the quantified costs outweigh the quantified benefits – in some cases, this difference can be quite significant. This conclusion does not change when qualitative scores and uncertainties for which there is some indication of their order of magnitude are taken into account. Option 3+ is expected to be the most effective option in terms of reducing reproductive ill health since it should lead to an earlier adoption of BOELVs for Reprotoxic 1A/1B substances that are not also C/M 1A/1B. It is, however, also likely to be the most costly option as a large number of companies would have to demonstrate compliance with the BOELVs. The costs under Option 3 are likely to be lower but, in the absence of scientific evaluations for all the relevant substances, it is not possible to determine which specific substances would be subject to CMD requirements. In addition, under Option 3, the costs and benefits would be staggered over time.

Under Options 2, 3, 3+, 4 and 5, the method of extending the CMD to cover Reprotoxic 1A/1B means that some companies would incur costs but would see no reductions in reproductive ill health since their workers are already exposed at levels below the thresholds for reproductive effects. This is a consequence of the extension of a non-threshold approach to threshold substances. The exemption from the exposure minimisation requirement under Option 3+ for companies that can demonstrate a 'safe level' of exposure would mitigate these costs but substantial costs would still be incurred in demonstrating compliance with BOELVs and due to the substitution and closed system requirements under the CMD. Option 3 avoids these consequences and, thus, is the and one, apart from the baseline options, least likely to result in unnecessary costs. However, reductions in ill health would be delayed under Option 3 as a determination by an EU scientific body would be necessary for CMD requirements to apply to non-threshold Reprotoxic 1A/1B substances. Furthermore, in the absence of scientific evaluations for all the relevant substances, it is not possible to determine which specific substances would be included into the scope of the CMD requirements.

## Illustrative Case Studies

The study includes illustrative case studies for the following substances: lead and lead compounds, borates and retinol. The case studies show that, while a very large workforce is exposed to borates and retinol, they are typically exposed at very low levels (although some data limitations have to be recognised). As a result, no cases of reproductive ill health have been estimated for these substances under any of the realistic scenarios. However, due to the large number of companies, even limited costs on a per company basis due to the need to document feasibility of substitution/closed system have the potential to result in significant overall costs.

The lead case study is a good example of a relatively small occupationally exposed population (although it should be recognised that data are not available for some sectors) with good data availability with regard to exposure (biomonitoring is carried out widely and a binding BLV under the CAD and voluntary industry targets are in existence). Lead and lead compounds account for a large proportion of the annual cases of reproductive ill health predicted as arising from exposures to the 30 substances, with the implication that lowering the Biological Limit Value (BLV) for lead under the CAD could deal with large part of the burden of reproductive ill health as estimated under the bottom-up approach. With regard to the Impact Assessment, it is of interest that there appears to be very little

difference between the policy options in terms of the cost impacts on the relevant companies and the benefits that could be achieved.

The borates case study is an interesting example of a group of substances with a very large exposed workforce, albeit at very low intensities below the thresholds for reprotoxic effects. As a result, no cases of reproductive ill health have been estimated under any of the realistic scenarios. However, it is expected that additional requirements designed for non-threshold substances such as those in the CMD could result in significant compliance costs for the relevant companies. Due to the large number of companies, even limited costs on a per company basis due to the need to document feasibility of substitution/closed systems have the potential to result in significant costs. Similar observations have been made in the retinol case study.


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