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

REPORT 2 – IMPACT ASSESSMENT

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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

March 2019

Final Report
REPORT 2 – IMPACT ASSESSMENT

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Executive Summary

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 dealt 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]

Eight EU Member States 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[3] to reprotoxic substances (Austria and Belgium) to the extension of one or 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 reprotoxic 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 (see Section A2 in Main Report 1).

The Burden of Ill-health Under the Baseline

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/1B[4]:

- under the bottom-up approach[5], 27 to 206 cases are expected to occur each year;
- under the top-down approach[6], 46 to 1,274 cases are estimated to occur each year; and
- when theoretical (unrealistic) worst-case assumptions are adopted for the bottom-up calculations, the figure rises to 1,429 cases per annum.

The economic cost of reproductive ill health is estimated to be between €0.5 and €2.8 million per year under the bottom-up approach and between €39 and €104 million per annum under the top-down analysis.[7] For the theoretical worst case under the bottom-up approach, the figure rises to €381 million per year.

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

4 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.

5 The bottom-up approach relies on extrapolations from a set of 30 shortlisted Reprotoxic 1A/1B substances.

6 The top-down approach draws on the use of population level incidence and prevalence data for health effects linked to exposures to reprotoxic substances.

7 This includes the direct, indirect, and intangible costs for workers & families, employers and the public sector.

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.

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[8]/ECEG[9]/ETUC[10]/IndustriAll[11] declaration[12] - 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.

[8] The European Chemical Industry Council
[9] The European Chemical Employers Group
[10] The European Trade Union Confederation
[11] IndustriAll European Trade Union
[12] 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 OSH guidance	No changes to EU OSH legislation but exposure may change due to other legislation and market developments. No additional guidance provided
O1: Baseline (no changes to EU OSH legislation, guidance)	No changes to EU OSH legislation but exposure may change due to other legislation and market developments. 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:
	- Substitution: stricter requirement than in the CAD:
	  ○ mandatory whenever workers 'are or are likely to be exposed'
	  ○ 'risk > slight risk' not a prerequisite
	- Closed system: second RMM in the hierarchy under the CMD vs. no explicit reference to closed systems in the CAD (except for intermediates);
	- Reduction of exposure to as low as technically feasible (minimisation requirement);
	- 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
	- 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: - A Binding OELV (risk or health based) would be established for Rs; - CMD requirements on prevention (substitution, closed system) would always apply to reprotoxic substances; - 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); - 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; - 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: - This would effectively be CAD and CMD in parallel but in one document; - Old terminology: language would not be updated or modernised; - 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: - CMD-equivalent requirements apply to CMR 1A/1B substances and CAD-equivalent requirements apply to other types of hazardous substances; - Common terminology for substances subject to CMD-equivalent and CAD-equivalent requirements; - Terminology brought into line with REACH; and - 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 of the CMD have the potential to increase compliance costs for companies in the Member States where these requirements are not currently 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 at between €400 million and €900 million, as indicated in Table 2.[13] 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. These costs 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.

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)
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

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. Although it is expected that

[13] 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.

additional BOELVs would also be adopted under the other options, earlier adoption of BOELVs under Option 3+ would result in greater overall compliance costs for companies; these would include the need to prove compliance through exposure measurements for companies in which exposure is already below the thresholds for effects.

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. There is, however, a large degree of uncertainty about the extent of this reduction, which has been estimated to be between 1 and 380 cases of reproductive ill health per year. These have a total monetary value between €20,000 and €31 million annually due to direct, indirect, and intangible costs for workers, their families, employers and the public sector.[14] A comparison of the policy options for each benefit impact category is provided in Table 3. These benefits are likely to occur under Options 2, 3+, 4 and 5, all of which involve the 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 to result in an earlier adoption of BOELVs for Reprotoxic 1A/1B substances that are not also C/M 1A/1B. Reductions in ill health under Option 3 would commence later as individual substances are identified one by one as having no threshold for reprotoxic effects and thereby being subject to the relevant requirements of the CMD.

[14] 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.

Table 3: Benefits of the different Policy Options *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 R1A/1B substances	Substitution and closed systems		0	0	++ 1-191 avoided repro cases p.a. €0.02-16m p.a.	++ Not possible to quantify but less than under O2, O3+, O4, and 05	++ 1-191 avoided repro cases p.a. €0.02-16m p.a.	++ 1-191 avoided repro cases p.a. €0.02-16m p.a.	++ 1-191 avoided repro cases p.a. €0.02-16m p.a.
	Exposure minimisation		0	0	++ 4-191 avoided repro cases p.a. €0.08-16m p.a.		++ 4-191 avoided repro cases p.a. €0.08-16m p.a.	++ 4-191 avoided repro cases p.a. €0.08-16m p.a.	++ 4-191 avoided repro cases p.a. €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 R1A/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 R1A/1B substances		***Workers & families, companies, authorities***	***0***	***+***	***+++ 1-382 avoided repro cases p.a.[1] €0.02-31m p.a.***	***++ Not quantified but less than under O2, O3+, O4, O5***	***+++ 1-382 avoided repro cases p.a.[1] €0.02-31m p.a.***	***+++ 1-382 avoided repro cases p.a.[1] €0.02-31m p.a.***	***+++ 1-382 avoided repro cases p.a.[1] €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									

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 costlier 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 substances 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 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 systems have the potential to result in significant overall costs.

The lead case study, on the other hand, is an example of a comparately smaller occupationally exposed population (although it should be recognised that data are not available for some sectors) which accounts for a large proportion of the annual number of cases of reproductive ill health predicted as arising from exposures to the 30 substances under the bottom-up approach.

Glossary of key acronyms

Acronym	Explanation
BLV	Biological limit value
BOELV	Binding Occupational Exposure Limit Value
CAD	Directive 98/24/EC - Chemical Agents Directive,
Cefic	The European Chemical Industry Council
C/M	Carcinogenic and Mutagenic
C/M 1A/1B	Carcinogenic 1A/1B and Mutagenic 1A/1B substances
CMD	Directive 2004/37/EC - Carcinogens and Mutagens Directive
CMR 1A/1B	Carcinogenic 1A/1B, Mutagenic 1A/1B and Reprotoxic 1A/1B substances
ECEG	The European Chemical Employers Group
ETUC	The European Trade Union Confederation
IndustriAll	IndustriAll European Trade Union
IOELV	Indicative Occupational Exposure Limit Value
OELV	Occupational Exposure Limit Value
OSH	Occupational Safety and Health
R 1A/1B	Reprotoxic 1A/1B substances
REACH	The REACH Regulation (EC) No 1907/2006

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[15] 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.[16]

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[17].

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);

[15] Directive (EU) 2017/2398, see https://eur-lex.europa.eu/eli/dir/2017/2398/oj
[16] See https://etendering.ted.europa.eu/document/document-file-download.html?docFileId=36431
[17] 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[18] 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)[19] 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.[20] 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

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

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

[20] 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[21], 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[22]:

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.

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

[22] 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[23]/ECEG[24]/ETUC[25]/IndustriAll[26] declaration[27] - 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. No additional guidance provided

[23] The European Chemical Industry Council
[24] The European Chemical Employers Group
[25] The European Trade Union Confederation
[26] IndustriAll European Trade Union
[27] 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. 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: - Substitution: stricter requirement than in the CAD: o mandatory whenever workers 'are or are likely to be exposed' o 'risk > slight risk' not a prerequisite - Closed system: second RMM in the hierarchy under the CMD vs. no explicit reference to closed systems in the CAD (except for intermediates); - Reduction of exposure to as low as technically feasible (minimisation requirement); - 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 - 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: - A Binding OELV (risk or health based) would be established for Rs; - CMD requirements on prevention (substitution, closed system) would always apply to reprotoxic substances; - 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); - 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; - 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: - This would effectively be CAD and CMD in parallel but in one document; - Old terminology: language would not be updated or modernised; - 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: - CMD-equivalent requirements apply to CMR 1A/1B substances and CAD-equivalent requirements apply to other types of hazardous substances; - Common terminology for substances subject to CMD-equivalent and CAD-equivalent requirements; - Terminology brought into line with REACH; and - 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 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.[28] 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)

[28] 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 *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.[29] 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

[29] 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 *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	++ 1-191 avoided repro cases p.a. €0.02-16m p.a.	++ Not possible to quantify but less than under O2, O3+, O4, and 05	++ 1-191 avoided repro cases p.a. €0.02-16m p.a.	++ 1-191 avoided repro cases p.a. €0.02-16m p.a.	++ 1-191 avoided repro cases p.a. €0.02-16m p.a.
	Exposure minimisation		0	0	++ 4-191 avoided repro cases p.a. €0.08-16m p.a.		++ 4-191 avoided repro cases p.a. €0.08-16m p.a.	++ 4-191 avoided repro cases p.a. €0.08-16m p.a.	++ 4-191 avoided repro cases p.a. €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***	***+***	***+++ 1-382 avoided repro cases p.a.[1] €0.02-31m p.a.***	***++ Not quantified but less than under O2, O3+, O4, O5***	***+++ 1-382 avoided repro cases p.a.[1] €0.02-31m p.a.***	***+++ 1-382 avoided repro cases p.a.[1] €0.02-31m p.a.***	***+++ 1-382 avoided repro cases p.a.[1] €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 costlier 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.

Glossary

Legal and Risk Management Terms	
AB	The Working Conditions Decree of 15 January 1997 regarding the safety, health and wellness in the workplace (Netherlands)
ACGIH	American Conference of Governmental Industrial Hygienists
ACSH	Advisory Committee on Safety and Health at Work
ADI	Acceptable Daily Intake
AF	Attributable Fractions
AFEMS	Association of European Manufacturers of Sporting Ammunition
AGS	Committee on Dangerous Substances (Germany)
ASchG	Act on the Protection of Safety and Health at Work (Austria)
ANSES	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (National Agency for Food Safety, Environment and Labor, France)
AR	The Working Conditions Regulation of 12 March 1997 (Netherlands)
ART	Assisted Reproductive Techniques
ASA	ASA register (of occupational exposure hazards and procedures in Finland)
AW	The Working Conditions Act (Netherlands)
BAT	Best Available Techniques
BAuA	Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (Federal Institute for Occupational Safety and Health, Germany)
BBP	Benzyl butyl phthalate
BCW	Well-Being at Work Code
BG RCI	The Berufsgenossenschaft Rohstoffe und chemische Industrie (Germany)
BMI	Body Mass Index
BLL	Blood Lead Levels
BLV	Biological limit value
BOELV	Binding Occupational Exposure Limit Values
BPA	Bisphenol A
BPR	Biocides Products Regulation
CAD	Chemicals Agent Directive
CAPEX	Capital expenditure
CEFIC	European Council of the Chemical Industry
CEPE	European Council of the Paint, Printing Ink and Artists' Colours Industry
CI	Confidence interval
CL	Liquid Chromatography
C&L	Classification and Labelling
CLI	Classified Labelling Inventory
CLH	Harmonised classification and labelling
CLP	Classification, labelling and packaging
Corr.	Corrosive
CM	Carcinogen and Mutagen
CMD	The Carcinogens and Mutagens Directive
CMR	Carcinogenic, Mutagenic, Reprotoxic substances
CNAMTS	National Fund for Health Insurance of Employees
CoRAP	Community Rolling Action Plan
COSHH	Control of Substances Hazardous to Health Regulations
CPG	Gas Phase Chromatography
CR	Polychlorprene rubber
CRL	Crown to Rump
CSA	Chemical Safety Assessment
CSR	Chemical safety report
DALY	Disability adjusted life years

DBP	Dibutyl phthalate
DEHP	Bis(2-ethylhexyl) phthalate
DIBP	Diisobutyl phthalate
DMAC	N,N-Dimethylacetamide
DMF	N,N-dimethylformamide
DNEL	Derived no effect limit
DMEL	Derived minimal effect level
DRR	Dose-Response Relationship
DW	Disability Weights
EBD	European Burden of Disease Study
ECEG	European Chemical Employers Group
ECETOT	European Centre for Ecotoxicology and Toxicology of Chemicals
ECHA	European Chemicals Agency
EDC	Endocrine-disrupting chemicals
EEA	European Economic Area
EFTA	European Free Trade Association
EMCEF	European Mine, Chemical and Energy Workers' Federation
EOGRTS	extended one generation reproductive toxicity study
EPA	Environmental Protection Agency
ES	Selective Electrode
eSDS	Extended Safety Data Sheet
ESPA	European Stabiliser Producers Association
ENZ	Enzymatic Method
EU	European Union
EUROBAT	Association of European Manufacturers of automotive, industrial and energy storage batteries
EUROCAT	European Surveillance of Congenital Anomalies
Eye Dam. 1	Eye Damage 1
F-AAS	Flame-Atomic Absorption Spectroscopy
FKM	fluorocarbon rubber
FLC	*French Labour Code*
FLUO	*Fluorescence Detector*
FID	*Flame Ionisation Detector*
GBD	Global Burden of Disease Study
GESTIS	Internationale Grenzwerte für chemische Substanzenm (International limits for chemical substances)
GHS	Globally Harmonized System
GM	Geometric mean
GPS	Global Product Strategy
GSD	Geometric standard deviation
HBM4EU	The European Human Biomonitoring Initiative
HEPA	High Efficiency Particulate Air
HPLC	High Performance Liquid Chromatography
HSE	Health & Safety Executive, United Kingdom
IA	Impact assessment
IARC	International Agency for Research on Cancer
ICCA	International Council of Chemical Associations
ICOH	The International Commission on Occupational Health
ICP	Inductively Coupled Plasma Mass Spectroscopy
IFA	Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung (Institute for Occupational Safety of the German Social Accident Insurance)
IFRA	International Fragrance Association
ILA	International Lead Association
ILO	International Labor Organisation
IMMUNO	Immunology Method

INERIS	The French national competence centre for industrial safety and environmental protection
INRS	National Institute for Research and Security
IOELV	Indicative Occupational Exposure Limit Values
IOM	Institute of Occupational Medicine
Irrit.	Irritant
ISO	The International Organization for Standardization
LEV	Local exhaust ventilation
LOAEL	lowest-Observed-Adverse-Effect Level
LOD	Level of detection
LOQ	Limit of quantification
MEGA	IFA's workplace exposure database
mg/m^3	Milligram per cubic meter
MS	Member States
NACE	"**n**omenclature statistique des activités **é**conomiques dans la **C**ommunauté **e**uropéenne" or the Statistical Classification of Economic Activities in the European Community
NBR	nitrile rubber
NIOSH	National Institute for Occupational Safety and Health
NMP	N-Methyl-2-pyrrolidone
NOAEC	*No Observed Adverse Effect Concentration*
NOAEL	*No-Observed Adverse Effect Level*
NONS	Notification of New Susbtances
NR	Natural rubber
NT	Non-threshold
OEL	Occupational exposure limit
OELV	Occupational exposure limit value
OR	Odds ratio
OPEX	*Operating expenditure*
OSH	Occupational health and safety
OSPA	Oxygenated Solvent Producers Association
PAF	Population attributable fraction
PACT	(ECHA) Public Activities Coordination Tool
PBT	Persistent, bio-accumulative and toxic
PEL	Permissible exposure limit
PIC	Prior Informed Consent
PNEC	Predicted no effect concentration
POP	Persistent Organic Pollutants
PPE	Personal protective equipment
ppm	*parts per million*
PPPE	Plant Protection Products Regulation
PROC	The process categories
PVC	Polyvinyl chloride
PWD	Pregnant Workers Directive
QC	Quality Contrl
R&D	Research and Development
RAC	(ECHA) Committee for Risk Assessment
RAR	Risk assessment report
REACH	Registration, Evaluation, Authorisation and restriction of Chemicals
RMM	Risk management measure
RMOA	Risk management options analysis
SAICM	The Strategic Approach to International Chemicals Management
SBS	Structural Business Statistics
SCOEL	Scientific Committee on Occupational Exposure Limits
SEA	Socio-economic analysis
SEAC	ECHA's Socio-Economic Analysis Committee

Sens.	Sensitiser
SDS	Safety Data Sheets
SHL	The Safety and Health at Work Laws of 1996 to 2011
Skin Corr. 1C	Skin Corrosive 1C
SME	Small and medium-sized enterprise
SMR	Standardised mortality ratio
STOT	Specific Target Organ Toxicity
SU	Sector of Use
STEL	Short term exposure limit
SUMER	Surveillance médicale des expositions aux risques professionnels (Medical Monitoring Survey of Professional Risks)
SVHC	Substance of very high concern
T	*Threshold*
TCE	trichloroethylene
TFEU	*Treaty on the Functioning of the EU*
TLV	*Threshold limit value*
TOX	Toxicity
tpa	*Tonne per annum*
TTC	Threshold for Coxicological Concern
TWA	Time weighted average
TWG	Technical Working Group
UNIDO	United Nations Industrial Development Organization
UIC	Union of Chemical Industrys
VOLY	Value of Statical Life Year
vPvBs	Very Persistent and very Bioaccumulative
VSL	Value of Statistical Life
WHO	World Health Organization
WTP	Willingness to pay
YLD	Years Lost due to Disability
YLL	Years of Life Lost
YPWD	Young Persons at Work Directive

1 Introduction

1.1 Background

As noted in the Communication on the EU Strategic Framework on Health and Safety at Work (2014-2020)[30], ensuring a safe and healthy work environment for over 217 million workers in the EU is a strategic goal for the European Commission. One of the main challenges highlighted in the Strategic Framework is the need to improve the prevention of work-related diseases by tackling existing, new and emerging risks. Occupational cancer and dealing with dangerous chemicals (including those with reprotoxic effects) in workplaces are considered to be particular priorities for occupational safety and health (OSH) policy, requiring continued effort to reduce occupational exposure to hazardous chemicals in general, and to carcinogenic, mutagenic and reprotoxic chemicals (CMR) in particular.

A range of legislative instruments are currently in place at EU level which regulate the use of CMR substances, with the objective of minimising exposures and reducing risks in the workplace. These include Directive 98/24/EC (Chemical Agents Directive, CAD) and Directive 2004/37/EC (Carcinogens and Mutagens Directive, CMD).

All reprotoxic substances are currently within the scope of the CAD and those reprotoxic substances that are also Carcinogens or Mutagens (C/M) 1A/1B are also within the scope of the CMD. However, a significant number of substances with a harmonised classification of Reprotoxic 1A or 1B are not also classified as C/M 1A/1B. As such, they are subject to less stringent regulatory requirements than those regulated under the CMD.

In Directive (EU) 2019/130[31], the European Parliament and the Council have called on the European Commission to assess the option of amending the scope of the CMD to include reprotoxic substances.

1.2 Aims of the study

The main study objective is to generate 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 or, based on a possible merger of the CMD and CAD, the necessary additional requirements that would be necessary to address risks from reprotoxic chemicals. This includes a number of specific tasks which are detailed in the Terms of Reference for the study[32].

1.3 Structure of this report

This report presents the outputs from the tasks that assess the impacts of the policy scenarios for the amendment of the CMD or a possible merger of the CAD and CMD. This report (Report 2) complements Report 1 which provides an analysis of the baseline scenario.

The report is organised as follows:

Part C: Impact Assessment of the Policy Options

- Section C1 summarises the baseline (problem definition);

[30] See http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52014DC0332&from=EN
[31] See https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32019L0130
[32] See https://etendering.ted.europa.eu/document/document-file-download.html?docFileId=36431

- Section C2 assesses the costs of the Policy Options;
- Section C3 considers the benefits of the Policy Options; and
- Section C4 deals with market effects.

Part D: Comparative Assessment of the Policy Options

- Section D1 summarises the costs, benefits and market effects for each Option;
- Section D2 provides a summary of the illustrative case studies; and
- Section D3 provides additional information for increased use of BLVs (potential consequence of one of the add-on elements under Option 5).

The report is complemented with the following annexes:

- Annex 1 provides additional information on the methodology for the qualitative assessment of the costs and benefits of the Policy Options;
- Annex 2 summarises Stage 2 of the consultation exercise;
- Annex 3 provides more information on the environmental impacts of reprotoxic substances;
- Annex 4 provides the lead case study;
- Annex 5 provides the borates case study;
- Annex 6 provides the retinol case study; and
- Annex 7 provides more information on BLVs.

Part C: Impact Asessment of the Policy Options

C1 Problem Definition and Summary of the Policy Options

C1.1 Number of exposed workers

Literature review and consultation for this study suggests that all workers potentially exposed to any reprotoxic substance (self-classified and R 1A/1B/2) for any period of time and at any exposure level make up 1%–2% of the workforce.

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).

Table C1-1: Scaling up from France (2010) to EU (2016)

Scenario		France (2010)		EU (2016)		
		Table 2-1	Doubled	Incidence	Rounded	% Workforce
Scenario 1 (strong/very strong exposure AND >10 hrs exposure)						
Males	Best (Low)	1,111	2,222	24,883	25,000	
	Worst (High)	6,822	13,644	152,729	153,000	
				Geometric Mean	**61,000**	**0.043%**
Females	Best (Low)	76	151	2,031	2,000	
	Worst (High)	1,127	2,254	30,222	30,000	
				Geometric Mean	**8,000**	**0.007%**
Scenario 2 (strong/very strong exposure AND >10 hrs exposure AND no collective measures)						
Males	Best (Low)	273	547	6,122	6,000	
	Worst (High)	3,486	7,004	78,399	78,000	
				Geometric Mean	**22,000**	**0.015%**
Females	Best (Low)	25	51	680	1,000	
	Worst (High)	657	1,315	17,624	18,000	
				Geometric Mean	**3,000**	**0.003%**

C1.2 Incidence/prevalence of ill health

C1.2.1 Bottom-up approach

The total extrapolated number of cases of ill-health is extrapolated below on the basis of the risk characterisation approach, the details of which are given in Report 1.

The table below summarises the estimated annual number of cases for the 30 substances analysed in the bottom-up assessment and extrapolated using the different approaches.

Table C1-2: Total number of cases per annum estimated under the bottom-up approach	
Substances	**Cases per annum* (extrapolated using risk characterisation)**
30 substances	24-180 (1,429)
All 'R 1A/1B but not C/M 1A/1B'	27-206 (1,633)
R2	215-1,623 (12,859)
Note: *Range: Scenarios 1A/1B-Scenario 2, value in brackets is for the theoretical worst-case scenario	

C1.2.2 Top-down approach

In Report 1, it was estimated that there may be between 7 and 219 cases of health effects based on the prevalence data given. Care is required in interpreting this estimate of developmental effects attributable to occupational exposures, as it does not take into account the fact that there is clearly some overlap in the various health effects for which data are presented individually within the Eurocat database.

Given that the analysis of the Sumer data indicates that only between 1,000 and 30,000 women may be exposed at levels and for durations sufficient to give rise to developmental effects, these estimates appear reasonable, given that they also include adjustments for other known risk factors.

However, it has not been possible to include in these estimates any impacts on IQ from occupational exposures. These are substance specific and we cannot establish a more general means of deriving estimates; note that any such estimates may also be confounded by other risk factors such as iodine deficiency, which has been found to have a high prevalence in the EU (i.e. 57% of the population) and to give rise to IQ effects.

C1.2.3 Key findings and limitations

The economic costs of the bottom-up calculations for the health burden from workplace exposures to Reprotoxin 1A and 1B substances are estimated at between (rounded):

- €460,113 for the 30 substances and €525,843 after extrapolation under Scenario 1a; and
- €38,382,746 for the 30 substances and €43,865,995 after extrapolation under Scenario 3.

The estimates under 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 and €24 million per annum for the geometric mean for developmental effects and between €30 and €76 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 €291 million for fertility and maternal effects.

C1.2.4 Results for the bottom up approach

The valuation methodology set out in Annex 1 to this report was applied in order to place a monetary value on the calculated baseline health burden for workers exposed to reprotoxins. Two different approaches to the valuation were applied:

- Valuation based on DALYs avoided; and
- Valuation based on the direct and indirect costs of illness.

Valuation based on DALYs avoided

Report 1 provides the estimated monetary value per case of health effects based on a DALY being valued at €100,000. These figures are given in present value terms, as they take into account the age at which life years would be lost for those specific effects where this is expected. Only those health effects relevant to this analysis are presented.

Valuation based on cost-of-illness

Cost of illness data were sourced through literature searches of Medline and Google and through health care service provider registries. European data was favoured and corroborated by other supporting data, where possible. These are, however, rough estimates of costs, as costs between member states can vary widely. The results are presented in Table C1-3.

Overall cost of ill health due to exposure

Based on the costs presented in Table C1-4 and the number of cases of ill health derived for each substance analysed in this report, an estimate for the total cost (direct, indirect and intangible) can be calculated. This is given inTable C1-5 below.

Table C1-3: Present value of expected (severity weighted) number of DALYs per case (discounted @4%, years 1 to 80)									
Health effect	**Individual impacted and link to exposures**		**Severity frequency**	**DALYs**			**Present value of DALYs lost (Euro, 2016)**		
	Worker or offspring	**Effect passed by Male/ Female**	**% by severity (mild, mod, severe)**	**Disability weights (DW)**	**Years lived with disability (L)**	**Years life lost (YLL)**	**Total discounted DALYs per severity case**	**Weighted, discounted DALYs per case**	**Present value Expected/average DALYs per case**
Impaired or reduced fertility female	Worker	F	100%	0.008	1	0	0.008	0.008	800
Impaired fertility - male	Worker	M	100%	0.008	1	0	0.008	0.008	800
Spontaneous abortion	Worker	F	100%	0.114	1	0	0.114	0.114	11,400
Still birth	Worker	F	100%	0.114	5	0	0.528	0.528	52,800
Low birth weight: normal–low	Offspring	F	100%	0.011	80	0	0.257	0.257	25,734
Low birth weight: low–very low			100%	0.185	70	10	4.849	4.849	484,886
Low birth weight: very low–extremely low			100%	0.421	40	40	12.455	12.455	1,245,538
Impaired cognitive development – per IQ point	Offspring	F	-	-	-	-	-	-	9,600
Skeletal effects or abnormalities of the limbs	Offspring	F	40%	0.028	80	0	0.670	6.425	642,477
			40%	0.317	80	0	7.581		
			20%	0.581	40	40	15.622		
Pre-eclampsia	Worker	F	100%	0.324	1	0	0.324	0.324	465,199
	Offspring	F	100%	0.185	70	10	4.328	4.328	
https://ecdc.europa.eu/sites/portal/files/documents/Haagsma-PopHealthMetrics-2014-Disability-weights.pdf *https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(15)00069-8/fulltext*									

Table C1-4: Indirect and direct cost-of-illness data for all relevant endpoints					
Description	**Direct/ Indirect cost**	**Cost per case (€)**	**Proportion by severity**	**Weighted cost per case (€)**	**TOTAL cost per case (€)**
Infertility – male or female					
Cost, per treated couple, of medically assisted reproductive treatment (irrespective of whether terminated by live birth)[a]	Direct	6,607	1	6,607	7,005
Productivity losses (15.6 days over 18 months) adjusted to 1 year – 2 people[b]	Indirect	398	1	398	
Spontaneous abortion					
Medical cost of spontaneous abortion without intervention[c]	Direct	693	0.971	673	734
Medical cost of spontaneous abortion with intervention[c]	Direct	2,105	0.029	62	
Still birth					
Medical costs of still birth, including investigations into cause of death[d]	Direct	2,223	1	2,223	6,691
Additional direct cost of care in subsequent pregnancies after still birth – high estimate[d]	Direct	1,978	1	1,978	
Productivity losses – year 1 – 50% normal work[d]	Indirect	2,490	1	2,490	
Low birth weight					
Paediatric Faltering Growth (Failure to Thrive) with CC Score 0[c]	Direct	1,112	1	1,112	1,112
Paediatric Faltering Growth (Failure to Thrive) with CC Score 1[c]	Direct	1,438	1	1,438	1,438
Cost of VLBW babies for first 18 months of life (Societal - direct (above))[e]	Direct & Indirect	30,230	1	30,230	30,230
Skeletal effects/abnormalities of limbs					
Total life-time costs for patients with spina bifida (inc. indirect costs and increased morbidity[f]	Direct & indirect	528,425	1	528,425	528,425
Pre-eclampsia					
Mean cost per woman of pre-eclampsia with expectant management (Euros, 2007). This includes direct medical costs, indirect costs to patients (travel and informal care), and productivity loss[g]	Direct & indirect	7,908	1	7,908	7,908
Impaired cognitive development					
Impaired cognitive development – per IQ point	Direct & indirect	9,600	1	9,600	9,600

[a]Christiansen *et al.* (2014) *Acta Obs Gyn Scand* 93;64–72; [b]Wu A *et al.* (2013) *Fertility and Sterility* 99;2025–30; [c]*NHS Reference costs (2017)* https://improvement.nhs.uk/resources/reference-costs/; [d]Heazzell *et al.* (2016) *Lancet* 387;604–16; [e]Cavallo M *et al.* (2015) *Italian J Paediatrics* 41;59; [f]Yi Y *et al.* (2011) *Eur J Paediatr;* 170;1391–400; [g]VIjgen SMC *et al.* (2010) *BJOG* 117;1577–85.

Table C1-5: Bottom-up estimates of the economic value of the burden of ill health (€)				
	SC1a	Sc1b	Sc2	Sc3
Total cost fertility related cases	378,178	1,326,073	1,737,469	2,559,144
Total cost developmental cases	20,266	15,200	286,711	10,753,781
Total cost cognitive development	31,680	72,000	76,800	19,526,400
Total – Bottom-up	**460,113**	**1,435,764**	**2,487,868**	**38,382,746**
Total after extrapolation	**525,843**	**1,640,873**	**2,843,277**	**43,865,995**

C1.2.5 Results for the top down approach

It was not possible for the study team to make linkages between the different types of congenital anomalies covered by the Eurocat database and DALYs (or indeed cost of illness estimates). As a result, we have used willingness to pay values developed for ECHA specific to chemical exposures and the types of effects associated with exposures to Reprotoxic 1A/1B substances.

The willingness to pay values used for these purposes as well as the resulting estimates are given in Report 1, Tables B4-4 and B4-5 for fertility and developmental effects respectively, and for both top down scenarios and the geometric mean of the two scenarios.

Most of the valuations included in the above table are based on stated preferences surveys undertaken for ECHA with the explicit aim of deriving economic valuations for use in the context of REACH Restrictions and Authorisation. The original study reports can be found on ECHA's website[33]. Because of concerns over how to interpret some of the study results, a critical review carried out by Dubourg for ECHA (2016)[34]. This review recommended the use of €21,600 for the value of a statistical pregnancy, €4,300 for a minor birth defect, €128,200 for a major internal birth defect, €25,700 for a major external birth defect, and €126,200 for very low birth weight. These lower estimates are recommended due to concerns over the validity of the upper bound values which reflect public good values and are considered to be impacted by the nature of the valuation scenario and other aspects of questionnaire design. In line with these recommendations, we have adopted the lower bound estimates for the purposes of this study, and adjusted them for 2018 prices.

C1.3 Examples of strategic and voluntary approaches

C1.3.1 Introduction

This section provides a summary of strategic approaches to controlling occupational risks from reproductive substances, voluntary industry initiatives adapted to reduce occupational exposure to reproductive substances and Social Partner Agreements. Further information on strategic approaches is presented in Annex 7 of Report 1.

[33] ECHA (n.d.): Willingness to pay to avoid certain health impacts. *ECHA.* Available at: https://echa.europa.eu/support/socio-economic-analysis-in-reach/willingness-to-pay-to-avoid-certain-health-impacts.

[34] ECHA (2016): Valuing selected health impacts of chemicals: Summary of the Results and a Critical Review of the ECHA study, February.

C1.3.2 Strategic approaches

International initiatives

The Strategic Approach to International Chemicals Management (SAICM)

The Strategic Approach to International Chemicals Management (SAICM) was created in 2006 to provide a common policy framework to promote chemical safety around the world. SAICM's overall objective is the achievement of the sound management of chemicals throughout their life cycle so that by the year 2020, chemicals are produced and used in ways that minimise significant adverse impacts on the environment and human health.[35] As part of this initiative, one of the global priorities is safeguarding the health of women and children by minimising chemical exposures before conception and through gestation.

Global Product Strategy (GPS)

The Global Product Strategy (GPS) is a global initiative set up by the International Council of Chemical Associations (ICCA) to support and enhance the chemical industry. This includes communicating handling and product risks. [36]

UNIDO Green Industry initiative for sustainable industrial development

The United Nations Industrial Development Organisation (UNIDO) has developed a Green Industry Initiative which places sustainable industrial development in the context of global sustainable development challenges. This was launched in 2009 and is aimed to contribute towards a green economy. One aspect of the initiative is ensuring the sound use of chemicals by assisting enterprises in reducing the risks and impacts from chemical use which includes controlling and managing hazardous chemicals. This includes increasing safety and protecting workers and includes substitution of hazardous chemicals. [37]

EU initiatives

Social dialogue

At the EU Level, chemical industry social partners have come together to commit to social dialogue in the chemicals sector. An example includes a framework of action signed by the European Chemical Employers Group (ECEG) and industriAll Europe on sustainable employment and career development. This framework also includes a set of guidelines enabling national member organisations to deal effectively with challenges, which includes promoting safe workplaces. [38]

[35] SAICM (2018): SAICM Overview. Strategic Approach to International Chemicals Management (SAICM). Available at: http://www.saicm.org/About/SAICMOverview/tabid/5522/language/en-GB/Default.aspx

[36] EuroChem (2018): Global Product Strategy (GPS). Available at: http://www.eurochemgroup.com/en/global-product-strategy-gps/

[37] UNIDO (2011): UNIDO Green Industry Initiative for Sustainable Industrial Development. United Nations Industrial Development Organization. Available at: http://www.greenindustryplatform.org/wp-content/uploads/2013/05/Green-Industry-Initiative-for-Sustainable-Industrial-Development.pdf

[38] Ibid

EU-OSHA Healthy Workplace Award

EU-OSHA along with Member States has launched a Healthy Workplaces Campaign 2018-2019. This campaign is in relation to the management of dangerous substances and raising awareness of occupational exposure to hazardous chemicals. This campaign also provides practical tools for minimising and preventing exposure. [39]

Surveillance and biomonitoring

The European Surveillance of Congenital Anomalies (EUROCAT) is a network of population-based registries for the epidemiologic surveillance of congenital anomalies. The network consists of 43 registries across 23 countries and covers 29% of the European birth population (with more than 1.7 million births surveyed per year in Europe). [40] This information could be used with occupational exposure data to identify potential links between occupational exposure and congenital exposure.

HBM4EU is a joint initiative (running for five years from 2017 to 2021) involving the EU-28 countries, the European Environment Agency and the European Commission and is co-funded under Horizon 2020. The aim of the initiative is to coordinate and advance human biomonitoring across Europe.[41] This biomonitoring data will be used for assessing exposure and their associated health impacts. Reprotoxic substances are included in both the first and second list of priority substances for assessment by HBM4EU.

National level initiatives

At national level, there are different initiatives and strategic approaches implemented by member states. This includes in France, Italy, Denmark, Germany and the United Kingdom. These initiatives are further discussed in Annex 7 in Report 1.

C1.3.3 Voluntary industry initiatives

Sectoral initiatives

Coatings Care

The Coatings Care initiative is a voluntary initiative that has been set up to improve the performance of the coatings industry for the following aspects: health, safety, environment, distribution and product stewardship. The main benefits of the initiative are helping companies making the efficient uses of resources to comply with health, safety and environmental regulations, pursuing a common management approach for health, safety and environmental programmes, increasing learning and identifying/evaluating areas for improvement.[42] Members of European Council of the Paint, Printing Ink and Artists' Colours Industry (CEPE) are also committed to the removal or substitution of hazardous substances which have an unacceptable environmental or human health impact.

[39] EU-OSHA (2018): Healthy Workplaces Campaign 2018-2019 Manage Dangerous Substances. The European Agency for Safety and Health at Work. Available at: https://healthy-workplaces.eu/

[40] EUROCAT (n.d.): What is EUROCAT? Available at: http://www.eurocat-network.eu/aboutus/whatiseurocat/whatiseurocat

[41] HBM4EU (n.d.): About HBM4EU. Available at: https://www.hbm4eu.eu/about-hbm4eu/

[42] CPCA (n.d.): The Benefits of Coatings Care. Canadian Paint and Coatings Association. Available at: http://www.canpaint.com/the-benefits-of-coatings-care/

Hairdressing Sector

In April 2012, UNI Europa and the employers' organisation Coiffure EU signed a framework agreement on a series of aims designed to improve occupational health and safety protection in the sector.[43] The agreement aims at building an integrated approach for the prevention and reduction of occupational safety and health risks for workers in the hairdressing sector, especially skin problems and musculoskeletal disorders, through the application of the principles of risk assessment, risk management and prevention. The agreement also contains several measures to reduce exposure to chemical agents including ventilation and personal protection equipment.

Member State industrial initiatives

In France, the Union of Chemical Industries (UIC) signed an agreement for the prevention of risks associated with CMR substances with the Ministry of Labour, INRS (National Institute for Research and Security) and CNAMTS (National Fund for Health Insurance of Employees) to testify to the commitment of the chemical industry to act to improve CMR risk prevention, both at its own sites and at its customers.[44]

In Germany, the Berufsgenossenschaft Rohstoffe und chemische Industrie (BG RCI) which is part of the part of the German social security has produced a leaflet "Reprotoxic substances" which provides information about regulations and directives and provides a list of reprotoxic substances. This is aimed at workers and employers.

In Italy, the Tuscany North Confindustria (a group of 30 Italian companies) joined the Greenpeace Detox commitments in 2016. The Detox Project promotes eco-sustainability, including the reduction of the use of carcinogenic and reprotoxic chemicals.

Substance Specific initiatives

Voluntary initiatives in relation to lead

The International Lead Association (ILA) has established a voluntary employee blood lead reduction programme, known as the Lead Action 21 programme. The Lead Action 21 Plan specifies as part of its charter that operations are managed responsibly and safely to continually reduce the impact to human health and the adoption of best practice is encouraged.[45] Sectoral targets are established with the latest being zero employees exceeding a blood lead content of 20µg/dL. The ILA voluntary programme also highlights the reproductive toxicity concerns with exposure of women to lead and recommends that blood lead levels of females of reproductive capacity) be maintained below 10µg/dL. As part of the initiative, there are also ten golden rules for good practice which includes clothing, handling and ventilation (further discussed in Annex 7 of Report 1).

[43] ETUI (2016): Union campaign criticises Commission apathy towards hairdressers' health. European Trade Union Institute. Available at: https://www.etui.org/Topics/Health-Safety-working-conditions/News-list/Union-campaign-criticises-Commission-apathy-towards-hairdressers-health

[44] Union des Industries Chimiques.

[45] International Lead Association (2018): LA21 Charter. Available at: https://www.ila-lead.org/responsibility/la21-charter

ELSIA (the European Lead Sheet Association) also has in place a Product Stewardship Program for reducing occupational exposure to lead.[46] This includes a code of practice for Product Stewardship and also the same ten golden rules as the ILA.

Other industry initiatives

Other industry initiatives include Product Stewardship, Responsible Care, and the ChemSec Business Group. These initiatives are not specifically aimed at reprotoxic substances; however, they could have an impact on reducing exposure. These are further discussed in Annex 7 of Report 1.

C1.3.4 Conclusion

The International Lead Association initiative is the only specific initiative that has been identified which only concerns occupational exposure to reprotoxic substances. This initiative includes blood monitoring, rules for reducing exposure and also best/good practice. There are other sectoral initiatives (such as coatings and hairdressers) that may have an impact of reducing occupational exposure to reprotoxic substances by risk management or reducing/substituting hazardous chemicals.

A number of strategic approaches have also been identified which even though they do not deal specifically with reprotoxic substances, may have an impact in reducing the occupational exposure to reprotoxic substances. These strategic approaches include communicating the risks of hazardous chemicals and minimising exposure to hazardous chemicals.

[46] European Lead Sheet Association (undated): Product Stewardship. Available at: https://elsia.org.uk/product-stewardship/

C1.4 Overview of the Policy Options

The Policy Options that are assessed in this report are summarised below.

Table C1-6: Policy Options	
Option	**Details**
O1-: Baseline without OSH guidance	No changes to EU OSH legislation but exposure may change due to a) other legislation (e.g. REACH, national legislation) and b) market developments. No additional guidance provided
O1: Baseline (no changes to EU OSH legislation)	No changes to EU OSH legislation but exposure may change due to a) other legislation (e.g. REACH, national legislation) and b) market developments. Provision of additional guidance on best available techniques and interpretation of the CMD/CAD

O2: R 1A/1B in CMD (no derogations)	Inclusion of R1A and 1B chemicals into the scope of the CMD with full application of the requirements in the CMD, including:
	- Substitution: stricter requirement than in the CAD:
	  o mandatory whenever workers 'are or are likely to be exposed'
	  o 'risk > slight risk' not a prerequisite
	- Closed system: second RMM in the hierarchy under the CMD vs. no explicit reference to closed systems in the CAD (except for intermediates);
	- Reduction of exposure to as low as technically feasible (minimisation requirement);
	- IOELVs for R 1A/1B substances would become BOELVs: it is assumed that IOELVs under the CAD for R 1A/1B substances would become BOELVs under the CMD; and
	- 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 that the substance in question has no threshold for reprotoxic effects. It is assumed that CAD IOELVs for R 1A/1B substances would become BOELVs under the CMD.
Cefic/ECEG/ETUC/Industrial Declaration: R 1A/1B in CMD with derogations	Inclusion of R 1A/1B into the scope of the CMD with the following requirements: - A Binding OEL (risk or health based) would be established for Rs; - CMD requirements on prevention (substitution, closed system) would always apply to Rs; - If prevention not possible then exposure must be reduced to a) a 'safe level' (see below) or b) as low as possible (minimisation requirement); - Safe level: a) the substance has a threshold, b) there is a health-based Binding OELV (for a start CAD IEOLVs->CMD BOELVs), c) it is proven by exposure measurements that the BOELV is complied with; - 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:

Table C1-6: Policy Options	
Option	**Details**
	- This would effectively be CAD and CMD in parallel but in one document; - Old terminology: language would not be updated or modernised; - 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 into a single directive, applying CMD-equivalent requirements to R 1A/1B substances and updating/modernising OSH-related terminology and requirements: - CMD-equivalent requirements would apply to CMR 1A/1B substances and CAD-equivalent requirements would apply to other types of hazardous substances; - Skin and respiratory sensitisers would also be subject to CMD-equivalent requirements; - Common terminology for substances subject to CMD-equivalent and CAD-equivalent requirements; - Terminology to be brought into line with REACH; and - Use of BLVs as part of health surveillance would not be mandatory.

For the purposes of the Impact Assessment, the Policy Options have been broken down into a number of components (specific measures). These are summarised below.

Table C1-7: Policy Options and their relevant components

Component		O1-: Baseline (no guidance)	O1: Baseline (including OSH guidance)	O2: R 1A/1B in CMD	O3: R 1A/1B in CMD (derogations)	O3+: Joint declaration	O4: R 1A/1B in CMD, merge CAD and CMD	O5: R 1A/1B in CMD, merge CAD and CMD, modernisation
Additional OSH guidance			✓	✓	✓	✓	✓	✓
Extension of CMD to R 1A/1B	Substitution, closed systems			✓	D	✓	✓	✓
	Exposure minimisation			✓	D	D	✓	✓
	IOELVs become BOELVs			✓*	✓*	✓**	✓*	✓*
	Record keeping			✓	D		✓	✓
Merging of the two directives							✓	✓
Threshold/non-threshold approach		C	C	C	I	I	C	C
Modernisation								✓
Add-on elements (BLVs, sensitisers)								✓

Notes:
Dark grey cells denote definite change when compared with the baseline. Light grey cells denote potential changes to the baseline, depending on whether individual substances are derogated or not (i.e. determined to have a threshold for adverse effects).
D: Depends on whether the substance is derogated or not
C: Collective (risk classification based) I: Individual (individual substance based)
**not a direct legal consequence of the extension of the CMD to R 1A/1B substances but modelled for the purposes of this Impact Assessment*
***under Option 3+, BOELVs would be established for all (or most) R 1A/1B substances*

C2 Costs of the Policy Options

Key findings

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 €410 million and €910 million – these are the costs of considering and documenting the feasibility of substitution and closed systems, as well as implementing closed systems and further exposure minimisation. Due to the large number of uncertainties involved in the estimation of these figures, the range should be seen as illustrative of the order of magnitude of the potential costs rather than a 'definite' estimate.

In addition, this range represents only a partial quantification -some relevant compliance costs could not be monetised. The costs of substitution and/or compliance/demonstrating compliance with additional 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 in 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 may take economic feasibility into account when enforcing this provision and that a general substitution requirement for substances where there is a risk already exists.

The costs set our above are likely to arise under Options 2, 3+, 4 and 5 which all involve an extension of the CMD to cover Reprotoxic 1A/1B substances. The costs under Option 3 are likely to be significantly lower but, in the absence of scientific evaluations to determine which specific substances would be included into the scope of CMD requirement, their quantification is not possible. In addition, their introduction would be staggered as non-threshold substances are included into the scope of the relevant requirements one by one. On the other hand, 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 introduction of a large process of BOELVs for all Reprotoxic 1A/1B substances that are not also C/M 1A/1B and would thus involve costs even for companies that are already below the threshold for effects but would still need to carry out measurements and demonstrate compliance.

In addition, it is expected that the preparation of 50 OSH guidance documents would cost around €10 million (all Options except O1-) and Member State would incur transposition costs of around €3 million under all Policy Options with the exception of the two baseline scenarios (O1- and O1).

Approach

The quantitative assessment relies on modelling that draws on a logical framework informed by assumptions based on consultation responses for this study and literature review carried out for this study. Some of the compliance costs are assessed quantitatively, others qualitatively. A detailed overview of the methodology for the estimation of the costs is provided in Annex 1.

Limitations/uncertainties

The key limitation is that some of the relevant cost categories could not be monetised. The cost of substitution, in particular, is highly uncertain but could be significant.

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 which sees exposure as signifying 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. studies and it is believed to be a reasonable worst-case scenario covering a lot of uncertainty.

The impacts of the extension of the CMD to cover Reprotoxic 1A/1B substances 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 or not have a threshold for effects and what would be the value of a health-based BOELV. As a result, estimation of the expected costs is difficult. Therefore, the analysis in this section should be taken as merely illustrative of the order of magnitude of the potential costs. Some of this uncertainty is captured in the ranges presented but much of it could not be included into the ranges.

Last but not least, it should be noted that much of analysis in this section reflects the responses to the consultation exercise carried out for this study. The numbers of responses to the specific questions represent only a small proportion of the companies that would be affected.

C2.1 Summary of the cost assessment framework

This section sets out the analytical framework that underpins the assessment of the costs that are expected to arise under the different Policy Options. This includes the determination of the most relevant cost categories and the associated questions that deal with specific cost aspects.

C2.1.1 Determination of the most significant cost categories

The most relevant cost categories were identified using the following process:

1) compiling a broad overview of all potentially relevant cost categories;
2) identifying the types of stakeholders that are likely to be affected; and
3) selecting the most significant cost categories using the following criteria:
    - the relevance of the impact category within the intervention logic;
    - the absolute magnitude of the expected impact;
    - the relative size of expected impact for specific stakeholders; and
    - the importance of the impacts for the Commission's horizontal objectives and policies.

The table below lists the full range of possible impacts listed in BR Tool #19. The impact categories under which costs are expected to arise are highlighted in green. Impact categories in bold items are considered in this section. Impact categories under which costs may arise but which are considered in the 'market impacts section' are italicised.

Table C2-1: Overview of impact categories		
Economic	**Social**	**Environmental**
Operating costs and conduct of business	**Employment**	The climate
Trade and investment flows *Sectoral competitiveness*	**Working conditions**	Fostering the efficient use of resources (renewable & non-renewable)
SMEs	Income distribution and social inclusion	Preserving the quality of natural resources / fighting pollution
Regulatory burden on businesses	Health & safety	Protecting biodiversity, flora, fauna and landscapes
Innovation and research	Job standards and quality	Reducing and managing waste
Technological development / Digital economy	Education	Minimizing environmental risks
Third countries and international relations	Crime and Security	Protecting animal welfare
Functioning of the Single Market and competition	Preserving the cultural heritage / multilingualism	International environmental impacts
Energy independence	Governance & good administration	
Deeper and fairer economic and monetary union		
Consumers and households		
Property rights		
Public authorities (and budgets)		
Economic and social cohesion		
Impacts in developing countries		
Sustainable development		
Fundamental Rights • General impacts • Dignity • Individuals, private and family life • Personal data • Asylum and protection of removal, expulsion or extradition • Property rights and the right to conduct a business • Gender equality, equality treatment and opportunities • Rights of the child • Good administration / Effective remedy/ Justice		
Source: Better Regulation Tool #19 *Notes: Green items are included in the costs. Bold items are covered in this section. Italicised items are covered under market effects.*		

C2.1.2 BR Guidelines - questions for the most significant impacts

The most significant impact categories, together with the key questions, are summarised below.

Table C2-2: Relevant questions for the most significant cost categories	
Impact category	**Key impacts**
One-off and running costs and conduct of business	Will it impose additional compliance costs on businesses? How does the Option affect the cost or availability of essential inputs? Will it entail the withdrawal of certain products from the market? Will it lead to new or the closing down of businesses? Are some products or businesses treated differently from others in a comparable situation? How are individual Member States affected?
Administrative burden on businesses	Does it affect the nature of information obligations placed on businesses (for example, the type of data required, reporting frequency, the complexity of submission process)?
Trade and investment flows	How will the Option affect exports and imports out of and into the EU? Will imported products be treated differently to domestic goods? How will investment flows be affected? Will the Option affect regulatory convergence with third countries?
Innovation and research	Does the Option stimulate or hinder research and development? Does it facilitate the introduction and dissemination of new production methods, technologies and products? Does it promote greater productivity/resource efficiency?
Employment	To what extent are new jobs created or lost? Are direct jobs created or lost in specific sectors, professions, regions or countries? Which specific social and or age groups are affected?
Working conditions	Does the Option affect wages, labour costs or wage setting mechanisms? Does the Option affect employment protection (the quality of work contracts, risk of false self-employment)? Does the Option affect work organisation? Does the Option affect occupational health and safety? Does the Option affect participation, information and consultation schemes for employees?
Source: BR Tool #19	

C2.1.3 Grouping of impacts

Taking the above into account, the relevant cost categories have been grouped as follows:

- Conduct of business & costs for companies – this section considers:
  - Compliance costs for companies (one-off and recurring)
  - Administrative costs for companies
  - Innovation & research
  - Trade & investment flows
- Costs for public authorities
- Employment and working conditions
- Determination of the key components of the Policy Options

C2.2 Discussion of the Policy Option components

C2.2.1 Introduction

The key components of the Policy Options are:

1) Substitution
2) Closed systems
3) Exposure minimisation
4) Introduction of additional OSH guidance
5) IOELVs become BOELVs
6) Record keeping
7) Merging of the two directives
8) Threshold/non-threshold approach
9) Health surveillance/BLVs
10) Sensitisers
11) Modernisation

C2.2.2 Substitution/consideration of substitution whenever exposure is likely

Summary - consideration of substitution/substitution

The CMD requires that the employer considers whether substitution is 'technically possible' whenever workers are exposed or are likely to be exposed to the relevant substance. The trigger is therefore 'exposure' or 'likely exposure'. A substitution requirement also exists in the CAD and in the OSH Framework Directive (Article 6)[47]. However, in the CAD, the trigger is 'risk from a hazardous chemical agent' (Article 6 of the CAD) as determined in risk assessment (Article 4). In addition, the slight risk applies (Article 5(4) of the CAD).

In addition, consultation for this study suggests that, in practice, the frequency with which feasibility of substitution is considered is not based solely on the legal differences between the CAD and the CMD but also reflects the fact that carcinogens and mutagens have had a higher profile than 'other hazard' substances, and consequently, there may have been a greater push for their replacement and risk management.

The key questions for the assessment of the costs of the substitution requirement include:

a) What proportion of companies have not yet considered substitution and would thus have to consider it? What is the cost of considering and documenting whether substitution is feasible?
b) What proportion of companies would substitute the relevant substance? (incl. how the Member State would assess this) What is the cost of substitution?

The logic framework for the costs that would arise from additional consideration of substitution and the associated documentation and from substitution is given in the figures below.

[47] https://osha.europa.eu/en/legislation/directives/the-osh-framework-directive/1

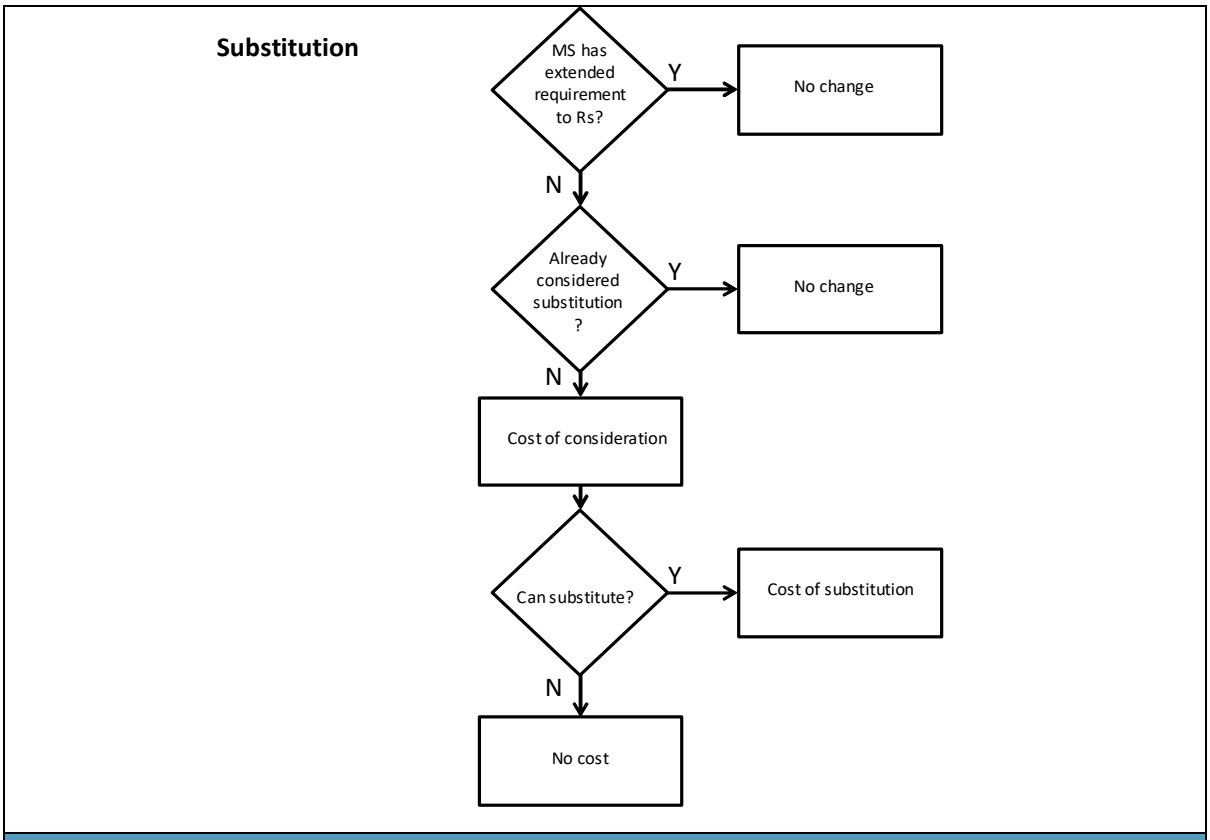

Figure C2-1: Decision tree – additional costs from the substitution requirement

The scenarios setting out the assumptions about the share of companies that have not yet considered feasibility of substitution and, subsequently, the proportion of these companies that would substitute are summarised below. These build upon the questionnaire responses received in the two rounds of stakeholder consultation carried out under this study.

Table C2-3: Scenarios - substitution

Response	Low	Mid	High	Reasons
A: % of companies that have not considered substitution	20%	30%	40%	See Note 1
B: % of companies under A above that would identify a technically feasible substitute	10%	25%	40%	See Note 2
C: % of all companies in the Member State with exposure to Rs that would substitute	2%	10%*	15%**	C=A*B

Table C2-3: Scenarios - substitution				
Response	**Low**	**Mid**	**High**	**Reasons**
Notes: 1: Round 1 suggests that around 35% of EU companies never considered substitution. These respondents were mainly (but not only) based in Member States that have not extended the CMD to cover Rs. It is recognised that a limited number of questionnaire responses have been received and that companies replying to the consultation exercise may be those that suffer from a self-selection bias, suggesting that the proportion of companies that have not carried out an assessment of substitution may be greater among non-respondents. However, since there is a general obligation in the OSH Framework Directive and an obligation to consider substitution where risk has been identified under the CAD, it is assumed that the proportion of companies that have not considered substitution is not significantly greater. 2: Round 1 suggests that, of the companies that have considered substitution, approximately 50% have or are in the process of substituting some or all of the relevant substances. The remaining 50% find it impossible to substitute. It is recognised that it is not clear whether this refers to substitution of some or all relevant substances. The responses to Round 2 suggest that only around 20% of companies that provided an answer to this question (or 10% of all companies that completed at least a part of the questionnaire) would find it possible to substitute. However, this conclusion is based on a very limited sample of companies (2 companies). * 30% x 25% = 7.5% rounded up to 10% * 40% x 40% = 16% rounded down to 15%				

The table below estimates the numbers of companies that would have to consider (and document) the feasibility of substitution as well as those that may carry out substitution, drawing on the logical framework outlined in the figure above and the three scenarios set out in the table above.

Table C2-4: Substitution – numbers of companies affected								
Member State	**Substitution of Rs when workers exposed or likely to be exposed?**	**Number of companies subject to changes in requirements**	**A: Number of companies that would have to consider substitution**			**C: Number of companies that would substitute**		
			Low 20%	**Mid 30%**	**High 40%**	**Low 2%**	**Mid 10%**	**High 15%**
Austria	Yes	0	0	0	0	0	0	0
Belgium	Yes	0	0	0	0	0	0	0
Bulgaria	No	6,000	1,200	1,800	2,400	120	600	900
Croatia	No	2,600	520	780	1,040	52	260	390
Cyprus	No	1,000	200	300	400	20	100	150
Czech Republic	Yes	0	0	0	0	0	0	0
Denmark	No	4,000	800	1,200	1,600	80	400	600
Estonia	No	1,400	280	420	560	28	140	210
Finland	Yes	0	0	0	0	0	0	0
France	Yes	0	0	0	0	0	0	0
Germany	Yes*	0	0	0	0	0	0	0
Greece	No	14,000	2,800	4,200	5,600	280	1,400	2,100
Hungary	No	9,600	1,920	2,880	3,840	192	960	1,440
Ireland	No	4,000	800	1,200	1,600	80	400	600
Italy	No	66,600	13,320	19,980	26,640	1,332	6,660	9,990
Latvia	No	2,000	400	600	800	40	200	300
Lithuania	No	3,400	680	1,020	1,360	68	340	510
Luxembourg	No	600	120	180	240	12	60	90
Malta	No	600	120	180	240	12	60	90
Netherlands	No	19,800	3,960	5,940	7,920	396	1,980	2,970
Poland	No	34,000	6,800	10,200	13,600	680	3,400	5,100

Table C2-4: Substitution – numbers of companies affected								
Member State	Substitution of Rs when workers exposed or likely to be exposed?	Number of companies subject to changes in requirements	A: Number of companies that would have to consider substitution			C: Number of companies that would substitute		
			Low 20%	Mid 30%	High 40%	Low 2%	Mid 10%	High 15%
Portugal	No	15,200	3,040	4,560	6,080	304	1,520	2,280
Romania	No	13,000	2,600	3,900	5,200	260	1,300	1,950
Slovakia	No	7,400	1,480	2,220	2,960	148	740	1,110
Slovenia	No	2,400	480	720	960	48	240	360
Spain	No	51,400	10,280	15,420	20,560	1,028	5,140	7,710
Sweden	Yes	0	0	0	0	0	0	0
United Kingdom	Where exposure	0	0	0	0	0	0	0
Total	-	259,000	51,800	77,700	103,600	5,180	25,900	38,850
Notes: Number of companies only for NACE codes B to E and G to N (industry, services), Agriculture (A) & Construction (F) not included. Assumed that max. 2% of enterprises have workers exposed to reprotoxic substances that are not C/M 1A/1B. *But C&M given priority over R								

It should be noted that substitution may not be possible in some scenarios at all, including: trade with the relevant substances; and construction.

Additional information – substitution check

The questionnaire consultation for this study asked whether companies have already considered substitution and the outcome of these deliberations. Of the companies that responded to the question on substitution in the consultation process, 35% stated that "substitution had not been considered", 13% that "substitution had been completed for some or all of the relevant substances", 17% said that "substitution is in progress, but not completed yet, and 35% said that "substitution was considered but not feasible".

Table C2-5: Questionnaire responses – substitution (1st round)		
Response	% of respondents that answered this question (number of respondents)	% of all questionnaire respondents (number of respondents)
No, substitution not considered	35% (9)	20% (9)
Yes, substitution considered but not feasible	35% (8)	20% (8)
Yes, substitution in progress but not completed yet	17% (4)	10% (4)
Yes, substitution completed for some or all of the relevant substances	13% (3)	10% (3)
No answer	N/A	40% (18)
Notes: Question: Has your company carried out any activities with regard to the replacement of the relevant substance(s)? Total number of responses: 24 answers to this question, 42 questionnaire respondents in total Totals may not add up due to rounding. Source: Questionnaire responses		

A more detailed response from a Belgian respondent noted that looking for substitution is a prerequisite before carrying out a risk assessment for all activities. Most respondents that have not considered substitution have facilities in the Member States that have not extended the CMD to cover reprotoxins; however, some of them also have facilities in Finland and France.[48] Generally speaking, the reasons why companies have not considered feasibility of substitution could include:

- the slight risk under Article 5(4) in the CMD;
- no risk identified in a risk assessment; or
- risk assessment has not been carried out.

Consultation for this study suggests that, in addition to the Member States that have not extended the CMD to reprotoxins, the slight risk is still available in at least one Member State (Germany). In addition, consultation for this study suggests that a relatively significant proportion of companies are making use of the slight risk provision; this was 20% among the respondents to the consultation exercise for this study but it is likely to be greater among non-respondents).

On the other hand, some of the respondents in the Member States that have not extended the CMD to cover reprotoxins have already considered substitution independently of a risk assessment (2 respondents, i.e. 13% of those that considered substitution); this is in addition to the companies that have considered substitution following the identification of a risk in a risk assessment. These two respondents are:

- a Croatian company noted that they consider substitution independently of risk assessment during purchasing; and
- a Danish company noted that they are running a hazard-based substitution programme for all CMR substances – if substitution is not possible, a risk assessment is carried out.

It is possible that, where workers are exposed to several hazardous substances, the need to carry out a risk assessment (and, consequently, consideration of substitution) may be triggered by exposure to another substance. In this regard, it is of interest that the data in Havet et al (2017)[49] suggest that 30% of workers that are exposed to CMRs are exposed to more than one substance.

Additional information – feasibility of substitution

The questionnaire consultation for this study also asked whether it would be feasible for companies to substitute reprotoxic substances. Most companies have stated that substitution is not possible. A variety of interpretations of the term 'technically possible' are being relied on when the feasibility of substitution is considered. There is evidence from consultation for this study as well as Pessala et al (2012)[50] that economic considerations are taken into account and for this reason companies have been asked about both 'technical feasibility' and 'economic viability'.

[48] The principle of substitution is highly underlined in the French legislation and guidance materials for workplaces. Source: https://publications.europa.eu/en/publication-detail/-/publication/c94c5caf-fca6-498e-8dff-f75c6e20147f/language-en

[49] See https://www.ncbi.nlm.nih.gov/pubmed/28074269

[50] Pessala et al (2012): Minimising chemical risk to workers' health and safety through substitution, available at https://publications.europa.eu/en/publication-detail/-/publication/c94c5caf-fca6-498e-8dff-f75c6e20147f/language-en

Table C2-6: Questionnaire responses – substitution (round 2 questionnaire)		
Response	**% of respondents that answered this question (number of respondents)**	**% of all questionnaire respondents (number of respondents)**
No, not technically feasible and/or economically viable	70% (12)	55% (12)
Yes	10% (2)	10% (2)
Do not know	20% (3)	15% (3)
No answer	N/A	25% (5)
Notes: Question: Would your company substitute any of the relevant R 1A/1B substance(s) if they were included into the scope of the CMD? Total number of responses: 17 answers to this question, 22 questionnaire respondents in total Totals may not add up due to rounding. Source: Questionnaire responses		

Pessala et al (2012) note that in a French campaign of substitution of CMRs, organised by the French Ministry of Labour, CNAMTS and INRS, which included around 2,000 participating companies, 60% tried to substitute CMR1/2 substances. Of these 60%, 70% succeeded, 18% were still in the process of considering substitutability and 10% found it impossible to substitute. Failure to substitute was often due to poor performance of the alternative and very rarely for economic reasons. However, due to a potential self-selection bias and focus on C/M substances, the results of the survey carried out for this study are preferred for the purposes of the modelling in this report.

The national guidance documents setting out the criteria for assessing feasibility of substitution are summarised below, reproduced from Pessala et al (2012).

Technical and cost consideration / country	France	Germany	Netherlands	UK
Technology constraints and technical assessments	Discussed in terms of functionality and efficiency.	Yes, covers technical requirements, suitability in process and whether realisable at current premises.	Functional analysis of why the chemical is used, and finding requirements and barriers (functional, process-based, physic-chemical, quality, logistical and economic).	Discussed in terms of functionality, compatibility and availability of alternatives; no specific assessment of technology.
Cost of substitution	Discussed in general terms, no specifics.	Tables provided for calculating costs using a comparative approach (increase or decrease), covering insurance, material, equipment, labour, transport, storage, disposal and protective measures.	Economic impacts, e.g. short and long term costs and benefits and investment requirements are discussed. The guidance contains a checklist for possible business impacts.	Discussed in terms of efficiency of resource utilisation and socio-economic consequences to the end consumer and to all the other actors in the supply chain. No specifics.
Direct and indirect consequences, e.g. costs of risk	Mentioned briefly.	Comparative increases or decreases through reduction. Risk not covered by costs.	Discussed shortly, no specific guidance.	Discussed in general terms, no specifics.

Figure C2-2: Criteria for considering feasibility of substitution in national guidance documents, reproduced from Pessala et al (2012)

Cost of considering substitution, including documentation

Consultation carried out for this study suggests that the burden on companies associated with consideration and documentation of substitutability varies widely, with indications that it may range from an exercise based on a one-page tick-box document to a complex process that involves extensive comparisons and discussions. The cost of considering feasibility of substitution depends on the following factors:

- Number of substances
- Depth of the assessment
- Documentation required
- Availability of R&D documentation

The **number of substances** to which workers are exposed is a key factor that determines the cost for a company. The number of hazardous substances that an individual company has to examine for substitutability can range from a single substance to thousands of substances (although it is recognised that only around a hundred reprotoxic substances would be brought into the scope of the CMD under Options 2, 4, and 5; the number of sensitising substances brought into the scope of the CMD under Option 5 would be at least 500). In the first round of the consultation exercise for this study, the number of reprotoxic substances relevant to a single company ranged from 1 to 60, with

the average number of substances being seven (when an outlier with a large number of substances is taken out, the average number of reprotoxic substances is five); however, it should be noted that the respondents to the consultation exercise are likely to be companies for which exposure to reprotoxic substances is a particularly relevant issue and they may therefore have on average more substances than other companies. Across all companies (respondents and non-respondents to the survey), it is expected that a typical company would have to consider substitutability for between one and five substances, with the number taken as the basis for estimates for this study being two.

The **depth of the assessment** is expected to vary widely, ranging from one-page tick-box document to a complex process that involves extensive comparisons and discussions. As noted in Pessala et al (2012):

- *"In France, the guidance focuses on CMRs and is built around nine steps: 1) Identify the substances that should be substituted, 2) create a working group, 3) define specification, 4) search alternative solutions, 5) try out the alternatives, 6) evaluate the consequences of the solution on safety and health, 7) compare the different Options, 8) implement and 9) evaluate and validate the solution. A web tool to support and help the industry to manage the substitution process of CMRs has also been developed[51]."*

- *"Technical Rule for Hazardous Substances (TRGS) 600 Substitution, which aims to help the employer to comply with the Hazardous Substance Ordinance. It is a framework guidance based on chemical risk, complemented with several other TRGSs with more detailed guidance on specific chemicals and specific uses and their potential substitutes. TRGS 600 includes a flowchart and is constructed around four themes: 1) Determination of substitution possibilities, 2) guiding criteria for the pre-selection of substitution possibilities with good prospects, 3) decision on substitution and 4) documentation. The guidance addresses occupational health and safety factors, cost and environmental concerns and recommends models to use for the comparative assessment of the health and safety hazards."*

Extensive guidance on substitution is also provided by the Subsport.eu[52] website.

An example comparison table is provided below, reproduced from Pessala et al (2012).

[51] http://www.substitution-cmr.fr
[52] https://www.subsport.eu/substitution-steps

Will chemical risk be lower?		
Hazard: Are there differences in hazard level?	R34 Causes burns/ Skin Corr. 1B, H314	R38 Irritating to skin/ Skin Irrit. 2, H315
Exposure normal use: Is it possible to breathe in the chemical or get it on skin/eyes/mouth during normal use?	Yes	Yes
Exposure time: How often do we use this chemical?	Same	Same
Exposure long term: Are there any hazards from long term use?	No	No
Protection: Are there more control measures or PPE needed for either?	Yes, this one	
Environmental risk: Are there differences in risk to the environment?	R53 ***May cause*** long-term adverse effects in the aquatic environment/ Aquatic Chronic 4, H413	No environmental risk phrases
Accident likelihood: Is there a difference in how the chemical is used that could increase/decrease the chance of an accident?	no	no
Chemical risk: Which of the chemicals has a higher risk?	This one	
COMPARE ALTERNATIVES – benefits and drawbacks	CURRENT	ALTERNATIVE
What are the other benefits and drawbacks?		
Other risks: Are there other than chemical risks from this use (e.g. vibration, noise, strains etc.)?	Yes, ergonomics	Yes, noise higher; ergonomics less
Legislation: Are there any specific legal obligations for this chemical that impact on us and what is it?	No	No
Costs: What are the material costs?	1000 €	1050 €
Costs: What would the change to alternative cost? (potential changes in equipment, PPE, training needed, storage requirements etc. per annum)	–	100 €
Time: How long does it take to do the task/process done with the chemical? Is it time critical?	30 min	25 min
Supply: Is the supply secure, i.e. will we get this chemical when we need it?	Yes	Yes
Waste: Does the use of the chemical create waste that needs special treatment?	**Yes**	**No**
Environment: Are there differences in discharges to water or emissions to air?	**No**	**No**
Which is better? Current or alternative?		This one
CHANGE OR NOT?		**YES**

Figure C2-3: Alternatives comparison table, reproduced from Pessala et al (2012)

The information above suggests that relatively extensive investigations may be carried out by some companies. However, other companies appear to only carry out a relatively simple check that quickly eliminates alternative due to, for example, performance reasons.

Although the extent of the **documentation** that companies have to provide on request to the authorities (Article 4(2) of the CMD) depends on national practices in the different EU Member States, it is expected that in the vast majority of cases, only a relatively limited summary of the investigations is required.

A key issue for the cost of considering substitution is the availability of **recent R&D documentation**. Where R&D documentation is available for a certain product/process, there is typically sufficient information to list the alternatives and compare them with the substance in use. In essence, substitutability has already been considered. Where R&D documentation is out of date or not available, more extensive costs may be incurred due to the need to identify and investigate the potential substitutes.

In most cases, it is expected that this will be a relatively simple process with limited costs. For the purposes of quantification, it is expected that most enterprises will only have a cost of around €1,000, i.e. two substances at two days per substance at a professional's day rate of around €250.[53] However, it is recognised that for a large company with a large number of substances and no recent R&D documentation, the cost could be in the order of € hundreds of thousands.

It is not expected that all companies would consider substitution immediately following the change of legislation. In particular, large companies with a large number of processes and substances may take several years to consider/carry out substitution. For the purposes of this Impact Assessment, it is assumed that it would take companies around five years to consider substitution (and in some instances to substitute). The costs of considering substitution are thus spread over a five-year period, discounted and annualised.

Cost of substitution

The cost of substituting a chemical could involve a one-off cost associated with changes to the (production) facilities and a recurring cost associated with material costs, RMMs, time required for production, waste disposal, emissions, accident/fire hazards, etc.

The costs of substitution and/or compliance/demonstrating compliance with additional 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 in 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 may take economic feasibility into account when enforcing this provision and that a general substitution requirement for substances where there is a risk already exists.

C2.2.3 Closed systems

Articles 5(1) and 5(2) of the CMD require that, where the results of a risk assessment reveal a risk and substitution is not technically possible, the employer shall ensure that the substance is, 'in so far as is technically possible, manufactured and used in a closed system.'

Although 'design of appropriate work processes and engineering controls and use of adequate equipment and materials, so as to avoid or minimise the release of hazardous chemical agents which

[53] Taken from the Standard Cost Model day rates for 2010-11, updated to 2018 using Eurostat's Harmonised Index of Consumer Prices (HIPC).

may present a risk to workers' safety and health at the place of work' is also required in the CAD (Article 6(2)a), Article 5(2) of the CMD can be seen as a stronger requirement to manufacture and use the relevant substance in a closed system. As a result, it can be expected that the extension of the CMD to cover reprotoxic substances would result in an increased number of companies considering the technical feasibility of a closed system, with some of them subsequently putting a closed system in place.

Summary – closed system

The key questions for the assessment of the costs of Article 5(2) of the CMD include:

a) What counts as a closed system?
b) What proportion of companies have not yet considered the feasibility of a closed system and would thus have to consider it? What is the cost of considering and documenting whether a closed system is technically possible?
c) What proportion of companies would put in place a closed system? (incl. how the Member State would assess this) What is the cost of putting in place a closes system?

The logic framework for the costs that would arise from additional consideration of a closed system and the associated documentation, and from a closed system is given below.

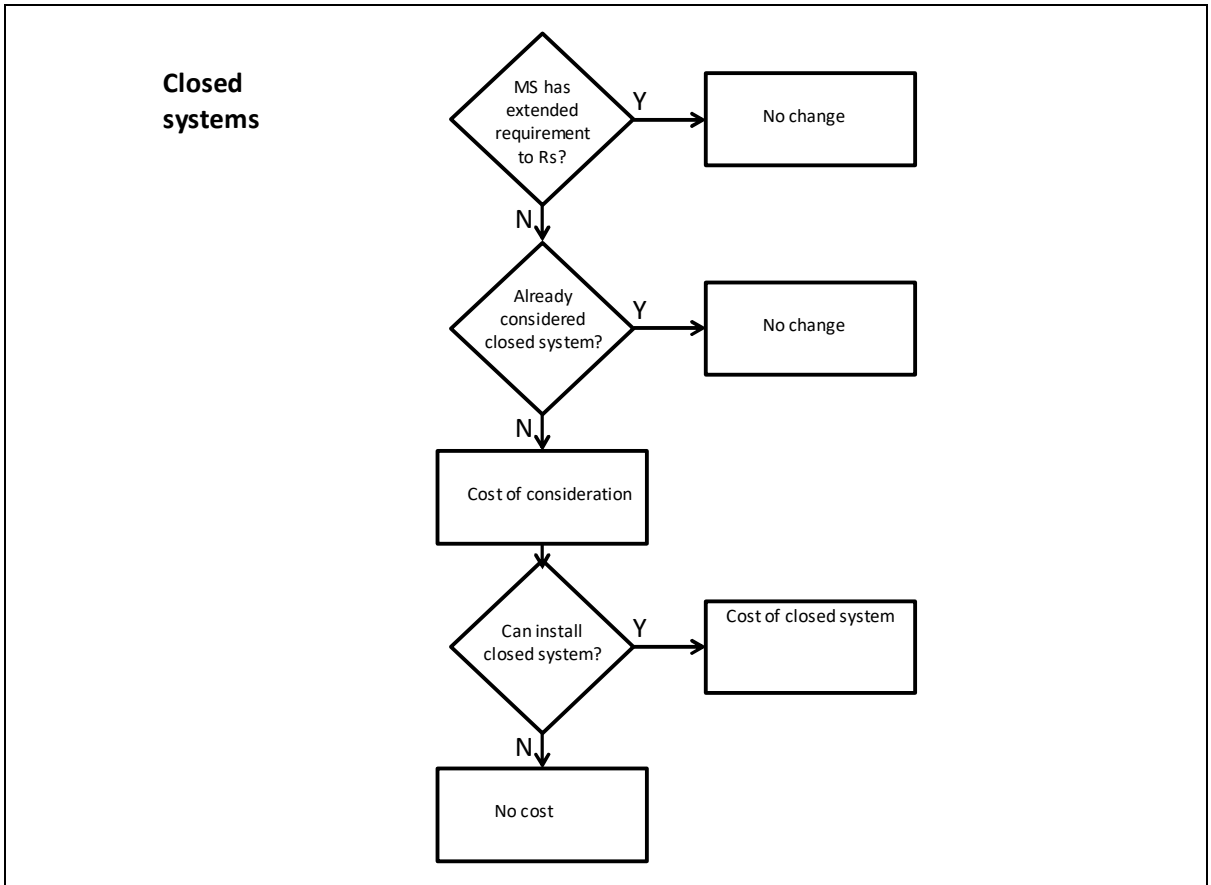

Figure C2-4: Decision tree – additional costs from the closed system requirement

The scenarios setting out the assumptions about the share of companies that have not yet considered the feasibility of a closed system and, subsequently, the proportion of these companies that would install a closed system are summarised below. These build upon the questionnaire responses received in the framework of the two rounds of stakeholder consultation carried out under this study.

Table C2-7: Scenarios – closed system				
Response	**Low**	**Mid**	**High**	**Reasons**
A: Companies that do not have a closed system	85%	90%	95%	See Note 1
B: Companies without closed system that have not considered the feasibility of one	85%	90%	95%	See Note 2
C: Companies without a closed system that would need to consider it	72% (61%*)	81% (73%*)	90% (88%*)	C=A*B
D: Companies without closed system that would install one	5%	10%	15%	See Note 2
E: % of all companies (with exposure to Rs) in the Member State that would install a closed system	4% (3%*)	8% (7%*)	14% (14%*)	E=A*B*D

Notes:
1: Almost all responses to this question in the first round of consultation indicated that they have collective measures in place or are in the process of installing them. However, these are expected to refer primarily to measures other than closed systems. In the second round, a limited number of respondents (15% of those that provided an answer to the relevant question) indicated that they had a closed system in place.
2: Assumed all would have considered as implied in the CAD.
3: In the second round, most respondents (80% of those that provided an answer to the relevant question) indicated that it would not be not technically feasible and/or economically viable to install a closed system. These were generally large companies that might be thought the most likely to install closed systems.
*In order to avoid double counting, values in brackets take into account companies that would substitute the substance following the extension of the CMD to cover R 1A/1B substances. Since the low scenario aims to model the lowest costs, the proportion of companies that have substituted under the high scenario is considered (10%). For the high scenario for closed systems, the proportion of companies that have substituted under the low scenario (2%) is considered.

The table below estimates the numbers of companies that would have to consider (and document) the feasibility of closed systems, as well as those that may install a closed system, drawing on the logical framework outlined in the figure above and the three scenarios set out in the table above.

Table C2-8: Closed system – numbers of companies affected								
Member State	**Closed system explicitly required as second RMM for Rs?**	**Number of companies subject to changes in requirements**	**C: Number of companies that would have to consider a closed system**			**E: Number of companies that would install a closed system**		
			Low 61%*	**Mid 73%***	**High 88%***	**Low 3%***	**Mid 7%***	**High 14%***
Austria	Yes	0	0	0	0	0	0	0
Belgium	Yes	0	0	0	0	0	0	0
Bulgaria	No	6,000	3,672	4,860	5,292	204	480	823
Croatia	No	2,600	1,591	2,106	2,293	88	208	357
Cyprus	No	1,000	612	810	882	34	80	137
Czech Republic	Yes	0	0	0	0	0	0	0
Denmark	No	4,000	2,448	3,240	3,528	136	320	549
Estonia	No	1,400	857	1,134	1,235	48	112	192

Table C2-8: Closed system – numbers of companies affected								
Member State	Closed system explicitly required as second RMM for Rs?	Number of companies subject to changes in requirements	C: Number of companies that would have to consider a closed system			E: Number of companies that would install a closed system		
			Low 61%*	Mid 73%*	High 88%*	Low 3%*	Mid 7%*	High 14%*
Finland	No	4,800	2,938	3,888	4,234	163	384	659
France	Yes	0	0	0	0	0	0	0
Germany	Yes	0	0	0	0	0	0	0
Greece	No	14,000	8,568	11,340	12,348	476	1,120	1,921
Hungary	No	9,600	5,875	7,776	8,467	326	768	1,317
Ireland	No	4,000	2,448	3,240	3,528	136	320	549
Italy	No	66,600	40,759	53,946	58,741	2,264	5,328	9,138
Latvia	No	2,000	1,224	1,620	1,764	68	160	274
Lithuania	No	3,400	2,081	2,754	2,999	116	272	466
Luxembourg	No	600	367	486	529	20	48	82
Malta	No	600	367	486	529	20	48	82
Netherlands	No	19,800	12,118	16,038	17,464	673	1,584	2,717
Poland	No	34,000	20,808	27,540	29,988	1,156	2,720	4,665
Portugal	No	15,200	9,302	12,312	13,406	517	1,216	2,085
Romania	Yes	0	0	0	0	0	0	0
Slovakia	No	7,400	4,529	5,994	6,527	252	592	1,015
Slovenia	No	2,400	1,469	1,944	2,117	82	192	329
Spain	No	51,400	31,457	41,634	45,335	1,748	4,112	7,052
Sweden	Yes	0	0	0	0	0	0	0
United Kingdom	No	42,200	25,826	34,182	37,220	1,435	3,376	5,790
Total	-	**293,000**	**179,317**	**237,331**	**258,427**	**9,962**	**23,440**	**40,200**

Notes:
Number of companies only for NACE codes B to E and G to N (industry, services), Agriculture (A) & Construction (F) not included. Assumed that max. 2% of enterprises have workers exposed to reprotoxic substances that are not C/M 1A/1B.
*Adjustment made for the numbers of companies that have already substituted (2-15%).

It should be noted that it may not be possible to install a closed system in some sectors at all, such as agriculture and construction.

Additional information – companies with collective measures in place

A relatively high proportion of companies have put in place collective measures but it is expected that only a few of them have in place what could be classed as a closed system. The table below suggests that 50% of companies have in place a collective measure but an analysis of the data by Jorge Costa-David (2014)[54] of the SUMER (2003)[55] survey appears to suggest that only 4% of workers exposed to reprotoxins work in a closed system. In addition, information provided by several respondents shows that even though they have 'collective measures' in place, inclusion of reprotoxins 1A and 1B

[54] See https://osha.europa.eu/sites/default/files/seminars/documents/presentation-costa-david.pdf

[55] SUMER (2003): Les expositions aux risques professionnels. Les produits chimiques. Résultats SUMER 2003. Direction de l'animation de la recherche, des études et des statistiques (DARES). [In French]

chemicals in the scope of the CMD would inevitably involve relevant changes for the risk management within the company's production process which would require expensive investments.

Table C2-9: Questionnaire responses -collective measures incl. closed systems (1st round)		
Response	**% of respondents that answered this question (number of respondents)**	**% of all questionnaire respondents (number of respondents)**
Yes, completed for some or all of the relevant substances	90% (22)	50% (22)
Yes, in progress but not completed yet	10% (3)	10% (3)
No answer	N/A	40% (18)
Notes: Question: Has your company carried out any activities with regard to prevention and reduction of exposure (collective measures)? Examples of collective measures include closed systems, ventilation, etc. Total number of responses: 42 Totals may not add up due to rounding. Source: Questionnaire responses.		

Additional information – feasibility of a closed system

The questionnaire consultation for this study also asked whether it would be feasible for companies to install a closed system. Most companies have stated that this is not possible. It should be noted that there is no universally accepted understanding of the terms 'technically possible' and 'closed system'.

Table C2-10: Questionnaire responses - feasibility of closed systems (round 2 questionnaire)		
Response	**% of respondents that answered this question (number of respondents)**	**% of all questionnaire respondents (number of respondents)**
No, not technically feasible and/or economically viable	70% (12)	55% (12)
No, already in place	20% (3)	15% (3)
Yes	5% (1)	5% (1)
Do not know	5% (1)	5% (1)
No answer	N/A	25% (5)
Notes: Question: Would your company put in place a closed system to control exposure to the relevant R 1A/1B substance(s) if they were included into the scope of the CMD? Total number of responses: 22 Totals may not add up due to rounding. Source: Questionnaire responses.		

Cost of a closed system

Three companies based in Italy, i.e. a CAD Member State (all of which have some collective measures in place, including in one case a partial closed system), expect the need for a significant investment from the extension of the CMD to reprotoxic substances with specific regard to the RMMs.

The annualised unit cost of a closed system is summarised below for three different company sizes. The initial investment and recurring costs over the whole lifespan of the equipment (discounted for the relevant year at 4%) is as follows:

- Small: €5,000
- Medium: €50,000
- Large: €200,000

These costs assume that the company was already operating an LEV2 and its operating costs are deducted from the operating costs of the closed system.

Table C2-11: Cost of a closed system in €									
Size of company	Small 2 workers exposed Exposed workers on 1 machine			Medium 27 workers exposed 14 machines			Large 75 exposed workers 40 machines		
Type of RMM	One-off 2017	Lifespan years	Recurring (% of one-off)	One-off 2017	Lifespan years	Recurring (% of one-off)	One-off 2017	Lifespan years	Recurring (% of one-ff)
LEV 3: Full enclosure	45,000	20	10%	440,000	20	10%	1,700,000	20	10%
Sources: One-off cost estimated based on high end of costs in IOM (2011), Recurring: 10% based on US-OSHA (1992) (most likely electricity, maintenance & repairs) Notes: Recurring costs are adjusted to deduct the running costs of LEV2 already installed. This is calculated as 10% of the one-off cost of LEV given in Table C2-18.									

Some RMMs such as closed systems are directly related to the size of the operation. The costs for each company will thus depend on the scale of the relevant activities (e.g. number of processing lines; number of workers, etc.). This is why it was necessary to estimate (at least broadly) the size distribution of the relevant companies. Distribution over class sizes within the EU SME definition has been taken as a proxy. The distribution of enterprises by size (micro and small, medium, large) in the industry (NACE B to E) and services (NACE G to N) is taken as a proxy for the distribution of the costs based on the operation sizes in the above table. According to Eurostat, the distribution of companies in the industry (NACE B to E) and services (NACE G to N) is as follows:

- Micro and small: 98.7%
- Medium: 1%
- Large: 0.2%

This means that the average annualised cost per company (weighted by size distribution in the total enterprise population) is €6,000.

C2.2.4 Exposure minimisation

The exposure minimisation requirement in the CMD means that companies are required to minimise exposure; this is based on the premise that any exposure signifies risk. On the other hand, the CAD focuses on reducing risk to a minimum. In some instances, companies have already reduced exposure to a minimum by targeting risk for minimisation. A change in the approach from targeting risk to targeting exposure (as a proxy for risk) would be unlikely to result in a significant change for these companies. However, there are likely to be companies, for which change can be expected due to the extension of the exposure minimisation requirement to reprotoxins, including:

- Companies currently under the CAD (Company Type A in the figure below) that have not yet reduced exposure to levels below the thresholds (e.g. for reasons of technical feasibility) and continue to operate with a certain level of risk: it is expected that, since these companies are unable to eliminate all risk, targeting exposure as a proxy for risk instead of risk would not result in any change for these companies;
- Companies that have reduced exposure below the threshold and have thus eliminated the risk (Company Type B in the figure below). These companies would be required to implement additional measures to further reduce exposure;
- Companies that rely on the slight risk (Company Type C in the figure below) may not have put in place the specific protection and prevention measures in Article 6 of the CAD and may thus face additional costs due the exposure minimisation requirement in the CMD since no such exemption exists in the CMD. It is, however, recognised that a) reducing to a minimum the number of workers exposed or likely to be exposed and b) reducing to a minimum the duration and intensity of exposure are among the general principles for the prevention of risks in Article 5 of the CAD and thus apply also to companies that are relying on the slight risk from the requirements in 6,7, and 10 of the CAD.

The typology of companies is shown below.

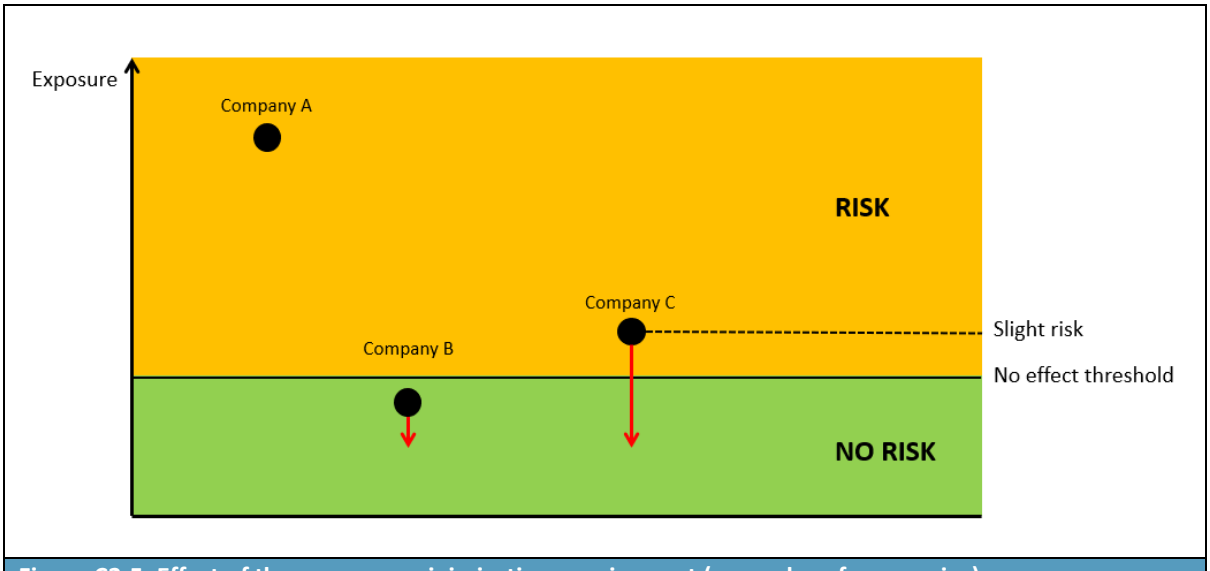

Figure C2-5: Effect of the exposure minimisation requirement (examples of companies)

The logic framework for the costs that could arise is given below.

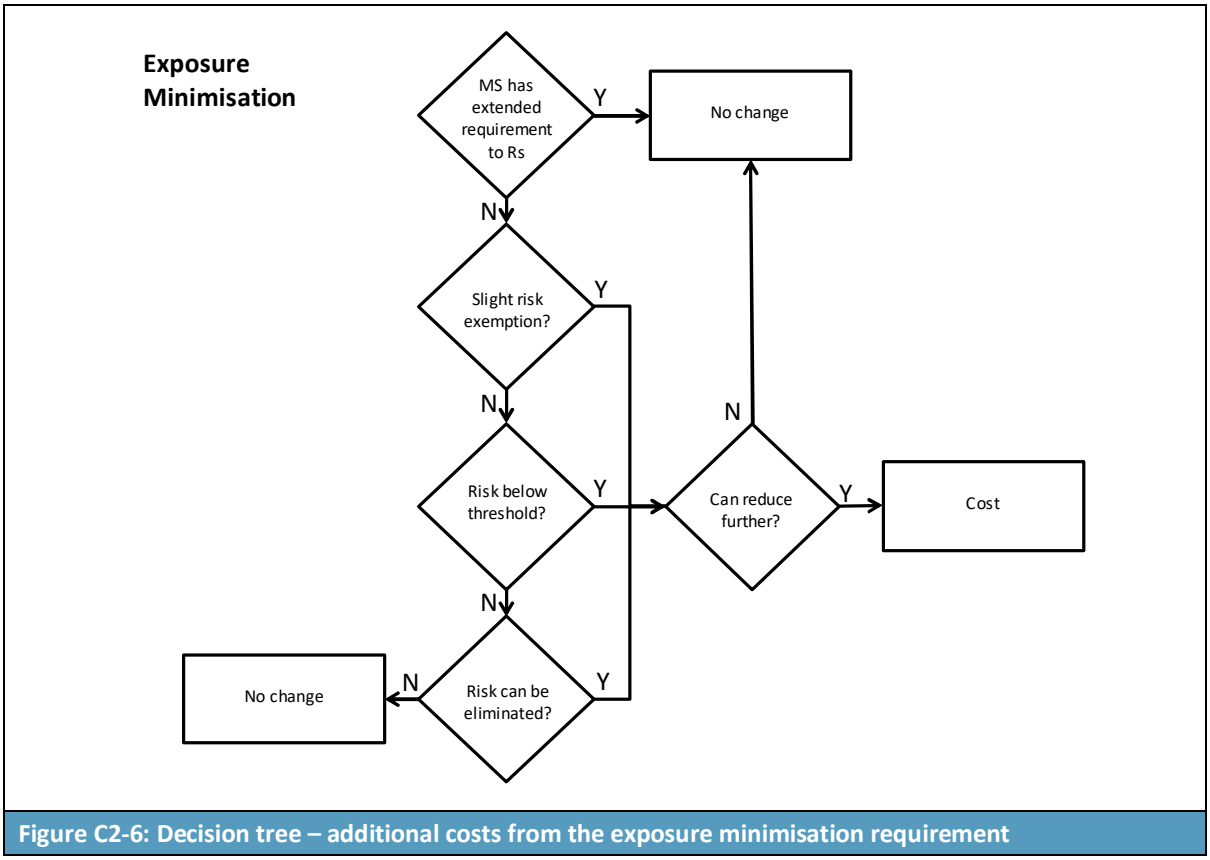

Figure C2-6: Decision tree – additional costs from the exposure minimisation requirement

The logic framework set out above suggests that, although operating with the highest level of risk, Type A companies would experience no further costs – this is because they are already reducing risk/exposure as much as they can. By contrast, Type B and C companies, which have better risk management in place would be required to further reduce exposure (if possible).

The key questions are:

a) What is the split between companies of Type A, B, and C?
b) What additional measures could be put in place?
c) What would be the cost of these measures?

Number of affected companies

The scenarios are given below. Please note that this section only focusses on thresholds for reprotoxic effects and does not take into account potential thresholds (or their absence) for other effects.

Table C2-12: Scenarios – exposure minimisation				
Response	**Low**	**Mid**	**High**	**Reasons**
A: Type A companies (risk: exposure >threshold)	30%	20%	10%	See Note 1

Table C2-12: Scenarios – exposure minimisation				
Response	**Low**	**Mid**	**High**	**Reasons**
B: Type B companies (no risk: exposure ≤ threshold)	60%	70%	80%	See Note 1
C: Type C companies (slight risk)	10%	10%	10%	See Note 2
D: Companies that have to consider minimisation	70%	80%	90%	D=B+C
E: Companies that have not substituted or installed closed systems	80%	80%	80%	See Note 3
F: % companies that could implement additional RMMs	20%	30%	40%	See Note 4
G: % of all companies (with exposure to Rs) that would implement additional RMMs	10%	20%	30%	G=(B+C) *E*F
Notes: 1: Based on the 27+3 substances considered in detail in the study, it is expected that most exposure is below the threshold. 2: Taken from consultation (1st round); 20% of companies that provided an answer to the relevant question indicated that they were making use of the slight risk. However, it is expected that the sample suffers from a self-selection bias and the use of the slight risk is greater among non-respondents. 3: Based on sum of the average of the mid values for percentage of companies that would substitute (10%) (from Table C2-3) and the mid values for percentage of companies that would install closed systems (8%) (Table C2-7), rounded to 20% and subtracted from 100%. 4: In the second round, all respondents indicated that they expect some costs from the 'exposure minimisation' requirement. It is therefore assumed that it would be technically feasible for all or almost all to implement some additional measures.				

The table below estimates the numbers of companies that would implement additional RMMs in each Member State.

Table C2-13: Exposure minimisation requirement – numbers of companies affected by Member State								
Member State	**Exposure minimisation requirement for Rs?**	**Number of companies subject to changes in requirements**	**D: Number of companies that would have to consider additional RMMs**			**G: Number of companies that would install additional RMMs**		
			Low 70%	**Mid 80%**	**High 90%**	**Low 10%**	**Mid 20%**	**High 30%**
Austria	Yes	0	0	0	0	0	0	0
Belgium	Yes	0	0	0	0	0	0	0
Bulgaria	No	6,000	4,200	4,800	5,400	600	1,200	1,800
Croatia	No	2,600	1,820	2,080	2,340	260	520	780
Cyprus	No	1,000	700	800	900	100	200	300
Czech Republic	Yes	0	0	0	0	0	0	0
Denmark	Yes	0	0	0	0	0	0	0
Estonia	No	1,400	980	1,120	1,260	140	280	420
Finland	No	4,800	3,360	3,840	4,320	480	960	1,440
France	Yes	0	0	0	0	0	0	0

Table C2-13: Exposure minimisation requirement – numbers of companies affected by Member State								
Member State	Exposure minimisation requirement for Rs?	Number of companies subject to changes in requirements	D: Number of companies that would have to consider additional RMMs			G: Number of companies that would install additional RMMs		
			Low 70%	Mid 80%	High 90%	Low 10%	Mid 20%	High 30%
Germany	Yes (exempt if below OEL)	0	0	0	0	0	0	0
Greece	No	14,000	9,800	11,200	12,600	1,400	2,800	4,200
Hungary	No	9,600	6,720	7,680	8,640	960	1,920	2,880
Ireland	No	4,000	2,800	3,200	3,600	400	800	1,200
Italy	No	66,600	46,620	53,280	59,940	6,660	13,320	19,980
Latvia	No	2,000	1,400	1,600	1,800	200	400	600
Lithuania	No	3,400	2,380	2,720	3,060	340	680	1,020
Luxembourg	No	600	420	480	540	60	120	180
Malta	No	600	420	480	540	60	120	180
Netherlands	No	19,800	13,860	15,840	17,820	1,980	3,960	5,940
Poland	No	34,000	23,800	27,200	30,600	3,400	6,800	10,200
Portugal	No	15,200	10,640	12,160	13,680	1,520	3,040	4,560
Romania	Yes	0	0	0	0	0	0	0
Slovakia	No	7,400	5,180	5,920	6,660	740	1,480	2,220
Slovenia	No	2,400	1,680	1,920	2,160	240	480	720
Spain	No	51,400	35,980	41,120	46,260	5,140	10,280	15,420
Sweden	Yes	0	0	0	0	0	0	0
United Kingdom	No	42,200	29,540	33,760	37,980	4,220	8,440	12,660
Total	-	***289,000***	***202,300***	***231,200***	***260,100***	***28,900***	***57,800***	***86,700***
Notes: Number of companies only for NACE codes B to E and G to N (industry, services), Agriculture (A) & Construction (F) not included. Assumed that max. 2% of enterprises have workers exposed to reprotoxic substances that are not C/M 1A/1B.								

Additional information - slight risk

20% of the respondents that answered the relevant questions (4 out of 22 respondents) are relying on the slight risk. However, it should be noted that these four companies already have collective measures in place, two have considered substitution (and one of the two has substituted which means that this is not a real use of the 'slight risk'). A respondent also noted that this is relevant to laboratory tests and another noted that RMMs including a closed cycle are in place. Another indicated use of collective and personal protective measures. One of the four noted their systems are designed so that risk is minimal.

It is of interest that one of the respondents noted that they would not use the slight risk for Reprotoxic 1A/1B substances.

Table C2-14: Questionnaire responses – use of the slight risk (Round 1 questionnaire)		
Response	% of respondents that answered this question (number of respondents)*	% of all questionnaire respondents (number of respondents)
Yes,	15% (4)	10% (4)
No	85% (20)	50% (20)
No answer*	Additional 18	40% (18)

Table C2-14: Questionnaire responses – use of the slight risk (Round 1 questionnaire)		
Response	**% of respondents that answered this question (number of respondents)***	**% of all questionnaire respondents (number of respondents)**
Source: Questionnaire responses. *Notes: *Only respondents that answered this question counted.* *Question: Has your company made use of the 'slight risk' exemption under the CAD? This relates to Article 5(4) of the CAD which provides an exemption from specific protection and prevention measures in cases whether the risk assessment shows "that, because of the quantities of a hazardous chemical agent present in the workplace, there is only a slight risk to the safety and health of workers" and compliance with the general the principles for prevention of risks is sufficient to reduce that risk.* *Total number of responses: 24 respondents answered this question, 42 respondents in total* *Totals may not add up due to rounding.*		

Additional RMMs and their cost

The variety of substances, applications, uses and RMMs already in place does not allows a reliable quantification of the costs of the exposure minimisation requirements.

The measures currently in place are summarised below.

Table C2-15: Questionnaire responses -measures in place (Round 1 questionnaire)	
Response	**% of respondents that answered this question that have these measures in place (number of respondents with measures in place)**
Collective measures	100% (23 of 23)
Restricted access to risk areas	75% (17 of 23)
Planning for unforeseen/accidental exposure	90% (20 of 23)
PPE	100% (23 of 23)
Personal hygiene requirements	100% (23 of 23)
Information/training to workers and their participation in decision making	100% (23 of 23)
Record keeping	80% (18 of 22)
Source: Questionnaire responses *Notes: Yes: includes those who have implemented or are implementing the measure for some substances only.* *No: includes companies that have considered the measure and concluded it is not feasible and those that have not considered the measure.* *Totals may not add up due to rounding.*	

It is clear that companies expect additional costs from the exposure minimisation requirement, most expect significant additional cost or are not able to estimate the magnitude of these costs. Two respondents that indicated significant additional costs added the following comments. The first is from a company handling borates, who explained that minimisation of exposure in their industrial settings would lead to a need for significant investments. The second was from a manufacturer using lead, who said that their plant had implemented the safety measures at highest world level.

Table C2-16: Questionnaire responses -exposure minimisation (Round 2 questionnaire)		
Response	**% of respondents that answered this question (number of respondents)**	**% of all questionnaire respondents (number of respondents)**
No additional cost	5% (1)	5% (1)
Moderate additional cost	10% (2)	10% (2)
Significant additional cost	50% (8)	35% (8)

Table C2-16: Questionnaire responses -exposure minimisation (Round 2 questionnaire)		
Response	**% of respondents that answered this question (number of respondents)**	**% of all questionnaire respondents (number of respondents)**
Some additional cost but value cannot be estimated	35% (6)	25% (6)
Do not know	0% (0)	0% (0)
No answer	N/A	25% (5)
Source: Questionnaire responses *Notes: Question: Would your company incur any additional costs due to the exposure minimisation requirement under the CMD?* *Total number of responses: 22* *Totals may not add up due to rounding.*		

For illustrative purposes, example RMM costs from publicly available literature are provided in the table below.

Table C2-17: RMM unit costs			
RMM	**One-off**	**Operating**	**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 Assume cylinder is then rented	Boconline (undated): €50 for one hour of work (cylinder rental & refill) 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 Assumed a new mask has to be purchased every two months due to wear	Hamikian et al (2015): €9 for a pair of HEPA filters Usage time 30 hours (Zeynep et al 2008)	Mask: 1 month, Filter: 30 hours

Table C2-17: RMM unit costs			
RMM	**One-off**	**Operating**	**Lifespan**
	and tear/accidental damage, etc. Cost per worker €150	Annual cost per worker €75, i.e. 50% of CAPEX	
RPE 1: Simple mask	Hakimian et al (2015): €1 per disposable mask 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) A large range of measures with different costs Assumed €1,000 per worker	Some data provided through consultation for Cd (ICdA) Zeynep et al (2008): Training annual instructor cost €540 A large range of measures with different costs Assumed 50%	Only incurred once
GDV1: General dilution ventilation	Hakimian et al (2015): €22 per cfm required Zeynep et al (2008): €10 per cfm Figure used: €20 per cfm Assumed 10 Air Changes Per Hour Assumed cfm required: Sm: 300 cfm, Me: 2,000 cfm, La: 5,000 cfm	Hakimian (2015): Approx. 30% of CAPEX Zeynep et al (2008): 30% but this is for 24hr operation 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 http://ec.europa.eu/social/BlobServlet?docId=10157&langId=en
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

The unit costs in the table above are differentiated below by company size. 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 C2-18: Cost of various RMMs in €									
Size of company	Small 2 workers exposed Exposed workers on 1 machine			Medium 27 workers exposed 14 machines			Large 75 workers 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									

Although the numbers of companies that would purchase the RMMs in the table above is not known, some illustrative calculations are given below for the theoretical scenarios in which all affected companies install LEV1 or LEV 2.

Table C2-19: Illustrative cost calculations			
Illustrative scenario	Low Annualised cost € million	Mid Annualised cost € million	High Annualised cost € million
All relevant companies installing LEV 1	100	200	300
All relevant companies installing LEV 2	150	250	400
All relevant companies installing other RMMs	30	60	90
All relevant companies installing LEV1, LEV2 or other RMMs, equally split	80	170	250
Notes: LEV1: This is based on an average annualised cost per company (weighted by size distribution in the total enterprise population) is €2,300. LEV2: This is based on an average annualised cost per company (weighted by size distribution in the total enterprise population) is €4,400. Other RMMs based upon an average annualised cost per company of €1,000			

C2.2.5 Introduction of OSH guidance

Although several stakeholders consulted for this study noted that there is no need for additional guidance in their Member State, this Impact Assessment assumes that such guidance would be developed at the EU level and would identify the Best Available Techniques based on examples from all EU Member States. The OSH guidance documents would subsequently be made available in all EU languages.

The questionnaire consultation for this study asked whether it would be useful to introduce additional guidance – OSH guidance – this is discussed in the section on benefits. This section focuses on the costs of developing and disseminating such guidance.

The consultation exercise for this study suggests that the OSH guidance should be sectoral or process based and it is assumed that the process used for their development would be similar to the development of BREFs for the Industrial Emissions Directive 2010/75/EU. This process is summarised below. It is recognised that a number of methodologies exist around the world for the development of documents that set out Best Available Techniques (OECD, 2018).[56] Similar to the Industrial Emissions BREFs which comprise 30 documents[57], which it is expected that at least 50 sectoral documents would be required.

Box C1-1: Working procedures to elaborate BREFs for the for the Industrial Emissions Directive 2010/75/EU
For each BREF, the European IPPC Bureau sets up a Technical Working Group (TWG) to carry out the exchange of information on BAT. A TWG usually consists of between 100 to 200 experts.

[56] See http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/JM/MONO(2018)21&docLanguage=En

[57] For an overview of BREFs, see http://eippcb.jrc.ec.europa.eu/reference/

Box C1-1: Working procedures to elaborate BREFs for the for the Industrial Emissions Directive 2010/75/EU
The European IPPC Bureau organises the work of the TWG, fosters the exchange of information, makes a scientific and technical analysis of the vast amount of information exchanged, proposes compromise solutions on issues when views of TWG members differ, and writes the BREF. The European IPPC Bureau acts as a neutral, technically competent and permanent body to all TWGs. The procedure used to elaborate or review a BREF includes a few plenary meetings of the TWG, sub-group meetings, visits to installations, and submission of draft BREFs for comments. Practical arrangements for the exchange of information are laid down in the specific guidance documents referred to in Article 13 (3)(c) and (d) of the Industrial Emissions Directive (IED), 2010/75/EU. These documents aim in particular at guiding the European IPPC Bureau and members of the technical working groups (TWGs) in the drawing up and reviewing the whole series of BREFs. Once it has been finalised, each BREF is presented by the European IPPC Bureau to DG Environment at the forum (Information Exchange Forum, IEF) established by the IED (ex IPPC Directive).
Source: Reproduced from http://eippcb.jrc.ec.europa.eu/about/working_procedures.html

Estimates of the costs of developing guidance documents include:

- €500,000;[58] and
- €50,000.[59]

The working procedures described in the box above for the Industrial Emissions Directive 2010/75/EU suggests a more resource intensive process. The cost of this process is estimated in the table below.

Table C2-20: Estimated cost of developing an OSH guidance	
Activity	**Cost**
Secretariat & co-ordination	200 days at €1,000 per day
Participation of 100 experts	500 days at €1,000 per day
Drafting of documents	200 days at €1,000 per day
Finalisation & translation	1,000 days at €1,000 per day
Dissemination	100 days at €1,000 per day
Total (per guidance document)	2,000 days at €1,000 per day = €2,000,000
Source: study team estimates	

It is expected that these costs would be incurred every 10 years due to the need to update the guidance documents in line with technological progress.

C2.2.6 IOELVs become BOELVs

Although this is not a direct consequence of the inclusion of Reprotoxic 1A/1B substances into the scope of the CMD, it is assumed (for the purposes of this Impact Assessment) that for the IOELVs for Reprotoxic 1A/1B substances that currently exist under the CAD (11 substances, see the table below),

[58] See https://ec.europa.eu/clima/sites/clima/files/strategies/2020/docs/streamlining_cc_ap_reporting_en.pdf

[59] 50 days at GBP 900, see https://www.legislation.gov.uk/ukdsi/2011/9780111512319/pdfs/ukdsiem_9780111512319_en.pdf

a corresponding BOELV would be established under the CMD. It is further assumed that future occupational exposure limits for reprotoxic substances would be adopted as BOELVs under the CMD.

The IOELVs under the CAD are summarised below.

Table C2-21: Indicative Occupational Exposure Limit Values (IOELVs) under the CAD for reprotoxic substances

Name	CAS No.	IOEL (8h TWA)		IOEL (short-term)		Notation	Directive	CLH
		mg/m³	ppm	mg/m³	ppm			
N,N-Dimethylacetamide	127-19-5	36	10	72	20	skin	2000/39/EC	R1B
Nitrobenzene	98-95-3	1	0.2	-	-	skin	2006/15/EC	R1B, C2
N,N Dimethylformamide	68-12-2	15	5	30	10	skin	2009/161/EU	R1B
2-Methoxyethanol	109-86-4	-	1	-	-	skin	2009/161/EU	R1B
2-Methoxyethyl acetate	110-49-6	-	1	-	-	skin	2009/161/EU	R1B
2-Ethoxy ethanol	110-80-5	8	2	-	-	skin	2009/161/EU	R1B
2-Ethoxyethyl acetate	111-15-9	11	2	-	-	skin	2009/161/EU	R1B
N-Methyl-2-pyrrolidone	872-50-4	40	10	80	20	skin	2009/161/EU	R1B
Mercury and divalent inorganic mercury compounds		0.02	-	-	-	-	2009/161/EU	R1B
Bisphenol A	201-245-8	2	-	-	-	-	2017/164/EU	R1B
Carbon monoxide	630-08-0	23	20	117	100	-	2017/164/EU	R1A

The logic framework for the costs that would arise is given below.

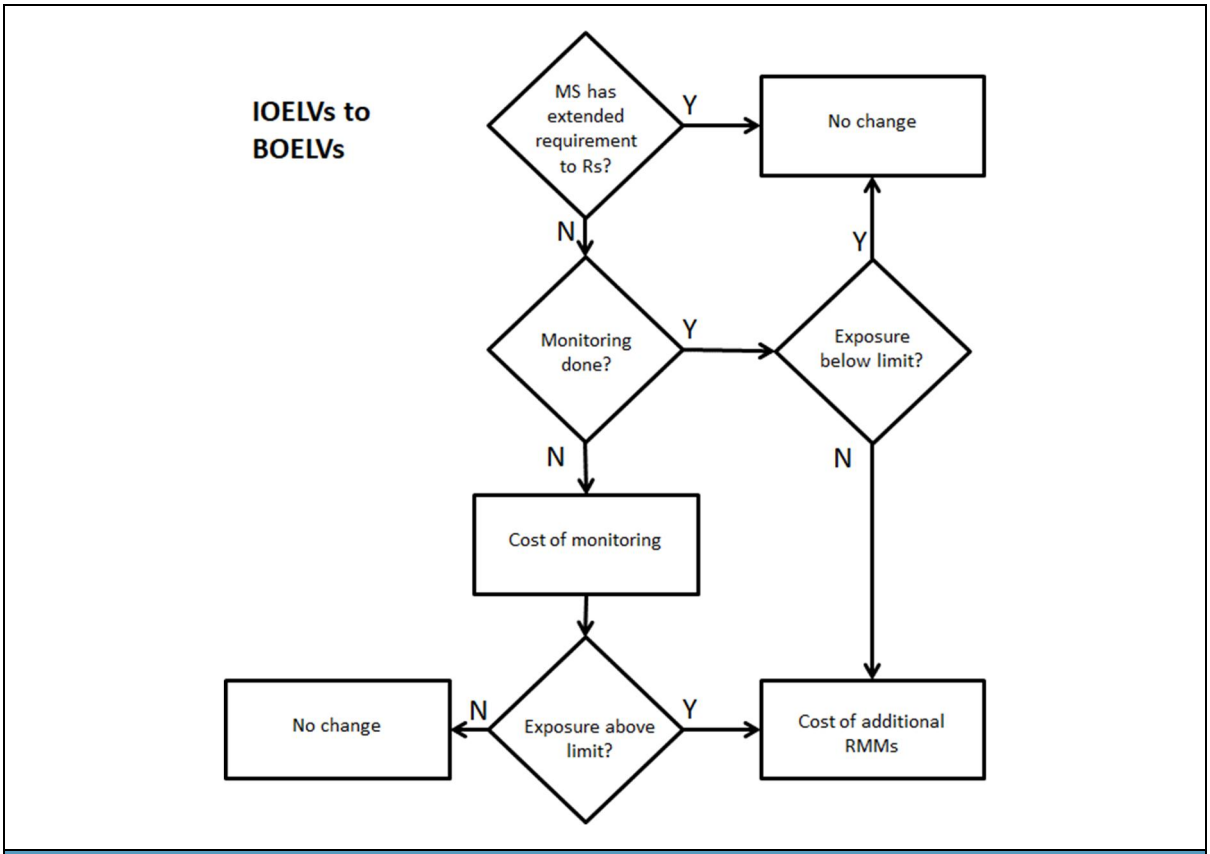

Figure C2-7: Decision tree – CAD IOELVs become CMD BOELVs

With regard to the 11 IOELVs in the table above, consultation for this study suggests that 23 of the 28 EU Member States have transposed them as binding limits. The exceptions are Finland, France, Italy, Lithuania, and Portugal, as summarised in the table below together with the numbers of companies that are not yet subject to binding OELs for these 11 substances.

Table C2-22: CAD IOELVs become CMD BOELVs – numbers of companies affected

Member State	A: CAD IOELVs for R 1A/1B already binding?	B: Number of companies subject to changes in requirements	C: Number of companies that would have to put in place additional RMMs		
			Low 5%	Mid 10%	High 15%
Austria	Yes	0	0	0	0
Belgium	Yes	0	0	0	0
Bulgaria	Yes	0	0	0	0
Croatia	Yes	0	0	0	0
Cyprus	Yes	0	0	0	0
Czech Republic	Yes	0	0	0	0
Denmark	Yes	0	0	0	0
Estonia	Yes	0	0	0	0
Finland	No	4,800	240	480	720
France	No	58,000	2,900	5,800	8,700
Germany	Yes	0	0	0	0
Greece	Yes	0	0	0	0

Table C2-22: CAD IOELVs become CMD BOELVs – numbers of companies affected					
Member State	A: CAD IOELVs for R 1A/1B already binding?	B: Number of companies subject to changes in requirements	C: Number of companies that would have to put in place additional RMMs		
			Low 5%	Mid 10%	High 15%
Hungary	Yes	0	0	0	0
Ireland	Yes	0	0	0	0
Italy	No	66,600	3,330	6,660	9,990
Latvia	Yes	0	0	0	0
Lithuania	No	3,400	170	340	510
Luxembourg	Yes	0	0	0	0
Malta	Yes	0	0	0	0
Netherlands	Yes	0	0	0	0
Poland	Yes	0	0	0	0
Portugal	No	15,200	760	1,520	2,280
Romania	Yes	0	0	0	0
Slovakia	Yes	0	0	0	0
Slovenia	Yes	0	0	0	0
Spain	Yes	0	0	0	0
Sweden	Yes	0	0	0	0
United Kingdom	Yes	0	0	0	0
Total		***148,000***	***7,400***	***14,800***	***22,200***
Notes: *Number of companies only for NACE codes B to E and G to N (industry, services), Agriculture (A) & Construction (F) not included. Assumed that max. 2% of enterprises have workers exposed to reprotoxic substances that are not C/M 1A/1B. The companies in column B are those whose workers are exposed to any R 1A/1B substance. Consequently, it is recognised that column B represents an overestimate of the number of companies that would be subject to the new requirement.*					

The companies in column B are those whose workers are exposed to any Reprotoxic 1A/1B substance – a conclusion on the share of companies that use the 11 substances is not possible on the basis of available information. Consequently, it is recognised that column B represents an overestimate of the number of companies that would be subject to the new requirement. It is also not known what proportion of companies that use these substances specifically are at exposure levels above the IOELV. It is expected that a very low proportion of companies would have to put in place additional measures. The cost of these measures is not known. However, with regard to Finland, a consultee noted that they believe that making them binding will not make much difference as they are already taken seriously and many workplaces consider them binding already. There has been a discussion in Finland about making them binding.

It is expected that no additional costs would arise for either companies or public authorities in the Member States where these limits already have a binding status. No impact on operating costs is expected. The requisite measures are already in place and companies are expected to routinely monitor exposure concentrations. In addition, there is a binding OEL and BLV for lead under the CAD. This is an 8-hour TWA IOELV for inorganic lead and its compounds (R1A) of 0.15 mg/m3 in the CAD and a BLV for lead and its ionic compounds (70 µg Pb/ 100 ml blood) in Annex II of the CAD.

C2.2.7 Additional BOELVs

Under Option 3+, a BOELV (risk or health based) would be established for all R 1A/1B substances, resulting in the need to monitor air concentrations and comply with the BOELVs. 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. It is also clear that this exemption would not be available immediately since there would a need to establish at least around 50 BOELVs and this process is likely to take a number of years. In the meantime, the exposure minimisation requirement would apply. In order to mitigate unnecessary costs that would be incurred in the period until all the BOELVs are adopted, it would be important to establish an effective system that prioritises the key substances that should be evaluated first, taking into account both the potential costs and benefits, possibly in a tripartite forum.

The questionnaire consultation for this study asked whether companies already carry out workplace air measurements of reprotoxic substances. This suggests that 60% of companies already carry out air monitoring. However, due to the possibility of a positive bias caused by self-selection of better performing companies for the survey, it is assumed that at the most 50% of companies already carry out air monitoring.

Table C2-23: Questionnaire responses – air monitoring of reprotoxic substances (round 1 questionnaire)

Response	% of respondents that answered this question (number of respondents)	% of all questionnaire respondents (number of respondents)
Yes	60% (15)	35% (15)
No	35% (8)	20% (8)
Do not know	5% (1)	2% (1)
No answer	N/A	40% (18)

Source: Questionnaire responses
Notes: Question: Does your company carry out workplace air measurements of the relevant reprotoxic substance(s)?
Total number of responses: 24 answers to this question, 42 questionnaire respondents in total
Totals may not add up due to rounding.

The questionnaire consultation for this study also asked whether the respondents would experience any impacts if the Indicative Occupational Exposure Limits (IOELVs) for Reprotoxic 1A/1B substances under the CAD became Binding Occupational Exposure Limits (BOELVs) under the CMD. Of the companies that could gave an opinion (excluding those that do not know or did not respond to this question) 50% (5) expect no change, 20% (2) expect moderate negative impacts and a further 30% (2) expect a significant negative impact. Most of the "Do not know" responses came from companies using borates and/or lead: borates do not have an IOELV and lead already has a binding OEL under the CAD.

Table C2-24: Questionnaire responses -CAD IOELVs become CMD BOELVs (round 2 questionnaire)

Response	% of respondents that answered this question (number of respondents)	% of all questionnaire respondents (number of respondents)
Significant positive impact	0% (0)	0% (0)
Moderate positive impact	0% (0)	0% (0)
No change	30% (5)	25% (5)
Moderate negative impact	10% (2)	10% (2)

Table C2-24: Questionnaire responses -CAD IOELVs become CMD BOELVs (round 2 questionnaire)		
Response	**% of respondents that answered this question (number of respondents)**	**% of all questionnaire respondents (number of respondents)**
Significant negative impact	20% (3)	15% (3)
Do not know	40% (7)	30% (7)
No answer	N/A	20% (5)
Source: Questionnaire responses *Notes: Question: Would your company experience any impacts if the Indicative Occupational Exposure Limits (IOELVs) for R 1A/1B substances under the CAD became Binding Occupational Exposure Limits (BOELVs) under the CMD?* *Total number of responses: 22* *Totals may not add up due to rounding.*		

Monitoring

Monitoring only has to be implemented if there is an OEL in place and, therefore, is required and incurs costs for Options that involve setting an OEL.

The logic framework for the costs that would arise from monitoring exposure levels is summarised below.

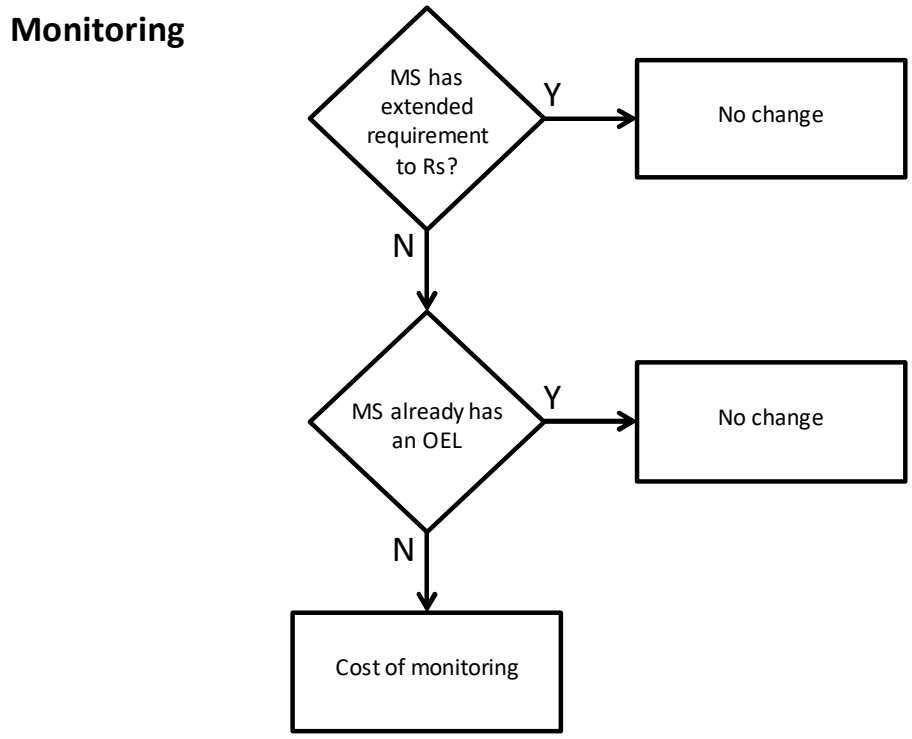

Figure C2-8: Decision tree – monitoring requirement

Because the logic is dependent upon whether the Member State has an existing OEL for the specific reprotoxin, this means that the number of companies that need to implement monitoring for the first time varies with reprotoxins. Therefore, it is not possible to arrive at a total number of companies that would have to implement monitoring for the first time for all reprotoxins.

For borates, the number of enterprises using borates in Member States that have not already extended is 350,000 and of these 220,000 are in member States that have an existing OEL for boric acid. Therefore, 130,000 enterprises would have to implement monitoring for the first time if an Option with OELs was introduced.

It is assumed that this requirement would cost each company €5,000 to set up with a €2,000 cost per year, which gives an annualised cost of €2,000 per year over a 40 year period[60].

C2.2.8 Record keeping for at least 40 years

The record-keeping requirements in the CAD and CMD are summarised below. It appears that some records need to be kept for a minimum of 40 years for substances within the scope of the CMD.

Table C2-25: Record keeping requirements in the CAD and CMD

CAD	CMD
Article 10: Health Surveillance. 2. Member States shall establish arrangements to ensure that for each worker who undergoes health surveillance in accordance with the requirements of paragraph 1, individual health and exposure records are made and kept up-to-date. 3. Health and exposure records shall contain a summary of the results of health surveillance carried out and of any monitoring data representative of the exposure of the individual. Biological monitoring and related requirements may form part of health surveillance. Health and exposure records shall be kept in a suitable form so as to permit consultation at a later date, taking into account any confidentiality. Copies of the appropriate records shall be supplied to the competent authority on request. The individual worker shall, at his request, have access to the health and exposure records relating to him personally. Where an undertaking ceases to trade, the health and exposure records shall be made available to the competent authority *There is no specific article on record keeping.*	<u>Article 12: Information for workers</u> Appropriate measures shall be taken to ensure that: (c) the employer keeps an up-to-date list of the workers engaged in the activities in respect of which the results of the assessment referred to in Article 3(2) reveal a risk to workers' health or safety, indicating, if the information is available, the exposure to which they have been subjected; <u>Article 14: Health Surveillance</u> 4. In cases where health surveillance is carried out, an individual medical record shall be kept and the doctor or authority responsible for health surveillance shall propose any protective or preventive measures to be taken in respect of any individual workers. <u>Article 15: Record keeping</u> 1. The list referred to in point (c) of Article 12 and the medical record referred to in Article 14(4) shall be **kept for at least 40 years** following the end of exposure, in accordance with national laws and/or practice. 2. Those documents shall be made available to the responsible authority in cases where the undertaking ceases activity, in accordance with national laws and/or practice.

The logic framework for the costs that would arise from keeping records for a minimum of 40 years is summarised below.

[60]These figures are line with previous studies by RPA.

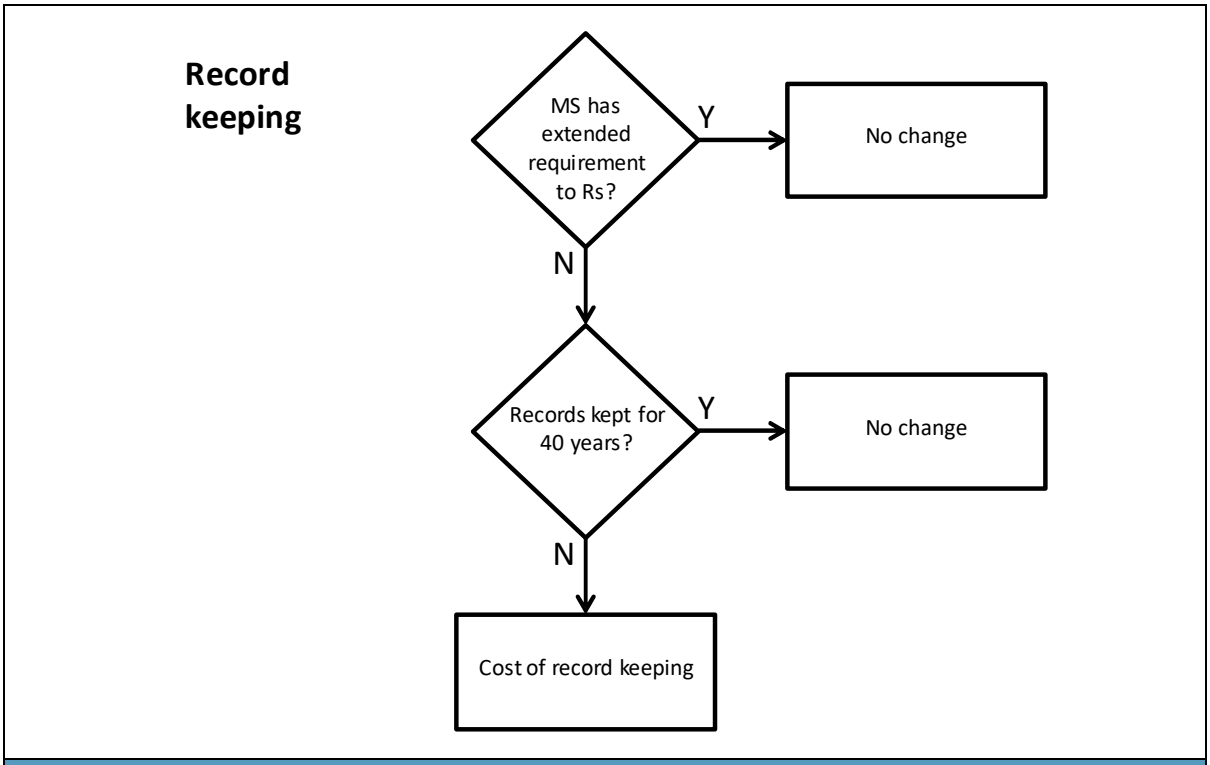

Figure C2-9: Decision tree – 40 year record keeping requirement

The scenarios setting out the assumptions about the share of companies that do not keep records for over 40 years are set out below. Some companies already keep records for 40 years or longer; for example, it is expected that companies that also handle CM substances already keep records for all relevant substances for the same period of time.

Table C2-26: Scenarios – 40 year record keeping requirement				
Response	**Low**	**Mid**	**High**	**Reasons**
A: Companies that do not keep records for over 40 years	50%	70%	90%	See Note 1
Note: 1: Havet et al (2017)[61] suggest that 30% of workers that are exposed to CMRs are exposed to more than one substance – this is taken as a proxy for the proportion of companies that also handle CM and thus already keep records for 40 years or longer. These scenarios are also broadly consistent with the consultation responses for the costs that would be incurred due to the 40 year record keeping requirement – these are summarised further on in this section of the report.				

The table below estimates the numbers of companies that would have to keep records for longer, drawing on the logical framework and scenarios set out above.

[61] See https://www.ncbi.nlm.nih.gov/pubmed/28074269

Table C2-27: Record keeping over 40 years – numbers of companies affected					
Member State	A: Record keeping for >40 years for Rs?	B: Number of companies subject to changes in requirements	C: Number of companies that currently do not keep records for 40 years		
			Low 50%	Mid 70%	High 90%
Austria	Yes	0	0	0	0
Belgium	Yes	0	0	0	0
Bulgaria	Yes[62]	0	0	0	0
Croatia	No	2,600	1,300	1,820	2,340
Cyprus	No	1,000	500	700	900
Czech Republic	Yes	0	0	0	0
Denmark	No	4,000	2,000	2,800	3,600
Estonia	No	1,400	700	980	1,260
Finland	No	4,800	2,400	3,360	4,320
France	Yes[63]	0	0	0	0
Germany	No	48,000	24,000	33,600	43,200
Greece	No	14,000	7,000	9,800	12,600
Hungary	No[64]	9,600	4,800	6,720	8,640
Ireland	No	4,000	2,000	2,800	3,600
Italy	No	66,600	33,300	46,620	59,940
Latvia	No	2,000	1,000	1,400	1,800
Lithuania	No	3,400	1,700	2,380	3,060
Luxembourg	No	600	300	420	540
Malta	No	600	300	420	540
Netherlands	No	19,800	9,900	13,860	17,820
Poland	No	34,000	17,000	23,800	30,600
Portugal	No	15,200	7,600	10,640	13,680
Romania	No	13,000	6,500	9,100	11,700
Slovakia	No	7,400	3,700	5,180	6,660
Slovenia	No	2,400	1,200	1,680	2,160
Spain	No	51,400	25,700	35,980	46,260
Sweden	No	13,000	6,500	9,100	11,700
United Kingdom	Yes	0	0	0	0
Total		***318,800***	***159,400***	***223,160***	***286,920***
Notes: Number of companies only for NACE codes B to E and G to N (industry, services), Agriculture (A) & Construction (F) not included. Assumed that max. 2% of enterprises have workers exposed to reprotoxic substances that are not C/M 1A/1B. The companies in column B are those whose workers are exposed to any R 1A/1B substance. Consequently, it is recognised that column B represents an overestimate of the number of companies that would be subject to the new requirement.					

The **key issue** here is the assumption that this would only involve to retaining records on current exposure for 40 years in the future, not the requirement to produce 40 years of records pertaining to past exposure immediately following the extension of the CMD to R 1A/1B substances. If companies

[62] Health records: 50 years (Ordinance No. 3 of 25 January 2008 on conditions and order for implementation of activities of occupational medicine services)

[63] Medical records: 50 years (R4624-22 to 28)

[64] However, 50 years for carcinogens.

had to presently provide records for exposure 40 years ago, this would be associated with significant costs and in many cases not be feasible as the records will have been destroyed.

The questionnaire consultation for this study also asked whether respondents would incur any additional costs due to the requirement to keep worker exposure and (if relevant) health surveillance records for a minimum of 40 years. Of the companies that could estimate the impacts, 80% expect some additional costs but most could not estimate the value of these costs.

Table C2-28: Questionnaire responses – Keeping records for a min. of 40 years (round 2 questionnaire)		
Response	**% of respondents that answered this question (number of respondents)**	**% of all questionnaire respondents (number of respondents)**
No additional cost	20% (3)	15% (3)
Moderate additional cost	5% (1)	5% (1)
Significant additional cost	35% (6)	25% (6)
Some additional cost but value cannot be estimated	40% (7)	30% (7)
Do not know	0% (0)	0% (0)
No answer	N/A	25% (5)
Notes: Question: Would your company incur any additional costs due to the requirement to keep worker exposure and (if relevant) health surveillance records for a minimum of 40 years? Total number of responses: 17 responses to this question, 22 respondents overall Totals may not add up due to rounding. Source: Questionnaire responses.		

It is assumed that this requirement would have an annualised cost per company of €500 per year (initial annual cost of €1,000 per year over a 40 year period). This is based on an application of the EU Standard Cost Model: 4 days of work at a professional's day rate of around €250.[65]

C2.2.9 Merging of the two directives

For the purposes of this Impact Assessment, it is assumed that combining the two pieces of legislation in one document would result in those Member States where the CAD and CMD have been transposed through two or more pieces of legislation combining their legislation into one single law. This amounts to a worst-case scenario from the cost perspective; a combination of two directives into one that does not involve substantive changes to the requirements may not result in any changes at the national level. It is expected that the process of merging of the two directives would only require minor terminological changes and it is not expected that these changes would force Member States to amend their legislation.

In fact, it is possible that a merger of the two directives may not result in Member States changing their national legislation at all.

For the purposes of this IA, it is assumed that the Member States that do not have the CAD and CMD in one piece of legislation would revise their national legislation. It is also expected that the companies in those Member States would incur some cost due to the need to familiarise themselves with the revised legislation. However, it is impossible to disaggregate the transposition and familiarisation

[65] Taken from the Standard Cost Model day rates for 2010-11, updated to 2018 using Eurostat's Harmonised Index of Consumer Prices (HIPC).

costs from those of the components and these are considered for all of the components/Policy Options together in Section C1.

The Member States that have not transposed the directives as one piece of legislation are given below.

Table C2-29: Merger of the two directives – numbers of companies affected		
Member State	**A: Record keeping for >40 years for Rs?**	**B: Number of companies subject to changes in requirements**
Austria	No	7,400
Belgium	Yes	0
Bulgaria	No	6,600
Croatia	No	2,600
Cyprus	No	1,000
Czech Republic	No	17,200
Denmark	No	4,000
Estonia	No	1,400
Finland	No	4,800
France	Yes	0
Germany	Yes	0
Greece	No	14,000
Hungary	No	9,600
Ireland	No	4,000
Italy	Yes	0
Latvia	No	2,000
Lithuania	No	3,400
Luxembourg	No	600
Malta	No	600
Netherlands	No	19,800
Poland	No	34,000
Portugal	No	15,200
Romania	No	13,000
Slovakia	No	7,400
Slovenia	No	2,400
Spain	No	51,400
Sweden	No	13,000
United Kingdom	Yes	0
Total		235,400
Notes: Number of companies only for NACE codes B to E and G to N (industry, services), Agriculture (A) & Construction (F) not included. Assumed that max. 2% of enterprises have workers exposed to reprotoxic substances that are not C/M 1A/1B. The companies in column B are those whose workers are exposed to any R 1A/1B substance. Consequently, it is recognised that column B represents an overestimate of the number of companies that would be subject to the new requirement.		

Most companies that responded to Round 2 of the consultation exercise expect negative impacts from Option 4 – however, these appear to primarily relate to the extension of CMD-equivalent requirements to reprotoxins rather than the consequences of having the requirements in one document. None of the associated comments refer to the merger of the two directives. As a result, it is expected that no costs, other than very limited familiarisation costs would be incurred by companies.

Table C2-30: Questionnaire responses –merging two pieces of legislation into one (round 2 questionnaire)		
Response	**% of respondents that answered this question (number of respondents)**	**% of all questionnaire respondents (number of respondents)**
Significant positive impact	5% (1)	5% (1)
Moderate positive impact	20% (3)	15% (3)
No change	20% (3)	15% (3)
Moderate negative impact	15% (2)	10% (2)
Significant negative impact	30% (5)	25% (5)
Do not know	15% (2)	10% (2)
No answer	N/A	25% (6)
Source: Questionnaire responses *Notes: Question: Do you expect any potential impacts from this option with regard to simplification from having one instead of two pieces of legislation?* *Total number of responses: 22* *Totals may not add up due to rounding.*		

C2.2.10 Threshold/non-threshold (T/NT) approaches

There are three issues relating to the designation of a threshold or not for reprotoxins:

- Is each substance treated individually or as a block (of reprotoxins, carcinogens and mutagens etc)?
- Is the threshold for reprotoxins only considered, or the threshold for all hazard classifications considered?
- Is any proposed threshold above the background level?

Although the issue of background concentrations is important, this is different for every substance and, therefore, is not considered further here.

It is easier to understand the other two issues in relation to two specific substances: borates and lead.

Borates are currently thought to be non-threshold, but this study shows that they do have a threshold. Options 2, 4 and 5 assume that all reprotoxins are non-threshold, which would subject companies using borates to high costs for no health benefits. Option 3 assumes that a reprotoxin is threshold unless proven, which would cause no costs for borates companies. Option 3+ assumes that a substance is non-threshold unless an OEL is introduced. This would subject companies using borates to high costs for no health benefits, unless OELs are introduced at the same time as the Option.

Lead has a threshold for reprotoxins and is non-threshold for neurotoxicity. It is difficult to see how lead could be considered as a reprotoxin alone: it seems sensible to treat it as a hazard classification, and therefore non-threshold due to its neurotoxicity. This means that Options 2, 3+, 4 and 5 treat it correctly. However, Option 3 is defined as giving derogations for reprotoxins, so this might mean that lead is exempted from the minimisation rules.

In the consultation, there was considerable support for each substance being treated individually. There was also support for giving limit values, either health based, or if these cannot be established or if the substance is non-threshold, giving a risk-based limit value.

In Round 1 of the consultation, question 27 asked: "Do you have any views on the question of how residual risks for non-threshold substances should be identified, assessed, and addressed? More specifically, do you believe that it is necessary to have different approaches for threshold and non-threshold substances?" Several respondents replied:

> Small Italian chemicals company: "*It could be useful to define a limit value when it's possible and where it's not feasible it could be established an acceptable threshold, consequently to an impact assessment study"*
>
> Large Italian chemicals company: "*For threshold substances an OEL can/should be set. Workers exposed to a lower concentration than the OEL should clearly not be considered as "worker exposed to CM". For non-threshold substances a legally "acceptable" risk level should be set (considering concentration and duration of exposure), and consequently workers exposed to concentrations/duration lower than the corresponding "acceptable" level should clearly not be classified as "worker exposed to CM"".*

C2.2.11 Add-on elements under Option 5

Health surveillance/Biological Limit Values

It is not possible within the scope of this study to estimate the costs of introducing a greater level of biomonitoring due to the introduction of binding Biological Limit Values (BLVs) for more substances because:

- the substances for which it would be feasible and acceptable to introduce them are not known
- there is a wide variation in methods, indicators and testing technologies available.

However, Section D3 provides a comparison of indicative costs associated with a biomonitoring campaign with that of air monitoring, and this suggests that the costs could be in the region of €761-€1,346 per company per year. This compares with figures for air monitoring of €573-€1,045 (where sampling analysis is performed by the company itself) and €1,150-€2,150 (in the event that sampling and analysis are performed by an external contractor). It is recognised that these costs relate to urine sampling. For blood monitoring, the costs would be higher due to the logistical effort required (the worker needs to be at a specific time in a specific place, shower before, etc.).

Overall costs will be influenced by the number of workers covered by the testing programme as well as the number of substances that companies are using and consequently requiring monitoring. For larger companies in particular, this will be significant, but they will have greater resources available and might also be able to benefit from economies of scale.

Consultation suggests that capacity for testing might be lacking in some countries, requiring potential additional investment in laboratory facilities etc. where it is not feasible or prohibitively expensive to send samples for testing outside of a particular Member State.

It has been suggested during consultation, however, that focusing on biomonitoring can distract from ensuring that all possible measures are taken to avoid exposure in the first place and that this might lead to greater exposure overall than might be achievable if the emphasis were placed on reducing exposure at source to "as low as technically feasible".

It is expected that this change would encourage more BLVs which would be adopted in addition to OELVs, not as their replacement.

Sensitisers

Implementing the CMD for all sensitizers could incur significant costs. Applying substitution, closed systems, exposure minimisation, OEL derivation and 40 year recordkeeping for nearly 300 - 400 sensitizers (classified and newly added to CMD) could impose a significant economic burden.

The total number of classified (CLH) and "self-classified" (CLI) sensitizers, and whether they are registered with REACH and C1A/1B is shown below.

Table C2-31: Skin sensitisers in the CLH and CLI, and registered with REACH

Response	All sensitisers	Sensitisers registered with REACH	Sensitisers registered with REACH and not C1A/1B
CLH – Sens 1	570	379	333
CLH – Resp 1	97	61	43
CLH – Sens 1 & Resp 1	75	47	29
CLI – Sens 1	6915	3374	3296
CLI – Resp 1	1554	585	560
CLI – Sens 1 & Resp 1	1210	501	477
Source: RPA analysis			

At present, under the CAD, regulators assume that thresholds exist. However, many companies are concerned about some individuals who are highly sensitive and also about the accuracy (or not) of current testing methodologies are. This leads to a tendency to treat everybody as sensitive, and companies often prefer to do everything to minimise respiratory exposure rather than simply achieve the threshold. As a result, PPE is the preferred method of preventing skin sensitisation[66] (sometimes an unnecessarily high amount of PPE) to ensure that the most sensitive individuals are protected. Risk or exposure minimisation appear to be already practiced extensively[67].

Therefore, moving to the CMD may not reduce exposure, but might change the methods of risk minimization. Substitution, closed systems and minimization could become more prevalent than PPE under the CMD, particularly as PPE is considered the RMM of last resort under the CMD. Larger enterprises have often implemented the more capital-intensive solutions, but smaller companies are more dependent upon PPE. Therefore, smaller business entities may be affected (on average) more than larger entities mostly due to lack of in-house resources.

Substitution would often result in major decreases of PPE related expenditures. However, substitution usually requires substantial investment of time and money at the outset, whereas PPE involves a higher long-term operating cost both in terms of kit and the time spent putting it on.

Substituting a sensitizer can be a difficult task but there are scientific methods that enable relatively rapid and accurate screening of candidate chemicals for sensitizing properties. However, testing

[66] Basketter, D., 2008. Skin sensitization: strategies for the assessment and management of risk. Brit J. Derm. 159(2), 267-273

[67] There may be great differences in degree of PPE and protectiveness between (very) small and large industry entities due to the in-house IH capabilities.

chemicals is never cheap although sensitizer testing may be more in the €100-500,000 range rather than the € millions range for other properties.

Modernisation

Half of the respondents giving an opinion believe that there would be no change as a result of the modernisation of the terminology. One respondent added that *"unifying terminology with REACH would help, but real impact for the business would probably be non-existing".*

Table C2-32: Questionnaire responses – terminology brought into line with REACH (round 2 questionnaire)		
Response	**% of respondents that answered this question (number of respondents)**	**% of all questionnaire respondents (number of respondents)**
Significant positive impact	10% (2)	10% (2)
Moderate positive impact	10% (2)	10% (2)
No change	50% (8)	35% (8)
Moderate negative impact	5% (1)	5% (1)
Significant negative impact	5% (1)	5% (1)
Do not know	20% (3)	15% (3)
No answer	N/A	25% (5)
Notes: Question: Do you expect any impacts from unifying the terminology in the CMD and CAD and bringing it into line with the terms used in the REACH Regulation? Total number of responses: 22 Totals may not add up due to rounding. Source: Questionnaire responses.		

C2.3 Assessment of the costs by Policy Option

As noted above, the cost categories considered below are:

- Conduct of business & costs for companies;
- Costs for public authorities; and
- Employment and working conditions.

The table below summarises the different components and how they relate to each Policy Option.

Table C2-33: Policy Options and their relevant components								
Component		**O1-: Baseline (no guidance)**	**O1: Baseline (including OSH guidance)**	**O2: R 1A/1B in CMD**	**O3: R 1A/1B in CMD (derogations)**	**O3+: Joint declaration**	**O4: R 1A/1B in CMD, merge CAD and CMD**	**O5: R 1A/1B in CMD, merge CAD and CMD, modernisation**
Additional OSH guidance			✓	✓	✓	✓	✓	✓
Extension of CMD to R 1A/1B	Substitution, closed systems			✓	D	✓	✓	✓
	Exposure minimisation			✓	D	D	✓	✓
	IOELVs become BOELVs			✓*	✓*	✓**	✓*	✓*
	Record keeping			✓	D		✓	✓

Table C2-33: Policy Options and their relevant components							
Component	**O1-: Baseline (no guidance)**	**O1: Baseline (including OSH guidance)**	**O2: R 1A/1B in CMD**	**O3: R 1A/1B in CMD (derogations)**	**O3+: Joint declaration**	**O4: R 1A/1B in CMD, merge CAD and CMD**	**O5: R 1A/1B in CMD, merge CAD and CMD, modernisation**
Merging of the two directives						✓	✓
Threshold/non-threshold approach	C	C	C	I	I	C	C
Modernisation							✓
Add-on elements (BLVs, sensitisers)							✓
Notes: *Dark grey cells denote definite change when compared with the baseline. Light grey cells denote potential changes to the baseline, depending on whether individual substances are derogated or not (i.e. determined to have a threshold for adverse effects).* *D: Depends on whether the substance is derogated or not* *C: Collective (risk classification based) I: Individual (individual substance based)* **not a direct legal consequence of the extension of the CMD to R 1A/1B substances but modelled for the purposes of this Impact Assessment* ***under Option 3+, BOELVs would be established for all (or most) R 1A/1B substances*							

C2.4 Costs for companies

Compliance costs are defined as the additional costs of complying with a legal requirement introduced as a result of the Policy Options. Administrative costs are defined as the costs of meeting legal obligations to provide information, either to public authorities or private parties. Both types of costs are expected to arise under some of the Policy Options.

The approximate total number of companies, percentage of companies and costs expected to be incurred by companies under the different components are set out in the tables below.

Table C2-34: Total number of companies affected by the different scenarios			
Component	**Low**	**Mid**	**High**
Consideration/documentation of substitutability	52,000	78,000	104,000
Substitution	5,000	26,000	39,000
Consideration of a closed system	179,000	237,000	258,000
Installing closed systems	10,000	23,000	40,000
Minimisation – illustrative calculation LEV 1-LEV2	29,000	58,000	87,000
Keeping records for 40 years	159,000	223,000	287,000
Source: RPA analysis			

Table C2-35: Total annualised cost for companies under the different scenarios			
Component	**Low (€ million)**	**Mid (€ million)**	**High (€ million)**
Consideration/documentation of substitutability	10	15	20

Table C2-35: Total annualised cost for companies under the different scenarios			
Component	**Low (€ million)**	**Mid (€ million)**	**High (€ million)**
Substitution	Not quantified but potentially high	Not quantified but potentially high	Not quantified but potentially high
Consideration of a closed system	180	210	260
Closed systems	60	120	240
Minimisation	80	170	250
Keeping records for 40 years (annual cost)	80	110	140
Source: RPA analysis *Note: minimisation is based upon the companies implementing LEV1, LEV2 or other RMMs based upon an equal three-way split. The annualised cost of RMMs is taken as €1,000 per year per enterprise*			

The costs as they relate to each Policy Option are set out below.

Table C2-36: Costs for companies under the different Policy Options (annualised cost in € million)									
Component			O1	O1+	O2	O3	O3+	O4	O5
Additional OSH guidance			0	++	++	++	++	++	++
Extension of CMD to R 1A/1B	Substitution	Co.	0	0	++ (€10-20m)	+*	++ (€10-20m)	++ (€10-20m)	++ (€10-20m)
		Im.	0	0	Potentially ++++[1]	++*	Potentially ++++[1]	Potentially ++++[1]	Potentially ++++[1]
	Closed systems	Co.	0	0	+++ (€180-260m)	++*	+++ (€180-260m)	+++ (€180-260m)	+++ (€180-260m)
		Im.	0	0	+++ (€60-240m)	++*	+++ (€60-240m)	+++ (€60-240m)	+++ (€60-240m)
	Exposure minimisation		0	0	+++ (€80-250m)	++*	++ (less than under O2, 4, 5)[2]	+++ (€80-250m)	+++ (€80-250m)
	lOELVs -> BOELVs		0	0	+	+	+	+	+
	Record keeping		0	0	++ (€80-140m)	+*	Unknown	++ (€80-140m)	++ (€80-140m)
Additional BOELVs			+	+	+	+	++++[3]	+	+
Merging of the two directives			0	0	0	0	0	+ (familiarisation)	+ (familiarisation)
Threshold/non-threshold approach			0	0	+++[4]	0	++[4]	+++[4]	+++[4]
Health surveillance/BLVs			0	0	0	0	0	0	Unknown
Sensitisers			0	0	0	0	0	0	Potentially +++[5]
Modernisation			+[6]	+[6]	+[6]	+[6]	+[6]	+[6]	Unknown

Notes:
All cost quantifications are illustrative.
Co.: consideration, Im.: implementation.
Qualitative assessment scale: Highest costs to highest benefits: ++++ +++ ++ + 0 + ++ +++ ++++ Key: ++++: very high costs, +++: high costs, ++: medium costs, +: limited costs, 0: no costs.
**less than under options with no derogation*
1: Cost unknown but potentially very high. Although substitution can result in cost savings over the long-term in instances where operating costs can be reduced, it is expected that in most instances companies would have switched to the alternative themselves if it were cheaper over the long term.
2: Due to derogations for some substances.
3: It is possible that the general trend towards more OELs would see additional BOELVs adopted even under the baseline. However, due to the central role of BOELVs in achieving a derogation from exposure minimisation, it is expected that the process of introducing BOELVs would be significantly accelerated under Option 3+, with more BOELVs being adopted over the coming, say, 5-10 years. As a result,

Table C2-36: Costs for companies under the different Policy Options (annualised cost in € million)							
Component	O1	O1+	O2	O3	O3+	O4	O5
companies would incur greater costs under Option 3+ due to the need to comply (and demonstrate compliance) with these BOELVs. Although the analysis carried out under this study for the 30 substances suggests that most exposure is already below the thresholds for reprotoxic effects, it is expected that some companies could incur relatively high costs. This is mitigated by means of the exposure minimisation derogation under Option 3+. 4: Unnecessary costs for substances that are deemed non-threshold due to hazard classification but which have a threshold. 5: Although there is a large number of sensitising substances, it is expected that minimisation is already extensively practiced. 6: Due to lack of clarity under the baseline							

The aggregation in the table above is by simple summation. Adjustments have been made to control for double-counting in cases where a company is engaged in several sectors/applications and the risk management measures and hence costs linked to one group of reprotoxic chemicals would also address exposures to another group of reprotoxic chemicals.

Since some or all of the cost increase could be transferred further down the value chain through an increase in the price of the goods, the net impact on companies may be more limited (depending on levels of competition and price elasticities of demand).

C2.5 Sensitivity analysis

Throughout this section, the percentage of companies out of all companies in the industries that are expected to use reprotoxins is assumed to be 2%. This percentage is difficult to determine and has a significant impact upon the numbers of companies affected and the potential costs. In Table C2-37, the number of companies affected by the main issues is given for two further percentages, 1% and 3%. As can be seen in the table below, the numbers deriving from the 2% assumption reflect the values already shown in the table above about the total number of companies affected. The range is determined by the rounded lower and upper bound values under the Low and High scenarios. Ranges associated with the other percentages are then derived accordingly from the ones of the 2% scenario. The 1% value is based upon SUMER (2015), while the 3% value is very likely to be a considerable overestimation erring on the side of caution.

Table C2-37: Companies impacted			
Measures	% of companies assumed to use R 1A/1B		
	1%	2%	3%
Considering substitution	25,000 – 50,000	50,000 - 100,000	75,000 – 125,000
Substitution	2,500 – 20,000	5,000 - 40,000	7,500 – 60,000
Considering installing closed system	90,000 – 130,000	180,000 – 260,000	270,000 – 390,000
Installing closed system	5,000 – 20,000	10,000 – 40,000	15,000 – 60,000
Implementing additional RMMs to minimise exposure	15,000 – 45,000	30,000 – 90,000	45,000 – 135,000
No. companies in MS where the requirement to keep records for 40 years would be newly introduced	80,000 – 145,000	160,000 – 290,000	240,000 – 435,000

The estimated costs under each Option, if the underlying assumption about the percentage of companies with exposure to Reprotoxic substances are changed from 2% to 1%, and to 3%, are illustrated in the following tables.

Table C2-38: Costs for companies under the different Policy Options (annualised cost in € million), assumption 1%									
Component			O1	O1+	O2	O3	O3+	O4	O5
Additional OSH guidance			0	++	++	++	++	++	++
Extension of CMD to R 1A/1B	Substitution	Co.	0	0	++ (€5-10m)	+*	++ (€5-10m)	++ (€5-10m)	++ (€5-10m)
		Im.	0	0	Potentially ++++[1]	++*	Potentially ++++[1]	Potentially ++++[1]	Potentially ++++[1]
	Closed systems	Co.	0	0	+++ (€90-130m)	++*	+++ (€90-130m)	+++ (€90-130m)	+++ (€90-130m)
		Im.	0	0	+++ (€30-120m)	++*	+++ (€30-120m)	+++ (€30-120m)	+++ (€30-120m)
	Exposure minimisation		0	0	+++ (€40-125m)	++*	++ (less than under O2, 4, 5)[2]	+++ (€40-125m)	+++ (€40-125m)
	IOELVs -> BOELVs		0	0	+	+	+	+	+
	Record keeping		0	0	++ (€40-120m)	+*	Unknown	++ (€40-120m)	++ (€40-120m)
Additional BOELVs			+	+	+	+	++++[3]	+	+
Merging of the two directives			0	0	0	0	0	+ (familiarisation)	+ (familiarisation)
Threshold/non-threshold approach			0	0	+++[4]	0	++[4]	+++[4]	+++[4]
Health surveillance/BLVs			0	0	0	0	0	0	Unknown
Sensitisers			0	0	0	0	0	0	Potentially +++[5]
Modernisation			+[6]	+[6]	+[6]	+[6]	+[6]	+[6]	Unknown

Notes:
All cost quantifications are illustrative
Co.: consideration, Im.: implementation
Qualitative assessment scale: Highest costs to highest benefits: ++++ +++ ++ + 0 + ++ +++ ++++ Key: ++++: very high costs, +++: high costs, ++: medium costs, +: limited costs, 0: no costs
**less than under options with no derogation*
1: Cost unknown but potentially very high. Although substitution can result in cost savings over the long-term in instances where operating costs can be reduced, it is expected that in most instances companies would have switched to the alternative themselves if it were cheaper over the long term.
2: Due to derogations for some substances.
3: It is possible that the general trend towards more OELs would see additional BOELVs adopted even under the baseline. However, due to the central role of BOELVs in achieving a derogation from exposure minimisation, it is expected that the process of introducing BOELVs would be significantly accelerated under Option 3+, with more BOELVs being adopted over the coming, say, 5-10 years. As a result, companies would incur greater costs under Option 3+ due to the need to comply (and demonstrate compliance) with these BOELVs. Although the analysis carried out under this study for the 30 substances suggests that most exposure is already below the thresholds for reprotoxic effects, it is expected that some companies could incur relatively high costs. This is mitigated by means of the exposure minimisation derogation under Option 3+.
4: Unnecessary costs for substances that are deemed non-threshold due to hazard classification but which have a threshold.
5: Although there is a large number of sensitising substances, it is expected that minimisation is already extensively practiced.
6: Due to lack of clarity under the baseline

Table C2-39: Costs for companies under the different Policy Options (annualised cost in € million), assumption 3%									
Component			O1	O1+	O2	O3	O3+	O4	O5
Additional OSH guidance			0	++	++	++	++	++	++
Extension of CMD to R 1A/1B	Substitution	Co.	0	0	++ (€15-30m)	+*	++ (€15-30m)	++ (€15-30m)	++ (€15-30m)
		Im.	0	0	Potentially ++++[1]	++*	Potentially ++++[1]	Potentially ++++[1]	Potentially ++++[1]

Table C2-39: Costs for companies under the different Policy Options (annualised cost in € million), assumption 3%									
Component			O1	O1+	O2	O3	O3+	O4	O5
	Closed systems	Co.	0	0	+++ (€270-390m)	++*	+++ (€270-390m)	+++ (€270-390m)	+++ (€270-390m)
		Im.	0	0	+++ (€90-360m)	++*	+++ (€90-360m)	+++ (€90-360m)	+++ (€90-360m)
	Exposure minimisation		0	0	+++ (€120-375m)	++*	++ (less than under O2, 4, 5)[2]	+++ (€120-375m)	+++ (€120-375m)
	IOELVs -> BOELVs		0	0	+	+	+	+	+
	Record keeping		0	0	++ (€120-210m)	+*	Unknown	++ (€120-210m)	++ (€120-210m)
Additional BOELVs			+	+	+	+	++++[3]	+	+
Merging of the two directives			0	0	0	0	0	+ (familiarisation)	+ (familiarisation)
Threshold/non-threshold approach			0	0	+++[4]	0	++[4]	+++[4]	+++[4]
Health surveillance/BLVs			0	0	0	0	0	0	Unknown
Sensitisers			0	0	0	0	0	0	Potentially +++[5]
Modernisation			+[6]	+[6]	+[6]	+[6]	+[6]	+[6]	Unknown

Notes:
All cost quantifications are illustrative
Co.: consideration, Im.: implementation
Qualitative assessment scale: Highest costs to highest benefits: ++++ +++ ++ + 0 + ++ +++ ++++ Key: ++++: very high costs, +++: high costs, ++: medium costs, +: limited costs, 0: no costs
**less than under options with no derogation*
1: Cost unknown but potentially very high. Although substitution can result in cost savings over the long-term in instances where operating costs can be reduced, it is expected that in most instances companies would have switched to the alternative themselves if it were cheaper over the long term.
2: Due to derogations for some substances.
3: It is possible that the general trend towards more OELs would see additional BOELVs adopted even under the baseline. However, due to the central role of BOELVs in achieving a derogation from exposure minimisation, it is expected that the process of introducing BOELVs would be significantly accelerated under Option 3+, with more BOELVs being adopted over the coming, say, 5-10 years. As a result, companies would incur greater costs under Option 3+ due to the need to comply (and demonstrate compliance) with these BOELVs. Although the analysis carried out under this study for the 30 substances suggests that most exposure is already below the thresholds for reprotoxic effects, it is expected that some companies could incur relatively high costs. This is mitigated by means of the exposure minimisation derogation under Option 3+.
4: Unnecessary costs for substances that are deemed non-threshold due to hazard classification but which have a threshold.
5: Although there is a large number of sensitising substances, it is expected that minimisation is already extensively practiced.
6: Due to lack of clarity under the baseline

C2.6 Costs for public authorities

The impacts on public authorities, mainly at the national level (but in some Member States also at the regional level), are expected to include, for example:

- Cost of adapting national legislation and procedures to the new treatment of reprotoxins, to the merging the CMD and CAD, or to changes in requirements with respect to new approaches to risk management, the use of biomonitoring or the use of BLVs; and
- Enforcement of changes in requirements.

Legislative change costs are one-off costs, while enforcement costs will depend on the number of reprotoxins identified as relevant and the number of sectors and companies within these that would

be affected under each scenario. In principle, national authorities already undertake inspections and should be checking workplace conditions against REACH exposure scenarios, as they have the general obligation of protecting workers.

C2.6.1 Transposition costs

For the purposes of this impact assessment, it is assumed that all Member States, except Belgium, would have to revise their national legislation. It is also expected that the companies in those Member States would incur some cost due to the need to familiarise themselves with the revised legislation.

In practice, the exact costs would depend on the legislation itself and the regulatory model used in each country to implement the legislation. These costs are therefore likely to vary significantly between Member States (for example, Sweden is obliged to carry out an impact assessment on new EU legislation; it is expected that this may not be the case in all Member States).

As noted in RPA (2012)[68], one UK impact assessment states that "the costs of amending current regulations to implement a Directive are thought to be around £700,000" (around €800,000). Although no details are given by the source of this estimate on the basis for this calculation, it is expected that these costs relate to a rather substantial legislative change and would include those costs of making (e.g. preparing an impact assessment, preparing a transposition note and presenting the legislation before parliament), printing and publishing the legislation. This estimate is significantly higher than the cost estimated in UK Department for Transport (2011) which notes that "a combination of legal and technical resources as well as policy advisors are usually required to implement such a change, costing approximately £15,687 per amendment" (approximately €20,000).

A transposition cost of approximately €100,000 per Member States is assumed because the work involved in this transposition is potentially greater than in the previous OELs impact assessments, which assumed a transposition cost of €50,000 (RPA 2018)[69].

[68] RPA (2012): Ex-Post Evaluation and Impact Assessment Study on Enhancing the Implementation of the Internal Market Legislation Relating to Motor Vehicles, http://www.rpaltd.co.uk/documents/J746_MotorVehicleLegislation_FinalReport_publ.pdf

[69] RPA (2018) 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 (unpublished)

Table C2-40: Summary of national legislation in the EU-28							
Member State	A: CAD & CMD in one piece of legislation?	B: Same rules for CMs and Rs?	C: Substitution of Rs whenever workers exposed or likely to be exposed?	D: Closed system explicitly required as second RMM for Rs?	E: Exposure minimisation requirement for Rs?	F: CAD 11 R IOELVs binding?	G: Record keeping for >40 years for Rs?
Austria	No	Yes (except G)	Yes	Yes	Yes	Yes	Yes
Belgium	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Bulgaria	No	No	No	No	No	Yes	Yes[70]
Croatia	No	No	No	No	No	Yes	No
Cyprus	No	No	No	No	No	Yes	No
Czech Republic	No	Yes	Yes	Yes	Yes	Yes	Yes
Denmark	No	No	No	No	Yes	Yes	No
Estonia	No	No	No	No	No	Yes	No
Finland	No	Some (only C)	Yes	No	No	No	No
France	Yes	Yes	Yes	Yes	Yes	No	Yes[71]
Germany	Yes	Some	Yes	Yes	Yes (exempt if below OEL)	Yes	No
Greece	No	No	No	No	No	Yes	No
Hungary	No	No	No	No	No	Yes	No[72]
Ireland	No	No	No	No	No	Yes	No
Italy	Yes	No	No	No	No	No	No
Latvia	No	No	No	No	No	Yes	No
Lithuania	No	No	No	No	No	No	No
Luxembourg	No	No	No	No	No	Yes	No
Malta	No	No	No	No	No	Yes	No
Netherlands	No	No	No	No	No	Yes	No

[70] Health records: 50 years (Ordinance No. 3 of 25 January 2008 on conditions and order for implementation of activities of occupational medicine services)

[71] Medical records: 50 years (R4624-22 to 28)

[72] But 50 years for carcinogens

Table C2-40: Summary of national legislation in the EU-28							
Member State	A: CAD & CMD in one piece of legislation?	B: Same rules for CMs and Rs?	C: Substitution of Rs whenever workers exposed or likely to be exposed?	D: Closed system explicitly required as second RMM for Rs?	E: Exposure minimisation requirement for Rs?	F: CAD 11 R IOELVs binding?	G: Record keeping for >40 years for Rs?
Poland	No	No	No	No	No	Yes	No
Portugal	No	No	No	No	No	No	No
Romania	No	No	No	No (3)	No (3)	Yes	No
Slovakia	No	No	No	No	No	Yes	No
Slovenia	No	No	No	No	No	Yes	No
Spain	No	No	No	No	No	Yes	No
Sweden	No	Yes	Yes	Yes	Yes	Yes	No
United Kingdom	Yes (2)	Some	Where exposure	No	No	Yes	Yes

Sources: RPA analysis, Milieu/RPA 2012, COWI reports, Consultation Round 1, Consultation Round 2
Notes: 1: Germany: slight risk available for Rs.
2 CAD and CMD are in 1 legal instrument – COSHH except for lead which is in separate legislation
3 In round 2, responded that no changes to their national legislation would be required if closed systems or minimisation requirement were used for Rs. However, this contradicts their national legislation where Rs are covered by CAD requirements.
Orange cells - presumed/inferred

C2.6.2 Enforcement costs

No real differences in enforcement although use of CM (and under some of the Policy Options Rs) may be seen as increasing risk and thus flag up the company for an inspection but an increase in the total number of inspections not expected. None of the Policy Options thus appears to imply a far greater degree of enforcement work than currently required.

C2.6.3 Costs for the EU

These include:

- Producing guidance documents (Option 1), see section CC2.2.5
- Revising legislation, scientific committee delibarations, adoption of legislation, development of OELs.

C2.6.4 Total costs for public authorities

Table C2-41: Costs for public authorities under the different scenarios – annualised costs	
Response	**Annualised cost (€)**
Costs for the EU for the development of 50 OSH guidance documents	€10 million
Member State transposition costs	€3 million

C2.7 Working conditions

Substitution and installing closed systems lead to better working conditions for workers compared with the use of personal protection equipment (PPE). Substitution and closed systems mean that

- workers do not have to wear cumbersome PPE;
- rotation of staff is not required to ensure lower exposure levels;
- male and female staff do not have to be treated differently.

The CMD tends to direct companies towards considering substitution and then closed systems, with PPE viewed as the risk management measure of last resort. Therefore, overall, all of the Options tend to improve working conditions.

C2.8 Summary of the costs

The table below provides a summary of the cost associated with the main analysis conducted under the assumption that 2% of companies have workers potentially exposed to Reprotoxic 1A/1B substances and would thus incur some costs.

Table C2-42: Costs under the different Policy Options									
Component			O1-	O1	O2	O3	O3+	O4	O5
Costs for companies (annualised cost in € million)									
Additional OSH guidance			0	++	++	++	++	++	++
Extension of CMD to R 1A/1B	Substitution	Co.	0	0	++ (€10-20m)	+*	++ (€10-20m)	++ (€10-20m)	++ (€10-20m)
		Im.	0	0	Potentially ++++[1]	++*	Potentially ++++[1]	Potentially ++++[1]	Potentially ++++[1]

Table C2-42: Costs under the different Policy Options									
Component			O1-	O1	O2	O3	O3+	O4	O5
	Closed systems	Co.	0	0	+++ (€180-260m)	++*	+++ (€180-260m)	+++ (€180-260m)	+++ (€180-260m)
		Im.	0	0	+++ (€60-240m)	++*	+++ (€60-240m)	+++ (€60-240m)	+++ (€60-240m)
	Exposure minimisation		0	0	+++ (€80-250m)	++*	++ (less than under O2, 4, 5)[2]	+++ (€80-250m)	+++ (€80-250m)
	IOELVs -> BOELVs		0	0	+	+	+	+	+
	Record keeping		0	0	++ (€80-140m)	+*	Unknown	++ (€80-140m)	++ (€80-140m)
Additional BOELVs			+	+	+	+	++++[3]	+	+
Merging of the two directives			0	0	0	0	0	+ (familiarisation)	+ (familiarisation)
Threshold/non-threshold approach			0	0	+++[4]	0	++[4]	+++[4]	+++[4]
Health surveillance/BLVs			0	0	0	0	0	0	Unknown
Sensitisers			0	0	0	0	0	0	Potentially +++[5]
Modernisation			+[6]	+[6]	+[6]	+[6]	+[6]	+[6]	Unknown
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
Workers									
Working conditions			0	0	Improvement	Slight Improvement	Improvement	Improvement	Improvement

Notes:
All cost quantifications are illustrative
Co.: consideration, Im.: implementation
Qualitative assessment scale: Highest costs to highest benefits: ++++ +++ ++ + 0 + ++ +++ ++++ Key: ++++: very high costs, +++: high costs, ++: medium costs, +: limited costs, 0: no costs
**: Less than under options with no derogation*
1: Cost unknown but potentially very high. Although substitution can result in cost savings over the long-term in instances where operating costs can be reduced, it is expected that in most instances companies would have switched to the alternative themselves if it were cheaper over the long term.
2: Due to derogations for some substances.
3: It is possible that the general trend towards more OELs would see additional BOELVs adopted even under the baseline. However, due to the central role of BOELVs in achieving a derogation from exposure minimisation, it is expected that the process of introducing BOELVs would be significantly accelerated under Option 3+, with more BOELVs being adopted over the coming, say, 5-10 years. As a result, companies would incur greater costs under Option 3+ due to the need to comply (and demonstrate compliance) with these BOELVs. Although the analysis carried out under this study for the 30 substances suggests that most exposure is already below the thresholds for reprotoxic effects, it is expected that some companies could incur relatively high costs. This is mitigated by means of the exposure minimisation derogation under Option 3+.
4: Unnecessary costs for substances that are deemed non-threshold due to hazard classification but which have a threshold
5: Although there is a large number of sensitising substances, it is expected that minimisation is already extensively practiced
6: Due to lack of clarity under the baseline

C3 Benefits of the Policy Options

Key findings

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 estimates to be between 1 and 380 cases of reproductive ill health per year which have a monetary value of between €20,000 and €31 million – these values include the direct, indirect, and intangible costs borne by workers, their families, employers and the public sector. It should be noted that some of the impacts could not be quantified suggesting that these figures are underestimates, although it should be also noted that the assumptions made in the course of modelling of the reductions in ill health due to 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 arise under Options 2, 3+, 4 and 5 which all involve an extension of the CMD to cover Reprotoxic 1A/1B substances. Similar benefits would also arise under Option 3 but their realisation would be staggered as non-threshold substances would have to be included into the scope of the relevant requirements one by one. This means that, when a longer timeframe is taken as basis for assessment, the benefits from Option 3 are likely to be less than those from the Options which involve an immediate application of the CMD to Reprotoxic 1A/1B substances. All in all, Option 3+ can be expected to be the most effective one in terms of reducing reproductive ill health since it is likely to stimulate a process of accelerated introduction of BOELVs for all Reprotoxic 1A/1B substances that are not also C/M 1A/1B, with the experience of Carcinogens suggesting that BOELVs are particularly effective in reducing occupational exposure.

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 range presented above.

A comparison of the Policy Options for each impact category is provided at the end of this section.

Approach

The quantitative assessment relies on modelling that draws on a logical framework that is also used for the assessment of the costs of the Policy Options. The same assumptions regarding the share of companies that would substitute, implement a closed system or further reduce exposure. By way of simplification, these shares are used as proxies for the potential reductions in ill health. These reductions are applied to the estimates developed for the baseline scenario under the bottom-up and top-down approach.

Other impacts are assessed qualitatively. This assessment is informed by the consultation exercise carried out for this study as well as literature review.

Limitations/uncertainties

The impacts of the extension of the CMD to cover Reprotoxic 1A/1B substances 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 or not have a threshold for effects and what would be the value of a health-based OEL. As a result, estimation of the expected benefits from the Policy Options is difficult. Therefore, the analysis in this section should be taken as merely illustrative of the order of magnitude of the potential benefits. Some of this uncertainty is captured in the ranges presented for the benefit categories that could be quantified but much of it could not be included into the ranges.

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 cannot be reliably monetised. Although an adjustment for these effects is presented in this section for the bottom-up estimate, the uncertainty about this adjustment means that there is some potential for the underestimation of the benefits.

C3.1 Summary of the approach

This section sets out the approach to the assessment of the benefits of the Policy Options. This includes:

- identification of the most important benefit categories and the stakeholders that would benefit as a result of the Policy Options;
- summary of the approach to the estimation of reproductive ill health reduction that would occur as a result of the extension of the CMD to Reprotoxic 1A/1B substances; and
- summary of key assumptions and limitations/uncertainties.

C3.1.1 Determination of relevant benefit categories and stakeholders

Determination of the most important benefit categories

There are a number of potential benefits that may be brought about by a change in policy in terms of amending the CAD and CMD. The benefit categories in Better Regulation Tool #19[73] have been

[73] Better Regulation Tool #19, available at https://ec.europa.eu/info/files/better-regulation-toolbox-19_en

reviewed and the benefit categories that are expected to be most significant are set out in the table below.

Table C3-1: Potential benefits of policy change	
Benefit category	**Detail**
Benefits to workers and their families	
Reduced ill-health	Reduction in reproductive (and non-reproductive) ill health – benefits for workers and their families in terms of reduced direct, indirect, and intangible costs of ill health
Fundamental rights impacts	Reducing exposure to reprotoxins has the potential to improve the right to found a family, for affected workers
	The potential for reduced exposure strengthens the rights of the child, as yet unborn, as it improves their health
Benefits to companies	
Reduced absenteeism/ improved productivity	Reduced ill-health due to reduction in reproductive and non-reproductive ill health would result in reduced absenteeism and the associated productivity impacts
Level playing field within the EU	Less variation between the Member States
Administrative simplification	Common terminology used across all substances and better alignment of EU chemicals legislation
Benefits to the public sector	
Reduced health-care and social security expenditure	Reduced ill-health due to reduction in reproductive and non-reproductive ill health would result in reduced expenditure (health-care and social security) to support affected workers and their families.
Administrative simplification	Common terminology used across all substances and better alignment of EU chemicals legislation
Legal coherence and ease of enforcement	Increased simplification and legal coherence may improve enforcement
Other considerations	
Distributional effects	Differential effects according to gender and pregnancy

Relevant stakeholders

The relevant stakeholder groups are:

- Workers and families
- Companies
- Public sector

C3.1.2 Approach to the estimation of the reduction in ill health

The annual number of cases of ill health estimated for the baseline scenario using the bottom-up and top-down approach is taken as the starting point for the estimation of the reduction of ill health.

It has been possible to quantify the health-related benefits, which impact on workers, companies and the public sector, in the following ways;

- Workers: the impact of reduced ill-health has a direct effect on quality of life, that can be quantified using DALYs, a measure of burden of disease. A willingness to pay (WTP) for a DALY averted can be used to allocate a cost;
- Companies: reduced ill-health can impact companies in terms of reduced absenteeism and avoided compensation. The former can be quantified in terms of lost productivity. The latter is more difficult to quantify; and
- Public sector: reduced ill-health results in reduced expenditure by health-care and social-security organisations, in terms of direct medical costs and the cost of supporting affected workers and their families (sick pay, welfare payments, etc.).

These health-related benefits are covered in more detail in the following sections, but it should be noted that for the purposes of quantifying the effects of reduced ill-health on an EU worker population, potentially exposed to Reprotoxic 1A/1B substances, it is necessary to do so, using the following approach, as set out in the Better Regulation Guidelines:[74]

- DALY approach – to quantify the intangible, reduced burden of disease, quantified using the value of a statistical life year (VOLY)
- Cost of illness approach – which quantifies the direct and indirect costs of illness, including medical costs, social security expenditure and lost productivity.

Details of the methods used to value the impact of ill health on EU workers from exposure to reprotoxic substances Reprotoxic 1A/1B, given the number of cases, are detailed in report 1. It important to note, however, that while we address the impacts of reduced ill-health here, in terms of workers, companies and the public sector, the valuation has combined these stakeholders. This is for a number of reasons, which are elaborated on in more details in the following sections.

In brief, however, the distribution of the burden of productivity loss (including absenteeism) is complex and depends on the social security system in each MS, as well as the type of reproductive or developmental effect. While it is possible to estimate a cost for this, where appropriate, in terms of lost productivity, it is not possible to say who would bear this cost. In some member states it may be the worker, where as in others the company or social security system would pay for their absence.

It should also be noted that it was not always possible to separate direct and indirect costs out, making allocation of these costs to specific stake-holders impossible. This is the literature on which these costs were based, did not always present enough detail to enable this.

For these reasons, separate analyses of how reduced ill-health impacts on companies and the public sector is not possible, but have been accounted for in the calculations for the baseline.

All other impacts can only be considered qualitatively.

A more detailed overview of the approach is provided in Annex 1.

[74] European Commision (2017) Better Regulation Guidelines https://ec.europa.eu/info/sites/info/files/better-regulation-guidelines.pdf

C3.1.3 Summary of the key assumptions and limitations/uncertainties

There are a number of assumptions that had to be taken by the study team in order to derive quantitative estimates of the benefits under the different Policy Options. The key uncertainties/limitations stem from the following assumptions:

- For the purposes of this report, it is assumed that substitution would eliminate all reprotoxic risks, and thus reduce overall health risks. However, this would not be the cases where a Reprotoxic 1A/1B is substituted for another Reprotoxic 1A/1B (or an R2) substance and where the replacement substance is associated with more adverse non-reprotoxic health effects. Similarly, there is a potential for overestimation of the reduction where workers are exposed to more than one reprotoxic 1A/1B substance and, following the substitution of one substance, they would continue to be exposed to other reprotoxic 1A/1B substances;

- As a simplification, a closed system is modelled to eliminate all exposure. This is a simplification which may result in overestimating the reduction in ill health. Firstly, the interpretation of the term 'closed' may differ between companies. Secondly, even in cases where a fully enclosed system is put in place, some (potentially high-level) exposure may continue to occur during maintenance and cleaning;

- In terms of the health impacts from further exposure minimisation, the proportion of workers that would benefit is taken a proxy for the theoretical reduction in ill health. However, this estimate is highly uncertain because the extent to which companies would find it possible to reduce exposure and the stringency with which Member States would enforce this provision are not known. In addition, although a certain proportion of workers would benefit, many of these workers may already be exposed at sub-threshold concentrations. In practice, it is expected that the gains from exposure minimisation would be limited since most companies are already minimising risk and, once the threshold has been reached, further exposure minimisation does not provide any further reduction in reproductive ill health. In addition, as noted in the cost section, the companies that would have to reconsider whether further minimisation is possible are likely to be those that have already minimised to a level where there is no risk or only slight risk, and for which there is only very limited scope to accrue substantial benefits. Consequently, the reduction in ill health due to further exposure minimisation estimated in this section is most likely an overestimate; and

- The key uncertainty/limitation for the assessment of benefits in terms of reduced ill health is the exclusive focus on reproductive ill health. Non-reprotoxic effects could not be monetised within the scope of this study and a determination of the extent to which they would be reduced or increased as a result of the different Policy Option has not been possible. However, this limitation/uncertainty is mitigated within the framework of the baseline assessment whereby an adjustment factor is applied to account for the potential non-reproductive effects of the relevant Reprotoxic 1A/1B substances. However, this adjustment is highly uncertain and should be treated as merely illustrative of the fact that an exclusive focus on reproductive effects underestimates the overall health impacts of occupational exposure to the relevant Reprotoxic 1A/1B not C/M 1A/1B substances.

C3.2 Health-related benefits

It is expected that the Policy Options would result in a reduction in the incidence/prevalence of reproductive ill health, thus resulting in positive impacts on workers and their families, companies, and the public sector – the subsequent sections consider the benefits are considered as they relate to each of the stakeholder groups. Given the subtle differences between Policy Options, the following sections consider each of the key components of the Policy Options, regardless of which Policy Option they relate to, and then bring them together by considering the total reduction of ill health as it applies to each Policy Options. The discussion of each component always includes an indication of which Policy Option the component applies to; this is also summarised below.

Table C3-2: Policy Options and their relevant components

Component		O1-: Baseline (no guidance)	O1: Baseline (including OSH guidance)	O2: R 1A/1B in CMD	O3: R 1A/1B in CMD (derogations)	O3+: Joint declaration	O4: R 1A/1B in CMD, merge CAD and CMD	O5: R 1A/1B in CMD, merge CAD and CMD, modernisation
Additional OSH guidance			✓	✓	✓	✓	✓	✓
Extension of CMD to R 1A/1B	Substitution, closed systems			✓	D	✓	✓	✓
	Exposure minimisation			✓	D	D	✓	✓
	IOELVs become BOELVs			✓*	✓*	✓**	✓*	✓*
	Record keeping			✓	D		✓	✓
Merging of the two directives							✓	✓
Threshold/non-threshold approach		C	C	C	I	I	C	C
Modernisation								✓
Add-on elements (BLVs, sensitisers)								✓

Notes:
Dark grey cells denote definite change when compared with the baseline. Light grey cells denote potential changes to the baseline, depending on whether individual substances are derogated or not (i.e. determined to have a threshold for adverse effects).
D: Depends on whether the substance is derogated or not
C: Collective (risk classification based) I: Individual (individual substance based)
**not a direct legal consequence of the extension of the CMD to R 1A/1B substances but modelled for the purposes of this Impact Assessment*
***under Option 3+, BOELVs would be established for all (or most) R 1A/1B substances*

C3.2.1 Benefits to workers

Introduction of additional OSH guidance

For the purposes of this Impact Assessment, it is assumed that additional guidance will be developed under the baseline scenario and, consequently, under all the Policy Options with the exception of Option 1- (baseline without the guidance). This guidance would be developed at the EU level to identify the Best Available Techniques (BAT) based on examples from all EU Member States. The guidance documents would subsequently be made available in all EU languages.

The questionnaire consultation for this study asked whether it would be useful to introduce additional guidance and the responses are shown below. Most industry respondents (companies and industry

associations) do not believe that additional guidance is needed. In contrast, most national authorities or statutory bodies, OSH experts and trade unions would welcome such guidance. With regard to the high number of industry respondents that do not see the need for additional guidance, it should be noted that (due to self-selection of interested companies) respondents to the consultation exercise for this study are likely to be more familiar with OSH issues than the average company.

Table C3-3: Questionnaire responses – need for additional guidance (round 2 questionnaire)					
Response	COMPANIES % of respondents that answered this question (number of respondents)	INDUSTRY ASSOCIATIONS % of respondents that answered this question (number of respondents)	MEMBER STATES % of respondents that answered this question (number of respondents)	OSH EXPERTS % of respondents that answered this question (number of respondents)	TRADE UNIONS % of respondents that answered this question (number of respondents)
Yes	30% (4)	20% (2)	70% (13)	75% (3)	100% (7)
No	60% (8)	80% (9)	10% (2)	25% (1)	0% (0)
Do not know	10% (2)	0% (0)	30% (3)	0% (0)	0% (0)
No answer	N/A (3)	N/A (2)	N/A (2)	N/A (1)	N/A (1)
Question: Do you believe that there is a need for additional guidance on the interpretation and/or implementation of the CAD and CMD (or the national legislation that has transposed them in your Member State)? This could include, for example, the 'Best Available Techniques' for preventing/reducing exposure to the relevant substances in different industry sectors. Total number of responses: 15 companies, 13 associations, 19 Member State authorities or statutory bodies, 5 OSH experts, and 7 trade unions Totals may not add up due to rounding. *Source: Questionnaire responses.*					

The high number of industry respondents that do not agree that there is a need for additional guidance suggests that for any guidance to provide added value, it would need to go significantly beyond the guidance that is already available. In this regard, it is of interest that OSH BAT guidance at the EU level would be better placed to achieve this than national guidance since it could draw on best practice examples from all Member States, whilst national guidance documents are more likely to draw on a more limited pool of best practice examples. Additional OSH guidance would also be the next logical step building on the work done by EU-OSHA on risk assessment (Online Interactive Risk Assessment OiRA).[75]

The key benefit of additional OSH guidance would be in providing a forum for exchange of experiences and reference points for benchmarking; there is diversity in terms of performance and this would increase convergence, and provide a target for minimisation whilst still allowing a degree of flexibility and adaptation to technical progress.

Given the degree of disagreement about the need for additional guidance and the absence of information on specific measures that could additionally be implemented, it is not possible to reliably quantify the benefit of additional OSH guidance in terms of reduction of reproductive ill health. It should be noted, however, that the benefits of additional OSH guidance would be greater than any reduction in reproductive ill health since the advice in the BAT documents could also be applied by companies that expose their workers to other chemical hazards.

[75] https://oiraproject.eu/en

Many workers are exposed to several substances and additional guidance might be an opportunity to provide more information on combined/mixed exposure – this is an issue that was raised during consultation for this study. For example, an industry association expressed a desire to improve legislation to include guidance on combined/mixed exposure. Although there are methods for calculating, for example, the cumulative exposure index, based on endpoints,[76,77] these are not available for all chemical substances. Calculating exposure to all agents cumulatively, as stated in the CAD, may be too conservative, especially when exposure data below limit of quantification (LOQ) is also incorporated.

In conclusion, the OSH guidance has the potential to reduce exposure and consequently reproductive ill health, however, the extent of this reduction cannot be quantified. These benefits would be accrued under all scenarios with the exception of O1-. Due to the

Table C3-4: Policy Options and OSH guidance

Component	O1-: Baseline (no guidance)	O1: Baseline (including OSH guidance)	O2: R 1A/1B in CMD	O3: R 1A/1B in CMD (derogations)	O3+: Joint declaration	O4: R 1A/1B in CMD, merge CAD and CMD	O5: R 1A/1B in CMD, merge CAD and CMD, modernisation
Reduced ill health due to OSH guidance	0	++	++	++	++	++	++

Qualitative assessment scale: Highest costs to highest benefits: ++++ +++ ++ + 0 + ++ +++ ++++ Key: ++++ substantial benefits, +++ significant benefits, ++ some benefits, + limited benefits, 0 no change.

Substitution, closed systems, exposure minimisation

Inclusion of reprotoxic substances into the scope of the CMD would involve exposure to reprotoxic 1A/1B substances being prevented or minimised in line with the CMD. Substitution and closed systems would apply under Options 2, 3+, 4, 5 and, if a derogation were to be revoked for a specific substance, under Option 3. Exposure minimisation would apply under Options 2, 4, 5, and 3+ (unless derogated) and 3 (if derogation were to be revoked for a specific substance).

The actual reduction in the exposed workforce and/or the levels of exposure depends on a number of factors many of which are likely to differ by Member State or specific company, such as:

1. The existing national legislation: are reprotoxic 1A/1B substances already covered by the CMD-equivalent requirements?

2. To what extent is substitution, closed systems or further minimisation possible for the specific substance they are potentially exposed to?

3. The criteria and tests that would be used to determine whether substitution, closed system or further exposure minimisation are technically feasible?

With regard to Point 1, the typology of existing national legislation and whether the CMD-equivalent requirements apply to Reprotoxic 1A/1B substances are summarised in Table C3-5.

[76] INRS http://www.inrs.fr/publications/outils/mixie.html
[77] IRSST http://www.irsst.qc.ca/mixie/

Table C3-5: Summary of national legislation relating to prevention and control measures				
Member State	**Substitution of Rs whenever workers exposed or likely to be exposed?**	**Closed system explicitly required as second RMM for Rs?**	**Exposure minimisation requirement for Rs?**	**% of workers in the EU-28**
Austria	Yes	Yes	Yes	2%
Belgium	Yes	Yes	Yes	2%
Bulgaria	No	No	No	1%
Croatia	No	No	No	1%
Cyprus	No	No	No	0.2%
Czech Republic	Yes	Yes	Yes	3%
Denmark	No	No	Yes	1%
Estonia	No	No	No	0.3%
Finland	Yes	No	No	1%
France	Yes	Yes	Yes	11%
Germany	Yes	Yes	Yes (except if below OEL)	18%
Greece	No	No	No	2%
Hungary	No	No	No	2%
Ireland	No	No	No	1%
Italy	No	No	No	10%
Latvia	No	No	No	0.5%
Lithuania	No	No	No	1%
Luxembourg	No	No	No	0.2%
Malta	No	No	No	0.1%
Netherlands	No	No	No	4%
Poland	No	No	No	7%
Portugal	No	No	No	2%
Romania	No	Yes	Yes	4%
Slovakia	No	No	No	1%
Slovenia	No	No	No	0.5%
Spain	No	No	No	8%
Sweden	Yes	Yes	Yes	2%
United Kingdom	Where exposure	No	No	14%
Proportion of EU-28 workforce NOT YET covered by CMD-equivalent requirements	48%	59%	57%	-
Proportion of EU-28 workforce ALREADY covered by CMD-equivalent requirements	52%	41%	43%	-
Sources: % of workers in the EU-28 based on Eurostat (all NACE codes)				

The table above shows that, with regard to substitution, closed systems, and exposure minimisation, approximately one half of the EU-28 workforce exposed to Reprotoxic 1A/1B substances is not yet covered by national requirements that are equivalent or more stringent than the CMD. Please note that this conclusion does not take into account the possibility that some of these workers are already covered due to simultaneous exposure to a C/M 1A/1B substance.

Substitution

As discussed elsewhere in this report, the CMD implies that, unlike the CAD, substitution must be considered in all cases where exposure takes place or is likely to take place, 'independently' of any conclusion on the risk. This implies substitution would need to be considered for all Reprotoxic 1A/1B substances, implemented where 'technically possible' and evidence of consideration produced, where not 'technically possible'.

If the CMD were extended to cover Reprotoxic 1A/1B substances, it is expected that some companies would either carry out an additional assessment of the feasibility of substitution or provide additional documentation to the authorities. In addition, it is expected that the need to compile such documentation can improve the quality of the assessment process.[78] Also, as estimated in the cost section, this could result in some additional substitutions, although the proportion of companies that would substitute at least one Reprotoxic 1A/1B substance is expected to be relatively low (estimated in the cost section to be between 2% and 15% of the companies subject to the new requirement).

From this, it might be concluded that, as a liberal estimate, between 2–15% of companies with exposure to Rs would substitute at least one reprotoxic substance if the CMD was extended to Rs, in Member States where this was not already the case. It is expected that the 'real' number will most likely be at the lower end of the range.

Referring back to Table C3-5, it is possible to estimate a proportion of workers that could benefit from a more stringent substitution requirement. Table C3-6 summarises the number of workers that might benefit, in terms of prevented exposure, from substitution of reprotoxic substances, as a result of extension of the CMD to Reprotoxic 1A/1B substances.

Table C3-6: Estimate of number of workers benefiting from substitution of R 1A/1B substances	
Requirement	**Reduction in the number of workers exposed (number of workers no longer exposed)**
Substitution	2–15%* of 48% = 1–7%
*Note: *It is expected that the 'real' number will mostly likely be at the lower end of the range.*	

It should be noted that a change in the legal requirements would not be the only benefit from the inclusion of the reprotoxic substances in the CMD. This would also elevate the profile of Reprotoxic 1A/1B substances and result in companies paying more attention to them. An example of this is the French substitution campaign for CMR substances[79] and the advice provided to companies on substitution.[80]

Also, in France, the French national competence centre for industrial safety and environmental protection (INERIS) has established a national helpdesk providing operational support for companies interested in solutions to substitute bisphenols (BPA, BPS and BPF) in French and English. The website provides information on various families of molecules that are alternatives to bisphenols or

[78] For example, Germany: For CMR-substances detailed documentation including reasons for decision against substitution is required and shall be provided to enforcement bodies on request. (Hazardous substances ordinance §6(8)3, § 18(3). https://www.baua.de/EN/Service/Legislative-texts-and-technical-rules/Rules/TRGS/TRGS-600.html

[79] https://www.anses.fr/en/content/substitution-carcinogens-mutagens-and-reprotoxins-cmrs-role-anses

[80] https://www.substitution-cmr.fr/index.php?id=18&no_cache=1

alternatives to materials that require bisphenols along with examples of substitution and experiences in the supply chain.[81]

The analysis presented above is based on the assumption that, under the CAD, substitution is considered whenever risk is identified in a risk assessment. However, it is possible that, in some instances, risk assessments may not have been carried out by companies or may not be sufficiently comprehensive to identify the risks. An increased focus on substitution whenever workers are or are likely to be exposed (and the associated documentation requirements) could be of benefit in such circumstances.

The estimates presented above do not take into account the possibility of a regrettable substitution. Although the wording of Articles 6(2) of the CAD and Article 4 in the CMD prohibits regrettable substitution, it cannot be ruled out, for example in cases where there is less evidence to support the same classification for the alternative substance. For example, traditionally one of the key sectors of occupational exposure to Bisphenol A (BPA) has been the production[82] and use of thermal paper. However, from 2 January 2020, BPA can no longer be used in thermal paper in the EU[83]. A market survey carried out by ECHA (2018) suggests that EU paper manufacturers have started to substitute BPA with BPS but the volume of BPS used remains relatively limited. According to ECHA (2018)[84]:

> *The substitution of BPA by BPS is worrisome given that ECHA's Risk Assessment Committee in its opinion on BPA indicated that BPS "is suspected to have many of the same adverse health effects as BPA."*

With regard to reprotoxic effects, it is of interest that BPS only has a self-classification as R2 which is noted in its REACH registration dossier.[85]

It should also be noted that some companies go beyond their legal obligations, for example:

- a Croatian company noted that they consider substitution independently of risk assessment during purchasing; and
- a Danish company noted that they are running a hazard-based substitution programme for all CMR substances – if substitution is not possible, a risk assessment is carried out.

[81] INERIS (n.d.): National Helpdesk – Bisphenols substitution. The French national competence centre for industrial safety and environmental protection. Available at: https://substitution-bp.ineris.fr/en/documents

[82] About 30 % of thermal paper used in the EU is imported from China, India, Japan, Korea and the US, suggesting that 70% is placed on the EU market by EU manufacturers. Source: https://echa.europa.eu/-/bpa-being-replaced-by-bps-in-thermal-paper-echa-survey-finds. Thermal paper manufacturers in the EU include ETPA (European Thermal Paper Association) members, and Ricoh Industrie SAS (France), Blumberg GmbH & CoKG (Germany), Smith and McLaurin Ltd (UK). Source: https://echa.europa.eu/documents/10162/22863068/bpa_in_thermal_paper_report_en.pdf/0d93cd76-345e-2ed4-698f-a3beaea6d755

[83] Commission Regulation (EU) 2016/2235 concerning the restriction of bisphenol A in thermal paper will enter into force on 2 January 2020.

[84] https://echa.europa.eu/-/bpa-being-replaced-by-bps-in-thermal-paper-echa-survey-finds

[85] https://echa.europa.eu/brief-profile/-/briefprofile/100.001.137

On the other hand, an industry association responding to the consultation exercise for this study noted that "different approaches should be considered, provided a practical threshold exists, provisions to put in closed systems and substitution are not justified and disproportionate."

Closed systems

As discussed previously, according to the provisions of the CMD, where substitution is not 'technically possible', Article 5.2 requires that "the carcinogen or mutagen is, in so far as is technically possible, manufactured and used in a closed system."

The requirement for closed systems, is a measure that is not specifically referred to under the CAD. Therefore, if the requirements of the CMD are extended to Reprotoxic 1A/1B substances, one might expect closed systems to be introduced by additional companies, where substitution is not technically possible and where closed systems are technically possible.

As noted in Table C2-7, as a liberal estimate, 4–14% of companies with exposure to Reprotoxic 1A/1B substances in the Member States where this requirement is not yet in place would put in place at least some closed systems if the CMD was extended to Reprotoxic 1A/1B substances. It is expected that the 'real' number will most likely be at the lower end of the range.

Referring back to Table C3-5, it is possible to estimate a proportion of workers that could benefit from more stringent rules with regard to the use of closed systems. Table C3-7 summarises the share of workers that might benefit, in terms of prevented exposure, from increased use of closed systems.

Table C3-7: Estimate of the proportion of workers benefiting from closed systems	
Requirement	**Reduction in the number of workers exposed (number of workers no longer exposed)**
Closed system	4–14%* of 55-58%** = 2–8%
*Notes: *It is expected that the 'real' number will most likely be at the lower end of the scale. **Adjusted to account for the workers that would first benefit from substitution. The pre-adjustment proportion is 59%.*	

Although there is no universally accepted definition of a closed system, it can be expected that it would in principle eliminate all, or the vast majority, of exposure. Other measures would, however, have to be used to minimise exposure during activities such maintenance, cleaning, servicing, quality control, etc. This further supports the assertion that the real reduction in exposed workforce is most likely be at the lower end of the range presented in the table above.

Exposure minimisation

As discussed previously, according to the provisions of the CMD, where substitution or manufacture/use in a closed system is not 'technically possible', Article 5.3 requires that "the level of exposure of workers is reduced to as low a level as is technically possible."

Beyond the use of closed systems, the principle of minimising exposure to as low as technically possible can be exploited through the use of various other collective measures, restricted access areas, personal protection measures, etc.

As noted in the cost section, as a liberal estimate, between 10–30% of companies in the Member States where this requirement is not yet in place would introduce additional measures if the CMD was extended to Reprotoxic 1A/1B substances. It is expected that the 'real' number will most likely be at the lower end of the range.

In order to estimate the proportion of the worker population that might benefit from the minimisation principle, following inclusion of Reprotoxic 1A/1B substances into the CMD, we follow a similar method to that outlined for substitution and the introduction of closed systems. For further information see Table C3-5 (% of workers already covered by the different requirements) and Table C2-12 (exposure minimisation scenarios – companies introducing additional measures).

Table C3-8: Estimate of number of workers benefiting from exposure minimisation		
Requirement	**Reduction in the number of workers exposed (number of workers no longer exposed)**	**Reduction in exposure levels (no. of workers benefitting)**
Exposure minimisation	0%	10–30%* of 46-54%** = 5–15%
*Note: * It is expected that the 'real' number will most likely be at the lower end of the scale. ** Adjusted to account for the workers that would first benefit from substitution or a closed system. The pre-adjustment proportion is 57%.*		

In practice, it is expected that the gains from exposure minimisation would be limited since most companies are already minimising risk and, once the threshold has been reached, further exposure minimisation does not provide any further reduction in reproductive ill health. In addition, as noted in the cost section, the companies that would have to reconsider whether further minimisation is possible are likely to be those that have already minimised to a level where there is no risk or only slight risk, and for which there is only very limited scope to accrue substantial benefits.

On the other hand, exposure minimisation can mitigate the consequences of uncertainties surrounding estimations of threshold value. The situation in Denmark is worth noting in the context of the minimisation principle. In Denmark, the legislation requires companies to reduce exposure to all hazardous chemicals to a level that is as low as technically feasible. Their legislation states that "unnecessary exposure to substances and materials shall be avoided."[86] It is, therefore, important to Danish trade unions, to maintain this principle as, in the case of threshold substances in particular, it goes further than an extension of the CMD requirements might.

Occupational Exposure Limit Values

CAD IOELVs become CMD BOELVs

Although not a direct legal consequence of the inclusion of Reprotoxic 1A/1B substances into the CMD, this study considers the impacts of the 11 CAD IOELVs for reprotoxic substances becoming BOELVs under the CMD. These are taken as indicative of the impacts that would be experienced if future OELVs for reprotoxic substances were set as binding limits under the CMD. It can also be argued that, with regard to adopting further OELVs in the future, it the decision process for adopting an IOELV under the CAD is less consuming than for a BOELV under the CMD.

Consultation for this study suggests that 25 of the 28 EU Member States have transposed the 11 CAD IOELVs for substances that are Reprotoxic 1A/1B as binding. The exceptions are Finland, France, Italy, Lithuania, and Portugal. Furthermore, consultation revealed that voluntary initiatives, such as the Responsible Care initiative (Chemical Industries Association) require companies to go beyond compliance with OSH regulation and cover companies throughout the EU, including those that have

[86] http://engelsk.arbejdstilsynet.dk/en/regulations/executive-orders/292-arb-med-stoffer-og-materialer

not already transposed IOELVs as binding. In addition, there is a binding OEL and BLV for lead under the CAD.

Therefore, any benefits arising from existing IOELVs for Reprotoxic 1A/1B substances becoming BOELVs would be minimal as the majority of companies are already treating them as such, due to national legislation and voluntary initiatives.

Table C3-9: Policy Options and CAD IOELVs becoming CMD BOELVs

Component	O1-: Baseline (no guidance)	O1: Baseline (including OSH guidance)	O2: R 1A/1B in CMD	O3: R 1A/1B in CMD (derogations)	O3+: Joint declaration	O4: R 1A/1B in CMD, merge CAD and CMD	O5: R 1A/1B in CMD, merge CAD and CMD, modernisation
CAD IOELVs becoming CMD BOELVs	0	0	0	0	0	0	0

Qualitative assessment scale: Highest costs to highest benefits: ++++ +++ ++ + 0 + ++ +++ ++++ Key: ++++ substantial benefits, +++ significant benefits, ++ some benefits, + limited benefits, 0 no change

Additional BOELVs under the CMD

Under Option 3+, the establishment of BOELVs for all Reprotoxic 1A/1B substances (including those that currently do not have a limit value) would result in significant changes and a large number of workers being subject to new limits. Under Option 3+, in order to qualify for a derogation from the exposure minimisation requirement, the BOELV would have to be set at the level of the threshold and its observance would have to be confirmed by exposure measurements. It is therefore expected that this Option would have a significant positive effect in terms of lowering exposure by providing companies with a specific binding limit value rather than just a general obligation to lower exposure to levels that are as low as technically feasible.

An impact assessment would be required for each substance to determine whether a health-based or risk-based BOELV is appropriate. In the absence of these impact assessments, it is presently not possible to estimate the proportion of substances for which a health-based limit would be set (as opposed to substances for which a higher, risk-based, BOELV would be introduced based on socio-economic considerations). However, it is reasonable to expect that health-based BOELVs would be introduced for a number of substances, with the resulting exposure reductions being greater than those than can be achieved on the basis of a general exposure minimisation requirement. Although the general trend towards more BOELVs suggests that additional BOELVs for Reprotoxic 1A/1B non-C/M 1A/1B substances would be adopted under all the Options (but less so under Option 3), the central role of BOELVs under Option 3+ in terms of derogating from the exposure minimisation requirement means that their introduction is likely to be brought forward and any corresponding benefits are likely to be accrued sooner, and, thus be greater.

Table C3-10: Policy Options and additional OELVs for R 1A/1B substances							
Component	**O1-: Baseline (no guidance)**	**O1: Baseline (including OSH guidance)**	**O2: R 1A/1B in CMD**	**O3: R 1A/1B in CMD (derogations)**	**O3+: Joint declaration**	**O4: R 1A/1B in CMD, merge CAD and CMD**	**O5: R 1A/1B in CMD, merge, modernise**
Additional OELVs for R 1A/1B substances	++	++	++	++	+++	++	++
Qualitative assessment scale: Highest costs to highest benefits: ++++ +++ ++ + 0 + ++ +++ ++++ Key: ++++ substantial benefits, +++ significant benefits, ++ some benefits, + limited benefits, 0 no change							

Summary: the impact of CMD prevention and exposure minimisation measures

The health benefits that would be achieved as a result of prevented or reduced exposure are summarised below for the components assessed in this section: substitution, closed systems, exposure minimisation, and additional BOELVs under Option 3+. The following estimates are presented:

- For substitution and closed systems, the reduction in the annual incidence of reproductive ill health has been estimated on the basis of the reductions in exposed workforce estimated in the preceding subsections. By way of simplification, substitution and closed systems are expected to prevent all cases of reproductive ill health for the relevant workforce.
- For exposure minimisation, the number of workers that are currently exposed to reprotoxins at levels which might be regarded as significant is taken as the basis for the estimate of the workforce that would accrue benefits from further exposure minimisation. Although a greater number of workers overall would see reduced exposure under this Option, it is unlikely that they are exposed at levels above the thresholds for reprotoxic effects and thus are not expected to benefit for the purposes of the estimation of reduction in reproductive ill health.
- For additional BOELVs, it has not been possible to derive quantitative estimates and a qualitative assessment is provided.

Table C3-11: Estimate of number of workers benefiting from substitution of Rs, closed systems and exposure minimisation		
Requirement	**Reduction in the number of cases of reproductive ill health (% workers no longer exposed)***	**Reduction in exposure levels (% workers benefitting)**
Substitution	1–7%	-
Closed system	2–8%	-
Exposure minimisation	-	5–15%
Total	***3–15%***	***5–15%****
Notes: *'Numbers of workers no longer exposed' column assumes that workers are only exposed to one reprotoxic substance. ** This corresponds to 3,450-10,350 workers. As noted in Report 1, when taking no account of collective measures, around 8,000 women (from the range 2,000 to 30,000) and 61,000 men (from the range 25,000 to 152,000) may be exposed to reprotoxins at levels which might be regarded as significant. This suggests that around 69,000 workers (range: 27,000 to 182,000) may be exposed to reprotoxins at significant levels. It is important to restate that these estimates are based on uncertain data (with significant portions of the data missing) and, as such, are based on taking the geometric mean of the 'best' and 'worst' cases. To put these figures into context, 8,000 women represent less than 0.01% of the female EU workforce while 61,000 men represents around 0.04% of the male EU workforce.		

Assuming that between 3–15% of exposed workers would benefit from avoided exposure as a result of substitution and closed systems, the reduction in ill health and its monetary value is estimated below, based on the assumption that the burden of ill health would be reduced by 3-15%. The reduction achieved as a result of exposure minimisation is uncertain (the extent to which it would be technically feasible to reduce exposure is unclear) but the reduction in the exposed workforce is taken as a proxy and a further 15% reduction in ill health is estimated in the table below (max. 15% for substitution and closed systems and max. 15% for exposure minimisation, resulting in a theoretical total reduction of 30%).

Table C3-12: Reduction in the annual number of cases linked to substitution and closed systems (3 and 15% reduction) and theoretical estimate for substitution, closed systems, and exposure minimisation (30%)

Substances (Bottom-Up/Top-Down approach)	3% reduction* Annual cases	3% reduction* Monetary value (€ million per annum)	15% reduction* Annual cases	15% reduction* Monetary value (€ million per annum)	30%** reduction Annual cases	30%** reduction Monetary value (€ million per annum)
BU: All 'R 1A/1B but not C/M 1A/1B' repro effects only	0.8-6	0.02-0.09	4-31	0.08-0.4	8-62	0.16-0.8
TD: All reprotoxic substances (repro effects only)	1.4-38	1-3	7-191	6-16	14-382	12-31

Notes:
*Substitution and closed systems (3-15%)
**Substitution, closed systems and exposure minimisation (up to 30%)

Record keeping

Under Options 2, 4, and 5, some records would have to be kept for a minimum of 40 years. Under Option 3, this would depend on whether the derogation for the specific substance has been revoked.

The requirements to keep records relating to health and surveillance data for workers exposed to Reprotoxic 1A/1B substances varies between Member States, depending, in part, on whether the CMD has been extended to cover Reprotoxic 1A/1B substances. Analysis of the Member State requirements on record keeping shows that 23 Member States, which between them cover 68% workers exposed to Reprotoxic 1A/1B substances, do not have a 40-year record keeping requirement in place (see Table C3-5).

The feedback from consultation suggests that the majority of stakeholders do not support extending record-keeping requirements for Reprotoxic 1A/1B substances to 40 years, as they do not perceive a benefit from doing so. This included representatives from trade unions, industry associations, OSH experts and companies. Some companies expressed concern regarding the costs that might be involved in implementing and maintaining such an extension. This is addressed in the section on costs.

With regard to the potential benefits, despite a lack of agreement from stakeholders, there are some that are worth considering. The purpose of long-term record-keeping is to allow links to be made between exposure and any health effects. The requirement, in the CMD, to keep health records in a suitable form for at least 40 years from the date of last entry, reflects the fact that there is often a

long period between exposure and onset of ill health.[87] Due to the long-term and even inter-generational effects that are possible in some cases exposure of two reprotoxic Reprotoxic 1A/1B substances, applying the same requirements is justifiable.

Potential long-term and intergenerational effects of R 1A/1B substances

The table below summarises the potential long-term and/or inter-generational effects that might relate to the outcomes that have been observed in this report.

Table C3-13: Potential long-term and inter-generational effects relating to outcomes measured in the report

Reproductive / developmental effect	Potential long-term effects	Potential inter-generational effects
Reproductive effects		
Spontaneous abortion	N/A	N/A
Still birth	N/A	N/A
Impaired fertility – male	N/A	The off-spring of parents who had problems conceiving, may be at higher risk of fertility problems themselves
Impaired fertility – female	N/A	The off-spring of parents who had problems conceiving, may be at higher risk of fertility problems themselves
Pre-eclampsia	As the usual treatment for pre-eclampsia is delivery of the baby, off-spring are often pre-term and of low birth weight. These can have long-term consequences (see below).	
Developmental effects		
Low birth-weight	Low birth-weight, particularly very low birth weight, is associated with several long-term complications, including behavioural, respiratory, neurological, intestinal and vision problems, as well as hearing loss and a greater susceptibility to infections[a]	Women who were born with low birth weight or small for gestational age, are at increased risk of infertility[b]
Impaired cognitive development	Impaired cognitive development is not apparent until the child starts to develop and achieve certain developmental mile stones. The consequences may only be fully apparent during teenage years or later, when they mature to adulthood.	Unknown

[87] HSE (2019). *Record keeping*. Retrieved from Health and Safety Executive: http://www.hse.gov.uk/health-surveillance/record-keeping/index.htm

Table C3-13: Potential long-term and inter-generational effects relating to outcomes measured in the report		
Reproductive / developmental effect	**Potential long-term effects**	**Potential inter-generational effects**
Skeletal effects / abnormalities of the limbs	More subtle skeletal abnormalities may only come to light later in life, as the child develops.	Unknown
Microphthalmia	Variable effects on vision, some of which may be degenerative, causing more serious visual impairment later in life.	Unknown
Sources: *a: https://www.marchofdimes.org/complications/long-term-health-effects-of-premature-birth.aspx* *b: https://bmjopen.bmj.com/content/4/3/e004197.short?g=w_open_current_tab*		

Testicular dysgenesis syndrome

A good example for the potential of inter-generational consequences of exposure to environmental or industrial chemicals, is testicular dysgenesis syndrome (TDS). This is a hypothesis that proposes that common reproductive disorders of new-born and adult human males may have a common foetal origin. These disorders include poor semen quality, testis cancer, undescended testicles (cryptorchidism) and hypospadias. It is theorised that TDS may be increasingly common due to environmental influences, resulting in disruption of embryonal programming and gonadal development during foetal life (Skakkebæk, et al, 2001).[88] Thus off-spring may present at birth with a developmental effect, such as cryptorchidism, which can be corrected, but then go on to experience problems with fertility or develop testicular cancer, much later in life. Furthermore, there is evidence that environmental/chemical exposure may act either directly or via epigenetic mechanisms. Epigenetic mechanisms involve the alterations that effect gene expression, rather than alterations to the DNA sequences, and its effects may impact several generations post-exposure.[89,90]

Benefits of long-term record keeping

Fertility and foetal development are physiologically highly complex and the causes of infertility and birth defects is an area of much research and great uncertainty. Given that the science in this area is constantly evolving and that there is evidence, though uncertain, that there may be long-term and even inter-generational effects, it is possible to envisage some benefits from a more rigorous system of long-term record keeping, for at least 40 years.

In the same way that such records are used for carcinogens and mutagens, long-term records could allow links to be made between exposure and health-effects that occur a long time after. In a similar way, this information could prove useful to employees or companies in cases of litigation. In addition, given that our understanding of the science behind these effects is changing and growing, it is possible that the way we regulate these substances may also evolve. Long-term data could assist the Commission and national authorities in setting limit values and working practices in the most appropriate way.

[88] Skakkebaek NE et al. *Hum Reprod* 2001; 16: 972–8.
[89] Skakkebaek NE et al. *Physiol Rev* 2016; 96: 55–97.
[90] Das L et al. *Frontiers in Bioscience* 2017; 9: 509–35.

Table C3-14: Policy Options and information benefits from the 40 year record keeping requirement							
Component	**O1-: Baseline (no guidance)**	**O1: Baseline (including OSH guidance)**	**O2: R 1A/1B in CMD**	**O3: R 1A/1B in CMD (derogations)**	**O3+: Joint declaration**	**O4: R 1A/1B in CMD, merge CAD and CMD**	**O5: R 1A/1B in CMD, merge CAD and CMD, modernisation**
Information benefits of the 40 year record keeping requirement	0	0	++	+	0	++	++
Qualitative assessment scale: Highest costs to highest benefits: ++++ +++ ++ + 0 + ++ +++ ++++ Key: ++++ substantial benefits, +++ significant benefits, ++ some benefits, + limited benefits, 0 no change							

Add-on elements under Option 5

Health surveillance/BLVs

Air monitoring can only provide values in terms of external exposure to chemicals at the workplace and then only via the inhalation pathway. This may not account for all forms of exposure, with different processes potentially involving dermal and even oral exposure, depending on their nature and general hygiene practices. The benefits of introduction of a greater number of BLVs for different substances and the use of biomonitoring, may include:

- reflection of exposure from all routes;
- ability to monitor repeated and cumulative exposures over time;
- accounting for individual variations in toxicokinetics as well as other physicochemical and biological factors of workers, and their influence on the amount of chemicals absorbed for a given atmospheric concentration by different workers;
- accounting for storage of the chemical in the body and the possibility that its levels in blood can take a long time to decline;
- accounting for any personal protective equipment worn by workers during the handling of chemicals; and
- accounting for exposures in different work tasks across the working environment's entire working day/week.

Introduction of health surveillance/BLVs had the potential to reduce ill-health amongst workers, by taking into account other routes of exposure, besides inhalation; dermal and oral exposure, for example.

Sensitisers

As discussed in Report 1, the default position for sensitisers is that thresholds for adverse effects (induction of sensitisation) exist. Health-based reference values, based on the threshold assumption, can likely be determined for skin sensitisers (despite some methodological difficulties). However, for respiratory sensitisers, thresholds are difficult to determine with currently available models and methods.

ECHA presented a discussion paper for a case-by-case assessment of SVHC properties of sensitisers. In this discussion paper, properties of skin and respiratory sensitisers were compared with the

properties of CMR substances, to develop a rationale for responding to the criteria in Art 57 (f). Among these properties also the following question was raised:

- "Is derivation of a 'safe concentration' possible?"

This question was answered with **no** for C and M properties, **yes** for reproductive toxicants.

For both respiratory and skin sensitisers the response to this question was:

"NO –

- Difficult to establish the threshold dose for induction and elicitation
- Derivation of safe concentration is not routinely possible"

This suggests that, despite the existence of thresholds, a non-threshold approach may be more practical in terms of controlling exposure, especially considering that there are around 300–400 sensitisers. Consequently, there could be some benefits in terms of reduced ill health from the extension of the non-threshold approach to sensitisers.

However, it is not clear how extensive these benefits could be. Many companies are concerned about some individuals who are highly sensitive and also about the accuracy (or not) of current testing methodologies. This leads to a tendency to treat everybody as sensitive, and companies often prefer to do everything to minimise respiratory exposure rather than simply achieve the threshold. As a result, PPE is the preferred method of preventing skin sensitisation[91] to ensure that the most sensitive individuals are protected. Therefore, exposure minimisation is already practiced[92]. In conclusion, although for practical reasons, a non-threshold may be a useful approach for respiratory sensitisers, the magnitude of the benefits may be lesser than could be expected when the extent of occupational exposure to sensitisers is considered.

Table C3-15: Policy Options and the add-on elements (BLVs, sensitisers)

Component	O1-: Baseline (no guidance)	O1: Baseline (including OSH guidance)	O2: R 1A/1B in CMD	O3: R 1A/1B in CMD (derogations)	O3+: Joint declaration	O4: R 1A/1B in CMD, merge CAD and CMD	O5: R 1A/1B in CMD, merge CAD and CMD, modernisation
Add on-elements (BLVs, sensitisers)	0	0	0	0	0	0	+++

Qualitative assessment scale: Highest costs to highest benefits: ++++ +++ ++ + 0 + ++ +++ ++++ Key: ++++ substantial benefits, +++ significant benefits, ++ some benefits, + limited benefits, 0 no change

Threshold/non-threshold approach

As noted elsewhere in this report, the majority scientific opinion is that thresholds do exist for nearly all reprotoxins.

[91] Basketter, D., 2008. Skin sensitization: strategies for the assessment and management of risk. Brit J. Derm. 159(2), 267-273

[92] There may be great differences in degree of PPE and protectiveness between (very) small and large industry entities due to the in-house IH capabilities.

The Policy Options considered in this study determine whether a chemical should be treated as a threshold or non-threshold substance (for reprotoxic effects) in two different ways:

- **Hazard classification approach:** designation of all substances belonging to a hazard classification as T or NT, e.g. all Reprotoxic 1A/1B substances are treated as either having or not having a threshold for effects; and
- **Individual substance approach:** differentiation between the T and NT status of individual substances, e.g. some Reprotoxic 1A/1B substances have a threshold whilst others do not.

The hazard classification (block) approach is the default approach in EU OSH legislation. On the other hand, Germany, for example, makes a distinction between threshold and non-threshold substances. For threshold substances, health-based occupational exposure limit values (AGWs) are derived – this enables an exemption from the exposure minimisation requirement where exposure has been reduced to a level below the threshold.

Under Options 1,2,4, and 5, Reprotoxic 1A/1B substances are treated as a block (hazard classification approach) and are all subject to the same controls, designed for either T or NT substances. Options 3 and 3+ make it possible to differentiate between T/NT Modes of Action of individual substances, and tailor the approach to 'risk minimisation' or 'exposure minimisation'. Under Option 3, all Reprotoxic 1A/1B non-C/M 1A/1B substances would be derogated from the NT approach, and specific substances could be brought back into the scope of the NT approach if it can be proven that they act through a non-threshold MoA. Under Option 3+, the default approach would be to treat Reprotoxic 1A/1B substances as non-threshold substances and exposure minimisation would apply, unless a health-based BOELV is established and adhered to.

For the 30 substances (12 substances or substance groups) considered in detail in this study, most exposure is already below the thresholds for reproductive effects and no additional benefits can be accrued from the extension of the NT approach (exposure minimisation) to these substances. For those substances for which cases of reproductive ill health have been estimated, these could be reduced to zero by reducing exposure to the threshold. No further gains with regard to reproductive effects can be expected from subsequent reductions in exposure. However, the non-threshold approach would be appropriate in cases where the reprotoxic substance also causes other, non-threshold, effects or where the threshold for reproductive effects is at the level of background exposure.

A large number of stakeholders responding to the consultation exercise for this study stated that the 'individual substance approach' should also apply to carcinogenic and mutagenic substances. This would bring the system in line with the current scientific knowledge and OEL derivation process.

Currently a hazard-classification approach is taken to the designation of substances as threshold/non-threshold, and this would continue to apply under Options 1,2,4 and 5. An individual substance approach to differentiating between threshold and non-threshold status (Options 3 and 3+) would not provide further benefits in terms of reduced reproductive ill health. The non-threshold approach would be appropriate in cases where the reprotoxic substance also causes other, non-threshold, effects or where the threshold for reproductive effects is at the level of background exposure. This suggests that an individual substance approach is preferable to the block approach. Due to the uncertainty and emerging science behind this, it is not possible to quantify such a benefit, in terms of reduced ill health.

Table C3-16: Policy Options and the individual substance approach to T vs NT							
Component	**O1-: Baseline (no guidance)**	**O1: Baseline (including OSH guidance)**	**O2: R 1A/1B in CMD**	**O3: R 1A/1B in CMD (derogations)**	**O3+: Joint declaration**	**O4: R 1A/1B in CMD, merge CAD and CMD**	**O5: R 1A/1B in CMD, merge CAD and CMD, modernisation**
Individual substance approach T vs NT – efficiency/fairness	0	0	Negative impact	++	Positive impact (Significant positive impact if extended to C/M)	Negative impact	Negative impact
Qualitative assessment scale: Highest costs to highest benefits: ++++ +++ ++ + 0 + ++ +++ ++++ Key: ++++ substantial benefits, +++ significant benefits, ++ some benefits, + limited benefits, 0 no change.							

C3.2.2 Benefits to companies

The potential benefits to companies were summarised in Table C3-1, and will be expanded on here, taking into account the analysis of the Policy Option components.

Reduced absenteeism

As well as the potential benefits to workers of reduced ill-health, a reduction in exposure may benefit companies in terms of reduced absenteeism. This impact has been taken into account when calculating productivity costs (see the analysis of the baseline) and includes costs to the worker and their families, companies and public sector. A qualitative discussion of impacts in terms of absenteeism specifically, is listed below.

If we consider each of the potential outcomes, as estimated in the baseline for the identified reprotoxic substances, the potential for absenteeism, as a result, is summarised in the following table.

Table C3-17: Absenteeism relating to potential outcomes of the identified reprotoxic substances		
Reproductive / developmental effect	**Potential effects on absenteeism**	**Estimated impact**
Reproductive effects		
Spontaneous abortion	Spontaneous abortion is likely to involve a short amount of time of work	Estimate: 1–3 days
Still birth[a]	Still birth has profound effects on productivity, with 10% of bereaved parents remaining off work for 6 months	Avg. 26% of normal work after 30 days Avg. 63% of normal work after 6 months
Impaired fertility – female/female	Couples pursuing fertility treatment usually dedicate large amounts of time to attaining their goal.	Avg. 15.6 days (assuming 8 hr work day) over 18-month period per couple[b] Time spent did not vary significantly whether it was male or female factor infertility. No indication of how much of this was during work hours or outside.

Table C3-17: Absenteeism relating to potential outcomes of the identified reprotoxic substances		
Reproductive / developmental effect	**Potential effects on absenteeism**	**Estimated impact**
Pre-eclampsia	Absenteeism as a result of pre-eclampsia would largely be covered by maternity leave, although early delivery may result in some productivity loss if any planned cover is not yet in place.	Avg. days of absence (management by induction): 2.8 hrs Avg. days of absence (expectant management): 1.7 hrs[d]
Developmental effects		
Low birth-weight	Absenteeism as a result of low birth-weight/prematurity would largely be covered by maternity leave, although early delivery may result in some productivity loss if any planned cover is not yet in place. Very low birth weight may result in serious on-going consequences for the off-spring that could impact on the parent's ability to work, beyond the period of maternity cover	VLBW. Productivity loss over 18 months, based on working days lost valued according to earnings: €9,730 additional compared to full term infants[c]
Impaired cognitive development	In this study we eamined a 2-point decrease in IQ. It is highly unlikely that this would have an impact on absenteeism	None
Skeletal effects / abnormalities of the limbs	Absenteeism as a result of skeletal abnormalities would be covered by maternity leave. Serious on-going consequences for the off-spring could impact on the parent's ability to work, beyond the period of maternity cover, but this is negligible and extremely difficult to quantify.	0
Microphthalmia	Absenteeism as a result of skeletal abnormalities would be covered by maternity leave. Serious on-going consequences for the off-spring could impact on the parent's ability to work, beyond the period of maternity cover, but this is negligible and extremely difficult to quantify.	0
Sources: [a]Heazell A, et al. (2016) Lancet, 387; pp. 604–16; [b]Wu A, et al. (2013) Fertil Steril, 99; pp. 2025–30. [c]Cavallo M et al. (2015) Ital J Pediatr, 41; 59; [d]Vijgen S et al. (2010) BJOG, 117; 1577–85.		

As illustrated in Table C3-17, a degree of absenteeism can be identified for reproductive effects. Studies have, for example, attempted to quantify the number of days spent pursuing the goal of having a child for an infertile couple. On average, this is estimated as 15.6 days. One can also expect a

spontaneous abortion to result in a short amount of time (1–3 days) absent from work. Still birth, which has profound and long-term effects on mental well-being is likely to result in some long-term absence from work, as a result of grief. Indeed, evidence suggests that 10% of bereaved parents remain off work for 6 months, and that, on average, individuals retain 63% of normal work capacity after 6 months. This is difficult to quantify in terms of impact to the employer, however, as maternity leave was already expected and the legislation in EU countries varies widely with regard to maternity leave policies relating to stillbirth:

Searches of the International Labour Organization database show that only 12 of 170 countries with maternity benefit policies also have specific provisions for stillbirth:

- An average of 11 days leave for mothers (range 28–84 days)
- An average of 1 days leave for fathers (range 1–5 days).

Policies relating to stillbirth or miscarriage were identified in 3 European countries. Governments would be expected to incur costs in these countries, where they extend maternity rights to the parents of a stillborn child.

In terms of developmental effects, the impact of absenteeism to the employer is likely to be negligible, as EU countries have significant parental leave policies. For example, the average amount of time missed for work due to pre-eclampsia is very low because the study from which these figures were drawn was based in the Netherlands, where women are permitted maternal leave for 3 months after childbirth, therefore productivity loss did not include this first 3 months and only included the 9 months after maternal leave. It can be assumed that this would be the case for most European countries, indeed, most have longer periods of paternal leave, so absenteeism as a result of pre-eclampsia, would be negligible. There may however, be some impacts to the company on productivity, given that mothers with pre-eclampsia often deliver early, so any planned cover may not yet be in place. In this case, you might assume a friction cost. This would be very low overall, however, as (1) the time period of lack of cover is likely to very short, (2) the number of pregnant women working in an environment where there is risk of exposure, will be very low, if not zero, given that there are few women of child-bearing age working in these environments, and of those, if they become pregnant, they are likely, due to legislation and company policy, to be moved to other jobs.

Figure C3-1 illustrates the complex distribution of productivity losses between workers and their families and the public sector. This study was conducted in Italy and should, therefore be interpreted in the specific context of Italian society, where female participation to the labour market is low compared with the rest of Europe. It does, however, illustrate the complex nature of who bears the cost of lost productivity and the difficulties of defining this across several countries, each with their parental leave policies and social security systems.

Productivity loss as a whole, without allocating specifically to workers, companies or the public sector) has, however, been taken into account in our calculations of cost under the assessment of the baseline. These are accounted for in terms of DALYs and 'productivity loss'.

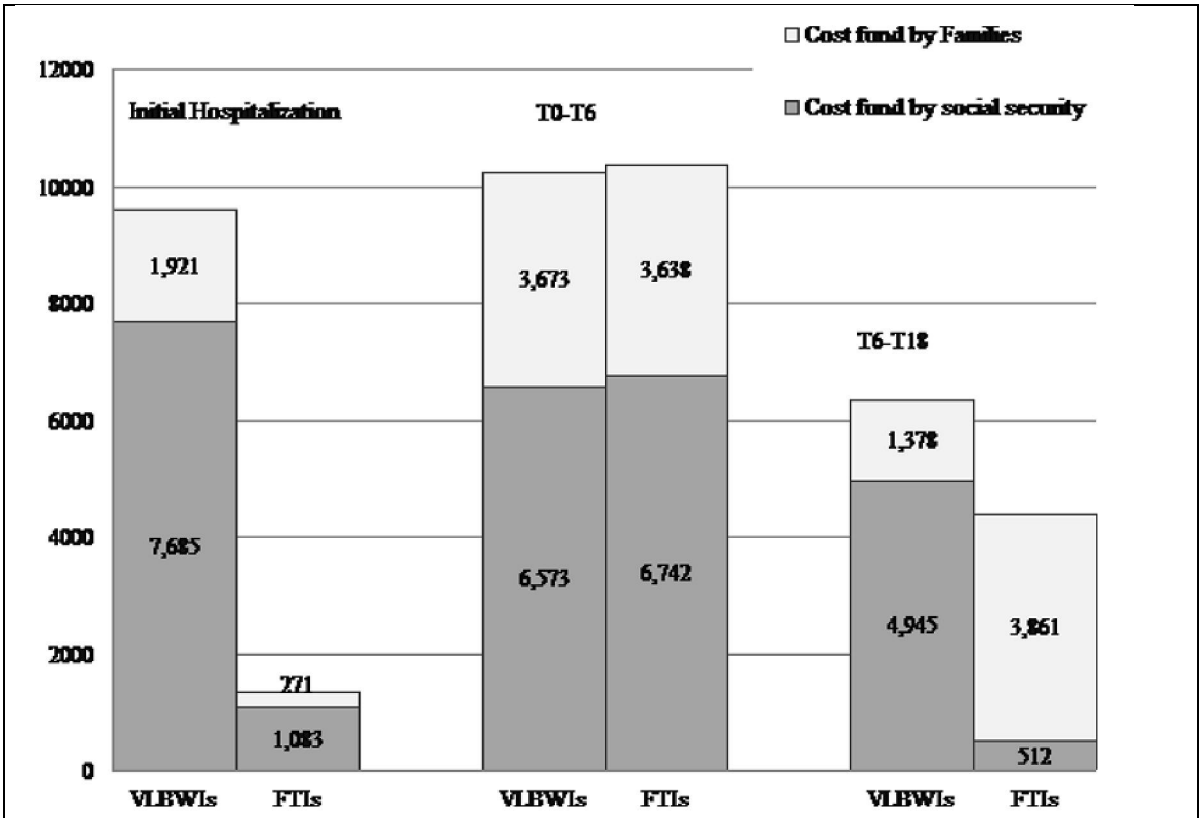

Figure C3-1: Productivity losses (€) from birth up to 18 months after discharge of very low birth weight (VLBW) infant
Source: Cavallo M et al. (2015) Ital J Pediatr, 41; pp. 59.

Avoided compensation

As indicated in the previous section, and section C3.2.3, compensation systems are different in every member state, therefore the impact of avoided compensation is difficult to attribute to a particular stake-holder (public sector or companies). Even in members states where private insurance companies act in the occupational field, there is always a public compensation system, as part of the social security system, covering at least part of the cost. The picture of who pays what is therefore a complex one and we have therefore not attempted to divide these by stake-holder, in terms of the benefits of reduced ill-health.

C3.2.3 Benefits to the public sector

The potential benefits to the public sector were summarised in Table C3-1, and will be expanded on here, taking into account the analysis of the Policy Option components.

Reduced health-care and social security expenditure

A reduction in exposure to Reprotoxic 1A/1B substances is likely to reduce spending by the public sector on health care and/or social security. These direct costs, as a result of health outcomes, including developmental and reproductive effects have been sourced from NHS reference costs[93] or the literature. NHS reference costs give an average unit cost to the NHS of providing defined services

[93] NHS. (2018) https://improvement.nhs.uk/resources/reference-costs/.

to NHS providers in a given financial year. They are a good indication of the cost of providing services for a specific health outcome. Where such information is available in other European populations in the literature, these have been used. Direct costs of each relevant developmental or reproductive effect used to estimate overall costs are summarised below.

Table C3-18: Direct costs relating to outcomes measured in the report				
Reproductive / developmental effect	**Direct cost**	**Proportion**	**Region**	**Reference**
Reproductive effects				
Spontaneous abortion – without intervention	€693	97.1%	England	NHS reference costs 2016/17
Spontaneous abortion – with intervention	€2,105	2.9%	England	NHS reference costs 2016/17
Still birth, including costs of investigations into cause of death	€2,223	100%	England/ Wales	Heazzell *et al.* (2016) *Lancet*
Still birth – additional cost of care in subsequent pregnancies	€1,978	100%	England/ Wales	Heazzell *et al.* (2016) *Lancet*
Impaired fertility – cost, per treated couple, of medically assisted reproductive treatment (irrespective out outcome)	€6,607	100%	Denmark	Christiansen *et al.* (2014) *Acta Obs Gyn Scand*
Pre-eclampsia – mean costs per woman. This figure includes direct medical costs, indirect costs to patient (travel and informal care), and productivity loss (not broken down in the reference)	€7,908	100%	Netherlands	Vijgen SMC *et al.* (2010) *BJOG*
Developmental effects				
Low birth-weight: normal to low – paediatric faltering growth with CC score 0	€1,112	100%	England	NHS reference costs 2016/17
Low birth-weight: low to very low – paediatric faltering growth with CC score 1	€1,438	100%	England	NHS reference costs 2016/17
Low birth-weight: very low to extremely low – cost of very low birth weight babies for first 18 months of life (includes direct and indirect costs)	€30,230	100%	Italy	Cavallo *et al.* (2015) *Italian J Paeiatr*
Impaired cognitive development	€0	-	Direct costs were difficult to quantify for a 2 IQ point decrease, so estimates for DALY loss were used alone.	
Skeletal effects / abnormalities of the limbs – total life-time costs for patients with spina bifida (including direct and indirect costs and increased morbidity)	€528,425	100%	Systematic review: European perspective	Yi Y *et al.* (2011) *Eur J Paediatr*
Microphthalmia	€0	-	Costs were difficult to quantify and with so few cases, considered unnecessary	

While the table above outlines mainly direct costs, depending on the source of information, it was not always possible to separate direct and indirect costs. For example, for very low birth weight babies and for pre-eclampsia, two thorough economic analyses had been conducted (Vijgen *et al.* 2010 and Cavallo *et al.* 2015, respectively). These used a bottom-up approach to calculating the indirect and direct costs of each outcome, but did not give detailed breakdowns of how these were distributed in

the final results. For our purposes, however, this is not required, as it is the overall cost to society that is required for our calculations.

As well as the difficulties of separating direct and indirect costs, given the sources of evidence, it is also difficult to attribute direct costs specifically to the public sector in terms of reduced expenditure on health and social care. This is because European nations fund their health services in different ways. Some countries, such as the UK, France, Italy, Norway, Spain and Sweden run government owned universal healthcare systems of some variety, others, including Germany, have a privatised but regulated system and the Netherlands has a more fully privatised system. This means that the burden of direct costs may vary from one nation to another. In some cases, private insurance companies bare the cost, where as in other the individual or public sector may bear some or all the cost.

For these reasons, separate analysis of just the reductions in healthcare and social security expenditure is not helpful, and these costs have been combined with indirect costs and DALY valuations to calculate the benefits of reduced ill-health overall.

Therefore, the degree to which exposure to Reprotoxic 1A/1B substances impacts on health-care and social security expenditure is already accounted for in calculations of the impact of reduced ill-health

C3.3 Other benefits

C3.3.1 Administrative simplification

There are several aspects of the Policy Options have a potential for administrative simplification.

- Inclusion of Reprotoxic 1A/1B substances into the scope of the CMD would simplify compliance for companies that have operations across several Member States, some of which may have included Reprotoxic 1A/1B substances into the scope of the CMD whilst other have not.

- Merger of the two directives would simplify compliance for companies that handle both Reprotoxic 1A/1B and C/M 1A/1B substances.

Companies

O1 baseline: This Option does not have any impacts for administrative simplification. Consultation responses indicate that there is currently demand for guidance, for example, on the application of best available technologies to decrease the aerodispersion of lead. However, this might mean more consistent application of the CMD and CAD across MS rather than administrative simplification as such.

Options 2, 3, 3+, 4 and 5: For Options 2, 3 and 3+, there is expected to be minimal administrative simplification, since those working with lead will need to consider both the CAD and CMD requirements. Under Options 4 and 5, the CAD and CMD are put together, thus there is some simplification in the sense that two directives become one. Under Option 4, the various requirements remain in parallel, but under Option 5, terminology is modernised and put in line with that of REACH. Option 5 therefore could have some benefits, since it is assumed to result in a more coherent directive than Option 4, and also provides for some consistency with REACH. As a regulation, REACH is expected to be more implemented consistently across MS, whereas the CAD and CMD directives have to be transposed into national legislation, allowing a degree of flexibility. Aligning terms with REACH could

result in Option 5 providing for more consistency of interpretation across MS, therefore benefiting companies with plants/operations in more than one MS. Options 4 and 5 could also benefit companies that deal with substances that are already covered by the CMD since they would be familiar with the requirements. Administrative simplification could therefore be a benefit of Option 5, and to some extent, Option 4.

For the purposes of this Impact Assessment, it is assumed that combining the two pieces of legislation in one document would result in those Member States where the CAD and CMD have been transposed through two or more pieces of legislation combining their legislation into a single law. However, it is recognised that this would not be a direct legal consequence of a merger of the two directives – as long as the legal requirements in them do not change, Member States may feel no need to amend their national legislation (in fact, it is possible that a merger of the two directives may not result in Member States changing their national legislation at all). This suggests that those Member States that have not extended the CMD to reprotoxins and would thus have to change their national legislation under Options 4 and 5 are the ones that are most likely to also use the opportunity to introduce one piece of legislation.

23 Member States have the CAD and CMD requirements in more than one piece of legislation, 20 of which currently do not have one set of rules covering C/M and R substances. These Member States cover 37% of all the workers exposed to reprotoxins in the EU.

Table C3-19: Simplification benefits of merging the CAD and CMD (round 2 questionnaire responses)

Response	COMPANIES % of respondents that answered this question (number of respondents)	MEMBER STATE AUTHORITIES OR STATUTORY BODIES % of respondents that answered this question (number of respondents)
Significant positive impact	10% (1)	5% (1)
Moderate positive impact	20% (3)	30% (5)
No change	10% (2)	20% (4)
Moderate negative impact	10% (2)	20% (4)
Significant negative impact	30% (5)	5% (1)
Do not know	10% (2)	20% (4)
No answer	N/A (0)	N/A (2)

Notes:
Question: Do you expect any potential impacts from this Option with regard to simplification from having one instead of two pieces of legislation?
Total number of responses: 15 companies, 19 Member State authorities or statutory bodies
Totals may not add up due to rounding.
Source: Questionnaire responses.

Stakeholders responding to the consultation exercise for this study have identified the following advantages of a single directive for CMR:

- a single CMR directive would bring legal coherence and better alignment of chemical legislation at the EU level; and
- a single framework would be easier to understand, implement and enforce, including for SMEs.

Table C3-20: Policy Options and their impact on administrative simplification							
Component	**O1-: Baseline (no guidance)**	**O1: Baseline (including OSH guidance)**	**O2: R 1A/1B in CMD**	**O3: R 1A/1B in CMD (derogations)**	**O3+: Joint declaration**	**O4: R 1A/1B in CMD, merge CAD and CMD**	**O5: R 1A/1B in CMD, merge CAD and CMD, modernisation**
Administrative simplification for companies	0	0	++	+	++	+++	+++
Qualitative assessment scale: Highest costs to highest benefits: ++++ +++ ++ + 0 + ++ +++ ++++ Key: ++++ substantial benefits, +++ significant benefits, ++ some benefits, + limited benefits, 0 no change							

Public authorities

Legal coherence

At the EU level, reprotoxins are treated differently across EU chemicals legislation. The REACH Regulation, Biocidal Products Regulation, Plant Protection Products Regulation and the Cosmetics Regulation all treat reprotoxins Cat 1A and 1B as being equivalent to carcinogens Cat 1A and 1B and generally equivalent to mutagens Cat 1A and 1B. This results in a lack of coherence across the legislation, with the outcome that workers using industrial chemicals may be exposed to a substance that is automatically banned under other legislation, unless specifically derogated. Extension of the scope of the CMD to cover Reprotoxic 1A/1B substances would result in an improvement in this regard.

Merging the two directives (Options 4 and 5) would provide an opportunity to improve legal coherence by unifying the terminology used in the two directives and clearly setting out the differences between the two sets of requirements in a single piece of legislation. However, it should be noted that, at a national level, Member States may feel no need to amend their national legislation since a merger in itself would not alter the substantive legal requirements.

Adoption of an individual substance approach to designation of Reprotoxic 1A/1B substances as threshold or non-threshold, as stipulated in Options 3 and 3+, has the potential to be of benefit in terms legal coherence. Given that scientific evidence regarding exposure to such substances, is continuously evolving and there is evidence that some C and M substances may have a threshold, while some R substances may not, a Directive or Directives, that have the flexibility to adapt to this, may prove useful in the future.

Modernisation of the language under Option 5 is expected to increase coherence with other EU chemicals legislation.

Table C3-21: Policy Options and their impact on legal coherence							
Component	**O1-: Baseline (no guidance)**	**O1: Baseline (including OSH guidance)**	**O2: R 1A/1B in CMD**	**O3: R 1A/1B in CMD (derogations)**	**O3+: Joint declaration**	**O4: R 1A/1B in CMD, merge CAD and CMD**	**O5: R 1A/1B in CMD, merge CAD and CMD, modernisation**
Legal coherence	0	+	++	+++	+++	+++	++++

Qualitative assessment scale: Highest costs to highest benefits: ++++ +++ ++ + 0 + ++ +++ ++++ Key: ++++ substantial benefits, +++ significant benefits, ++ some benefits, + limited benefits, 0 no change

Ease of enforcement

OSH guidance (Option 1) has the potential to provide a reference for benchmarking and thus provide clearer methodology to aid enforcers of existing regulation to set out achievable targets for industry. Such guidance could also provide clarity on the calculation and implementation of actions to control combined/mixed exposure. This is likely to aid in enforcement, making the process more consistent and efficient.

Inclusion of Reprotoxic 1A/1B substances into the scope of the CMD has the potential to ease enforcement by increasing the legal coherence for CMR substances which are treated as a group in other EU legislation (see above).

Modernisation of the Directives, as stipulated in Option 5, could include improvements in (for example):

- Language and terminology;
- Handling of risk assessment and residual risk; and
- Alignment of OSH and REACH methods.

The impact of such modernisation is not possible to quantify but such improvements are likely to ease the enforcement of the Directives.

Table C3-22: Policy Options and their impact on ease of enforcement

Component	O1-: Baseline (no guidance)	O1: Baseline (including OSH guidance)	O2: R 1A/1B in CMD	O3: R 1A/1B in CMD (derogations)	O3+: Joint declaration	O4: R 1A/1B in CMD, merge CAD and CMD	O5: R 1A/1B in CMD, merge CAD and CMD, modernisation
Ease of enforcement	0	+	++	+	++	++	+++

Qualitative assessment scale: Highest costs to highest benefits: ++++ +++ ++ + 0 + ++ +++ ++++ Key: ++++ substantial benefits, +++ significant benefits, ++ some benefits, + limited benefits, 0 no change

Reduced cost of developing OELs

The benefit of mirroring EU-level values would be the avoidance of the costs of scientific evaluation. Costs savings can be expected, in particular, under Option 3+.

C3.3.2 Level playing field

As noted elsewhere in this report, eight EU Member States have extended all or most of the requirements in the CMD to Reprotoxic 1A/1B substances, whilst other Member States have not. The legal analysis of the baseline scenario (see Report 1) shows that a range of different systems are place across the EU; companies with exposure to Reprotoxic 1A/1B substances are thus subject to different requirements depending on the Member State. The cost of the extension of the scope of the CMD to cover Reprotoxic 1A/1B substances which has been partially quantified elsewhere in this section of

the report can be taken as indicative of the order of magnitude[94] of the competitive advantage enjoyed by companies in the Member States with less stringent regulation compared with companies that are subject to all the requirements in the CMD.

Some improvements can be expected under Option 1 due to more consistent uptake of best practice as a result of availability of OSH guidance. However, these improvements will not significantly reduce the problem.

Thus, the current system is leading to an uneven playing field with companies in different Member States being subject to different requirements.

The Policy Options that would bring Reprotoxic 1A/1B substances into the scope of the CMD without derogations (Options 2, 4, 5) can thus be expected to lead to a more level playing field across the EU, with Options 3+ and 3 having this effect to a lesser degree.

Option 3+ would involve establishing BOELVs for all Reprotoxic 1A/1B substances and thus contribute to establishing a more level playing field with regard to exposure limits. Level playing field issues already arise under both the CAD and the CMD with Member States able to set different levels for IOELVs (including higher where they can provide justification) and BOELVs. They are also able to set national OELs for substances for which EU-level OELVs have not been set; the number of national OELs can vary from a few hundred to over 1000. Again, this impacts on the degree to which there is a level playing field across the EU at present.

The differences in the legal standing of IOELVs and BOELVs can give rise to issues with respect to ensuring a level playing field across the internal market. Under Article 3 (5) of CAD, for any chemical agent for which a BOELV value is established at EU level, Member States must establish a corresponding national binding OEL value which can be stricter but cannot exceed the Community limit value.[95] This helps ensure a level playing field across Member States and ensures that none can set its OEL so as to achieve a competitive advantage in relation to worker exposures to non-threshold chemical agents. However, the fact that Member States can set more stringent OELs has been identified by industry as leading to an un-level playing field across the EU. In contrast, as IOELVs are non-binding, Member States are able to set national OELs at higher levels, resulting in higher worker exposures and an un-even playing field across the EU.

A solution that can be implemented in a relatively short period of time would reduce the risk of individual member states taking action at national level, complicating the operations of EU companies.

[94] The estimated cost of the extension of the CMD presented in this chapter is the cost incurred by all companies in all Member States from a full application of all the CMD requirements and thus includes not only the cost of the companies that are subject to less stringent requirements achieving the level of their direct competitors but the cost arising from all companies achieving compliance with all the requirements in the CMD.

[95] Methodology for the Derivation of Occupational Exposure Limits Scientific Committee on Occupational Exposure Limits (SCOEL). Available at: https://circabc.europa.eu/sd/a/1bd6666f-5c8c-4d13-83c2-18a73dbebb67/SCOEL%20methodology%202013.pdf

Table C3-23: Policy Options and their impact on level playing field							
Component	**O1-: Baseline (no guidance)**	**O1: Baseline (including OSH guidance)**	**O2: R 1A/1B in CMD**	**O3: R 1A/1B in CMD (derogations)**	**O3+: Joint declaration**	**O4: R 1A/1B in CMD, merge CAD and CMD**	**O5: R 1A/1B in CMD, merge CAD and CMD, modernisation**
Level playing field	0	+	+++	++	++++	+++	+++
Qualitative assessment scale: Highest costs to highest benefits: ++++ +++ ++ + 0 + ++ +++ ++++ Key: ++++ substantial benefits, +++ significant benefits, ++ some benefits, + limited benefits, 0 no change.							

C3.3.3 Fundamental rights

The Charter of Fundamental Rights of the European Union (2000/C 364/01) Title II, Article 9 – Right to marry and right to found a family, guarantees "the right to marry and the right to found a family."[96]

Title III, Article 24 – The rights of the child, includes the statement that "in all actions relating to children, whether taken by public authorities or private institutions, the child's best interests must be a primary consideration."

It should, however, be noted that the matter of legal protection for unborn or future children is complex. It could be argued that legal personality currently starts at birth, so future and unborn children, in principle, may by implication not be legal persons that are subjects of rights. However, legal challenges, aiming to protect the unborn or future child from harm, have been brought to court.[97]

The United Nations Convention on the Rights of the Child, ratified by all the EU Member States[98] stipulates:

1. In all actions concerning children, whether undertaken by public or private social welfare institutions, courts of law, administrative authorities or legislative bodies, the best interests of the child shall be a primary consideration.

2. States Parties undertake to ensure the child such protection and care as is necessary for his or her well-being, taking into account the rights and duties of his or her parents, legal guardians, or other individuals legally responsible for him or her, and, to this end, shall take all appropriate legislative and administrative measures.

3. States Parties shall ensure that the institutions, services and facilities responsible for the care or protection of children shall conform with the standards established by competent authorities, particularly in the areas of safety, health, in the number and suitability of their staff, as well as competent supervision.

The Convention does not specify when childhood begins, leaving it open whether or not its rights and duties apply to unborn children.

[96] EUR-Lex (2010). Charter of Fundamental Rights of the European Union. https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2010:083:0389:0403:en:PDF.

[97] Ten Haaf, L. (n.d.) https://germanlawjournal.squarespace.com/s/GLJ_Vol_07_No_04_Pichon-fhld.pdf.

[98] United Nations (1989) https://www.ohchr.org/EN/ProfessionalInterest/Pages/CRC.aspx.

The EU also has an obligation to promote the protection of the rights of the child, in line with the Treaty on European Union. In 2006, the European Commission proposed a strategy for protecting the rights of the child, and in 2011 adopted the 'EU Agenda for the rights of the child'.

The degree to which each Policy Option impacts on the fundamental rights outlined above, would correlate positively with the degree to which ill-health is reduced, i.e. an improvement in fertility, as a result of reduced exposure to Reprotoxic 1A/1B substances, would impact positively on the right to found a family. In the same way, a reduction in developmental defects, as a result of reduced exposure to Reprotoxic 1A/1B substances, would impact positively on the rights of the child (as yet unborn). The effectiveness of the Policy Options in terms of improving fundamental rights thus correlates with the reduction in reproductive effects achieved under each of the Policy Options. In the immediate term, Options 2, 4 and 5 (followed by Option 3+) would therefore have the greatest beneficial impact on the fundamental right to found a family and the rights of the child. Option 3 would have some potential beneficial impact due to the delay in achieving benefits, the immediate impact (as well as total impact over a number of years) is likely to be less than under Options 2, 4, 5, as well as 3+.

Table C3-24: Policy Options and their impact on fundamental rights

Component	O1-: Baseline (no guidance)	O1: Baseline (including OSH guidance)	O2: R 1A/1B in CMD	O3: R 1A/1B in CMD (derogations)	O3+: Joint declaration	O4: R 1A/1B in CMD, merge CAD and CMD	O5: R 1A/1B in CMD, merge CAD and CMD, modernisation
Fundamental rights	0	+	+++	++	+++	+++	+++

Qualitative assessment scale: Highest costs to highest benefits: ++++ +++ ++ + 0 + ++ +++ ++++ Key: ++++ substantial benefits, +++ significant benefits, ++ some benefits, + limited benefits, 0 no change.

C3.3.4 Benefits from modernisation

The current system (CAD and CMD) dates back to the 1990s. The CMD was introduced in 2004, building on the requirements in Directive 90/394/EEC (which was repealed with the entry into force of the CMD). The CAD was introduced in 1998, repealing three directives from the 1980s (Directives 80/1107/EEC, 82/605/EEC and 88/364/EEC). In the intervening period, there have been numerous developments in modern occupational health and safety practice/terminology and legislation protecting workers, not least the introduction of the REACH regulation in 2006.

This section explores issues raised by stakeholders as well as highlighting different areas of the Directives where terminology used may be subject to interpretation and which might consequently lead to differences in how the obligations set out in the CAD and CMD are implemented.

Language and terminology

Roundtable discussion

A roundtable discussion was held on 12th November 2018 in Brussels, involving members of the study team, representatives from industry and trade unions, Member State authorities and staff of the Commission. Amongst other issues, the meeting discussed certain definitions within the CMD and CAD and approaches to risk assessment and risk management. Key observations by attendees are presented below.

"Risk Assessment" – there is wide variation in how this is interpreted and carried out. One of the participants argued that there is a need for minimum standards and a uniform approach to risk assessment in order to ensure accuracy as well as consistency.

"Slight Risk" – this term is used within the CAD and its definition is key since if any risk identified in the risk assessment carried out by the employer is determined to be a "slight risk" because of the quantities of a hazardous chemical agent present in the workplace, and the measures taken in accordance with paragraphs 1 and 2 of Article 5 are sufficient to reduce that risk, then Articles 6, 7 and 10 of the Directive do not apply. Article 6 covers specific prevention measures including substitution (preferable), reducing risk to a minimum level through engineering controls etc., introduction of measures such as ventilation/organisational measures and use of PPE. Article 7 deals with accidents, incidents and emergencies, and Article 10 deals with health surveillance.

The term "slight risk" is not defined in the legislation.

"Substitution" – stakeholders discussed the extent to which this should be considered mandatory under the two directives when considering threshold and non-threshold substances in the context of situations where limit values are being met. The issue of what is necessary to demonstrate that substitution has been considered and concluded it is not feasible (e.g. in terms of analysis, documentation etc.) was also highlighted.

"Technically feasible" – differences in the understanding of exactly what is meant by this term were raised, but noted that it is something that could be interpreted differently, leading to potential inconsistent application of the legislation.

"Minimisation" – the obligation in the CMD requires that the level of exposure of workers is reduced to as low a level as is technically possible. In the CAD, this is expressed as reducing exposure to a minimum by application of protection and prevention measures, consistent with the assessment of the risk. Similar to the discussion on substitution, this discussion also considered whether there was a need to continually reduce exposure when it is already below the limit value, with one stakeholder suggesting that the regulations leave this open to interpretation.

"Threshold vs non-threshold substances" – discussions centred around whether substances falling under each of these different categories (as opposed to grouping substances under their effects being carcinogenic/mutagenic or reprotoxic) should be treated differently when it comes to obligations for substitution, adopting closed systems and minimisation of exposure. The potential for compliance with limit values for threshold substances meaning that no further exposure reduction would be necessary was considered, with non-threshold substances still being subject to substitution, introduction of closed systems and reducing exposure to levels which are as low as technically possible.

The consequence of adopting this approach would be that if there is no agreed OEL, then the substitution, closed system and minimisation requirements would apply. A key issue is the fact that there are currently a limited number of indicative and binding OELs developed under both the CAD and CMD at EU level in comparison with the number of Reprotoxic 1A/1B and carcinogen/mutagen 1A/1B substances and it could take decades to develop and agree on significant numbers. In addition, there may also be measurement issues for OELs that might be set at very low levels. In addition, OELs are set for exposure to inhalation and for some substances and work processes, other routes of exposure (dermal, oral) are also important sources of exposure.

Questionnaires

Two key questions were put to industry, trade unions, MS and OSH expert stakeholders in relation to terminology and definitions during a second round of consultation covering the 5 Options in order to assess their potential impacts on industry, MS authorities as well as occupational safety and health. Responses identifying potential areas for consideration are presented below.

What, if any, impacts would there be if the opportunity to update/change any of the key terminology or definitions in the CAD or CMD were not used?

Industry associations:

- Negative impact because we could take the opportunity to review the way to define chemical agents: with a possible health based OEL or not. (x4)
- I think it is better to leave things as they are
- Significant negative impacts if derogations for substitution, closed systems and minimization of exposure are not put in place. The impact would be similar as with Option 2.

OSH experts:

- We lose the opportunity to modernize the legislation taking into account the current scientific knowledge. For example, differentiation between threshold and non-threshold substances, taking into account also e.g. non-threshold respiratory sensitizers.
- May be longer term impact on substances where regulator takes enforcement action, otherwise a limited impact. Could be some benefit in retaining existing language (familiarity) but this requires expertise to interpret, and this is lacking across all industry.
- Merging CAD and CMD into one single directive is a very useful approach, because many basic protective measurements are the same for CM-substances or non-CM-substances. The CAD is 20 years old (1998), the CMD is 14 years old (2004), so terminology and definitions urgently need to be updated and modernised to increase comprehensibility! One example: In the last years there have been many new evidences, e.g. concerning the derivation of health-based OELs for carcinogenic substances (see TRGS 900 in Germany: beryllium, diesel engine emissions, 1,2-epoxybutan, formaldehyde, indium phosphide, isoprene, propylene oxide, trichloromethane): no acute or chronic effects for the health of workers in general are to be expected if these OELs for carcinogenic substances are met

Trade Unions:

- Compliance and enforcement will suffer from not updating the terminology. But we fear that this Option will too time-consuming.
- If there are minimum possibilities to exposure, of course it helps
- If the CMD is extended with reprotoxic substances is still a major step forward regarding preventing workers from exposure. But if the CAD and CMD are merged, the terminology should be adapted.
- No positive impact

Do you expect any impacts from unifying the terminology in the CMD and CAD and bringing it into line with the terms used in the REACH Regulation?

Companies:

Of 22 respondents to the companies questionnaire, 8 indicated they anticipated no impacts on companies with 4 indicating there would be a significant or moderate positive impact, 2 indicating a significant or moderate negative impact and 8 providing no answer or "don't know" response.

Comments received in response to this question included:

- Unifying terminology with REACH would help, but real impact for the business would probably be non-existing.
- If the definitions of exposure and contact are clarified.
- In workplace we adopt the word "risk" as current terminology
- NO, not under Option 5. It would have been YES with Option 3, provided that, the existing Restrictions for general public and no intention of lowering the SCLs to a single GCL are taken in to account at the same time.

Industry Associations:

- It is currently not possible to asses all possible effects in detail. -In general, the terminology used in the directive is not the main factor influencing the impact of a regulatory option. The meaningful distinction of measures and definitions between CAD and CMD should be maintained. The focus should be on the harmonisation of occupational exposure limit values (multiple)
- In principle, the harmonization of OSH and REACH terminology is considered as being favourable on longer term. However, moderate to significant negative impact is expected on short-term, as REACH terminology is only partly understood by OSH experts. Vice versa REACH experts are not or only partly familiar with OSH terminology and approaches. Thus, significant efforts would be required for awareness raising and training to successful implementation into practice. The distinction of definitions and the provisions for workplace controls should hence be maintained between CMD and CAD. We propose that the focus of a harmonization should be on deriving occupational exposure limit values. (multiple)
- A meaningful distinction of measures and definitions between carcinogenic and non-carcinogenic substances should be maintained. This should nevertheless take into account that for threshold substances a minimization of exposure below that threshold can find an end. The focus should be on the harmonisation of occupational exposure limit values.

OSH experts:

- Terms used in REACH Regulation are not the same used in OHS (occupational health and safety) or to put it another way: Reach is product safety, CAD and CMD are occupational safety. e.g.: the "TOP-order of priority of protective measures" has a much greater significance in OHS than in REACH.

Trade Unions:

- Easier to understand. More compliance. Better prevention and protection.
- The same terminology often makes communication easier, but such an exercise should not reduce the level of protection.

Member State Authorities:

- Clearer text for better compliance.

- If understand from the question that it is about unifying the terminology of legislation that already applies, not about changing the protection level, so I do not see a significant compliance problem.
- Different terminology in legislation leads to regulation misinterpretations and non-compliance
- Compliance and understanding by employers would be improved with consolidated and modernised legislation that interfaces with REACH
- There would be less impact on companies, because the Member State legislation knows about most of the suggested measures.

Interviews

Finally, a series of interviews was also carried out to explore in greater depth some of the issue around the different Policy Options, and included asking stakeholders if they had any issues/views associated with terminology and definitions, as well as any views on potential ways to modernise the legislation with respect to risk assessment and risk management measures. Only a limited set of responses were forthcoming in these areas however.

Industry Associations:

- Having a substance in the CMD with a binding OEL could qualify as an exemption from authorisation under Article 58(2) of the REACH Regulation.

Article 58(2) states:

"Uses or categories of uses may be exempted from the authorisation requirement provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled. In the establishment of such exemptions, account shall be taken, in particular, of the proportionality of risk to human health and the environment related to the nature of the substance, such as where the risk is modified by the physical form."

- There needs to be a better definition of "technically feasible" – this could mean different things in different contexts.
- Should harmonise OELs and DNELs.
- BLVs – should make it easier to adopt these under the CMD.
- There should be harmonisation with REACH (REACH requires substitution that is technically feasible and economically viable, OELs vs DNELs).

National Authorities:

- The different use of language and interpretation of the two directives (CMD and CAD) is a problem

OSH experts:

- The distinction in legislation should take a scientific approach and be based on mode-of-action and the shape of the dose response curve, not just on the substance classification.
- Preference, amongst the Options, is to merge and modernise, based on threshold/non-threshold distinction

- The most scientific approach would be to distinguish CMD and CAD according to threshold/non-threshold mode of action.

Trade Unions:

- Wording, as regards the minimisation principle, in legislation is open to interpretation
- Some additional explanatory wording could be included within the legislation with respect to minimisation
- While a single piece of legislation would be more coherent, it is not necessarily needed at EU level
- If directives were to be merged, it is not just modernisation of language that would be helpful, but also the opportunity to take into account issues, such as sensitizers
- Threshold/non-threshold approach conflicts with exposure minimisation approach
- The science is always changing and it cannot be said for certain that all Rs have a threshold.
- Rs should be included together with C/M to ensure coherence with other legislation (REACH) which tends to group them

Conclusions

A range of terminology and definitions having the potential to be interpreted in a number of different ways (and consequently potentially leading to situations where compliance might be less than optimum) have been highlighted by stakeholders.

On balance, there appears to be a majority view across stakeholder groups on adopting an approach that distinguishes between threshold and non-threshold effects on an individual substance level, with different obligations (or priorities of the different obligations) for reducing exposure on that basis. There were strong views expressed on the industry side that where exposure levels are below the threshold, then there should not be a requirement to continually minimise as there would be no additional health benefits.

The use of a consistent approach to exposure limits across legislation was also raised as an important issue, given the current differences in approaches between OSH legislation (where OELs are the primary measure for exposure) and REACH (which focusses on DNELs/DMELs). Action 12 of the second REACH review (March 2018) by the European Commission already addresses this, as it aims to "interface REACH and OSH legislation." Specifically, one of the steps the Commission proposes is to "align methodologies to establish safe levels of exposure to chemicals at the workplace by first quarter 2019."[99]

It was also highlighted that where REACH requires substitution, it should be "technically feasible and economically viable", whereas the CMD requires it when "technically possible" and CAD requires it unless "the nature of the activity does not permit risk to be eliminated by substitution".

A caveat introduced to making changes in legislation, by trade unions and MS authorities in particular, was that any amendments/clarifications should not have the effect of reducing protection for workers.

In conclusion, although the precise benefits from this Option would depend on the nature and degree of modernisation, it can be expected that clarification of such terms as identified above and the

[99] European Commission. (2018) https://ec.europa.eu/docsroom/documents/28201.

adoption of consistent methodologies across EU chemicals legislation would likely assist in making obligations clear and unequivocal to employers, facilitating their compliance as well as enforcement by national authorities.

Table C3-25: Policy Options and modernisation							
Component	O1-: Baseline (no guidance)	O1: Baseline (including OSH guidance)	O2: R 1A/1B in CMD	O3: R 1A/1B in CMD (derogations)	O3+: Joint declaration	O4: R 1A/1B in CMD, merge CAD and CMD	O5: R 1A/1B in CMD, merge CAD and CMD, modernisation
Modernisation	0	0	0	0	0	0	+++
Qualitative assessment scale: Highest costs to highest benefits: ++++ +++ ++ + 0 + ++ +++ ++++ Key: ++++ substantial benefits, +++ significant benefits, ++ some benefits, + limited benefits, 0 no change.							

Discussion of risk assessment and residual risk

More than one consultee during the study has suggested that the effectiveness of both the CAD and CMD could be improved by the development of an agreed methodology for deriving safe limits. It is suggested that this would provide greater transparency on the level of residual risk for each substance for which an OEL is set.

The measures required in the CMD are based on the assumption that there is no safe level and thus that carcinogens require 'substitution' and 'use of closed systems' whenever technically possible; where this is not technically possible, then minimisation of exposure is required. Wherever it is not possible to substitute (or use a closed system), exposure is minimised but residual risk remains (although for health-based OELVs for carcinogens with an MoA-based threshold, any remaining risk only relates to scientific uncertainty, see below).

Box C3-1: Residual risk & carcinogens with an MoA-based threshold

Where a MoA-based threshold can be confidently established, the resulting recommendation for an OEL sets a level of exposure where it is assumed that there will be ***no expectation of a significant residual risk and that the remaining uncertainties are clearly described. In this case the employer, worker and public authorities can be assured that exposure at or below the OEL does not present an additional lifetime cancer risk to the workers.*** *At the same time, since there is no significant residual risk, this provides a level of confidence that the OEL will not be revised downwards over time as the legislator seeks to further reduce the level of any residual risk.* ***The only scientific reason for revising the OEL would be on the basis of new scientific evidence."***

With the exception of REMAINING UNCERTAINTY: "*Although a substance may have one or more MoA-based thresholds, it does not necessarily mean that the indicated level is safe - some uncertainties with regard to residual risk may remain. However, there should be sufficient evidence of an overall threshold to indicate that the risks are substantially lower below a certain level of exposure."*

Source: RAC/SCOEL

Risk characterising under REACH adopts a quantitative and semi-quantitative approach, and derived no-effect levels (DNELs) are established for each exposure scenario. The box below illustrates how exposure is assessed with respect to whether or not it is adequately controlled. Where the risk characterisation ratio (RCR) is <1, exposure is considered to be adequately controlled.

Box C3-2: Quantitative risk characterisation under REACH[100]

$$RCR = \frac{Exposure}{DNEL}$$

If exposure < DNEL → Risk is adequately controlled

If exposure > DNEL → Risk is NOT controlled

Non-threshold effects can be associated with a derived minimal effect level (DMEL) in the event that it is not possible to establish a DNEL. DMELs may be expressed as a low/theoretical risk i.e. tolerable risk or in terms of lifetime cancer risks e.g. a risk of cancer in 1 per 100,000 exposed or 1,000,000 exposed. The DMEL approach is considered particularly useful when assessing remaining/residual likelihood of risks for workers.

In the context of risk characterisation for non-threshold effects (e.g. for non-threshold carcinogenicity), a semi-quantitative risk characterisation can be conducted where if exposure is less than the DMEL, it is considered to be controlled to a risk level of low concern, whereas if it is higher, then the risk is NOT controlled.

In both cases the interpretation of the risk characterisation should be accompanied by a qualitative discussion, used to further elaborate the risk characterisation in both the quantitative and semi-quantitative approaches and should include uncertainties related to the exposure assessment as well as the hazard assessment. The ECHA guidance continues to include a description of the process required, if it is determined that risk is not controlled:

"If the risk characterisation shows that risk is not controlled, an iteration of the chemical safety assessment (CSA) is needed. This can be done by generating more refined exposure and/or hazard information or by introducing new RMMs. Iterations of the CSA process should continue until the risk characterisation shows that risks are controlled/risks are of very low concern or if it is concluded that it is not possible to demonstrate control of risk."

Residual risk exists where exposure risk remains after other realistic controls have been put in place.[101] In general terms, the default approach within the CMD is to deal with residual risk via the minimisation principle, requiring employers to continue to reduce exposure to as low as is technically possible.

Quantification of an accepted (or tolerated) risk for carcinogens is not part of the OEL methodology in many countries. However, some countries (e.g. the Netherlands, Germany) associate certain risk levels with acceptability. Acceptability may then be linked to an OEL. This may subsequently result in different OELs, depending on the size of the "acceptable" (or "tolerable") risk level.

In Germany[102], the approach to assessing excess risk from cancer is quantified and specific concentrations are regarded as "tolerable" (usually 4:1000) or "acceptable" (target: 4:100,000;

[100] Guidance on Information Requirements and Chemical Safety Assessment Part E: Risk Characterisation, Version 3.0 May 2016

[101] Adapted from Guidance for Human Health Risk Assessment, Volume III Human Health, Part B Risk Assessment, Draft Version 2.0 May 2015

[102] It is noted that other countries, such as the Netherlands and possibly Poland have also adopted similar approaches to assessing excess risk.

interim: 4:10,000). Health-based OELs are also calculated for carcinogens, but only become effective, if lower than the "tolerable risk" concentration from carcinogenic effects. In this case, the non-cancer health-based OEL becomes "binding" (upper limit). However, exposure reduction is still requested, as indicated by the "acceptable" cancer risk concentration ("indicative"). Figure C3-2 provides a graphical representation of these risk limits.

The list of OELs is published regularly, but updated only if new data are available and assessed (meeting of decision panel: twice/year).

In Denmark, there is a national methodology to derive OELs, but the respective publication was not available for evaluation. OELs are mainly health-based, but technical and socio-economic considerations can be included in setting the value. For carcinogens, Denmark is considering an acceptable risk as an excess cancer risk of 1:1,000,000 or in special cases 1:100,000 for working lifetime exposure. The list of OELs is updated when need arises, usually, when implementing EU OELs.

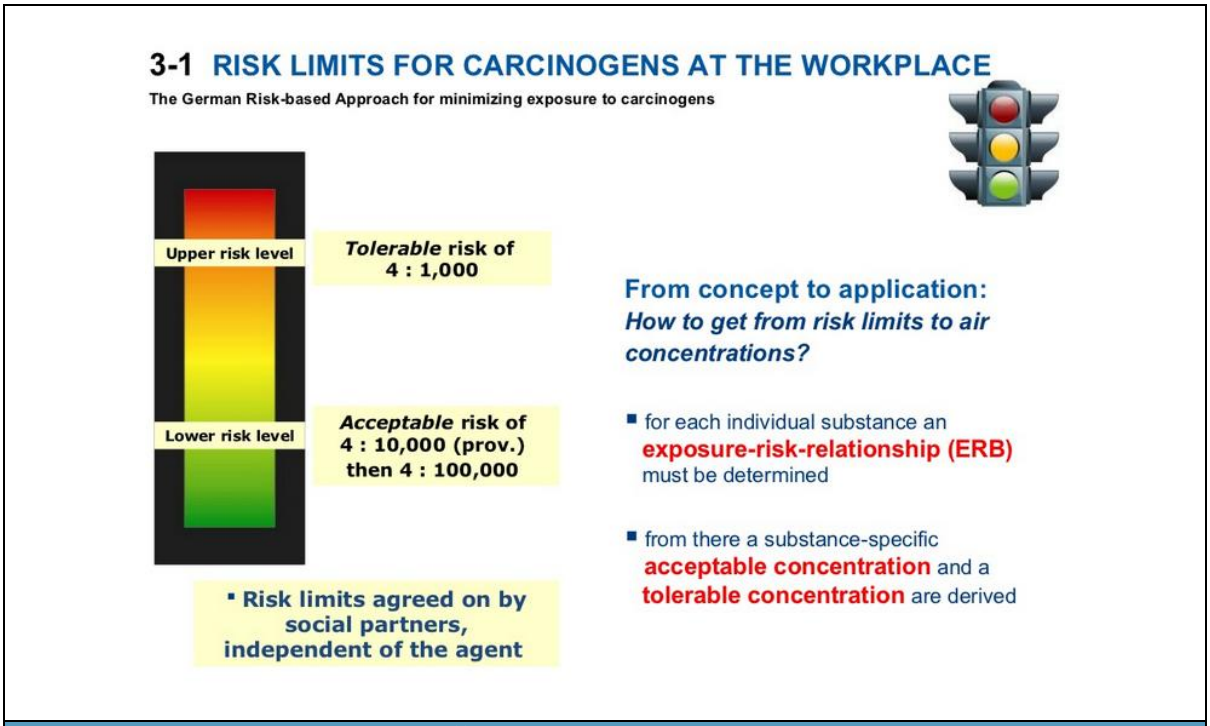

Figure C3-2: Risk limits for carcinogens[103]

In Ireland, the risk assessment approach of the Health & Safety Authority[104] is described as the consideration of the severity of a hazard and its potential outcomes together with the level of exposure and the numbers of persons exposed and the risk of that hazard being realised. There are a number of ways to calculate the overall risk from basic calculations using high, medium and low categories to complicated algorithms to calculate risks at Nuclear power stations and other high-risk work locations.

[103] Source: Derivation of OELs – The German risk-based approach for minimizing exposure to carcinogens, Gisela H. Degen, Leibniz Research Centre for working Environment and Human Factors at the TU Dortmund (IfADo), 2012

[104] https://www.hsa.ie/eng/Topics/Hazards/

The general approach taken is to ensure that the residual risk following implementation of control measures is 'as low as is reasonably possible' (ALARP) and that for a risk to be ALARP it must be possible to demonstrate that the cost involved in reducing the risk further would be grossly disproportionate to the benefit gained.

One Australian approach[105] to risk assessment for OSH involves a two-stage approach. The Workplace Manager and/or Management Occupational Health and Safety Nominee are required to ensure that an inherent and residual risk assessment is completed for each specific hazard and that it is added to the workplace OHS Risk Register. The inherent risk assessment is completed first and involves scoring the risk level of the hazard without considering any OHS controls. A second assessment of any residual risk is than carried out, including a residual risk rating which involves scoring the OHS risk level of the hazard after considering current existing risk controls that are in place. The residual risk rating must be regularly reviewed as new controls are identified and implemented.

Comparing the inherent risk rating to the residual risk rating, the Workplace Manager and/or Management OHS Nominees are required to demonstrate to relevant authorities (e.g. the Department, WorkSafe and external auditors) that the controls in place are effective in reducing residual risk levels to a tolerable level.

In the USA, the National Institute for Occupational Safety and Health (NIOSH) Recommended Exposure Limits (RELs) are authoritative Federal Agency recommendations established according to the legislative mandate for NIOSH to recommend standards to the Occupational Safety and Health Administration (OSHA). RELs are intended to limit exposure to hazardous substances in workplace air to protect worker health. According to their website[106] NIOSH has changed policy with regard to carcinogenic substances: "Under the old policy, RELs for most carcinogens were non-quantitative values labelled "lowest feasible concentration (LFC)". […] The effect of the new policy will be the development, whenever possible, of quantitative RELs that are based on human and/or animal data, as well as on the consideration of technological feasibility for controlling workplace exposures to the REL. […]."

NIOSH will set a "risk management limit for a carcinogen" or an "RML-CA," at the concentration corresponding to the 95% lower confidence limit of the 1 in 10,000 risk estimate, but only when occupational measurement of the carcinogen at the RML-CA is analytically feasible. When measurement of the occupational carcinogen at the RML-CA is not analytically feasible at the 1 in 10,000 risk estimate, NIOSH will set the RML-CA at the limit of quantification (LOQ) or reliable quantitation limit (RQL) of the analytical method for that occupational carcinogen.

An excess lifetime risk level of 1 in 10,000 is considered to be a starting point for continually reducing exposures in order to reduce the remaining risk.

As noted in guidance[107] provided to Labour Inspectors, *"Although REACH and CAD/CMD should ultimately complement one another, their requirements overlap to some extent and this has the potential to give rise to inconsistencies in their application."*

[105] OHS Risk Management Procedure, Victoria State Govt. Australia

[106] https://www.cdc.gov/niosh/npg/nengapdxa.html

[107] GUIDANCE for National Labour Inspectors on the interaction of the Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (REACH) (Regulation (EC) No. 1907/2006), the Chemical Agents

One of the key differences are DNELs and OELs, designed in each set of legislation to reduce exposure to harmful chemicals, but utilising different methodologies and often coming up with different values.

ECHA's internal note[108] of 2015 provided a mandate to the Risk Assessment Committee (RAC) to create a joint task force with the Scientific Committee on Occupational Exposure Limits (SCOEL) for the comparative critical assessment of REACH DNEL and OEL methodologies a) for the inhalation route and b) for dermal route, including 'skin notation' and dermal DNEL. In this note, it is stated that:

"The processes for deriving REACH 'derived no effect levels' (DNELs) and occupational safety and health (OSH) 'occupational exposure limits' (OELs) are carried out separately and often result in different numerical values for exposure limit values and derived effect threshold levels for the same chemical, principally as a result of the different use of expert judgement and methodologies, which in turn reflect the different contexts in which each concept has been developed."

The difference in values derived for DNELs and OELs were highlighted in an article[109] in the British Occupational Hygiene Society (BOHS) Exposure Magazine in 2014. The authors observe that the DNEL/DMEL derived under REACH utilise a standardised process, dividing the no adverse effect levels, derived from animal, experimental toxicity studies by one or more fixed safety factors, and that this process differs substantially from the more holistic, human health-based OELV setting by organisations such as SCOEL at EU level and the German DFG, or the Dutch Health Council at Member State levels. The article states that observational epidemiological results in occupational target groups play an important role in the OELV but are ignored at large in the DNEL/DMEL.

The differences in approach mean that the DNELs/DMEL and OELV numbers can differ substantially despite their being based on the same scientific data sets. The differences are highlighted in the Figure C3-3 that used data from the DOHSBaseCompare[110] database (containing approximately 3,800 OELVs at the time) and linked these to DNEL data included in the GESTIS database. 411 substances were identified as having DNELs and OELVs and values are plotted in the figure, with the horizontal axis representing the 11 orders of magnitude of the values of existing DNELs, with OEL values (12 orders of magnitude) on the vertical axis.

The article highlights that there is an almost linear relation between the DNEL/DMEL and there is no tendency for DNELs to be systematically higher or lower than the OELVs (apart from in the upper right part of the graph where DNELs seem to be somewhat higher than OELVs). The 87 green triangles near the trend line represent the substances with the DNELs/DMELs equal to the OELVs. (approximately

Directive (CAD) and the Carcinogens and Mutagens Directive (CMD), Senior Labour Inspector's Committee (SLIC) 2013

[108] Note for the attention of Dr Tim Bowmer, Chairman of the Committee for Risk Assessment. Ref: Request to the Committee for Risk Assessment to create a joint task force with the Scientific Committee on Occupational Exposure Limits (SCOEL) on scientific aspects and methodologies related to the exposure of chemicals at the workplace and to prepare a report on their scientific evaluation, https://echa.europa.eu/documents/10162/13641/rac_mandate_attention_en.pdf/7931cbb7-8f3d-4f65-a081-728fad8a237e

[109] Careful with that DNEL, Occupational Hygienist! By Theo Scheffers, Geert Wieling, BOHS Exposure Magazine, Issue 3, June 2014

[110] DOHSBaseCompare is a database product with a focus on occupational hygiene relevant substance information. It was established in the late 1980s as an initiative within the Dutch Occupational Hygiene Society (from which it received its name) and was privatised in 1995.

18% of the 411). 63% of the DNELs/DMELs are different to the OELs by up to one order of magnitude (in yellow) and those in red differ by more than one order of magnitude.

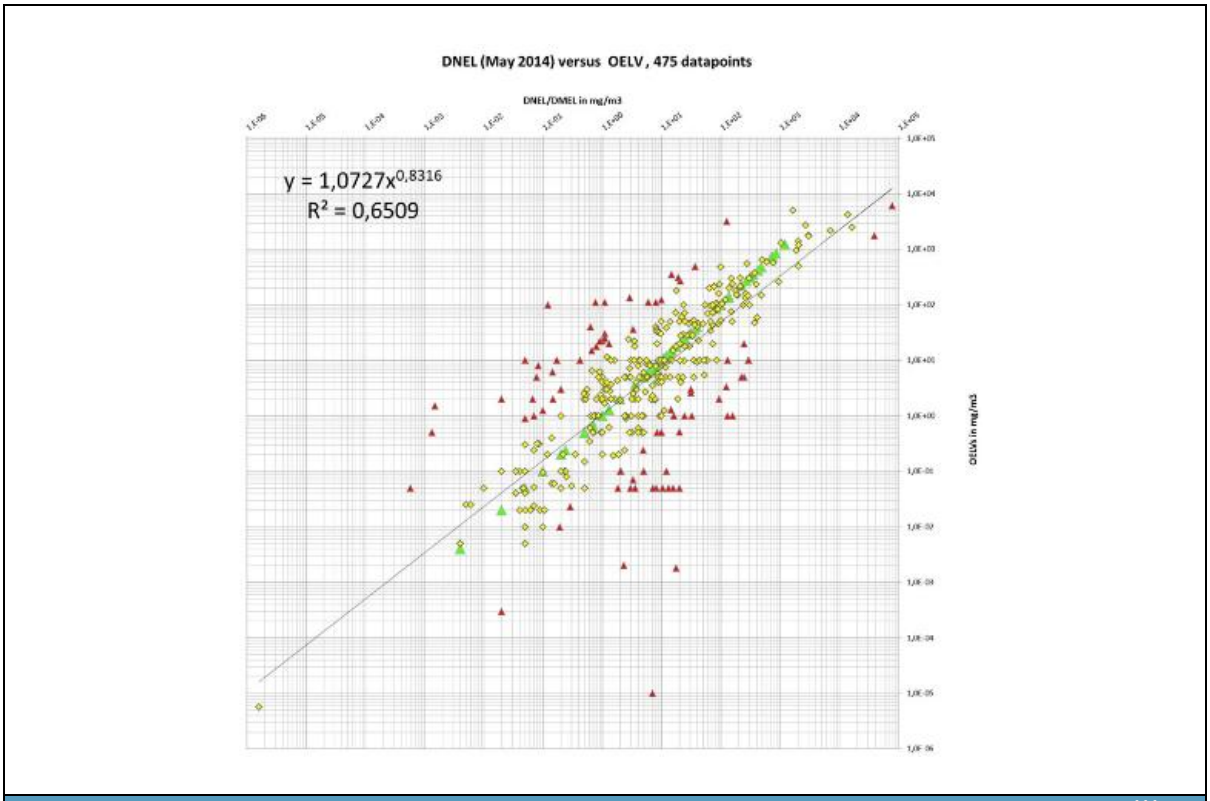

Figure C3-3: Comparison of DNEL/DMEL and OELV for 411 substances for which both are established[111]

C3.4 Distributional effects

The benefits that would arise under the different Policy Options differ by stakeholder group (workers and families, companies, public sector) as well as within stakeholder groups. A direct comparison of the benefits by stakeholder group is not possible since only the benefits from a reduction have been monetised whilst other benefit categories are assessed qualitatively.

It is, however, of note that the potential health effects as a result of exposure to Reprotoxic 1A/1B substances impact men and women differently, as women of reproductive age are at higher risk of suffering consequences, as a result of exposure. This is because many of the impacts are related to developmental defects that result from exposure while pregnant and women do not know that they are pregnant in the very early stages of pregnancy.

How impacts on reproductive health, in terms of fertility affect men and women differentially, is not made clear from the toxicological evidence available, but it is likely that the impact on men and women is different, but the outcome affects consensual couples equally. For women that know they are pregnant and have declared this to their employers, the impact is likely to be removal from any work environment that presents a risk, even theoretical. While the risk of health effects as a result is

[111] Scheffers T, Wieling G (2014): Careful with that DNEL, Occupational Hygienist! *BOHS Exposure Magazine*, 3 June.

removed at this point, the woman concerned experiences impacts relating to their productivity and potentially to their well-being, depending on the nature of arrangements.

It should also be noted that some of the benefits would be delayed under Option 3. The two options that involve a merger of the CAD and CMD would also likely involve a delay in terms of the time when the benefits would start being accrued. The merger of the CAD and CMD (i.e. introduction of a new directive and repeal of the existing two directives), would be complicated and there are many issues that would need to be addressed. Solving the many issues that are likely to arise would involve costs and require time. This means that the benefits of these policy options could also be delayed.

C3.5 Synthesis of findings

See the table overleaf.

Table C3-26: Benefits of the different Policy Options									
Component		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	++ 1-191 avoided repro cases p.a. €0.02-16m p.a.	++ Not possible to quantify but less[1] than under O2, O3+, O4, and 05	++ 1-191 avoided repro cases p.a. €0.02-16m p.a.	++ 1-191 avoided repro cases p.a. €0.02-16m p.a.	++ 1-191 avoided repro cases p.a. €0.02-16m p.a.
	Exposure minimisation		0	0	++ 4-191 avoided repro cases p.a. €0.08-16m p.a.		++ 4-191 avoided repro cases p.a. €0.08-16m p.	++ 4-191 avoided repro cases p.a. €0.08-16m p.a.	++ 4-191 avoided repro cases p.a. €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	++	++	++	++	+++[2]	++	++
Add-on elements (BLVs and sensitisers)		Workers and their families	0	0	0	0	0	0	+++[4]
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 (T vs NT)		Companies	0	0	Significantly negative	++	++ (but +++ if extended to C/M)	Significantly negative	Significantly negative
Overall health benefits for R 1A/1B substances		***Workers & families, companies, authorities***	***0***	***+***	***+++ 1-382 avoided repro cases p.a. €0.02-31m p.a.***	***++ Not quantified but less[1] than under O2, O3+, O4, O5***	***+++ 1-382 avoided repro cases p.a. €0.02-31m p.a.***	***+++ 1-382 avoided repro cases p.a. €0.02-31m p.a.***	***+++ 1-382 avoided repro cases p.a. €0.02-31m p.a.***

Notes: All benefit estimates are illustrative of the order of magnitude and the actual benefits depend on a number of uncertain factors. All monetary values are annualised benefits in € million. Qualitative assessment scale: Highest costs to highest benefits: ++++ +++ ++ + 0 + ++ +++ ++++ Key: ++++ substantial benefits, +++ significant benefits, ++ some benefits, + limited benefits, 0 no change. 1: This is due to the fact that the benefits would be phased in over time – a derogation would be applied to all R 1A/1B substances that are not also C/M 1A/1B and these would be brought into the scope of CMD requirements should it be determined that they have no threshold for effects. 2: It is possible that the general trend towards more OELs would see additional BOELVs adopted even under the baseline. However, due to the central role of BOELVs in achieving a derogation from exposure minimisation, it is expected that the process of introducing BOELVs would be significantly accelerated under Option 3+, with more BOELVs being adopted over the coming, say, 5-10 years. As a result, companies would incur greater costs under Option 3+ due to the need to comply (and demonstrate compliance) with these BOELVs. Although the analysis carried out under this study for the 30 substances suggests that most exposure is already below the thresholds for reprotoxic effects, it is expected that some companies could incur relatively high costs – due to monitoring and in some instances RMMs. 3: Unnecessary costs for substances that are deemed non-threshold due to hazard classification but which have a threshold 4: Although there is a large number of sensitising substances, it is expected that minimisation is already extensively practiced

C4 Market effects

Key findings

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 R1A /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).

Approach

The conclusions are broadly based on modelling the numbers of companies manufacturing and using the different Reprotoxic 1A/1B substances that will be impacted and assessing the effect of adopting groups of measures on their overall turnovers, based on Eurostat data for the average level of turnover in the bread sectors in which the substances are used. The results are qualitatively analysed at the sectoral level in order to establish the significance of these changes and potential responses predicted.

Limitations/uncertainties

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 clearly has 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.

C4.1 Summary of the market impacts assessment framework

This section sets out the analytical framework that underpins the assessment of the market impacts that are expected to arise under the different Policy Options.

The Better Regulation guidelines set out the different impacts to be assessed as follows:

- Impacts on sectoral competitiveness
- Impacts on Research & Innovation
- Impacts on SMEs
- Impacts on competition
- Impacts on the internal market
- Impacts on employment

These impacts are assessed in the following sections in turn.

Each Policy Option is considsidered against the baseline Option (Option 1-, which involves no changes) with respect to the various impacts. Whilst the potential introduction of additional OSH guidelines under Option 1 might requires some changes to be made by companies using/manufatucirng Reprotoxic 1A/1B substances, this Option involves no major regulatory changes and are not expected to have significant impacts at the market level.

C4.2 Impacts on sectoral competitiveness

Competitiveness impacts are likely to arise when a sector's capacity to produce products at a lower cost and/or offer them at a more competitive price (cost/price competitiveness). In addition, the innovative or distinctive nature of products may be impacted as a result of complying with regulations, thereby reducing competitiveness. Impacts on market shares in international markets might also occur.

C4.2.1 Numbers of companies

In order to fully assess the market level impacts of the different Policy Options, it is necessary to estimate the number of companies that are likely to be affected under each scenario. However, data limitations have meant that this has not been possible to do with any certainty. Some of the key issues are:

- In many sectors, there is no available information to determine the number of companies specifically using the different reprotoxic substances, in absolute numbers nor in percentage terms
- The number of companies affected under the different Options will be significantly influenced by current levels of exposure. In many cases, the information identified in terms of exposure levels is insufficient to determine the precise level of exposure and whether or not it is above or below threshold levels for specific substances. For example, the SUMER estimates for exposure from 2010 are based on self-declarations which include significant numbers of workers exposed at very low or low concentrations for short periods of time
- The current situation for many substances and in many sectors in terms of what measures companies have already implemented (in terms of consideration of substitution, substitution, closed systems and exposure minimisation in particular) is unknown, and consequently it is

not possible to fully estimate the number of companies that will be required to implement different additional measures. This makes it difficult to determine overall market effects.

Consequently, the study has adopted an approach (also in Section C2 on costs arising from the different Policy Options) which provides an indicative assessment based on the assumption that 2% of workers are exposed to reprotoxins across all substances. In line with this assumption, it is further assumed that 2% of companies in each sector have workers exposed and will potentially be required to implement various measures of the Policy Options. After then applying

Adopting this approach Table C4-1 below sets out an indicative number of companies likely to be affected by various measures arising from the Policy Options.

Table C4-1: Companies affected by different measures

	Low	Mid	High
Considering substitution	52,000	78000	104,000
Substitution	5,000	26,000	39,000
Considering Closed systems	179,000	237,000	258,000
Closed systems	10,000	23,000	40,000
Considering Exposure minimisation	202,300	231,200	260,100
Exposure minimisation	28,900	57,800	86,700
IOELVs becoming BOELVs	7,400	14,800	22,200
Keeping records for 40 years	159,000	223,000	287,000

C4.2.2 Socio-economic characteristics of the relevant sectors

Detailed descriptions of the uses of the focal reprotoxic substances covered in this study are provided in Annexes 10 to 21 in Report 1. The table overleaf provides a summary of the socio-economic characteristics of the sectors where some workers may be exposed to the shortlisted substances. Please note that the data in this table relate to high-level sectors at NACE 1-3 digit level and cover both companies with workers exposed to reprotoxic substances and those with no exposure.

Table C4-2: Summary of main economic indicators for all relevant sectors, by size of enterprise (if available)																												
Sector	2-(4-tert-butylbenzyl)propionalid	2-ethoxyethanol	Borates	BPA	Dinoseb	Dodecyl phenols	ETU	Lead	Organotins (dibutyltin dichloride)	pTBBA	Retinol	Aprotic Solvents	TOTAL No. firms	Micro				Small				Medium				Large			
														% of total	No. firms	Ave. turnover/ €m	Ave. GOS/ €m	% of total	No. firms	Ave. turnover/ €m	Ave. GOS/ €m	% of total	No. firms	Ave. turnover/ €m	Ave. GOS/ €m	% of total	No. firms	Ave. turnover/ €m	Ave. GOS/ €m
A1.1							✓						-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A1.2							✓						-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A1.4											✓		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
A2.1							✓						-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B06												✓	463	74%	342	8.8	-	10%	48	96.7	-	6%	30	1,094	-	9%	43	1,909	-
C10			✓								✓		264,350	78%	207,260	0.28	-	17%	44,540	3.16	-	4%	10,160	273,000	-	1%	2,400	204.17	-
C13												✓	79,000	65%	51,000	0.17	-	9%	7,462	2.78	-	3%	2,000	15.17	-	23%	18,538	1.06	-
C14.1												✓	108,230	87%	94,529	0.1	-	10%	10,974	1.47	-	2%	2,386	6.96	-	0.3%	341	54.05	-
C15												✓	36,962	78%	28,736	0.19	-	18%	6,728	2.21	-	4%	1,330	11.68	-	0.5%	168	102.67	-
C17				✓									19,580	65%	12,630	0.39	-	23%	4,490	4.05	-	10%	1,980	60,980	-	3%	490	209.41	-
C18.1		✓											112,440	89%	100,320	0.15	-	10%	10,960	2.11	-	2%	1,690	26,407	-	0%	110	139.89	-
C20			✓			✓		✓				✓	29,590	66%	19,580	0.68	-	21%	6,240	5.49	-	10%	2,950	132,655	-	3%	830	417.31	-
C20.1	✓	✓		✓	✓		✓		✓		✓		8,980	58%	5,190	1.32	-	22%	2,010	9.66	-	11%	980	68,909	-	4%	360	650.99	-
C20.2	✓				✓		✓						630	57%	360	0.54	-	22%	140	6.09	-	16%	100	4,697	-	3%	20	250.25	-
C20.3				✓				✓		✓			3,910	58%	2,280	0.50	-	28%	1,080	4.79	-	11%	430	13,846	-	3%	120	173.69	-
C20.4	✓	✓									✓		9,560	74%	7,090	0.33	-	17%	1,600	3.66	-	7%	680	17,418	-	2%	170	277.44	-
C20.5								✓					6,190	64%	3,940	0.69	-	24%	1,460	9.52	-	11%	660	26,001	-	2%	120	280.98	-
C21			✓								✓	✓	4,560	49%	2,240	1.64	-	21%	960	9.13	-	18%	820	26,346	-	12%	540	427.66	-
C22						✓				✓		✓	61,910	65%	40,470	0.33	-	24%	14,810	3.44	-	9%	5,600	108,995	-	2%	1,030	129.73	-
C22.1							✓	✓	✓				7,690	66%	5,090	0.31	-	23%	1,740	3.03	-	8%	640	10,533	-	3%	230	259.14	-
C22.2				✓	✓			✓				✓	54,220	65%	35,490	0.32	-	24%	13,050	3.56	-	9%	4,900	98,462	-	1%	780	100.89	-

Table C4-2: Summary of main economic indicators for all relevant sectors, by size of enterprise (if available)																												
Sector	2-(4-tert-butylbenzyl)propionalde	2-ethoxyethanol	Borates	BPA	Dinoseb	Dodecyl phenols	ETU	Lead	Organotins (dibutyltin dichloride)	pTBBA	Retinol	Aprotic Solvents	TOTAL No. firms	Micro				Small				Medium				Large			
														% of total	No. firms	Ave. turnover/ €m	Ave. GOS/ €m	% of total	No. firms	Ave. turnover/ €m	Ave. GOS/ €m	% of total	No. firms	Ave. turnover/ €m	Ave. GOS/ €m	% of total	No. firms	Ave. turnover/ €m	Ave. GOS/ €m
C23			✓										93,900	84%	78,860	0.22	-	12%	11,370	3.02	-	3%	2,920	58,296	-	1%	740	134.93	-
C23.1				✓									15,340	81%	12,490	0.16	-	13%	1,920	2.18	-	4%	690	11,432	-	2%	240	121.40	-
C24			✓				✓						16,460	62%	10,240	0.55	-	22%	3,640	6.21	-	11%	1,880	71,133	-	4%	690	351.93	-
C25			✓					✓				✓	386,050	82%	316,850	0.18	-	15%	57,050	2.35	-	3%	10,840	159,000	-	0%	1,310	99.24	-
C25.9												✓	49,877	80%	39,878	0.20	-	15%	7,699	2.93	-	4%	2,000	16.5	-	0.6%	300	93.94	-
C26			✓	✓				✓					40,440	75%	30,230	0.37	-	17%	7,000	3.43	-	6%	2,510	51,321	-	2%	700	285.71	-
C26.1		✓										✓	10,170	71%	7,230	0.30	-	20%	2,040	2.83	-	7%	700	10,697	-	2%	190	209.12	-
C27								✓				✓	46,530	74%	34,390	0.24	-	17%	8,130	3.24	-	7%	3,060	59,568	-	2%	950	220.00	-
C29			✓			✓		✓					19,700	62%	12,200	0.47	-	20%	3,900	3.75	-	12%	2,280	59,377	-	7%	1,320	721.91	-
F41				✓									870,000	94%	820,300	-	-	5%	43,400	-	-	1%	5,100	-	-	0.1%	470	-	-
G						✓		✓					6,306,120	93%	5,895,270	-	-	6%	357,990	-	-	1%	45,060	-	-	0%	7,800	-	-
M72		✓											65,750	91%	59,950	-	-	6%	4,140	-	-	2%	1,330	-	-	1%	330	-	-
Q86				✓									12,650	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Source: Eurostat's Structural Business Statistics database

A1.1 Agriculture – growing of non-perennial crops; A1.2 Agriculture – growing of perennial crops; A1.4 Agriculture: Animal production; A2.1 Silviculture and other forestry activities; B06: Extraction of crude petroleum ; C10 Manufacture of food products; C13: Manufacture of textiles; C14.1: Manufacture of wearing apparel, except fur apparel; C15: Manufacture of leather and related products;C17 Manufacture of paper and paper products; C18.1 Printing and service activities related to printing; C20 Manufacture of chemicals and chemical products; C20.1 Manufacture of basic chemicals, fertilisers and nitrogen compounds, plastics and synthetic rubber in primary forms; C20.2 Manufacture of pesticides and other agrochemical products; C20.3 Manufacture of paints, varnishes and similar coatings, printing ink and mastics; C20.4 Manufacture of soaps and detergents, cleaning and polishing preparations, perfumes and toilet preparations; C20.5 Manufacture of explosives; C21 Manufacture of basic pharmaceutical products and pharmaceutical preparations; C22 Manufacture of rubber and plastic products; C22.1 Manufacture of rubber products; C22.2 Manufacture of plastic products; C23 Manufacture of other non-metallic mineral products (glass and ceramics); C23.1 Manufacture of glass and glass products; C24 Manufacture of basic metals; C25 Manufacture of fabricated metal products, except machinery and equipment; C25.9: Manufacture of other fabricated metal products; C26 Manufacture of computer, electronic and optical products; C26.1 Manufacture of electronic components and boards; C27 Manufacture of electrical equipment; C29 Manufacture of motor vehicles, trailers and semi-trailers; F41 - Construction of buildings; G Wholesale and retail trade; repair of motor vehicles and motorcycles; M72 Scientific research and development; and Q86 Human health activities.

C4.2.3 Enterprises operating in more than one Member State

A more general overview of EU companies with operations in more than one Member State is provided below. This information does not relate specifically to companies using reprotoxic substances, but rather provides background information to support the analysis of potential impacts arising in the eventuality that companies might switch operations outside the EU.

Although some data on companies with multiple sites in different Member States are available for specific substances (e.g. for Bisphenol A producers and their production sites), no such data are available for most of the substances and sectors. However, Eurostat publishes experimental statistics on multinational enterprise groups in the EU[112] and these are taken as representative of the situation the sectors for which no other data are available.

A multinational enterprise group is defined as an enterprise group comprising at least two enterprises or legal units located in different countries. These statistics are extracted directly from the EuroGroups Register (EGR). The EuroGroups Register (EGR) is a statistical business register of multinational enterprise groups having at least one legal unit in the territory of the EU or EFTA countries. It is important to note that the following statistics are classified as experimental since EGR data are incomplete, i.e. large chemical companies based in countries such as Germany are not included. No other statistics on this topic are currently published by Eurostat (e.g. a breakdown by sector, in particular the sectors where Reprotoxic 1A/1B substances are used).

Most of registered multinational enterprise groups are based in Italy, Spain, and the Czech Republic.

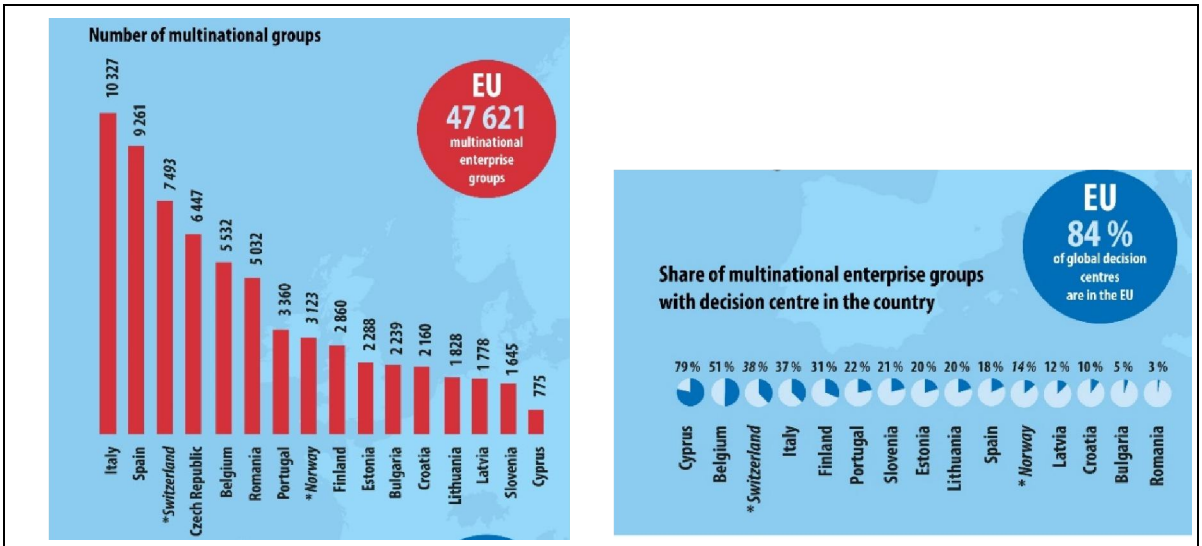

Figure C4-1: Number of multinational groups in selected EU Member States
Source: EuroGroups Register [113] based on Eurostat

[112] January, 2018, https://ec.europa.eu/eurostat/web/experimental-statistics/multinational-enterprise-groups

[113] https://ec.europa.eu/eurostat/web/structural-business-statistics/structural-business-statistics/eurogroups-register

An overview of the proportion of small, medium-sized and large groups by country is presented below. Groups are classified as small if they have fewer than 250 employees, as medium-sized if they have 250 to 2,499 employees, and as large if they have more than 2,500.

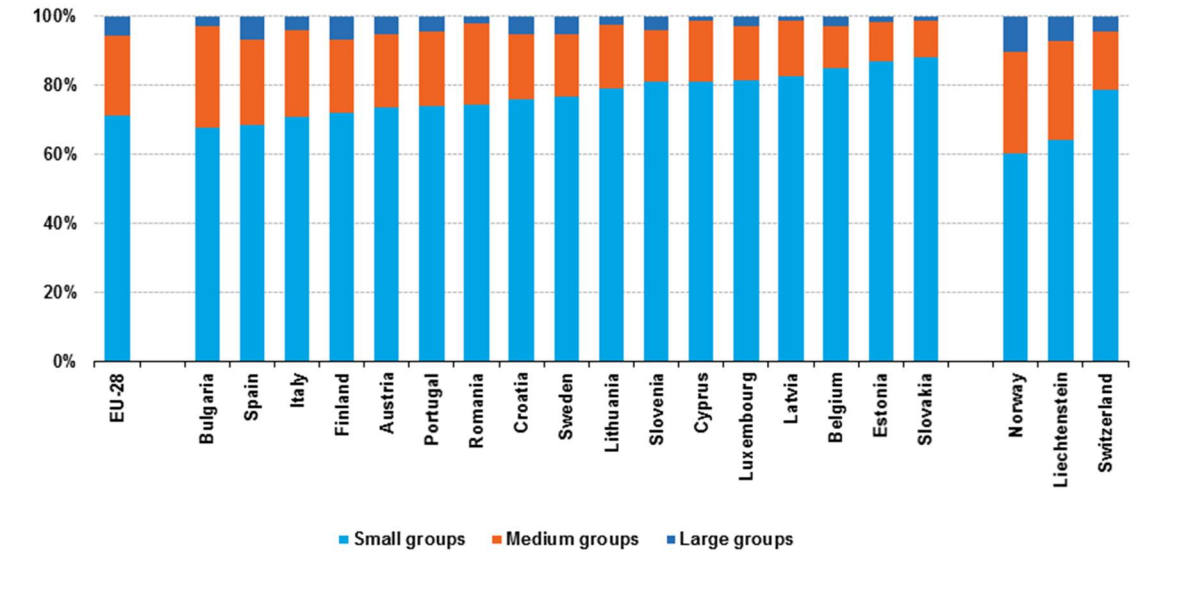

Figure C4-2: Small, medium-sized and large groups by country of group in 2016
Source: EuroGroups Register [114] on Eurostat

A group's complexity is defined by the variety of activities carried out by its enterprises. Mono-active groups operate in only one activity (based on NACE divisions, for example 'manufacture of food products' or 'water transport'). Diversified groups operate in two to four economic activities, and very diversified ones in five or more.

[114] Ibid

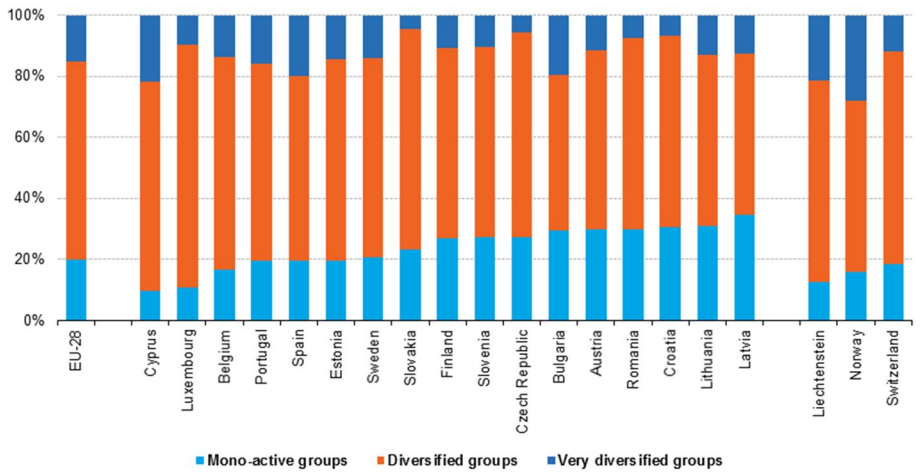

Figure C4-3: Complexity of multinational enterprise groups
Source: EuroGroups Register [115] on Eurostat

Multinational groups in the EU usually are present in only a few countries. The following figure shows the proportion of EU groups that have a low European presence (with employment in one or two EU countries), a medium European presence (with employment in three to five EU countries), and a high European presence (with employment in six or more EU countries).

[115] Ibid

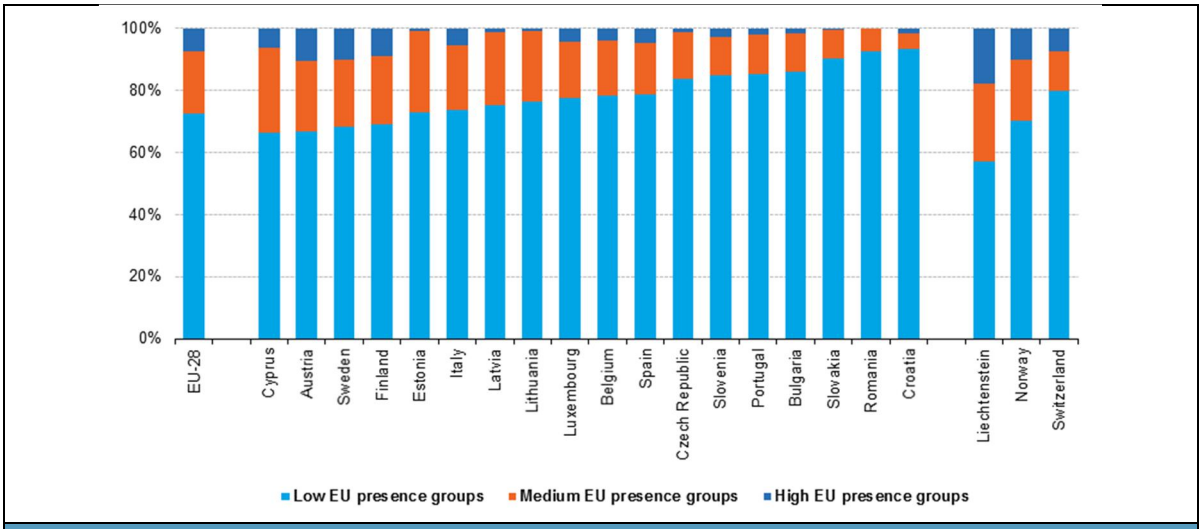

Figure C4-4: European presence of multinational enterprise groups
Source: EuroGroups Register [116] on Eurostat

C4.2.4 Market impacts arising from the Policy Options

Introduction

The Policy Options will differ in their impacts on sectoral competitiveness according to the extent that companies operating within the different sectors in different MS are required to change their practices, the number of companies that are affected and their importance in the sectoral market as a whole. The collective changes and impacts on these companies will be key elements in determining any overall market effects arising. However, only very limited data has been identified regarding the specific numbers of companies using Reprotoxic 1A/1B substances in the different sectors where these are known to be used. Consequently, predicting overall market impacts is difficult.

The shift in requirements to comply with obligations under the CMD under Policy Options 2, 3, 4 and 5 are the most significant changes for companies working with Reprotoxic 1A/1B substances and this section will focus on impacts arising from these. The focus is on the potential changes in costs to companies arising from the changes and the implications arising from these with respect to the decisions that companies make for the overall sector.

Cost data generated through modelling under this study has utilised broad assumptions regarding the proportion of companies with workers potentially exposed to Reprotoxic 1A/1B substances and applied these to Eurostat data covering NACE codes B-E and G-N to generate estimates for the numbers of companies likely to be affected by the regulations and overall cost estimates. It is noted that there is likely to be significant variation in the proportions of companies using Reprotoxic 1A/1B substances in the specific sectors and sub-sectors identified in Table C4-2 above, but as indicated, it has not been possible to identify specific estimates for these in most cases. Consequently, this section will make use of the estimates generated using NACE codes B-E and G-N for numbers of companies using Reprotoxic 1A/1B that are likely to be impacted from the changes in obligations under the different Options although it is noted that there may be a significant degree of uncertainty in adopting this approach.

[116] Ibid

C4.2.5 Number of companies affected under Options 2, 3, 4 and 5 and associated costs

Section C2 on Costs above has developed estimates of the number of companies that are likely to be affected by requirements to consider substitution, installing closed systems, introduce additional RMMs to minimise exposure and keep records for a 40-year period, along with likely costs. These are summarised (utilising the mid-level estimates) in the table below.

Table C4-3: No.s of firms required to take actions and associated costs per firm		
	No. of companies	**Costs per company**
Considering substitution	78,000	€1,000, annualised (weighted by size distribution in the total enterprise population). Assuming a micro company only does this for 1 substance, costs for a larger companies (assumed to be 30 substances) could be €30,000 or even higher, particularly if additional research is required at this stage
Substitution	26,000	Unknown (High)
Considering installing closed system	237,000	€1,000, annualised (comment as for considering substitution)
Installing closed system	23,000	Small: €5,000 annualised over 20 years Medium: €50,000 annualised over 20 years Large: €200,000 annualised over 20 years Average annualised cost per company (weighted by size distribution in the total enterprise population) is approximately €6,000.
Considering minimising exposure	231,000	€1,000, annualised (comment as for considering substitution and closed systems)
Implementing additional RMMs to minimise exposure	58,000	Average annualised cost per company for installing LEV 1 (weighted by size distribution in the total enterprise population) is €2,300. Average annualised cost per company for installing LEV 2 (weighted by size distribution in the total enterprise population) is €4,400. Average annualised cost per company for installing other RMMs (weighted by size distribution in the total enterprise population) is €1,000.
No. companies in MS where the requirement to keep records for 40 years would be newly introduced	318,000	Annualised cost of €500 per year over a 40 year period
No. companies that currently do not keep records for this time	223,000	€500 (annualised) per company per year

C4.2.6 Impacts of cost increases on company turnover

The following table provides data from Eurostat on the average turnover of micro, small, medium and large companies.

Table C4-4: Average company turnover (€ million), NACE Codes B-E and G-N					
Member State	**Total**	**Micro**	**Small**	**Medium**	**Large**
Austria	2.16	0.43	4.27	35.22	211.29
Belgium	1.91	0.49	9.11	50.19	362.66
Bulgaria	0.36	0.09	1.28	7.44	52.52
Croatia	0.59	0.13	1.72	10.07	77.69
Cyprus	0.60	0.20	2.38	12.94	75.98
Czech Republic	0.50	0.09	2.57	14.71	121.54
Denmark	2.48	0.51	5.16	30.00	302.11
Estonia	0.81	0.26	2.61	12.05	66.70
Finland	1.82	0.31	4.99	27.75	272.61
France	1.36	0.29	5.80	31.08	391.41
Germany	2.83	0.40	2.90	21.18	271.48
Greece	0.30	0.09	1.73	17.20	162.02
Hungary	0.55	0.11	2.00	12.91	129.80
Ireland	3.22	0.85	7.24	35.48	519.90
Italy	0.85	0.22	4.02	30.48	271.60
Latvia	0.47	0.12	2.06	9.70	58.66
Lithuania	0.45	0.09	1.73	9.52	71.47
Luxembourg	4.81	0.82	9.95	88.54	343.85
Malta	n/a	n/a	n/a	n/a	n/a
Netherlands	1.41	0.23	6.64	50.16	340.45
Poland	0.61	0.14	2.49	12.24	119.54
Portugal	0.41	0.10	2.38	16.30	113.50
Romania	0.62	0.11	1.38	8.04	67.63
Slovakia	0.50	0.11	3.16	14.49	133.85
Slovenia	0.68	0.16	3.48	19.48	121.97
Spain	0.76	0.18	3.09	24.52	211.06
Sweden	1.27	0.25	5.21	31.90	332.54
United Kingdom	2.05	0.36	3.25	21.13	346.14

Companies in MS will be affected by the introduction of different measures to comply with CMD requirements as follows:

None	
All measures	
All except 40 years record keeping	
All except exposure minimisation	
All except substitution	
40 years record keeping only	
Substitution and 40 years record keeping	

Indications of the median and mean turnovers for firms broken down by size class are provided in the following.

Table C4-5: Analysis of average turnover, by size class (€ million)				
Data	**Micro**	**Small**	**Medium**	**Large**
Median	0.20	3.09	19.48	162.02
Mean	0.26	3.80	24.25	205.55
Highest	0.85	9.95	88.54	519.90
Lowest	0.09	1.28	7.44	52.52

With the exception of substitution costs, the cost analysis presented in the above tables indicates that even for MS where the average turnover of large companies is at its lowest (€52 million per year), the costs of complying with Policy Options 2-5 are relatively low.

However, for small and micro-enterprises, the costs appear much more significant. Clearly the ultimate cost will depend on the specific measures that the company is required to take, but even when considering the highest average annual turnover of €850,000 per year for micro-enterprises, the costs indicated in Table C4-3 above could amount to a more significant proportion of companies' turnover as indicated in the box below. It is noted that the examples provided do no cater for any substitution costs.

Box C4-1 – Examples of Cost as a % of turnover

Micro-enterprise with highest average turnover of €850,000 per year
Cost of considering substitution = €1,000
Cost of considering closed system = €1,000
Cost of installing a closed system = €5,000
Cost of considering exposure minimisation = €1,000
Cost of installing LEV2 = €4,400
Total Cost = €12,400

Cost as a % of turnover = 1.46%

Micro-enterprise with lowest average turnover of €90,000 per year
Cost of considering substitution = €1,000
Cost of considering closed system = €1,000
Cost of considering exposure minimisation = €1,000
Cost of installing LEV2 = €4,400
Total Cost = €7,700

Cost as a % of turnover = 8.56%

Large enterprise with median average turnover of €162 million per year
Cost of considering substitution = €30,000
Cost of considering closed system = €30,000
Cost of installing a closed system = €220,000
Cost of considering exposure minimisation = €30,000
Cost of installing LEV2 = €86,000
Cost of installing LEV1 = €57,000
Total Cost = €453,000

Cost as a % of turnover = 0.28%

Large enterprise with lowest average turnover of €52.52 million per year
Cost of considering substitution = €30,000
Cost of considering closed system = €30,000
Cost of installing a closed system = €220,000
Cost of considering exposure minimisation = €30,000
Cost of installing LEV2 = €86,000
Cost of installing LEV1 = €57,000
Total Cost = €453,000

Cost as a % of turnover = 0.86%

Consultation responses received regarding potential impacts of complying with CMD measures included highlighting that other than closed systems, other measures could include ventilation and personal protection measures. Three companies commented that inclusion of repro 1A/1B chemicals in the scope of the CMD would inevitably involve re-evaluation of their risk management measures within the company's production process, which would require considerable investment, especially for SMEs of the sector. Investment would be necessary as part of the re-evaluation process and implementation of any further RMMs.

It would appear that whilst for large companies, the costs of installing various protective measures to control exposure might be large in terms of absolute value, the overall impact on turnover would not appear to be hugely significant. However, for small and micro-enterprises, depending on the measures they would be required to adopt in order to follow the requirements of the CMD, the impact of Options 2-5 is likely to be much more significant.

Given the nature and scale of the potential costs and the average turnover of micro- and small enterprises, it is likely that at least some micro and small companies would exit the market as a result, although it is not possible to quantify this.

It is to be noted that not all companies in all MS will be required to implement changes as a result of the different Options equally. Some companies manufacturing or using Reprotoxic 1A/1B substances will have already considered potential substitution, installation of closed systems and exposure minimisation measures comprehensively in their recent R&D activities and consequently would not need to incur these again if the CMD requirements were introduced for R1A and 1B substances. Also, as indicated by the colour coding in Table C4-4 above, not all obligations in the CMD would be new requirements in all MS, since some countries have already incorporated reprotoxins into the CMD, and companies should have already implemented the relevant obligations.

Option 3 involves derogations from the requirements for substitution, closed systems, minimisation and record keeping requirements of the CMD for threshold substances and would only require companies to fulfil these obligations if an EU scientific committee confirms that the substance in question has no threshold. Consequently, this Option would not result in any increase in costs for the majority of Reprotoxic 1A/1B substances as they are generally confirmed to have threshold effects for reprotoxic effects.

In terms of Option 3+, only those substances where there is a binding OELV and companies can demonstrate through measurement that the limit is being met would be eligible for the derogation from substitution, closed systems and exposure minimisation requirements of the CMD. It is assumed that IOELVs would become binding OELVs under this Option but it is noted that only 11 of these are currently in place, meaning that the vast majority of Reprotoxic 1A/1B substances and companies using them would be required to comply with the CMD requirements. It is also the case that threshold substances which are C or M could be exempted from these requirements. However, the vast majority of C&M substances are non-threshold, so relatively few companies would benefit from this in the short term or medium term. In any event, this would only likely apply to companies beginning production/use of the substances in the future since any already producing or using them should have already implemented the substitution, closed system and minimisation requirements. It is however noted that some CM substances that are acknowledged to have a threshold effect (e.g. formaldehyde, respirable silica dust, nickel compounds) are used in large number of sectors and consequently a significant number of individual companies may realise important benefits arising from any exemptions.

C4.2.7 Potential for companies leaving the EU

The review of regulation of CMR substances outside EU/EEA/EFTA countries carried out for this study (see Section C2) did not find any other countries, with the exception of India and the US State of California, that have adopted specific legal acts for occupational exposure to CM or CMR substances, with regulation generally carried out under broader measures dealing with chemicals or workplace safety and health in general. The focus is generally on carcinogens (as opposed to mutagens or reprotoxins) in countries including Brazil, South Korea and the USA.

The analysis notes that none of the regulation in non-EEA/EFTA countries appears to require the substitution of C, M or R substances as a predominant feature of risk management approaches, with emphasis placed on control of exposure through OELs and the communication of hazard information through labelling and classification requirements.

Companies faced with stricter requirements regarding the consideration of Reprotoxic 1A/1B substances as a result of having to comply with CMD requirements may therefore consider re-locating outside the EU in order to avoid the costs identified here. This may be a particular Option for large multi-national companies with existing bases in third countries where regulation is less stringent than that being proposed with the introduction of CMD requirements under Option 2, Option 3+, Option 4 and Option 5.

Lager companies in general may be considered to have greater possibilities than smaller ones in terms of re-locating due to the resources required to establish new operations. It is noted that there are a large number of large companies operating in the sectors identified as using/manufacturing Reprotoxic 1A/1B substances, with the proportion of large companies operating in the sector higher than the EU average of 0.2% for NACE codes B-E and G-N. For some, the proportion of large companies is significantly higher than the EU average across all of industry and services e.g. C13 Manufacture of textiles (23% large), C21 Manufacture of basic pharmaceutical products and pharmaceutical preparations (12%) and C29 Manufacture of motor vehicles, trailers and semi-trailers (7%).

C4.2.8 International competitiveness

Impacts on the competitiveness of EU enterprises vis-à-vis their competitors from third countries as a result of the introduction of the different Policy Options will be influenced by differences in regulation of CMR substances faced by the respective companies. Annex 3 in this report sets out third country measures and approaches to the regulation of CMR substances. It notes that Iceland, Liechtenstein, Norway and Switzerland have regulations which are relatively close to those of the EU, and like those Member States that have extended the CMD to include reprotoxic substances, Iceland and Norway have also extended at least part of the scope of their national measures dealing with carcinogens and mutagens to include reprotoxic substances, (although Norway also has specific provisions for carcinogens and mutagens only).

In contrast, none of the other non-EEA/non-EFTA third countries studied (with the exception of India and the State of California in the United States) have adopted specific legal acts for occupational exposure to CMR substances and in Annex 3, it is explained that these substances fall under broader measures which may deal with chemicals or workplace safety and health in general. The table below provides a brief summary of how CMRs are treated in selected other countries.

Table C4-6: Regulation of CMRs in third countries

Country	CMRs treated same as other chemicals	R treated differently
Australia	Yes	No
Brazil	Yes	No
Canada	Yes	No
China	Yes	Questionable
India	Yes, with exception[a]	Selected employment of women only
Japan	Yes	No
USA	Yes, except California (see below)	California only

[a] Under The Factories Act, 1947, employment of women in hazardous processes which might cause a potential effect on their reproductive health is restricted

None of the other countries studied require substitution of C, M and/or R as the focal approach to protecting workers from exposure as the main risk management measure to be taken when dealing with such chemical agents. Generally, there is a focus on carcinogens rather than on reprotoxic substances, with OELs and communicating hazard information being the preferred measures for limiting exposure.

The US approach in California (commonly referred to as Prop.65) has been identified as an 'advanced' approach and includes de minimis or 'Safe Harbor' total exposure limits for selected chemicals, above which a warning is required.

It would appear from the information available that regulation in many other parts of the world is not as strict as the existing regulations in the EU and that Policy Options 2-5, which set out to strengthen these controls, might be considered even stricter. As such, they may be taken into consideration by companies when making decisions about possible relocation in other countries as a response to changes in regulations under the different Policy Options.

However, that said, as indicated throughout this section, the potential increase in costs resulting from any of the different Options do not represent a significant increase in costs relative to average turnover. Given the costs involved in relocation, whilst some companies, particularly those that might end up substituting Reprotoxic 1A/1B substances, may be affected to a greater extent, it is not expected that significant numbers would relocate to other countries.

C4.3 Impacts on research and innovation

Research and development (R&D) are key activities in an industry's capacity to develop new products and produce existing ones more efficiently and sustainably, in a way that protects the safety of workers. In 2016, Eurostat reported that expenditure in the EU on R&D was approximately €300 billion in 2015, representing 2.03% of GDP. The largest contributor to this level of expenditure was the business enterprise sector, accounting for 65%, or approximately €195 billion.

The ability of the different sectors to engage in R&D activities is likely to be affected by:

- The availability of financial resources to invest in R&D;
- The availability of human resources to conduct R&D activities;
- The regulatory environment and whether or not it is conducive to investing in R&D activities.

R&D is an important factor in the development of many of the sectors using R1A and 1B substances. For example, according to the European Tyre Industry[117], the tyre industry is a highly innovative sector, investing approximately 3.5% of its annual turnover in innovation. They highlight that the major companies hold approximately 5,000 patents (products, processes and equipment) and that ETRMA members operate 86 plants within Europe and have 16 R&D centres.

C4.3.1 Measures under the Policy Options and their impacts on R&D

The Policy Options require companies to undertake different measures, only some of which might affect R&D and companies' capacity to innovate. These are analysed in the following table, with those anticipated to have more significant effects considered in greater depth below.

[117] The European Tyre Industry Facts and Figures, 2017 Edition - European Tyre & Rubber Manufacturers' Association

Table C4-7: Impacts of different measures on R&D							
Measure	**O1-: Baseline (no guidance)**	**O1: Baseline (including OSH guidance)**	**O2: R 1A/1B in CMD**	**O3: R 1A/1B in CMD (derogations)**	**O3+: Joint declaration**	**O4: R 1A/1B in CMD, merge CAD and CMD**	**O5: R 1A/1B in CMD, merge CAD and CMD, modernisation**
OSH guidance	No significant impacts on R&D anticipated	No significant impacts on R&D anticipated	No significant impacts on R&D anticipated	No significant impacts on R&D anticipated	No significant impacts on R&D anticipated	No significant impacts on R&D anticipated	No significant impacts on R&D anticipated
Substitution, closed systems. Exposure minimisation			May have positive impacts due to new designs, processes, use of new substances. Potential negative impacts on R&D due to increased costs and impact on availability of finance for R&D.	May have positive impacts due to new designs, processes, use of new substances. Potential negative impacts on R&D due to increased costs and impact on availability of finance for R&D.	May have positive impacts due to new designs, processes, use of new substances. Potential negative impacts on R&D due to increased costs and impact on availability of finance for R&D.	May have positive impacts due to new designs, processes, use of new substances. Potential negative impacts on R&D due to increased costs and impact on availability of finance for R&D.	May have positive impacts due to new designs, processes, use of new substances. Potential negative impacts on R&D due to increased costs and impact on availability of finance for R&D.
IOELVs become BOELVs			Existing IEOLVs become BOELVs, so those companies using these substances will be impacted.	Costs likely less than Option 2 as numerous substances derogated so fewer companies impacted	Overall costs could be significantly more than Option 2 as some will be derogated, but ALL companies will have to meet BOELVs.	Existing IEOLVs become BOELVs, so those companies using these substances will be impacted.	Existing IEOLVs become BOELVs, so those companies using these substances will be impacted.
Record keeping			No significant impacts on R&D anticipated				

Increased costs for companies that are required to implement measures resulting from changes in the regulations may put pressure on the availability of funds to pursue additional R&D activities for product development. The analysis above suggests that cost increases resulting from the different Options may be of significance, particularly for small and micro-enterprises, leading to potential reductions in spending on R&D.

It is noted that the requirement to consider and implement substitution is likely to result in some companies engaging in specific research and development to identify alternative substances and processes. In this sense, there could also be some positive outcomes on R&D arising from the implementation of CMD requirements.

C4.3.2 Impacts on SMEs

As described above, SMEs are likely to incur significantly higher costs as a proportion of turnover than large companies as a result of Option 2, the CEFIC/ECEG/ETUC/Industrial Declaration, Option 4 and Option 5. The nature of closed systems and LEV equipment installed as part of the exposure minimisation requirement is such that it is relatively expensive, requiring a significant up-front investment. Smaller companies are likely to face greater problems in securing finance for these investments than their larger counterparts who may even be able to fund the investment from their own funds. Securing finance in highly regulated sectors, such as those involving the use of hazardous substances including R1A /1B substances may be more difficult than for other less regulated sectors, particularly where there may be expectations that further regulation will be introduced in the future.

In general, smaller companies also face higher finance charges than larger companies, who can provide greater amounts of collateral and will benefit from economies of scale in production to spread the costs of finance. Such a situation is likely to place SMEs at a further disadvantage.

Furthermore, conducting detailed analysis of the feasibility of substitution, introducing closed systems and exposure minimisation required under the CMD are often highly technical tasks carried out by specialists. Large companies are likely to have their own employees that carry out these tasks, whereas smaller companies are more likely to have to contract in specialist staff to do this. So, whilst the SME may only have to do the work for a small number of employees and only one substance, these costs will represent a much higher “per capita” cost than will be the case for large companies who will undertake the work often for multiple sites involving hundreds or thousands of workers. In the event that IOELVs become BOELVs and that measurement is required in order to benefit from derogations under, for example, Option 3+, it is likely that SMEs may also need to contract out this works at higher cost to specialist measurement companies whereas large companies may have in-house capacity to do this work. As illustrated in Section D3.1 which discusses the issue of biomonitoring, an illustrative cost for running annual testing for exposure from air inhalation can vary from €573-€1,045 when sampling and analysis is performed in-house to €1,150-€1,150 when performed by an external contractor. These costs will represent a higher proportion of SMEs turnover and thus place a heavier burden on them.

It has not been possible to identify the number of SME’s using the different Reprotoxic 1A/1B substances. Table C4-2 above does provide data on the representation of SMEs in different sectors, and the following tables illustrate those sectors where SMEs using the different Reprotoxic 1A/1B substances are most and least represented.

Table C4-8: Representation of SMEs	
Sectors	**Percentage of Microenterprises**
Highest SME representation	
F41 - Construction of buildings	94%
G Wholesale and retail trade; repair of motor vehicles and motorcycles	93%
M72 Scientific research and development	91%
C18.1 Printing and service activities related to printing	89%
Lowest SME representation	
C21 Manufacture of basic pharmaceutical products and preparations	49%
C20.2 Manufacture of pesticides and other agrochemical products	57%
C20.1 Manufacture of basic chemicals, fertilisers and nitrogen compounds, plastics and synthetic rubber in primary forms	58%
C20.3 Manufacture of paints, varnishes and similar coatings, printing ink and mastics	58%

Table C4-9: Representation of SMEs	
Sectors	**Percentage of Small companies**
Highest SME representation	
C20.3 Manufacture of paints, varnishes and similar coatings, printing ink and mastics	28%
C20.5 Manufacture of explosives	24%
C22 Manufacture of rubber and plastic products	24%
C22.2 Manufacture of plastic products	24%
Lowest SME representation	
F41 - Construction of buildings	5%
G Wholesale and retail trade; repair of motor vehicles and motorcycles	6%
M72 Scientific research and development	6%
C13: Manufacture of textiles	9%

Table C4-10: Representation of SMEs	
Sectors	**Percentage of Small and Microenterprises**
Highest SME representation	
F41 - Construction of buildings	99%
G Wholesale and retail trade; repair of motor vehicles and motorcycles	99%
C18.1 Printing and service activities related to printing	99%
C14.1: Manufacture of wearing apparel, except fur apparel	97%
M72 Scientific research and development	
Lowest SME representation	
C21 Manufacture of basic pharmaceutical products and pharmaceutical preparations	70%
C13: Manufacture of textiles	74%
C20.2 Manufacture of pesticides and other agrochemical products	79%
C20.1 Manufacture of basic chemicals, fertilisers and nitrogen compounds, plastics and synthetic rubber in primary forms	80%
B06: Extraction of crude petroleum	84%
C24 Manufacture of basic metals	84%

Microenterprises are particularly highly represented in the construction, wholesale and retail trade; repair of motor vehicles and motorcycles and scientific research and development sectors. They are less represented in a number of manufacturing sectors.

Consequently, impacts for SMEs overall might be potentially higher in those sectors where they are more highly represented.

C4.3.3 Competition

Since the Policy Options will apply to all companies using/manufacturing Reprotoxic 1A/1B substances, they might be expected to impact on all companies equally across the EU. However, it is noted that a number of MS have already included Reprotoxic 1A/1B substances within the scope of the CMD to a greater or lesser extent, with MS such as Austria, Belgium, Czech Republic and France all having adopted the CMD requirements for consideration of substitution, closed systems, minimisation of exposure and keeping records for 40 years for R1A and 1B substances. Companies in these MS will theoretically already have incurred any costs associated with this extension of regulation. With the introduction of the CMD requirements across the EU, it is likely that companies in these countries may experience a slight competitive advantage as other companies incur additional costs.

Of course, this could also be seen as a "rebalancing" of competition since companies would have likely been incurring additional costs whilst others operating in other MS which hadn't extended to CMD were not required to implement the CMD provisions. However, those operating in Austria, Belgium, the Czech Republic and France in particular will have had time to adjust and establish their markets.

C4.3.4 Internal market

The main impact on the internal market arising from introducing requirements for Reprotoxic 1A/1B substances is likely to be a stronger alignment of legislation relating to CMR substances across the EU. As mentioned previously and highlighted in Table C4-4 above, MS differ in whether or not they apply the CMD to Reprotoxic 1A/1B substances and the extent to which this is done. This means that companies operating across more than one MS will need to comply with multiple sets of requirements which differ MS to MS. As noted above in Figure C4-1 to Figure C4-4 detailing Eurostat experimental data on multinationals operating within the EU, there are significant number of companies operating multiple sites in more than one MS, and whilst the data is for all sectors, the relatively high proportion of large companies operating in the sectors associated with Reprotoxic 1A/1B highlighted above means that is likely that a number of these are included in these figures.

Operating in MS with different regulatory requirements means that companies have to engage in additional research in order to keep up with the multiple regulations so that they remain compliant in all MS. They may also have to adapt procedures and processes for risk identification and management in order to accommodate such differences. This acts as a disincentive to companies wishing to benefit from the internal market.

C4.3.5 Employment

Impacts on the level of employment

Any impacts on the level of employment arising from the various Policy Options will be primarily influenced by changes in the demand for affected companies' products (as a result of increases in price due to cost implications of the various different measures). In extreme cases, companies may close down as a result of becoming uncompetitive in their respective markets leading to job losses, or others may decide to relocate their operations outside of the EU where costs are lower or regulation is less stringent.

The analysis presented above concludes that there are unlikely to be significant numbers of business closures or relocations outside of the EU as a result of the additional costs that would be incurred under Options 2-5. As discusses, the costs likely to be incurred under the different Options are uncertain, but based on the modelled costs generated through the study, the overall increases do not appear to represent a significant percentage of turnover for large companies in particular. SMEs would likely be more impacted as the cost increases might represent a greater percentage of their lower turnover but it is impossible to quantify the number that might see significant reductions in sales or close down as a result.

Based on the assumption that 2% of companies in the different sectors using Reprotoxic 1A/1B substances might have workers with some potential for exposure, and that of these, many are already compliant with existing OELs at EU and Member State level, then the number of companies likely to be impacted in a way that threatens company closure would be considered as being low.

The potential impacts on employment under the different Policy Options are summarised in the following Table.

Table C4-11: Summary of the employment impacts of the Policy Options

Impact	Option 1-	Option 1	Option 2	Option 3	Option 3+	Option 4	Option 5
Level of employment	0	0	0/-	0/-	0/-	0/-	0/-

C4.4 Summary of market impacts

Error! Reference source not found. below provides a summary of market impacts likely arising from the Policy Options based on the information available and analysis provided above.

Table C4-12: Summary of the market impacts of the Policy Options									
Impact	**Stakeholders affected**	**Relevant components/ type of impact**	**Option 1-**	**Option 1**	**Option 2**	**Option 3**	**Option 3+**	**Option 4**	**Option 5**
Sectoral competitiveness	Companies	Costs relative to turnover. Relocation of companies	No change	No change	Increased cost for some companies, in some cases significant (where substitution is undertaken) but majority expected to be relatively low % of turnover. Companies unlikely to relocate due to relatively low costs as % of turnover and high costs of relocation	Increased cost for some companies, in some cases significant (where substitution is undertaken) but majority expected to be relatively low % of turnover. Companies unlikely to relocate due to relatively low costs as % of turnover and high costs of relocation	Increased cost for some companies, in some cases significant (where substitution is undertaken) but majority expected to be relatively low % of turnover. Potentially lower costs from exposure minimisation likely to lead to fewer companies affected. Companies unlikely to relocate due to relatively low costs as % of turnover and high costs of relocation	Increased cost for some companies, in some cases significant (where substitution is undertaken) but majority expected to be relatively low % of turnover. Companies unlikely to relocate due to relatively low costs as % of turnover and high costs of relocation	Increased cost for some companies, in some cases significant (where substitution is undertaken) but majority expected to be relatively low % of turnover. Companies unlikely to relocate due to relatively low costs as % of turnover and high costs of relocation
			0	0	++	++	++	++	++
Impact on R&D and innovation	Companies	Increase in costs relative to R&D expenditures	No change	No change	Cost increases for some R 1A/1B companies, potentially threatening R&D expenditures. Overall limited	Cost increases for some R 1A/1B companies, potentially threatening R&D expenditures, but less than Option 2 due to derogations. More will be affected if derogations removed	Cost increases for some R 1A/1B companies, potentially threatening R&D expenditures. Overall limited	Cost increases for some R 1A/1B companies, potentially threatening R&D expenditures. Overall limited	Cost increases for some R 1A/1B companies, potentially threatening R&D expenditures. Overall limited

Table C4-12: Summary of the market impacts of the Policy Options									
Impact	**Stakeholders affected**	**Relevant components/ type of impact**	**Option 1-**	**Option 1**	**Option 2**	**Option 3**	**Option 3+**	**Option 4**	**Option 5**
			0	++	++	++	++	++	++
Impact on SMEs			No change	No change	Greater impact on costs as % of turnover for SMEs. Some more threatened with closure	Greater impact on costs as % of turnover for SMEs. Some more threatened with closure	Greater impact on costs as % of turnover for SMEs. Some more threatened with closure	Greater impact on costs as % of turnover for SMEs. Some more threatened with closure	Greater impact on costs as % of turnover for SMEs. Some more threatened with closure
					+++	+++	+++	+++	+++
Internal Market and Competition			No change	No change	Companies in MS that have already extended CMD to include Rs will be at competitive advantage. However, this represents levelling of playing field	Companies in MS that have already extended CMD to include Rs will be at competitive advantage. However, this represents levelling of playing field	Companies in MS that have already extended CMD to include Rs will be at competitive advantage. However, this represents levelling of playing field	Companies in MS that have already extended CMD to include Rs will be at competitive advantage. However, this represents levelling of playing field	Companies in MS that have already extended CMD to include Rs will be at competitive advantage. However, this represents levelling of playing field
			0	0	0	0	0	0	0
Employment	Workers	Job losses	No change	No change	Low likelihood that companies will go out of business or relocate suggests little impact on employment, although some SMEs may lose jobs	Low likelihood that companies will go out of business or relocate suggests little impact on employment, although some SMEs may lose jobs	Low likelihood that companies will go out of business or relocate suggests little impact on employment, although some SMEs may lose jobs	Low likelihood that companies will go out of business or relocate suggests little impact on employment, although some SMEs may lose jobs	Low likelihood that companies will go out of business or relocate suggests little impact on employment, although some SMEs may lose jobs
			0	0	+	+	+	+	+
Qualitative assessment scale: Highest costs to highest benefits: ++++ +++ ++ + 0 + ++ +++ ++++ Key: ++++: very high negative impact, +++: high negative impact, ++: medium negative impact, +: limited negative impact, 0: no negative impact.									

Part D: Comparative Assessment of the Policy Options

D1 Summary of the Costs and Benefits of the Policy Options

D1.1 Introduction

Due to the fact that the assessments of the costs, benefits, and market effects relies on a mixture of quantitative and qualitative approaches, Multi-Criteria Analysis (MCA) is used in this section to compare the impacts of the different Policy Options. The costs, benefits and market impacts are compared below by Policy Option.

D1.2 Options 1 – and 1 (baseline without/with additional guidance)

The table below summarises the different components and how they relate to Options 1- and 1.

Table D1-1: Components of Options 1- and 1

Component		O1-: Baseline (no guidance)	O1: Baseline (including OSH guidance)
Additional OSH guidance			✓
Extension of CMD to R 1A/1B	Substitution, closed systems		
	Exposure minimisation		
	IOELVs become BOELVs*		
	Record keeping		
Additional BOELVs for R 1A/1B substances		✓	✓
Merging of the two directives			
Threshold/non-threshold approach		C	C
Modernisation			
Add-on elements (BLVs, sensitisers)			

Notes:
Dark grey cells denote definite change when compared with a no change scenario.
C: Collective (risk classification based) I: Individual (individual substance based)
**not a direct legal consequence of the extension of the CMD to R 1A/1B substances but modelled for the purposes of this Impact Assessment*

The table below summarises the costs, benefits and market impacts from Options 1- and 1.

Table D1-2: Costs, benefits, and market effects of Options 1- and 1

Component/Option			Costs		Benefits		Market effects	
			O1-	O1	O1-	O1	O1-	O1
			Compliance costs (annualised cost in € million)		***Reduced ill health (annualised savings in € million)***			
Additional OSH guidance			0	++	0	++		
Extension of CMD to R 1A/1B	Substitution	Co.	0	0	0	0		
		Im.	0	0				
	Closed systems	Co.	0	0				
		Im.	0	0				
	Exposure minimisation		0	0	0	0		
	IOELVs -> BOELVs		0	0	0	0		
	40 years record keeping		0	0	0	0		

Table D1-2: Costs, benefits, and market effects of Options 1- and 1							
Component/Option		Costs		Benefits		Market effects	
		O1-	O1	O1-	O1	O1-	O1
Overall health benefits for R 1A/1B substances (workers & families, companies, authorities)				0	++		
Additional BOELVs for R 1A/1B		+	+	++	++		
Merging of the two directives		0	0				
Individual substance approach (T vs NT)		0	0	0	0		
Add-on elements	Health surveillance/BLVs	0	0	0	0		
	Sensitisers	0	0	0	0		
Modernisation of terms		+[6]	+[6]	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 – authorities (legal coherence)				0	+		
Administrative simplification – authorities (ease of enforcement)				0	+		
Level playing field - companies				0	+		
Sectoral competitiveness – companies						No change 0	No change 0
Impact on R&D and innovation - companies						No change 0	No change -
Impact on SMEs						No change	No change
Internal market and competition						No change 0	No change 0
EU – development of OSH guidance (total cost in € million)		0	€10m				
Member States – transposition cost (total cost in € million)		0	0				
Working conditions (workers)		0	0				
Fundamental rights (workers)				0	++		
Job losses (workers)						No change 0	No change 0

*Notes on costs: All cost quantifications are illustrative, Co.: consideration, Im.: implementation, Qualitative assessment scale: Highest costs to highest benefits: ++++ +++ ++ + 0 + ++ +++ ++++ Key: ++++: very high costs, +++: high costs, ++: medium costs, +: limited costs, 0: no costs *: Less than under options with no derogation, 1: Cost unknown but potentially very high. Although substitution can result in cost savings over the long-term in instances where operating costs can be reduced, it is expected that in most instances companies would have switched to the alternative themselves if it were cheaper over the long term. 2: Due to derogations for some substances.3: It is possible that the general trend towards more OELs would see additional BOELVs adopted even under the baseline. However, due to the central role of BOELVs in achieving a derogation from exposure minimisation, it is expected that the process of introducing BOELVs would be significantly accelerated under Option 3+, with more BOELVs being adopted over the coming, say, 5-10 years. As a result, companies would incur greater costs under Option 3+ due to the need to comply (and demonstrate compliance) with these BOELVs. Although the analysis carried out under this study for the 30 substances suggests that most exposure is already below the thresholds for reprotoxic effects, it is expected that some companies could incur relatively high costs. This is mitigated by means of the exposure minimisation derogation under Option 3+. 4: Unnecessary costs for substances that are deemed non-threshold due to hazard classification but which have a threshold 5: Although there is a large number of sensitising substances, it is expected that minimisation is already extensively practiced 6: Due to lack of clarity under the baseline*

Notes on benefits: All benefit estimates are illustrative of the order of magnitude and the actual benefits depend on a number of uncertain factors. All monetary values are annualised benefits in € million. Qualitative assessment scale: Highest costs to highest benefits: ++++ +++ ++ + 0 + ++ +++ ++++ Key: ++++ substantial benefits, +++ significant benefits, ++ some benefits, + limited benefits, 0 no change 1: This is due to the fact that the benefits would be phased in over time – a derogation would be applied to all R 1A/1B substances that are not also C/M 1A/1B and these would be brought into the scope of CMD requirements should it be determined that they have no threshold for effects. 2: It is possible that the general trend towards more OELs would see additional BOELVs adopted even under the baseline. However, due to the central role of BOELVs in achieving a derogation from exposure minimisation, it is expected that the process of introducing BOELVs would be significantly accelerated under Option 3+, with more BOELVs being adopted over the coming, say, 5-10

Table D1-2: Costs, benefits, and market effects of Options 1- and 1						
Component/Option	Costs		Benefits		Market effects	
	O1-	O1	O1-	O1	O1-	O1
years. As a result, companies would incur greater costs under Option 3+ due to the need to comply (and demonstrate compliance) with these BOELVs. Although the analysis carried out under this study for the 30 substances suggests that most exposure is already below the thresholds for reprotoxic effects, it is expected that some companies could incur relatively high costs – due to monitoring and in some instances RMMs. 3: Unnecessary costs for substances that are deemed non-threshold due to hazard classification but which have a threshold 4: Although there is a large number of sensitising substances, it is expected that minimisation is already extensively practiced						

D1.3 Option 2 (extension of the CMD to R 1A/1B substances)

The table below summarises the different components and how they relate to Option 2.

Table D1-3: Option 2 and the relevant components		
Component		**O2: R 1A/1B in CMD**
Additional OSH guidance		✓
Extension of CMD to R 1A/1B	Substitution, closed systems	✓
	Exposure minimisation	✓
	IOELVs become BOELVs*	✓*
	Record keeping	✓
Merging of the two directives		
Threshold/non-threshold approach		C
Modernisation		
Add-on elements (BLVs, sensitisers)		
*Notes: Dark grey cells denote definite change when compared with the baseline. C: Collective (risk classification based) I: Individual (individual substance based) *not a direct legal consequence of the extension of the CMD to R 1A/1B substances but modelled for the purposes of this Impact Assessment*		

The table below summarises the costs, benefits and market impacts from Option 2.

Table D1-4: Costs, benefits, and market effects of Option 2					
Component/Option			Costs	Benefits	Market effects
			O2	O2	O2
			Compliance costs (annualised cost in € million)	***Reduced ill health (annualised savings in € million)***	
Additional OSH guidance			++	++	
Extension of CMD to R 1A/1B	Substitution	Co.	++ (€10-20m)	++ 1-191 avoided repro cases p.a. €0.02-16m p.a.	
		Im.	Potentially ++++[1]		
	Closed systems	Co.	+++ (€180-260m)		
		Im.	+++ (€60-240m)		
	Exposure minimisation		+++ (€80-250m)	++ 4-191 avoided repro cases p.a. €0.08-16m p.a.	
	IOELVs -> BOELVs		+	0	
	40 years of records		++ (€80-140m)	++	
Overall health benefits for R 1A/1B substances (workers & families, companies, authorities)				***+++ 1-382 avoided repro cases p.a. €0.02-31m p.a.***	
Additional BOELVs for R 1A/1B			+	++	

Table D1-4: Costs, benefits, and market effects of Option 2				
Component/Option		Costs	Benefits	Market effects
		O2	O2	O2
Merging of the two directives		0		
Individual substance approach (T vs NT)		+++[4]	Negative impact	
Add-on elements	Health surveillance/BLVs	0	0	
	Sensitisers	0		
Modernisation of terms		+[6]	0	
Reduced absenteeism - companies			Included in health-related benefits (see above)	
Reduced healthcare and social sec. expenditure - authorities				
Administrative simplification – companies			++	
Administrative simplification – authorities (legal coherence)			++	
Administrative simplification – authorities (ease of enforcement)			++	
Level playing field - companies			+++	
Sectoral competitiveness – companies				Increased cost for some companies, in some cases significant (where substitution is undertaken) but majority expected to be relatively low % of turnover. Companies unlikely to relocate due to relatively low costs as % of turnover and high costs of relocation ++
Impact on R&D and innovation - companies				Cost increases for some R 1A/1B companies, potentially threatening R&D expenditures. Overall limited ++
Impact on SMEs				Greater impact on costs as % of turnover for SMEs. Some more threatened with closure +++
Internal market and competition				Companies in MS that have already extended CMD to include Rs will be at competitive advantage. However, this represents levelling of playing field 0
EU – development of OSH guidance (total cost in € million)		€10m		
Member States – transposition cost (total cost in € million)		€3m		
Working conditions (workers)		Improvement		
Fundamental rights (workers)			+++	
Job losses (workers)				Low likelihood that companies will go out of business or relocate suggests little impact on employment, although some SMEs may lose jobs +
*Notes on costs: All cost quantifications are illustrative, Co.: consideration, Im.: implementation, Qualitative assessment scale: Highest costs to highest benefits: ++++ +++ ++ + 0 + ++ +++ ++++ Key: ++++: very high costs, +++: high costs, ++: medium costs, +: limited costs, 0: no costs *: Less than under options with no derogation, 1: Cost unknown but potentially very high. Although substitution can result*				

Table D1-4: Costs, benefits, and market effects of Option 2			
Component/Option	Costs	Benefits	Market effects
	O2	O2	O2
in cost savings over the long-term in instances where operating costs can be reduced, it is expected that in most instances companies would have switched to the alternative themselves if it were cheaper over the long term. 2: Due to derogations for some substances.3: It is possible that the general trend towards more OELs would see additional BOELVs adopted even under the baseline. However, due to the central role of BOELVs in achieving a derogation from exposure minimisation, it is expected that the process of introducing BOELVs would be significantly accelerated under Option 3+, with more BOELVs being adopted over the coming, say, 5-10 years. As a result, companies would incur greater costs under Option 3+ due to the need to comply (and demonstrate compliance) with these BOELVs. Although the analysis carried out under this study for the 30 substances suggests that most exposure is already below the thresholds for reprotoxic effects, it is expected that some companies could incur relatively high costs. This is mitigated by means of the exposure minimisation derogation under Option 3+. 4: Unnecessary costs for substances that are deemed non-threshold due to hazard classification but which have a threshold 5: Although there is a large number of sensitising substances, it is expected that minimisation is already extensively practiced 6: Due to lack of clarity under the baseline *Notes on benefits: All benefit estimates are illustrative of the order of magnitude and the actual benefits depend on a number of uncertain factors. All monetary values are annualised benefits in € million. Qualitative assessment scale: Highest costs to highest benefits: ++++ +++ ++ + 0 + ++ +++ ++++ Key: ++++ substantial benefits, +++ significant benefits, ++ some benefits, + limited benefits, 0 no change 1: This is due to the fact that the benefits would be phased in over time – a derogation would be applied to all R 1A/1B substances that are not also C/M 1A/1B and these would be brought into the scope of CMD requirements should it be determined that they have no threshold for effects. 2: It is possible that the general trend towards more OELs would see additional BOELVs adopted even under the baseline. However, due to the central role of BOELVs in achieving a derogation from exposure minimisation, it is expected that the process of introducing BOELVs would be significantly accelerated under Option 3+, with more BOELVs being adopted over the coming, say, 5-10 years. As a result, companies would incur greater costs under Option 3+ due to the need to comply (and demonstrate compliance) with these BOELVs. Although the analysis carried out under this study for the 30 substances suggests that most exposure is already below the thresholds for reprotoxic effects, it is expected that some companies could incur relatively high costs – due to monitoring and in some instances RMMs. 3: Unnecessary costs for substances that are deemed non-threshold due to hazard classification but which have a threshold 4: Although there is a large number of sensitising substances, it is expected that minimisation is already extensively practiced*			

D1.4 Option 3 (extension with automatic derogation)

The table below summarises the different components and how they relate to Option 3.

Table D1-5: Option 3 and the relevant components		
Component		O3: R 1A/1B in CMD (derogations)
Additional OSH guidance		✓
Extension of CMD to R 1A/1B	Substitution, closed systems	D
	Exposure minimisation	D
	IOELVs become BOELVs*	✓*
	Record keeping	D
Merging of the two directives		
Threshold/non-threshold approach		I
Modernisation		
Add-on elements (BLVs, sensitisers)		
Notes: *Dark grey cells denote definite change when compared with the baseline. Light grey cells denote potential changes to the baseline, depending on whether individual substances are derogated or not (i.e. determined to have a threshold for adverse effects).* *D: Depends on whether the substance is derogated or not* *C: Collective (risk classification based) I: Individual (individual substance based)* **not a direct legal consequence of the extension of the CMD to R 1A/1B substances but modelled for the purposes of this Impact Assessment*		

The table below summarises the costs, benefits and market impacts from Option 3.

Table D1-6: Costs, benefits, and market effects of Options 3					
Component/Option			**Costs**	**Benefits**	**Market effects**
			Compliance costs (annualised cost in € million)	***Reduced ill health (annualised savings in € million)***	
Additional OSH guidance			++	++	
Extension of CMD to R 1A/1B	Substitut-ion	Co.	+	++ Not possible to quantify but less[1] than under O2, O3+, O4, and 05	
		Im.	++		
	Closed systems	Co.	++		
		Im.	++		
	Exposure minimisation		++		
	IOELVs -> BOELVs		+	0	
	40 years record keeping		+	+	
Overall health benefits for R 1A/1B substances (workers & families, companies, authorities)				++ Not quantified but less1 than under O2, O3+, O4, O5	
Additional BOELVs for R 1A/1B			+	+	
Merging of the two directives			0		
Individual substance approach (T vs NT)			+++	Negative impact	
Add-on elements	Health surveillance/BLVs		0	0	
	Sensitisers		0		
Modernisation of terms			+	0	
Reduced absenteeism - companies				Included in health-related benefits (see above)	
Reduced healthcare and social sec. expenditure - authorities					
Administrative simplification – companies				+++	
Administrative simplification – authorities (legal coherence)				+++	
Administrative simplification – authorities (ease of enforcement)				+	
Level playing field - companies				++	
Sectoral competitiveness – companies					Increased cost for some companies, in some cases significant (where substitution is undertaken) but majority expected to be relatively low % of turnover. Companies unlikely to relocate due to relatively low costs as % of turnover and high costs of relocation ++
Impact on R&D and innovation - companies					Cost increases for some R 1A/1B companies, potentially threatening R&D expenditures, but less than Option 2 due to derogations. More will be affected if derogations removed ++
Impact on SMEs					Greater impact on costs as % of turnover for SMEs. Some more threatened with closure +++

Table D1-6: Costs, benefits, and market effects of Options 3			
Component/Option	**Costs**	**Benefits**	**Market effects**
Internal market and competition			Companies in MS that have already extended CMD to include Rs will be at competitive advantage. However, this represents levelling of playing field 0
EU – development of OSH guidance (total cost in € million)	€10m		
Member States – transposition cost (total cost in € million)	€3m		
Working conditions (workers)	Slight improvement		
Fundamental rights (workers)		++	
Job losses (workers)			Low likelihood that companies will go out of business or relocate suggests little impact on employment, although some SMEs may lose jobs +
*Notes on costs: All cost quantifications are illustrative, Co.: consideration, Im.: implementation, Qualitative assessment scale: Highest costs to highest benefits: ++++ +++ ++ + 0 + ++ +++ ++++ Key: ++++: very high costs, +++: high costs, ++: medium costs, +: limited costs, 0: no costs *: Less than under options with no derogation, 1: Cost unknown but potentially very high. Although substitution can result in cost savings over the long-term in instances where operating costs can be reduced, it is expected that in most instances companies would have switched to the alternative themselves if it were cheaper over the long term. 2: Due to derogations for some substances.3: It is possible that the general trend towards more OELs would see additional BOELVs adopted even under the baseline. However, due to the central role of BOELVs in achieving a derogation from exposure minimisation, it is expected that the process of introducing BOELVs would be significantly accelerated under Option 3+, with more BOELVs being adopted over the coming, say, 5-10 years. As a result, companies would incur greater costs under Option 3+ due to the need to comply (and demonstrate compliance) with these BOELVs. Although the analysis carried out under this study for the 30 substances suggests that most exposure is already below the thresholds for reprotoxic effects, it is expected that some companies could incur relatively high costs. This is mitigated by means of the exposure minimisation derogation under Option 3+. 4: Unnecessary costs for substances that are deemed non-threshold due to hazard classification but which have a threshold 5: Although there is a large number of sensitising substances, it is expected that minimisation is already extensively practiced 6: Due to lack of clarity under the baseline* *Notes on benefits: All benefit estimates are illustrative of the order of magnitude and the actual benefits depend on a number of uncertain factors. All monetary values are annualised benefits in € million. Qualitative assessment scale: Highest costs to highest benefits: ++++ +++ ++ + 0 + ++ +++ ++++ Key: ++++ substantial benefits, +++ significant benefits, ++ some benefits, + limited benefits, 0 no change 1: This is due to the fact that the benefits would be phased in over time – a derogation would be applied to all R 1A/1B substances that are not also C/M 1A/1B and these would be brought into the scope of CMD requirements should it be determined that they have no threshold for effects. 2: It is possible that the general trend towards more OELs would see additional BOELVs adopted even under the baseline. However, due to the central role of BOELVs in achieving a derogation from exposure minimisation, it is expected that the process of introducing BOELVs would be significantly accelerated under Option 3+, with more BOELVs being adopted over the coming, say, 5-10 years. As a result, companies would incur greater costs under Option 3+ due to the need to comply (and demonstrate compliance) with these BOELVs. Although the analysis carried out under this study for the 30 substances suggests that most exposure is already below the thresholds for reprotoxic effects, it is expected that some companies could incur relatively high costs – due to monitoring and in some instances RMMs. 3: Unnecessary costs for substances that are deemed non-threshold due to hazard classification but which have a threshold 4: Although there is a large number of sensitising substances, it is expected that minimisation is already extensively practiced*			

D1.5 Option 3+ (extension and subsequent derogations from exposure minimisation)

The table below summarises the different components and how they relate to Option 3+.

Table D1-7: Components of Option 3+		
Component		**O3+: Joint declaration**
Additional OSH guidance		✓
Extension of CMD to R 1A/1B	Substitution, closed systems	✓
	Exposure minimisation	D
	IOELVs become BOELVs*	✓**
	Record keeping	

Table D1-7: Components of Option 3+	
Component	**O3+: Joint declaration**
Merging of the two directives	
Threshold/non-threshold approach	I
Modernisation	
Add-on elements (BLVs, sensitisers)	
Notes: Dark grey cells denote definite change when compared with the baseline. Light grey cells denote potential changes to the baseline, depending on whether individual substances are derogated or not (i.e. determined to have a threshold for adverse effects). *D: Depends on whether the substance is derogated or not* *C: Collective (risk classification based) I: Individual (individual substance based)* **not a direct legal consequence of the extension of the CMD to R 1A/1B substances but modelled for the purposes of this Impact Assessment* ***under Option 3+, BOELVs would be established for all (or most) R 1A/1B substances*	

The table below summarises the costs, benefits and market impacts from Option 3+.

Table D1-8: Costs, benefits, and market effects of Option 3+					
Component/Option			**Costs**	**Benefits**	**Market effects**
			O3+	**O3+**	**O3+**
			Compliance costs (annualised cost in € million)	***Reduced ill health (annualised savings in € million)***	
Additional OSH guidance			++	++	
Extension of CMD to R 1A/1B	Substitution	Co.	++ (€10-20m)	++ 1-191 avoided repro cases p.a. €0.02-16m p.a.	
		Im.	Potentially ++++[1]		
	Closed systems	Co.	+++ (€180-260m)		
		Im.	+++ (€60-240m)		
	Exposure minimisation		+++ (€80-250m)	++ 4-191 avoided repro cases p.a. €0.08-16m p.a.	
	IOELVs -> BOELVs		+	0	
	40 years of records		++ (€80-140m)	0	
Overall health benefits for R 1A/1B substances (workers & families, companies, authorities)				***+++ 1-382 avoided repro cases p.a. €0.02-31m p.a.***	
Additional BOELVs for R 1A/1B			+	+++[2]	
Merging of the two directives			+ (familiarisation)		
Individual substance approach (T vs NT)			+++[4]	Positive impact (significant positive impact if extended to C/M)	
Add-on elements	Health surveillance/ BLVs		Unknown	0	
	Sensitisers		Potentially +++[5]		
Modernisation of terms			Unknown	0	
Reduced absenteeism - companies				Included in health-related benefits (see above)	
Reduced healthcare and social sec. expenditure - authorities					
Administrative simplification – companies				+++	
Administrative simplification – authorities (legal coherence)				+++	

Table D1-8: Costs, benefits, and market effects of Option 3+			
Component/Option	Costs	Benefits	Market effects
	O3+	O3+	O3+
Administrative simplification – authorities (ease of enforcement)		++	
Level playing field - companies		++++	
Sectoral competitiveness – companies			Increased cost for some companies, in some cases significant (where substitution is undertaken) but majority expected to be relatively low % of turnover. Potentially lower costs from exposure minimisation likely to lead to fewer companies affected. Companies unlikely to relocate due to relatively low costs as % of turnover and high costs of relocation ++
Impact on R&D and innovation - companies			Cost increases for some R 1A/1B companies, potentially threatening R&D expenditures. Overall limited ++
Impact on SMEs			Greater impact on costs as % of turnover for SMEs. Some more threatened with closure +++
Internal market and competition			Companies in MS that have already extended CMD to include Rs will be at competitive advantage. However, this represents levelling of playing field 0
EU – development of OSH guidance (total cost in € million)	€10m		
Member States – transposition cost (total cost in € million)	€3m		
Working conditions (workers)	Improvement		
Fundamental rights (workers)		+++	
Job losses (workers)			Low likelihood that companies will go out of business or relocate suggests little impact on employment, although some SMEs may lose jobs +

*Notes on costs: All cost quantifications are illustrative, Co.: consideration, Im.: implementation, Qualitative assessment scale: Highest costs to highest benefits: ++++ +++ ++ + 0 + ++ +++ ++++ Key: ++++: very high costs, +++: high costs, ++: medium costs, +: limited costs, 0: no costs *: Less than under options with no derogation, 1: Cost unknown but potentially very high. Although substitution can result in cost savings over the long-term in instances where operating costs can be reduced, it is expected that in most instances companies would have switched to the alternative themselves if it were cheaper over the long term. 2: Due to derogations for some substances.3: It is possible that the general trend towards more OELs would see additional BOELVs adopted even under the baseline. However, due to the central role of BOELVs in achieving a derogation from exposure minimisation, it is expected that the process of introducing BOELVs would be significantly accelerated under Option 3+, with more BOELVs being adopted over the coming, say, 5-10 years. As a result, companies would incur greater costs under Option 3+ due to the need to comply (and demonstrate compliance) with these BOELVs. Although the analysis carried out under this study for the 30 substances suggests that most exposure is already below the thresholds for reprotoxic effects, it is expected that some companies could incur relatively high costs. This is mitigated by means of the exposure minimisation derogation under Option 3+. 4: Unnecessary costs for substances that are deemed non-threshold due to hazard classification but which have a threshold 5: Although there is a large number of sensitising substances, it is expected that minimisation is already extensively practiced 6: Due to lack of clarity under the baseline*

Notes on benefits: All benefit estimates are illustrative of the order of magnitude and the actual benefits depend on a number of uncertain factors. All monetary values are annualised benefits in € million. Qualitative assessment scale: Highest costs to highest benefits: ++++ +++ ++ + 0 + ++ +++ ++++ Key: ++++ substantial benefits, +++ significant benefits, ++ some benefits, + limited benefits,

Table D1-8: Costs, benefits, and market effects of Option 3+			
Component/Option	Costs	Benefits	Market effects
	O3+	O3+	O3+
0 no change 1: This is due to the fact that the benefits would be phased in over time – a derogation would be applied to all R 1A/1B substances that are not also C/M 1A/1B and these would be brought into the scope of CMD requirements should it be determined that they have no threshold for effects. 2: It is possible that the general trend towards more OELs would see additional BOELVs adopted even under the baseline. However, due to the central role of BOELVs in achieving a derogation from exposure minimisation, it is expected that the process of introducing BOELVs would be significantly accelerated under Option 3+, with more BOELVs being adopted over the coming, say, 5-10 years. As a result, companies would incur greater costs under Option 3+ due to the need to comply (and demonstrate compliance) with these BOELVs. Although the analysis carried out under this study for the 30 substances suggests that most exposure is already below the thresholds for reprotoxic effects, it is expected that some companies could incur relatively high costs – due to monitoring and in some instances RMMs. 3: Unnecessary costs for substances that are deemed non-threshold due to hazard classification but which have a threshold 4: Although there is a large number of sensitising substances, it is expected that minimisation is already extensively practiced			

D1.6 Option 4 (merger, extension, no modernisation)

The table below summarises the different components and how they relate to Option 4.

Table D1-9: Components of Option 4		
Component		O4: R 1A/1B in CMD, merge CAD and CMD
Additional OSH guidance		✓
Extension of CMD to R 1A/1B	Substitution, closed systems	✓
	Exposure minimisation	✓
	IOELVs become BOELVs*	✓*
	Record keeping	✓
Merging of the two directives		✓
Threshold/non-threshold approach		C
Modernisation		
Add-on elements (BLVs, sensitisers)		
Notes: *Dark grey cells denote definite change when compared with the baseline.* *C: Collective (risk classification based) I: Individual (individual substance based)* **not a direct legal consequence of the extension of the CMD to R 1A/1B substances but modelled for the purposes of this Impact Assessment*		

The table below summarises the costs, benefits and market impacts from Option 4.

Table D1-10: Costs, benefits, and market effects of Options 4					
Component/Option			Costs	Benefits	Market effects
			Compliance costs (annualised cost in € million)	***Reduced ill health (annualised savings in € million)***	
Additional OSH guidance			++	++	
Extension of CMD to R 1A/1B	Substitution	Co.	++ (€10-20m)	++ 1-191 avoided repro cases p.a. €0.02-16m p.a.	
		Im.	Potentially ++++		
	Closed systems	Co.	+++ (€180-260m)		
		Im.	+++ (€60-240m)		
	Exposure minimisation		+++ (€80-250m)	++ 4-191 avoided repro cases p.a. €0.08-16m p.a.	

Table D1-10: Costs, benefits, and market effects of Options 4				
Component/Option		**Costs**	**Benefits**	**Market effects**
	IOELVs -> BOELVs	(+)	0	
	40 years record keeping	++ (€80-140m)	++	
Overall health benefits for R 1A/1B substances (workers & families, companies, authorities)			+++ 1-382 avoided repro cases p.a. €0.02-31m p.a.	
Additional BOELVs for R 1A/1B		+	++	
Merging of the two directives		+ (familiarisation)		
Individual substance approach (T vs NT)		+++	Negative impact	
Add-on elements	Health surveillance/BLVs	0	0	
	Sensitisers	0		
Modernisation of terms		+	0	
Reduced absenteeism - companies			Included in health-related benefits (see above)	
Reduced healthcare and social sec. expenditure - authorities				
Administrative simplification – companies			+++	
Administrative simplification – authorities (legal coherence)			+++	
Administrative simplification – authorities (ease of enforcement)			++	
Level playing field - companies			+++	
Sectoral competitiveness – companies				Increased cost for some companies, in some cases significant (where substitution is undertaken) but majority expected to be relatively low % of turnover. Companies unlikely to relocate due to relatively low costs as % of turnover and high costs of relocation +
Impact on R&D and innovation - companies				Cost increases for some R 1A/1B companies, potentially threatening R&D expenditures. Overall limited ++
Impact on SMEs				Greater impact on costs as % of turnover for SMEs. Some more threatened with closure +++
Internal market and competition				Companies in MS that have already extended CMD to include Rs will be at competitive advantage. However, this represents levelling of playing field 0
EU – development of OSH guidance (total cost in € million)		€10m		
Member States – transposition cost (total cost in € million)		€3m		
Working conditions (workers)		Improvement		
Fundamental rights (workers)			+++	

Table D1-10: Costs, benefits, and market effects of Options 4			
Component/Option	**Costs**	**Benefits**	**Market effects**
Job losses (workers)			Low likelihood that companies will go out of business or relocate suggests little impact on employment, although some SMEs may lose jobs +
*Notes on costs: All cost quantifications are illustrative, Co.: consideration, Im.: implementation, Qualitative assessment scale: Highest costs to highest benefits: ++++ +++ ++ + 0 + ++ +++ ++++ Key: ++++: very high costs, +++: high costs, ++: medium costs, +: limited costs, 0: no costs *: Less than under options with no derogation, 1: Cost unknown but potentially very high. Although substitution can result in cost savings over the long-term in instances where operating costs can be reduced, it is expected that in most instances companies would have switched to the alternative themselves if it were cheaper over the long term. 2: Due to derogations for some substances.3: It is possible that the general trend towards more OELs would see additional BOELVs adopted even under the baseline. However, due to the central role of BOELVs in achieving a derogation from exposure minimisation, it is expected that the process of introducing BOELVs would be significantly accelerated under Option 3+, with more BOELVs being adopted over the coming, say, 5-10 years. As a result, companies would incur greater costs under Option 3+ due to the need to comply (and demonstrate compliance) with these BOELVs. Although the analysis carried out under this study for the 30 substances suggests that most exposure is already below the thresholds for reprotoxic effects, it is expected that some companies could incur relatively high costs. This is mitigated by means of the exposure minimisation derogation under Option 3+. 4: Unnecessary costs for substances that are deemed non-threshold due to hazard classification but which have a threshold 5: Although there is a large number of sensitising substances, it is expected that minimisation is already extensively practiced 6: Due to lack of clarity under the baseline* *Notes on benefits: All benefit estimates are illustrative of the order of magnitude and the actual benefits depend on a number of uncertain factors. All monetary values are annualised benefits in € million. Qualitative assessment scale: Highest costs to highest benefits: ++++ +++ ++ + 0 + ++ +++ ++++ Key: ++++ substantial benefits, +++ significant benefits, ++ some benefits, + limited benefits, 0 no change 1: This is due to the fact that the benefits would be phased in over time – a derogation would be applied to all R 1A/1B substances that are not also C/M 1A/1B and these would be brought into the scope of CMD requirements should it be determined that they have no threshold for effects. 2: It is possible that the general trend towards more OELs would see additional BOELVs adopted even under the baseline. However, due to the central role of BOELVs in achieving a derogation from exposure minimisation, it is expected that the process of introducing BOELVs would be significantly accelerated under Option 3+, with more BOELVs being adopted over the coming, say, 5-10 years. As a result, companies would incur greater costs under Option 3+ due to the need to comply (and demonstrate compliance) with these BOELVs. Although the analysis carried out under this study for the 30 substances suggests that most exposure is already below the thresholds for reprotoxic effects, it is expected that some companies could incur relatively high costs – due to monitoring and in some instances RMMs. 3: Unnecessary costs for substances that are deemed non-threshold due to hazard classification but which have a threshold 4: Although there is a large number of sensitising substances, it is expected that minimisation is already extensively practiced*			

D1.7 Option 5 (merger, extension, modernisation, add-on elements)

The table below summarises the different components and how they relate to Option 5.

Table D1-11: Components of Option 5		
Component		**O5: R 1A/1B in CMD, merge CAD and CMD, modernisation**
Additional OSH guidance		✓
Extension of CMD to R 1A/1B	Substitution, closed systems	✓
	Exposure minimisation	✓
	IOELVs become BOELVs	✓*
	Record keeping	✓
Merging of the two directives		✓
Threshold/non-threshold approach		C
Modernisation		✓
Add-on elements (BLVs, sensitisers)		✓
Notes: *Dark grey cells denote definite change when compared with the baseline.* *C: Collective (risk classification based) I: Individual (individual substance based)*		

not a direct legal consequence of the extension of the CMD to R 1A/1B substances but modelled for the purposes of this Impact Assessment

The table below summarises the costs, benefits and market impacts from Option 5.

Table D1-12: Costs, benefits, and market effects of Option 5

Component/Option			Costs	Benefits	Market effects
			O5	O5	O5
			Compliance costs (annualised cost in € million)	***Reduced ill health (annualised savings in € million)***	
Additional OSH guidance			++	++	
Extension of CMD to R 1A/1B	Substitution	Co.	++ (€10-20m)	++ 1-191 avoided repro cases p.a. €0.02-16m p.a.	
		Im.	Potentially ++++[1]		
	Closed systems	Co.	+++ (€180-260m)		
		Im.	+++ (€60-240m)		
	Exposure minimisation		+++ (€80-250m)	++ 4-191 avoided repro cases p.a. €0.08-16m p.a.	
	IOELVs -> BOELVs		+	0	
	40 years of records		++ (€80-140m)	++	
Overall health benefits for R 1A/1B substances (workers & families, companies, authorities)				***~~+++~~ 1-382 avoided repro cases p.a. €0.02-31m p.a.***	
Additional BOELVs for R 1A/1B			+	++	
Merging of the two directives			-0 (familiarisation)		
Individual substance approach (T vs NT)			+++[4]	Negative impact	
Add-on elements	Health surveillance/BLVs		Unknown	+++	
	Sensitisers		Potentially +++[5]		
Modernisation of terms			Unknown	+++	
Reduced absenteeism - companies				Included in health-related benefits (see above)	
Reduced healthcare and social sec. expenditure - authorities					
Administrative simplification – companies				++++	
Administrative simplification – authorities (legal coherence)				++++	
Administrative simplification – authorities (ease of enforcement)				+++	
Level playing field - companies				+++	
Sectoral competitiveness – companies					Increased cost for some companies, in some cases significant (where substitution is undertaken) but majority expected to be relatively low % of turnover. Companies unlikely to relocate due to relatively low costs as % of turnover and high costs of relocation ++
Impact on R&D and innovation - companies					Cost increases for some R 1A/1B companies, potentially threatening R&D expenditures. Overall limited ++

Table D1-12: Costs, benefits, and market effects of Option 5			
Component/Option	Costs	Benefits	Market effects
	O5	O5	O5
Impact on SMEs			Greater impact on costs as % of turnover for SMEs. Some more threatened with closure +++
Internal market and competition			Companies in MS that have already extended CMD to include Rs will be at competitive advantage. However, this represents levelling of playing field 0
EU – development of OSH guidance (total cost in € million)	€10m		
Member States – transposition cost (total cost in € million)	€3m		
Working conditions (workers)	Improvement		
Fundamental rights (workers)		+++	
Job losses (workers)			Low likelihood that companies will go out of business or relocate suggests little impact on employment, although some SMEs may lose jobs +
*Notes on costs: All cost quantifications are illustrative, Co.: consideration, Im.: implementation, Qualitative assessment scale: Highest costs to highest benefits: ++++ +++ ++ + 0 + ++ +++ ++++ Key: ++++: very high costs, +++: high costs, ++: medium costs, +: limited costs, 0: no costs *: Less than under options with no derogation, 1: Cost unknown but potentially very high. Although substitution can result in cost savings over the long-term in instances where operating costs can be reduced, it is expected that in most instances companies would have switched to the alternative themselves if it were cheaper over the long term. 2: Due to derogations for some substances.3: It is possible that the general trend towards more OELs would see additional BOELVs adopted even under the baseline. However, due to the central role of BOELVs in achieving a derogation from exposure minimisation, it is expected that the process of introducing BOELVs would be significantly accelerated under Option 3+, with more BOELVs being adopted over the coming, say, 5-10 years. As a result, companies would incur greater costs under Option 3+ due to the need to comply (and demonstrate compliance) with these BOELVs. Although the analysis carried out under this study for the 30 substances suggests that most exposure is already below the thresholds for reprotoxic effects, it is expected that some companies could incur relatively high costs. This is mitigated by means of the exposure minimisation derogation under Option 3+. 4: Unnecessary costs for substances that are deemed non-threshold due to hazard classification but which have a threshold 5: Although there is a large number of sensitising substances, it is expected that minimisation is already extensively practiced 6: Due to lack of clarity under the baseline* *Notes on benefits: All benefit estimates are illustrative of the order of magnitude and the actual benefits depend on a number of uncertain factors. All monetary values are annualised benefits in € million. Qualitative assessment scale: Highest costs to highest benefits: ++++ +++ ++ + 0 + ++ +++ ++++ Key: ++++ substantial benefits, +++ significant benefits, ++ some benefits, + limited benefits, 0 no change 1: This is due to the fact that the benefits would be phased in over time – a derogation would be applied to all R 1A/1B substances that are not also C/M 1A/1B and these would be brought into the scope of CMD requirements should it be determined that they have no threshold for effects. 2: It is possible that the general trend towards more OELs would see additional BOELVs adopted even under the baseline. However, due to the central role of BOELVs in achieving a derogation from exposure minimisation, it is expected that the process of introducing BOELVs would be significantly accelerated under Option 3+, with more BOELVs being adopted over the coming, say, 5-10 years. As a result, companies would incur greater costs under Option 3+ due to the need to comply (and demonstrate compliance) with these BOELVs. Although the analysis carried out under this study for the 30 substances suggests that most exposure is already below the thresholds for reprotoxic effects, it is expected that some companies could incur relatively high costs – due to monitoring and in some instances RMMs. 3: Unnecessary costs for substances that are deemed non-threshold due to hazard classification but which have a threshold 4: Although there is a large number of sensitising substances, it is expected that minimisation is already extensively practiced*			

D2 Illustrative Case Studies

D2.1 Summary of the lead case study

D2.1.1 Application of the Policy Options to lead

Lead is an interesting case in that there could potentially be very little difference between five of the Policy Options. This is due to the issue of whether or not there is a threshold for lead for reprotoxic effects, and if so, what level this threshold is set at. If there is no threshold, then lead does not receive a derogation under Options 3 and 3+, thus these are effectively the same as Option 2 (full application of the CMD requirements to lead). However, considering the evidence gathered on reprotoxic effects for this study, there may well be a threshold for lead, but this could be at a very low level, potentially making it indistinguishable from background exposure. This threshold would be far below any existing values in the CAD (note that the current binding OELV in Annex I of the CAD is not health-based[118]). If the threshold is so low that it is not feasible to measure occupational exposure separately to background exposure, then there is effectively no threshold. Thus, for any of the Policy Options where there is a derogation for threshold substances (e.g. Options 3 and 3+), there is effectively no threshold for lead. This results in the full application of the CMD requirements to lead under all potential Policy Options with the exception of Option 1, the current baseline.

The table below summarises the application of the Policy Options to lead.

Table D2-13: Summary of the Policy Options and their implications for lead

Policy Option	Situation for lead
O1: Baseline (no changes to EU OSH legislation)	The current baseline situation would continue, with development of guidance on best available techniques and interpretation of the CAD assumed to occur. The baseline includes the voluntary agreement by the Battery Council International, EUROBAT and the ILA to decrease worker blood lead levels to 20 µg/dl by 2025 (or earlier for certain sectors)[119]
O2: R 1A/1B in CMD (no derogations)	Lead, lead di(acetate) and trilead dioxide phosphate are classified as R 1A/1B so full application of CMD requirements would occur
O3: R 1A/1B in CMD (with derogations)	Lead, lead di(acetate) and trilead dioxide phosphate are classified as R 1A/1B so are included in the CMD. Whilst there may be a threshold for reprotoxic effects for lead, this could well be too low to enable distinction between occupational exposure and background exposure, thus effectively meaning that the substance does not have a threshold. Full application of CMD requirements therefore occurs
O3+: R 1A/1B in CMD with derogations (Joint Declaration)	Lead, lead di(acetate) and trilead dioxide phosphate are classified as R 1A/1B so are included in the CMD. Lead is assumed not to have a threshold or safe level (the existing BOELV in Annex I of the CAD Is not health based), thus full application of the CMD occurs

[118] European Commission (2010): Guidance for employers on controlling risks from chemicals, Interface between Chemicals Agents Directive and REACH at the workplace, accessed at: https://osha.europa.eu/da/file/40569/ on 28 November 2018.

[119] ILA, EUROBAT and Battery Council International (2017): Lead and lead battery industries announce ambitious new targets to protect workers, accessed at: https://www.eurobat.org/news-publications/press-releases/100-lead-and-lead-battery-industries-announce-ambitious-new-targets-to-protect-workers on 29 November 2018.

Table D2-13: Summary of the Policy Options and their implications for lead	
Policy Option	**Situation for lead**
O4: Merge CMD and CAD into a single directive but no modernisation	Lead, lead di(acetate) and trilead dioxide phosphate are classified as R 1A/1B so captured by the requirements of the CMD
O5: Merge CAD and CMD and modernise in a single directive	Lead, lead di(acetate) and trilead dioxide phosphate are classified as R 1A/1B so CMD requirements would apply

D2.1.2 Benefits of the Policy Options for lead

The main benefits of the Policy Options relate to decreased worker exposure levels. However, reductions are expected to be felt under the baseline due to the voluntary agreement between the Battery Council International, EUROBAT and the ILA to decrease worker blood lead levels to 20 µg/dl by 2025. Considering the current situation, the majority of cases of ill health relate to impaired male fertility (note that the SUMER data indicate that the sex ratio for workers exposed to lead is 9:1 male:female[120]). The threshold identified for such effects within this study is 25 µg/dl. Decreasing worker blood lead levels to 20 µg/dl would avoid these cases. Based on ILA data, the majority of the exposed workers are within the battery sector, which can be assumed to be covered by the voluntary agreement. Assuming that half of male lead battery workers whose blood lead level is currently estimated to be over 20 µg/dl have their level reduced to under this target by 2025, this could result in around 35 fewer cases of impaired male fertility per year. This reduction is relatively significant given that the total number of cases for all effects has been estimated as 111.4 (scenario 2) and 125 (scenario 3). This reduction is expected under the baseline, assuming the target is met as per the voluntary agreement[121]. There may be further benefits under the other Policy Options through companies not party to the agreement taking further action to reduce worker exposure (e.g. implementing closed systems where technically feasible), but the extent of these is uncertain.

D2.1.3 Costs of the Policy Options for lead

Inclusion within the CMD would require lead companies to follow a hierarchy of risk management measures (substitution, use of closed systems and minimisation of exposure). Consultation responses have indicated that substitution is not possible, with closed systems often being technically infeasible. However, there may be some scope for installing closed systems in the ceramic ware and lead crystal glass production.

D2.2 Summary of the borates case study

The borate reprotoxins case study looks at the impact, particularly the benefits and costs, of three of the Policy Options, 2, 3 and 3+ and is described in full in Annex 5.

[120] Cavet, M et al., INRS (2016): Les Expositions aux cancerogenes, mutagenes et reprotoxique: un zoom sur huit produits chimiques TF 233, accessed at: http://www.inrs.fr/media.html?refINRS=TF%20233 and Vinck, L. and Memi, S., SUMER (2015): Les expositions aux risques professionnels les produits chimiques, accessed at:https://dares.travail-emploi.gouv.fr/dares-etudes-et-statistiques/etudes-et-syntheses/synthese-stat-synthese-eval/article/les-expositions-aux-risques-professionnels-les-produits-chimiques on 2 December 2018.

[121] Note that a previous agreement did achieve reductions.

D2.2.1 Benefits

The estimated number of cases/year due to decrease in foetal body weight/litter are, from Annex 12 in Report 1, Borates:

- Normal to low body weight: 2.5 cases/year
- Low to very low body weight: 0.1 cases/year
- Very low to extremely low body weight: 0.03 cases/year

A further 0.11 cases/year of increased % malformed foetuses are also estimated each year. The estimated cost of all cases of ill health is €400,000/year. Therefore, the maximum monetary benefit that can be derived from reducing exposure to borates is €400,000/year.

Option 2 is expected to reduce this health cost by 40-60%, Option 3 will cause no change and Option 3+ is expected to reduce the health costs by 80%. There are no other significant benefits from any of the Options.

D2.2.2 Costs

Companies will face both initial investment costs and ongoing annual operating costs for three aspects of the requirements of the CMD:

- Complying with requirements for substitution, closed systems and minimisation
- Record keeping
- Monitoring

The numbers of companies using borates and operating in Member States that have extended their legislation or not, and/or have OELs for borates, is shown below.

Table D2-1: Borate reprotoxins – number of enterprises in Member States that have extended their legislation, in Member States that have a binding OEL for borates (boric acid) and that have workers exposed to high exposure levels

	Member State has extended legislation	Member State has not extended legislation	
		Exposure levels below threshold (95%)	Exposure levels above threshold (5%)
Member States has OELs for borates (boric acid)	165,000	220,000	12,000
Member States has no OELs for borates (boric acid)	55,000	130,000	7,000
Total	**220,000**	**350,000**	**19,000**
Sources: RPA analysis			

Enterprises in Member States that have already extended their legislation are assumed to be already doing everything necessary. The companies most affected by changes in all three Options are those in Member States that have not extended their legislation, and particularly those that have employees working at exposure levels above the threshold.

Even if the actions required by these companies is minimal, and in some cases it is not, the sheer numbers of enterprises involved indicates of the level of upheaval and cost that requiring them to do anything will entail. The vast majority of the companies are operating below threshold, so there will be no health benefits from this activity. Even for companies operating above threshold, the benefits from this activity are can only be small.

The total cost estimates for companies are shown below. Professional users in agriculture, construction and other industries are excluded and, if included, would increase the costs by a factor of approximately ten.

Table D2-2: Borate reprotoxins – comparison of total annualised costs for companies for the three Options

	Substitution, closed systems and minimisation	Record keeping	Monitoring	Total
Option 2	€400 million	€370 million	0	€770 million
Option 3	0	0	0	0
Option 3+	€400 million	€370 million	€260 million	€1 billion

Sources: RPA analysis

The only other significant costs could be under Option 3+, if the OEL is set much lower than the DNEL and the threshold, this would lead to higher costs of risk management measures to achieve the lower OEL, the removal of products from the market and the closure of businesses, but it seems unlikely that the OELs would be set lower than the health threshold.

D2.3 Summary of the retinol case study

Retinol (Vitamin A) is classed as an essential nutrient/vitamin. It plays an essential role in vision, growth and tissue maintenance. However, in some cases, retinol can also cause adverse effects. Undesirable effects have been reported both from lack and excess of dietary Vitamin A.

D2.3.1 Non-monotonic dose-response curve

Retinol has a bimodal human dose-response curve, i.e. has multiple thresholds, with possible reproductive effects at both lower and higher levels of exposure with a no adverse effect zone in between these two curves.

D2.3.2 Exposed workforce and exposure concentration

There are 6.23m – 6.33m of potentially exposed workers to retinol in the EU. The biggest contributor is the agricultural sector (in particular animal production sector) with 6.2m exposed workers. The rest, i.e. 30,000 – 130,000 workers, are exposed during manufacture of food products, basic chemicals, cosmetic products and pharmaceutical products.

Only limited information on the current exposure levels in occupational setting is available. The exposure concentrations are generally assumed to be very low since retinol is being used in highly controlled sectors (e.g. the manufacture of chemicals and chemical products and the manufacture of pharmaceutical products) or in an outdoor setting (e.g. the agricultural sector). Workers in the food manufacturing sector are exposed to concentrations of 7.2 mg/m^3 (= 6.9 mg/m^3 during formulation of

food additives + background exposure of 0.3 mg/m^3). This is below the threshold for reprotoxic effects (i.e. skeletal effects and low birthweight).

D2.3.3 Self-classification

No harmonized hazard classifications are currently available for retinol as it is not listed in Annex VI of the CLP Regulation. Individual manufacturers and suppliers need to decide on the classification, i.e. follow the process of self-classification. Most manufacturers and suppliers have classified retinol as Repr. 1B/Eye Irrit. 2/Skin Sens. 1/Acute Tox. 4 and retinyl palmitate as Repr. 1B/ Skin Irrit. 2. However, the lack of data on hazardous properties of retinol makes it difficult for companies to meet the obligations for self-classification, e.g. 25 notifiers in the C&L Inventory have failed to classify retinol and retinyl palmitate as R 1A/1B/2. Some companies therefore are not required to comply with the requirements of the Pregnant Workers Directive and Young Persons Directive.

Pregnant Workers Directive is inconsistent in terms of prevention. Measures to avoid exposure do not have to be taken until the worker informs her employer that she is pregnant, which occurs around the 10th week of pregnancy. However, exposure to retinol (as well as other reprotoxins) during the early weeks of gestation can result in miscarriage or a higher risk of congenital defects. The Options of changing job or possibly taking leave from work, as recommended in the Directive, therefore come too late to prevent these risks.

D2.3.4 Costs and benefits under each Policy Option

Workers in the EU are occupationally exposed to low concentrations of retinol, below the threshold for reprotoxic effects. There are currently no cases of reprotoxic ill-health due to retinol at any realistic exposure level. Therefore, there is no benefit that can be costed.

Costs to be incurred by companies under each Policy Option are presented in table below.

Table D2-3: Retinol – total annualised costs for companies under each Option

Option	Substitution, closed systems and minimisation	Record keeping	Monitoring	Total
Option 2	€50m-€100m	€16.6m-€33.2m	0	**€66.6m-€133.2m**
Option 3	0	0	0	**0**
Option 3+	€50m-€100m	€16.6m-€33.2m	€33m-€66.5m	**€99.6m-€199.7m**
Option 4	€50m-€100m	€16.6m-€33.2m	0	**€66.6m-€133.2m**
Option 5	€50m-€100m	€16.6m-€33.2m	0	**€66.6m-€133.2m**

D3 Other Considerations Relating to the Add-on Elements Under Option 5

D3.1 Current and potential future use of biomonitoring

D3.1.1 Introduction

As defined by the European Environment Agency, "Human biomonitoring allows us to measure our exposure to chemicals by measuring the substances themselves, their metabolites or markers of subsequent health effects in body fluids or tissues. Information on human exposure can then be linked to data on sources and epidemiological surveys, in order to inform research on the exposure response relationships in humans."[122]

SCOEL refers to biological monitoring in its methodology paper[123] setting out the framework for decision making on occupational exposure limits as follows: Biological monitoring entails the measurement of chemical agents and/or their metabolites in biological media (e.g. blood, urine or breath), and the recording of biological effects induced by the respective chemical agents.

Biomonitoring programmes have been established to monitor occupationally exposed individuals, as well as provide population-wide exposure estimates. There is precedent, particularly in Germany, Canada and the USA for such programmes. Although the majority of these programs are aimed at "environmental" exposures of the general population, design parameters and the structure of these programmes could be eminently adaptable to occupational biomonitoring, with the main EU-wide example being biomonitoring of blood lead levels. In this respect, one would regard biomonitoring as an early warning system, i.e. detection of effects prior to the detection of ill health symptoms. A well-designed biomonitoring program may potentially increase the overall effectiveness of worker protection programme even though it would necessitate amendment of Directive 2004/37/EC.

The Commission published a set of BLVs recommended by SCOEL[124] in June 2014, containing 22 substances (25 separate CAS no.s). The Advisory Committee on Safety and Health at Work (ACSH), a tripartite body set up in 2003 by a Council Decision (2003/C 218/01) to streamline the consultation process in the field of occupational safety and health (OSH) and rationalise the bodies created in this area by previous Council Decisions[125], reviewed the Commission services consultation on a possible amendment of Directive 2004/37/EC to incorporate the biological values recommended by SCOEL for carcinogens and mutagens in October 2016 and January 2017 and adopted an opinion[126] in May 2017. The opinion indicated that at that time, the committee did not support an amendment of Annex II to Directive 2004/37/EC to state that health surveillance should include biological surveillance in respect

[122] https://www.eea.europa.eu/themes/human/human-biomonitoring/introduction

[123] Methodology for derivation of occupational exposure limits of chemical agents - The General Decision-Making Framework of the Scientific Committee on Occupational Exposure Limits (SCOEL), 2017 (adopted 6 December 2017)

[124] List of recommended health-based biological limit values (BLVs) and biological guidance values (BGVs) Scientific Committee on Occupational Exposure Limits (SCOEL)

[125] http://ec.europa.eu/social/main.jsp?catId=148&langId=en&intPageId=683

[126] Opinion on a possible amendment of Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work2 to incorporate provisions regarding biomonitoring, Doc 665/17, Adopted on 31/05/2017

of the biological values recommended by SCOEL and to list those values in Annex II, nor did it support an amendment of the CMD to include the possibility to set binding biological limit values in Annex III.

It did however support the use of biomonitoring in workers' health and safety protection, provided biological indicators are scientifically valid and bring added value to worker protection and prevention of occupational ill-health. It also promoted the development of EU level guidance on biological monitoring for substances under both the CMD and CAD and agreed with a potential amendment of Annex II to state that:

"Where biological surveillance is carried out, those undertaking such surveillance should take into consideration biological values recommended by SCOEL as well as other available guidance and information at national and EU level".

D3.1.2 Acceptability of biomonitoring, data use and data protection related issues

Key issues regarding the acceptability of biomonitoring relates to the workers agreement to participate in testing and the handling of information that is generated during the process. These issues are discussed in the following sub-sections.

Worker consent

Member States vary in terms of workers' need to give consent to biomonitoring and the sharing of data in this regard, and Table X7-6 in Section X7.3 of Annex 7 provides some examples across the EU. The RPA 2017 study[127] collected information on the requirement for workers to provide consent to providing samples for biomonitoring purposes and identified 6 MS where consent was required and 6 MS where it was not or workers were obliged to provide samples. In 2 MS it was not clearly identified if consent was required, one indicated there was an obligation to undergo a health examination (but did not clearly state that they had to provide a sample) and one MS indicated that employees were legally obliged to provide a blood or urine sample but that informed consent was required to take the sample. Further details on consent to providing samples for testing are provided in Annex 7.

Data handling

EU-OSHA[128] points to the fact that individual biomonitoring results are medical data and as such, should be handled accordingly. Data handling, storage and communication are important issues in the EU, subject to data protection and privacy laws. In light of this, EU-OSHA highlight that communication (and interpretation) of individual results should be made only to the worker concerned and that ethical considerations must be considered during the entire process of a biomonitoring study.

The International Commission on Occupational Health (ICOH) code of ethics[129] states that *'Biomarkers must be chosen for their validity and relevance for protection of the health of the worker concerned,*

[127] RPA, Second study to collect updated information for a limited number of chemical agents with a view to analyse the health, socio-economic and environmental impacts in connection with possible amendments of Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work, January 2017, Final Report

[128] https://oshwiki.eu/wiki/Biological_monitoring_(biomonitoring)

[129] International Code of Ethics for Occupational health professionals - Third Edition

with due regard to their sensitivity, their specificity and their predictive value'. Principles of this internationally agreed document are:

- Biomonitoring should not be used as screening tests or for insurance purposes.
- Current knowledge in biomonitoring of susceptibility does not justify job opportunity discrimination of affected workers.
- Priority should be given to non-invasive (urine) and easily collected sampling (spot). In these cases, informed consent is usually not required for routine procedures using validated biomarkers.
- Invasive tests or tests posing a health risk calls for a risk-benefit analysis, and informed consent of the worker.

The code requires occupational health professionals to maintain records with an appropriate degree of confidentiality and that the results of medical investigations should be maintained in confidential medical files. The protection of health data and of the privacy of workers is identified as part of the duty of the occupational health profession.

The RPA 2017 study noted that workers' consent to the sharing of information with an employer is a requirement for most Member States. There are some however where consent is not required (e.g. Bulgaria, Hungary and Latvia) and in some (e.g. Denmark, Lithuania) the results appear to be provided to the employer first, and are then shared with the worker. Further details on the requirement to gain workers' consent to share data are provided in Annex 7.

The issue of what happens to medical records in the event of the closure of a company is also of note. In the RPA 2017 report, it was noted that in Lithuania, monitoring data on health care and chemical agents must be transmitted to the archive to store in accordance with the law on documents and archives of the Republic of Lithuania. In Romania, where a business ceases to trade, the health and exposure records must be made available to the territorial health authority.

GDPR related issues

Regulation (EU)2016/679 of 27 April 2016 (with corrigendum published in the OJEU of 23 May 2018) sets out rules relating to the protection of natural persons with regard to the processing of personal data and rules relating to the free movement of personal data. As such, it is of direct relevance to health surveillance information collected and stored on workers exposed to CMR substances.

The European Human Biomonitoring Initiative (HBM4EU)[130] has identified key issues relating to the use of biomonitoring samples and data in its own context in a Legal and Ethics Policy Paper[131] and which highlights key issues of relevance for the monitoring of BLVs and health surveillance of workers. These are briefly summarised in the following paragraphs.

The GDPR requires data to be stored, processed and accessed in a manner which reflects a number of key principles protecting the rights of the individual that data is related to (the data subject). The HBM4EU Policy paper states the following:

[130] https://www.hbm4eu.eu/

[131] Legal and Ethics Policy Paper, Update August 2018 - HORIZON2020 Programme Contract No. 733032 HBM4EU Ref. Ares(2018)4865890 - 21/09/2018

The data must be processed *"…lawfully, fairly, and in a transparent manner" (Art. 5.1a), and for specific purposes, and not further processed in an incompatible manner (Art.5.1b). … The principle of data minimisation requires that only personal data sufficient for the purpose be processed (Article 5.1c), and that it should be accurate (Art. 5.1d)."*

The paper stresses the importance of the data subject granting consent for the processing of data. In this context, consent from the data subject must be given for processing the data, with the purpose of any data processing clearly explained using clear and plain language, and consent should be as easy to withdraw as to grant. However, as indicated below, this level of consent does not appear to be consistently required in a number of MS in relation to biomonitoring data collected in the context of samples collected in the monitoring of BLVs.

Other areas highlighted in the HBM4EU policy paper include:

- **Notification of data breach** – where the data subject is entitled to be informed of any data breach likely to "result in a risk for the rights and freedoms of individuals" within 72 hours of the controller of the data being aware of the breach
- **Right to access and further rights of notification** – the data subject is entitled to receive a copy of the personal data held in electronic form and be informed by the data controller whether or not their data is being processed, where and for what purpose
- **Right to be forgotten** – the data subject is entitled to have their data erased and any further dissemination of their data ceased, particularly in the case where they withdraw consent to data being processed

The GDPR caveats a number of the above and other provisions in terms of where the data serves the public interest, and it is noted that this will be subject to the interpretation of legal systems in different Member States and, presumably, ultimately at the Court of Justice of the European Union.

D3.1.3 Capacity to implement biomonitoring

Technical capacities

Literature review and consultation have not provided comprehensive information regarding the differing capacities of companies/laboratories to implement biomonitoring of CMR substance on an EU-wide basis. However, the RPA 2017 study collected data illustrating that BLVs were in effect for 106 different CMR substances across the EU. This list of substances covered all Member States and details on the number of CMR substances for which BLVs have been set in the different Member States are provided in Annex 7. In many cases, there are more than one BLV set for a particular substance, which can reflect different lengths of exposure, different media, different biomarkers etc.

In total, there were 705 biological limit values identified across the 106 different chemical agents and of these chemical agents (with the exception of lead which is applicable in all Member States), there were 25 agents (approximately 24%) where BLVs were applied in seven or more Member States that had identified biological values (biological limit values or guidance values) for that particular chemical agent.

It is assumed that sufficient capacity (at company and laboratory levels) is within each Member State to be able to implement biomonitoring requirements for these existing BLVs, although it is noted that from consultation responses in this study, not all companies currently carry out biomonitoring other than for lead (which is mandatory) and that many other BLVs are not mandatory. It is noted also that

biomonitoring may be carried out for a wide range of other purposes and substances other than just CMRs, meaning that general capacities for biomonitoring are likely to be significantly higher than just for CMRs.

Cost of biomonitoring

An increase in the use of biomonitoring through the establishment of additional binding BLVs at EU level under Option 5 would result in additional costs to both companies required to obtain and analyse blood/urine samples as well as for MS authorities in monitoring and enforcing compliance. It is also the case they biomonitoring technologies are not available for all substances and therefore in order to introduce more BLVs and monitor exposure against these, new technologies and testing methods will need to be developed, incurring R&D costs. This section provides a discussion on the nature of the costs to companies that might be envisaged under an expansion of the use of biomonitoring, along with other additional potential barriers.

A large range of analytical methods are available (43 different analytical methods are listed in the Institut National de Recherche et Sécurité - INRS 'Biotox' database[132]). The main families of analytical methods included within the database are (with acronyms from the French):

- CPG: gas phase chromatography
- CL: liquid chromatography
- HPLC: high performance liquid chromatography
- FLUO: fluorescence detector
- FID: flame ionisation detector
- ES: selective electrode
- CO-oximetry: measure of carboxyhaemoglobin
- MO: optical microscope
- ENZ: enzymatic method
- IMMUNO: immunology method
- RMIN: nuclear magnetic resonance
- SAA: atomic absorption spectroscopy
- ICP: inductively coupled plasma mass spectroscopy
- Colorimetry

Cost for analysing samples vary significantly according the chemical substance, media being tested (blood, urine etc.) and parameter being tested for. Data on sample analysis costs using different analytical methods which were extracted from the INRS database during the RPA 2017 study for a range of substances are presented in Annex 7.

Cost comparison – Biomonitoring and Air Monitoring

It is not feasible within the context of this study to estimate the scale of costs associated with the range of potential BLVs (e.g. as presented in the SCOEL paper). However, a detailed comparison of the costs of biomonitoring and air monitoring for trichloroethylene (TCE) were presented in the RPA 2017 study. It was noted that costs will vary according to the country in which monitoring is performed and that this applies to staff costs involved as well as to analytical costs charged by laboratories. All

[132] http://www.inrs.fr/publications/bdd/biotox.html

assumptions included in the cost model, as well as the estimates for biomonitoring and air-monitoring are presented in Annex 7.

The following table summarises the costs estimates for biomonitoring and air monitoring per company per year based on the assumptions made in the RPA 2017 study.

Table D3-1: Comparison of biomonitoring and air monitoring costs for TCE at the workplace per company per year			
Parameter	Biomonitoring	Air monitoring	
		Scenario 1*	Scenario 2**
Total estimated costs (€)	761-1,346	573-1,045	1,150-2,150

* Sampling and analyses performed by company; ** sampling and analyses performed by external contractor

The resulting cost estimates show:

- A monitoring campaign for TCE may be implemented for around €1,000 per year with minimum and maximum estimates about a factor of 2 below and above this value.
- Differences in labour costs and the question whether air monitoring can be performed by the company itself appear to be the most important factors[133]

Whilst the above cost comparison was specifically for measuring TCE concentrations TCE, it does provide an order of magnitude for biomonitoring costs. In the event that biomonitoring were to be implemented on an EU-wide basis for CMR substances, the cost per company would be influenced significantly by the number of CMR substances used.

It is recognised that these costs relate to urine sampling. For blood monitoring, the costs would be higher due to the logistical effort required (the worker needs to be at a specific time in a specific place, shower before, etc.).

D3.1.4 Extent to (and reliability with) which biomonitoring results can be used

Introduction

The main pathways for exposure to chemical substances in the workplace are via inhalation, dermal and oral routes, with inhalation and dermal being of primary concern. It is noted that these pathways are specific to each substance, can vary from individual to individual and can be influenced by a range of other environmental factors.

Identifying levels of occupational exposure from different chemical substances involves a range of approaches that may involve measuring through air monitoring in the workplace, measuring the presence of substances on work surfaces and biomonitoring of workers, through the monitoring of biological markers which reflect worker exposure.

Biological monitoring involves measuring biological markers in different media (e.g. blood, urine) of workers exposed to chemicals and can include:

[133] This latter issue is related to the question whether the company has the required instrumentation (e.g. a gas chromatograph) in place anyway

- the toxic substance itself;
- one or more of its transformation products or metabolites.

SCOEL's methodology for deriving occupational exposure limits indicates that measurement techniques should be able to assess exposure at:

- 0.1 times the OEL for 8-hour TWA
- 0.5 times the OEL for 15 min STEL.
- 0.1 times the BLV
- for a BGV, levels found in a non-occupationally exposed population, or at the limit of detection of the most sensitive method.

A basic comparison of biomonitoring and air monitoring is provided in the table below.

Table D3-2: Comparison of biological and workplace air monitoring[134]		
	Biological monitoring	**Workplace air monitoring**
Quantifying	Internal dose	External dose
Absorption	All routes	Inhalation only
Confounders	Metabolic phenotype	Personal protective equipment, substances with similar structure/chemical properties
Standardisation	Difficult	Easy
Interpretation	Difficult	Moderately difficult
Measurement	Indirect (biomarkers)	Usually indirect (dangerous substance)

In addition to reflecting total exposure from all routes, which is an additional advantage over air monitoring, biomonitoring also takes into account any personal protective equipment worn during handling of chemicals. In contrast, air monitoring only provides a value for the external exposure. Furthermore, as highlighted by ANSES[135], biomonitoring also takes into account repeated exposure throughout a worker's working life. SCOEL 2013 points out that inter-individual variation in toxicokinetics, as well as in other physicochemical and biological factors, may lead to differences in the amount absorbed for a given atmospheric concentration by different workers. Biomonitoring would pick up these higher-level concentrations in those workers that absorb greater amounts, whereas air monitoring alone would not. Similarly, working in different areas with different concentrations of chemicals during a shift means that individuals may be subject to greater levels of exposure than some of their counterparts. Again, biomonitoring would be able to pick up such variations.

The remainder of this section sets out some of the key processes involved in biomonitoring and highlights the issues associated with its use as an indicator for workplace exposures and subsequent ill-health resulting from different chemicals.

[134] Manno, M., Viau, C., in collaboration with Cocker, J., Colosio, C., Lowry, L., Mutti, A., Nordberg, M. & Wang, S., 'Biomonitoring for occupational health risk assessment (BOHRA)', Toxicology Letters, 2010

[135] https://www.anses.fr/en/content/biological-limit-values-chemicals-used-workplace

Required understanding for biomonitoring

According to EU OSHA[136], biomarkers can be used effectively to determine exposure and potential health effects if their toxicological background in terms of the following is understood:

- the fate of the chemical and/or its metabolites in the body (toxicokinetics);
- the mechanism of the disease/adverse effect (toxicodynamics);
- the way in which the individual factor promotes the chemical to cause disease/adverse effect (susceptibility).

EU-OSHA notes that there are a number of factors which can lead to the chemical substance transforming in the body in different ways, including gender, age, body mass, the non-workplace environment (e.g. diet, alcohol consumption, medication etc. In addition, the different metabolisms of individuals can also affect transformation.

As such, biomonitoring strategies will need to account for such variations when determining actual levels of exposure to chemicals. It is also noted that the toxicokinetic features of many substances mean that they are not appropriate for biomonitoring as a result of their short half-life and/or their disappearance from blood or urine which means they are unable to be measured appropriately.

Sampling and chemical analysis

Several factors may affect the quality of samples taken for measuring exposure, thereby influencing the quality of results. These include:

- type of biological media in which the substance is being measured
- point in time of collection (due to the varying half-lives if different substances)
- containers and preservatives and other additives used to stabilise the sample
- storage temperature
- transport time.

The concentration of a substance can vary significantly with its half-life, leading to widely fluctuating concentrations during the working day or week, meaning that the timing of sampling is essential. Samples can therefore reflect exposure over a short time and may not be representative of average long-term exposure. This means that multiple samples are required in order to accurately estimate exposure, increasing costs and inconvenience for workers. Ensuring that samples are not contaminated is also critical to the reliability of results, with SCOEL noting in its 2013 of its methodology paper for determining OELs[137] that contamination can be a source of errors in results.

[136] https://oshwiki.eu/wiki/Biological_monitoring_(biomonitoring)

[137] Methodology for the Derivation of Occupational Exposure Limits - Scientific Committee on Occupational Exposure Limits (SCOEL), Key Documentation (version 7) June 2013

ANSES (2011)[138] also notes the importance of other factors affecting the concentration of chemical agents in samples and this is an important consideration when identifying the sampling strategy. Deutsche Forschungsgemeinschaft (2015)[139] highlights that sampling should take account of both exposure conditions at the workplace and the pharmacokinetics of the chemical agent, and that factors affecting the concentration of chemical agents in blood and tissues are also important. These include level of physical activity during exposure, where the blood/air distribution is larger than 10 and extent to which workers are exposed to hyperbaric pressure. In such cases, more frequent sampling is needed.

There are also a number of factors that need to be taken into account individually (Deutsche Forschungsgemeinschaft, 2015; Christensen et al, 1999[140]):

- The dynamics of pathophysiological processes
- The short-term effects of exposure-free periods
- The long-term effects of ageing
- The specific workplace conditions
- Background exposures
- External factors such as workload, exposure to several chemical agents at the same time, intake of medicines, alcohol and smoking.

It is noted that urine samples are more readily accepted by workers than blood samples due to its less invasive nature.

The selection of an appropriate analytical method is critical for the validity/reliability of a biomarker and the following qualities all have a significant influence:

- accuracy
- precision
- reproducibility
- recovery
- sensitivity

EU-OSHA notes the importance of using reliable and validated analytical methods, supported by internal quality control and external quality assurance schemes. Similarly, the 2017 SCOEL methodology notes the importance of using appropriate biomonitoring and analytical methods and

[138] ANSES (France) (2011): Des recommandations relatives à la surveillance biologique des expositions en milieu professionnel aux agents chimiques publiés au 30 novembre 2011, available at: https://www.anses.fr/documents/ANSES-Ft-VLB.pdf on 12 September 2016

[139] Deutsche Forschungsgemeinschaft (Germany) (2015): List of MAK and BAT Values 2015: maximum concentrations and biological tolerance values at the workplace, Permanent Senate Commission for the Investigation of Health Hazards of chemical Compounds in the Work Area, Report No. 51, available at: http://onlinelibrary.wiley.com/doi/10.1002/9783527695539.fmatter/summary on 13 September 2016.

[140] Christensen JM et al (Denmark) (1999): Biomarkører og biologisk monitering (translation: Biomarkers and biological monitoring), Kapital/Chapter 6, available at: http://www.arbejdsmiljoforskning.dk/upload/toksik-i-kap-vi.pdf on 19 September 2016

that these can change over time. It is therefore essential that those facilities charged with implementing biomonitoring remain fully up-to-date with the appropriate and up-to-date methods.

Variation in results

EU-OSHA notes that:

"the predictive value of an effect biomarker is the extent to which that particular biomarker is capable of correctly separating subjects with a likelihood of impairment or disease from those without it and it may be influenced by different factors".

Measurement uncertainty can be increased by the fact that concentration levels for biomarkers can decrease when disease/negative health effects materialise. Significant variations may also exist between different workers and between different days for the same worker, further leading to uncertainty over whether or not there is exposure above the safe limit suggested by a BLV. It is also important to take into consideration that BLVs are established for healthy workers and do not cater specifically for those with particular health issues. EU-OSHA suggests that biomonitoring should be reassessed to accommodate these workers and that an individual approach may be required.

Interpretation of biomonitoring results

The French Agency for Food, Environmental and Occupational Health & Safety (ANSES)[141] observes that whilst biological monitoring includes all of the routes through which exposure may occur (inhalation, dermal, oral), it is not possible to identify the relative contribution of different routes and exposure sources, and nor can it identify exposure peaks. Consequently, whilst it may be able to identify that exposure is an issue, it has limitations as a tool to assist in identifying and remedying/mitigating the causes of exposure.

When comparing to appropriate reference values (EU-OSHA recommends that these are locally determined due to the influence of socio-economic factors and environment) it is noted by EU-OSHA that those interpreting biomonitoring results need to be aware of all the uncertainties involved in the results and how the reference is defined. Better interpretation of biomonitoring data may be achieved when variability factors are taken into consideration.

SCOEL 2013 notes the difficulties associated with interpreting results and as with results of laboratory investigations, biomonitoring results have to be evaluated whilst considering the whole picture, bearing in mind factors such as:

- the dynamics of pathophysiological processes,
- the short-term effects of exposure-free periods,
- the long-term effects of ageing,
- the specific workplace conditions,
- intensive physical activity and unusual conditions of atmospheric pressure and
- any individual background exposures

[141] https://www.anses.fr/en/content/biological-limit-values-chemicals-used-workplace

Appropriateness of biomonitoring

The Commission guidelines on the CAD[142] set out circumstances when it is appropriate or not appropriate to use biomonitoring.

Table D3-3: Appropriateness of biomonitoring	
Appropriate for	**Not appropriate for**
Confirmation of the results of an environmental assessment when this raises doubts, for example if it is difficult to obtain representative environmental measurements	Monitoring exposure to chemical agents for which reliable indicators are not available
Detection of potential absorption by routes other than the respiratory tract. The initial risk assessment, based exclusively on environmental data, may be changed as a result	Automatically replacing environmental monitoring of exposures to chemical contaminants which penetrate exclusively by inhalation
Assessing the effectiveness of using personal protective equipment or other prevention measures introduced	Evaluating the state of a worker's health, even though a clear relationship with this may exist
Detection of non-work exposures (environmental, domestic, in leisure activities, etc.)	Making a clinical diagnosis of a disease
Detection of individuals with a possible physical work overload in a group of workers theoretically operating under the same conditions	Evaluating risks or effects due to acute exposures
Detection of exposures which, while not constituting a risk, could be reduced by improving work and personal hygiene habits	Determining the work source of the contaminant analysed

D3.1.5 Information from consultation

The consultation carried out under this current study sought the views of Member State authorities, industry associations, companies and OSH professionals on the usefulness of introducing BLVs under the CMD. Of those companies that answered questions in this area (24 companies), 8 indicated that they thought it would be useful, 4 that it would not, 7 that they didn't know and 5 did not answer this specific question. Of the 24 companies responding, 9 indicated that they already carried out some biomonitoring, 12 that they didn't and 3 did not provide any indication in this regard.

Of those that expressed a view, clearly the majority were in favour of introducing BLVs under the CMD.

All stakeholder groups were asked to comment on the strengths and weaknesses of biomonitoring in respect of protecting workers. Detailed responses are provided in Annex 7 and feedback received can be summarised as follows:

Positive Feedback

Biomonitoring is considered useful as it Incorporates exposure from all exposure pathways and can bridge the gap between risk assessments and personal variations. It was felt that it could be used in the absence of but also to complement OELVs and that results could be important for early diagnosing

[142] Practical Guidelines of a Non-Binding Nature on the Protection of the Health and Safety of Workers from the Risks Related to Chemical Agents at Work, June 2005, European Commission

of potential disease in the absence of clinical signs. It was noted by OSH expert that biomonitoring for lead at least is widely accepted and legally enforced.

Negative Feedback

Member State authorities and OSH experts expressed views that where indicators are recorded in excess of permitted levels, results may be manipulated though extending time intervals between samples or replacing workers with longer term exposure with new ones. Some stressed that it can result in a "blame the worker" strategy and that reductions in exposure rarely occur. Differences in the effects of exposure on biomarkers in different people was also highlighted.

Other comments received during consultation relating to the use of biomonitoring are presented below.

MS authorities

- BLVs should be introduced but always in combination with binding OELs.
- Biomonitoring should take national context and provisions into context (so should not set at EU level)
- For many carcinogens, the best way to measure exposure and to show compliance would be biological limit values. However, CMD does not allow this.
- Taking into account that concepts on biomonitoring still need to be developed, we do not favour to give them a prominent place in the Directive, e.g. by explicitly listing them for specific substances.
- In order that the valuable work of SCOEL is visible and accessible we would propose to add in Annex II „Practical recommendations for the health surveillance of workers" a reference that SCOEL (and possibly national) values are available and the internet link to SCOEL values
- Additionally, we note an increase in biological monitoring generally in Industry so there is a demand for authoritative values. Such values should not be limited only to CMD but be included under CAD also.
- Introducing BLVs or BGVs is important for prevention of diseases.
- There is value in using biological monitoring (and recommended values) to assist employers and others in determining if controls are sufficient; raising awareness amongst employees of the importance of observing the controls in place, etc. However, the place for this information is in guidance not law.
- BLVs/BGVs need to be developed taking into account the variances in the potentially exposed population (e.g. sex, size, fat levels, etc.), all of which could impact on what a 'safe' recommendation in the Directive is.
- There is the danger that, given the focus that many put on numbers, including a specific table of BLVs so prominently in Annex II will focus attention on that, at the expense of other health surveillance aspects.
- Health surveillance should encompass a range of activities including:
    - review of information on exposure, e.g. the results of air monitoring or biological monitoring and any related ill health;
    - review of the risk assessment and any modifications made when necessary;
    - checks by a responsible person such as a supervisor or manager, e.g. for chrome ulceration or skin checks for dermatitis;

- enquiries about symptoms, inspection or examination by a suitably qualified person, e.g. an occupational health professional;
- medical surveillance, i.e. a specific type of health surveillance under the supervision of an appointed doctor for the purpose of regulation 11(5). This may include clinical examination.

Trade Unions

- The existing EU limit values for lead and lead compounds are outdated and should be revised.
- CMD and CAD require modernisation regarding exposure and/or biological limits

OSH Professionals

- Biomonitoring for lead has been widely accepted with MS establishing BLVs and is legally enforced.
- Biomonitoring of exposure should not be considered as health surveillance but rather in terms of exposure monitoring. It should be possible to set BLVs under both CMD and CAD and their use should be promoted and all EU limit values should be binding to the Member States.

Industry associations

- There is a need to further strive for alignment/coherence of methodologies (e.g. RAC and SCOEL) to derive a threshold Exposure and/or biological limits: Need to consider biological monitoring/limits more actively. Other: Need to reflect about combined/mixed exposures.
- OELVs set under the Carcinogens Directive are binding. A trade association consulted fully opposes considerations to introduce Biological Limit or Guidance Values under the Carcinogens Directive for the following reasons:
  - overall highly unsatisfactory experiences with Indicative OELV-setting procedures currently in place;
  - heterogeneous handling of Indicative OELVS at national level and resulting distortions of competition;
  - only the establishment of Binding OELVs takes into account science, socio-economic impact, technical feasibility and analytical measurability and thus is more likely to lead to the setting of safe, but workable limit values.

D3.1.6 BLVs and Health Surveillance

Biomonitoring and Health Surveillance in CAD

Article 10 paragraph 1 of Directive 98/24/EC specifies the following in relation to Health Surveillance:

"Where a binding biological limit value has been set as indicated in Annex II, health surveillance shall be a compulsory requirement for work with the hazardous chemical agent in question, in accordance with the procedures in that Annex. Workers shall be informed of this requirement before being assigned to the task involving risk of exposure to the hazardous chemical agent indicated."

Member States are required to establish arrangements to ensure that individual health and exposure records are made and kept up to date for all workers undergoing such health surveillance and the

Directive notes that biological monitoring and related requirements may form part of this health surveillance.

Annex II currently only identifies a binding BLV of 70 µg Pb/100 ml blood for lead and sets down the procedures for health/medical surveillance. It indicates:

> Medical surveillance is carried out if:
>
> - exposure to a concentration of lead in air is greater than 0,075 mg/m^3 , calculated as a time-weighted average over 40 hours per week, or
> - a blood-lead level greater than 40 µg Pb/100 ml blood is measured in individual workers.
>
> Practical guidelines for biological monitoring and medical surveillance must be developed in accordance with Article 12(2). These must include recommendations of biological indicators (e.g. ALAU, ZPP, ALAD) and biological monitoring strategies.

The Commission's non-binding guidance (referred to in Article 12(2)) provides guidance on the steps that should be followed when establishing a health surveillance programme as follows:

- deciding, in light of the directive, whether a health surveillance programme is required;
- determining appropriate procedures and frequency;
- providing the material and human resources for this surveillance to take place;
- ensuring workers and their representatives can appropriately participate and have suitable information;
- applying the necessary prevention measures in line with the results obtained;
- reviewing the effectiveness of the prevention measures applied.

It is noted for lead that medical surveillance is required a blood-lead level greater than 40 µg Pb/100 ml blood is measured in individual workers. This being lower than the BLV of 70 µg Pb/100 ml blood points to a level of potential uncertainty over the true threshold level or residual risk and the guidance document identifies a series of "lowest level of observation of effects" linked to differing levels of lead in blood in this respect.

Based on the above, a number of scenarios and factors can be envisaged to imagine differing circumstances and justifications for maintaining or relaxing the link between BLVs and the mandatory requirement for health surveillance under the CAD.

These are presented in turn below with a discussion of the key parameters involved.

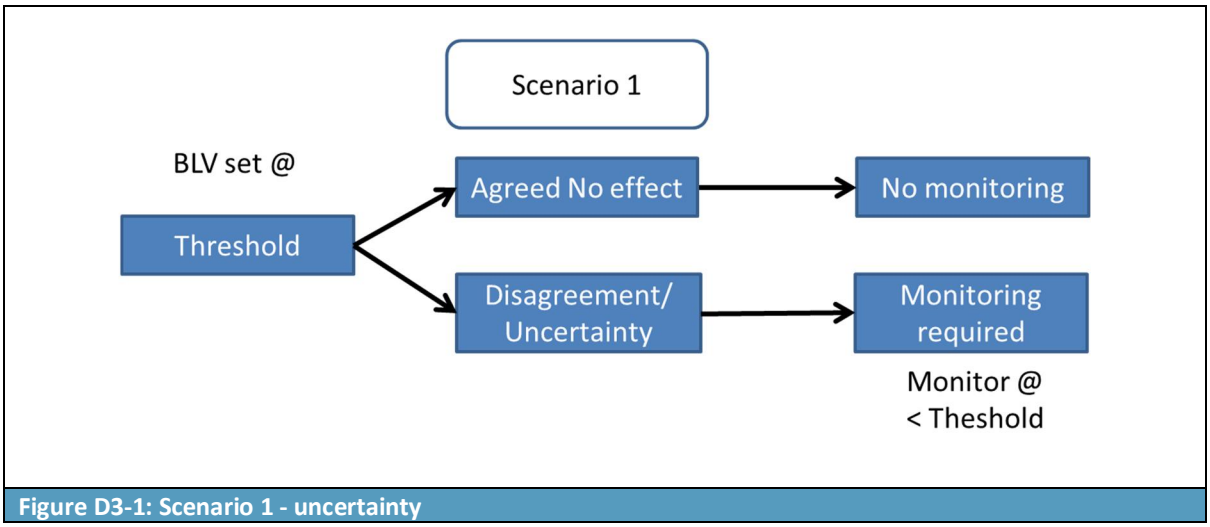

Figure D3-1: Scenario 1 - uncertainty

As a general principle, reprotoxic chemicals have a threshold for health effects. Assuming that biomonitoring is properly carried out, if the measured concentrations are below the BLVs (which take into account thresholds), then there would be no effects and consequently no need for additional health monitoring. In any event, it is difficult to monitor for a number of reprotoxic effects e.g. early pregnancy loss.

Under Scenario 1, where there is uncertainty over the threshold or some scientific disagreement over its level, health surveillance would be indicated

In the context of lead, other factors which might point to relaxing the requirement for health surveillance is that exposure levels appear to have fallen significantly since the introduction of the binding BLV under CAD. As indicated in this report, lead exposure levels in the workplace are now close to background levels, making them difficult to monitor and even more difficult to monitor health effects on workers that are likely to be attributable to exposure.

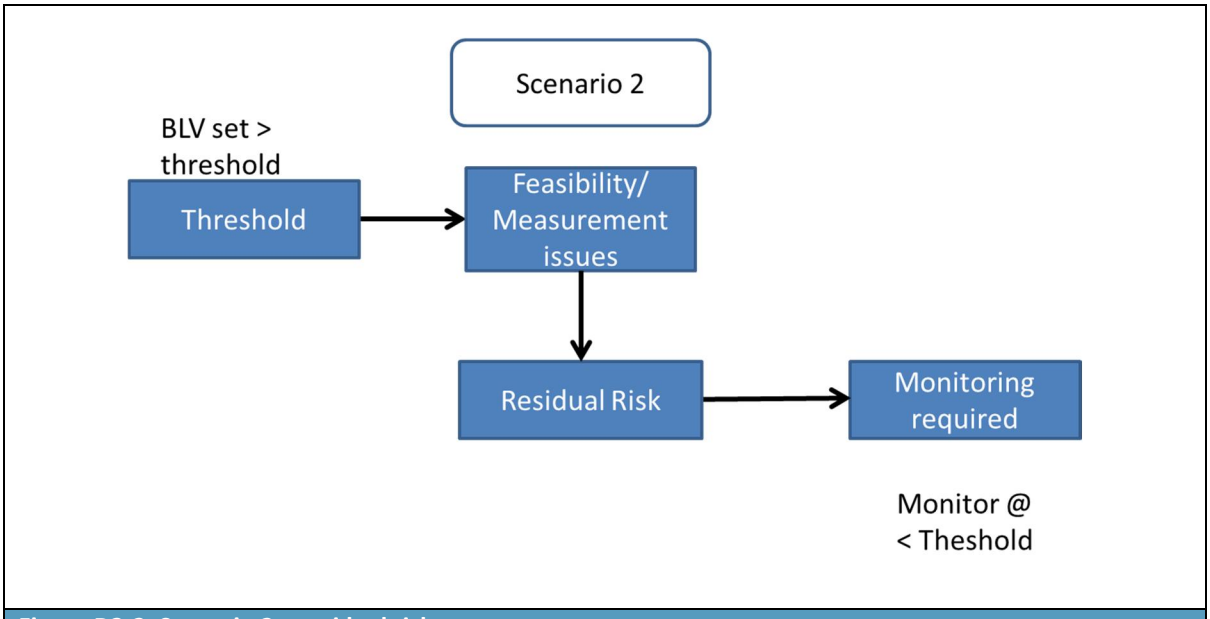

Figure D3-2: Scenario 2 – residual risk

In the event that there are feasibility issues in setting thresholds/BLVs, biomarkers are difficult or expensive to measure or there is disagreement over the level at which a BLV is set, it may be the case that a politically acceptable solution is required in order to reach an agreement. Scenario 2 identifies that residual risks may remain and under these circumstances, health surveillance would be important to ensure that any warning signs over the health of individual workers are detected early and remedial actions taken.

However, if it can be demonstrated that exposure at the workplace is maintained at levels below the DNELs established for a substance, residual risk should be all but eliminated, or very low at least. In such circumstances, it might be considered that it would not be as necessary to carry out health surveillance.

Existing BLV/BGVs

Directive 98/24/EC identifies that health surveillance is compulsory where binding biological values have been set for hazardous chemical agents. For Directive 98/24/EC this relates specifically to lead and its ionic compounds, but there are numerous Member States that have set binding and non-binding biological limit values for other hazardous chemical agents as well, including substances controlled under the CMD. In total, 106 substances were found in the RPA 2017 report to have associated BLVs across the EU. Those relating to reprotoxic chemicals are discussed below. Table D3-4 provides the SCOEL and national BLV-related limits for those of the 27 focal substances in this current study where they have been identified.

Lead and its compounds are specifically identified in Annex II of the CAD and there is a corresponding obligation to introduce binding BLVs across the EU. BLVs identified for lead as being in place across Member States are set out in Annex 7. Additional BLVs from the longer list of repro 1A/1B substances developed earlier in the study (659 substances) were also identified and these are presented in Annex 7.

It is noticeable from the data that there are considerable differences in the BLVs set across Member States, in the level of the BLV, the biological media and the approach to measuring concentrations. This potentially indicates differing opinions on threshold levels and could be a significant factor if/when it comes to attempting to set BLVs and binding BLVs at the EU level.

If biomonitoring requirements are to be extended to other substances, and additional binding BLVs are to be set, the process involved in doing this may identify a number of the issues and factors identified above, including issues of uncertainty, residual risk, feasibility, measurability etc. This being the case, it would appear prudent to maintain the link between binding BLVs and mandatory health surveillance with the ability to set monitoring requirements in accordance with measured exposure levels, as with lead.

Table D3-4: BLVs associated with the focal list of 27 reprotoxic substances

EC Number	CAS Number	Name	SCOEL recommended BLV	National BLV-related limits
R1 Fully registered CLH RA				
201-245-8	80-05-7	4,4'-isopropyl-idenediphenol		BLW - total urinary bisphenol A, after hydrolysis, at 80 mg / L (at the end of the shift) (Germany)
231-100-4	7439-92-1	Lead	30 µg/100 ml (Jan 2002) (Limit of 70 µg/100 ml in CAD Directive)	Details provided separately in Annex 7

Table D3-4: BLVs associated with the focal list of 27 reprotoxic substances				
EC Number	**CAS Number**	**Name**	**SCOEL recommended BLV**	**National BLV-related limits**
R1 Fully Registered CLH No RA				
203-804-1	110-80-5	2-ethyoxyethanol	50 mg 2-ethoxyacetic acid/l urine or 40 mg/g. creatinine (Aug 2007) at the end of the working week.	USA BEI - 2-ethoxyacetic acid/l urine = 100mg/g creatinine at ned of shift and end of working week (1994). Urinary ethoxyacetic acid = 50 mg / L after several shifts (last modification <2000) (Germany). For exposure to 2-ethoxyethanol and 2-ethoxyethylacetate: Urinary 2-ethoxyacetic acid = 20 mmol / mol creatinine (i.e. 18 mg / g creatinine) at end of shift, weekend (last modification <2007).
R1 Fully Registered Self				
None identified				

Potential Impacts of breaking the mandatory link between BLVs and health surveillance

The issues of consent to testing by workers and for the processing and use of medical data in health surveillance in the workplace have been discussed above. These major ethical issues provide a potential barrier to the adoption of BLVs on a wider scale. Whilst monitoring of BLVs requires testing and processing of data, a mandatory link to wider health surveillance as it currently exists within CAD may not be considered necessary and removing that link could potentially result in the wider adoption and use of BLVs (due to more limited intrusion in terms of processing of information about workers health). Consultation carried out for this study involved asking stakeholders whether there might be potential impacts that might result from breaking this link and Figure D3-3 below sets out the results.

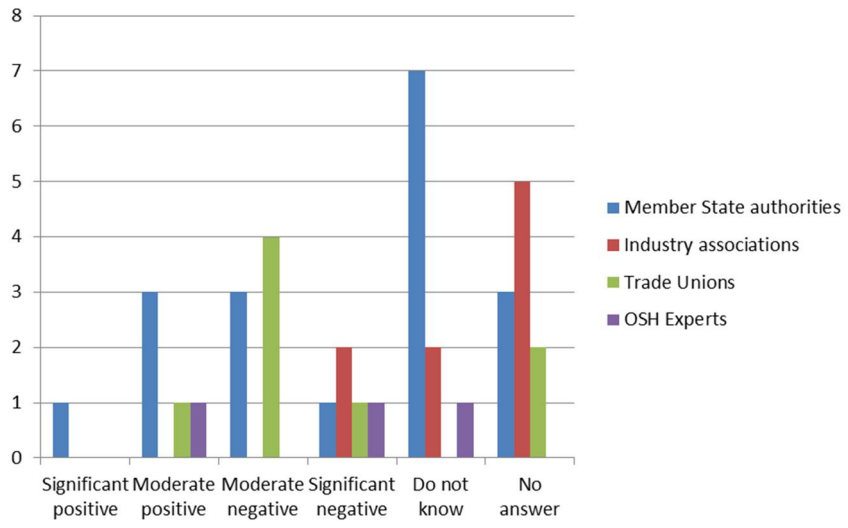

Figure D3-3: Impacts from breaking the link between binding Biological Limit Values (BLVs)s and health surveillance

Table D3-5: Member State authorities comments on impacts	
Member State	**Comment**
FI	The acceptance of BLVs as a legislative option would increase at the EU level.
UK	Do not understand why you break the link. If the limit values are binding their use is mandatory and it makes no sense not to use them as part of health surveillance
DK	I don't suspect that there would be any impact, as biomonitoring would still be a natural part of the health surveillance if a biological limit value exists but I can't be sure.
FR	No requirement would produce inequalities. The principle of using it when appropriate should be mandatory, but the means to perform the biomonitoring do not need regulatory prescriptions
EE	Biological limit value would probably be beneficial for the monitoring of workers' health and for the risk management by employers. But the Biological Limit Values should be optional not mandatory.
IT	In Italy we have only the BLV for Pb, which is compulsory in health surveillance. There are no other official BLVs in our law
RO	Biological Limit Values (BLVs)s are part of health surveillance.

Table D3-6: Trade Unions comments on impacts	
Member State	**Comment**
DK	Only for some substances it is important to use BLV in health surveillance. For other substances it can have a negative impact on prevention and the focus on keeping exposure as low as possible at all times.
DK	BLVs does matter for prevention for instance regarding lead exposure so one should keep the link between BLVs and health surveillance.
DE	Human biomonitoring is a valuable option for a comprehensive exposure assessment. However, it can only be a supplement to air monitoring as human biomonitoring can be conducted on a voluntary basis only. Mandatory application is legally not possible in Germany. A very similar comment was provided by another German stakeholder

Table D3-7: OSH experts comments on impacts	
Member State	**Comment**
FI	If I understood this question correctly, in this case BLVs can be given under combined CAD/CMD but it is not mandatory to use those as part of health surveillance. According to our experience from the survey made under HBM4EU project legislation is one of the main reason to perform biomonitoring. Thus, if there are no BLVs, no biomonitoring is done in some countries. On the other hand, if breaking the link would make it easier to give BLVs under CAD/CMD, it might have positive impact even though it is not mandatory to do biomonitoring as part of health surveillance. Anyway, the main problem currently is that there is only one BLV set under CAD (for lead) and therefore, in some countries lead is the only substance biomonitored.
AT	Biological monitoring is to be reduced and repressed, it must not be mandatory. Very often biological monitoring is part of a "blame-the-worker" strategy or tends towards to become something like this.
UK	I'm unsure about breaking the link, but biological monitoring techniques are improving, and can be useful indicators in harness with air monitoring

Regarding monitoring compliance with BLVs and whether or not approaches should be determined at EU or MS level, Figure D3-4 below shows the responses of differnet stakeholder groups. The figure

indicates that the majority of MS authorities responding were of the view that this should be determined at MS level, with industry associations not generally favouring this approach. 5 of the 8 Ms providing additional comments all highlighted ethical issues around consent to testing and confidentiality of health data and the different approaches adopted by MS in accordance with local customs/culture.

Industry associations made no comments on their answers to whether or not MS should determine their own approaches to monitoring compliance with BLVs. 3 companies (from Denmark and Finland) providing views on potential impacts expressed a desire for adopting a common across the EU. OSH experts from Finland, Austria and UK highlighted that monitoring of BLVs was still a developing field with associated ethical implications regarding consent and confidentiality, they should not be mandatory in MS but that a common approach should be adopted across the EU to ensure that all workers are protected.

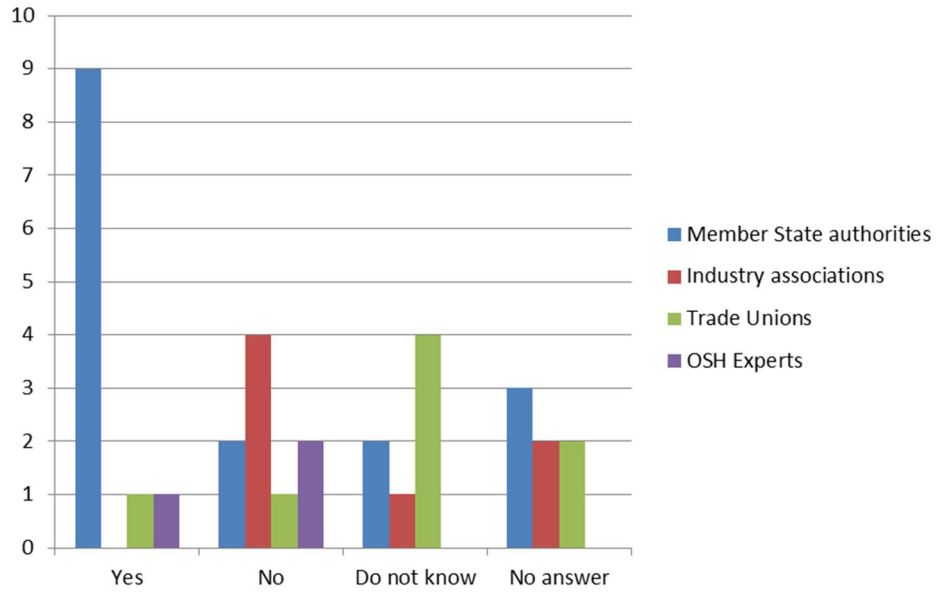

Figure D3-4: Should MS determine own approach to monitoring compliance with BLVs?

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Annex 1 Methodology

X1.1 Health terms

Health Terms	
Abortion (spontaneous)	The termination of a pregnancy. It can be spontaneous (also called miscarriage) or induced.
Adenocarcinoma	A malignant tumour originating in the glandular epithelium
Anencephaly	A neural tube defect, in which most of the brain and skull do not develop. Babies with anencephaly are usually stillborn or die shortly after birth (Rijk, van Duursen and van den Berg, 2016).
Aneuploidy	Having a chromosome number that is not an exact multiple of the usual haploid number
Ankyloglossia	Tongue-tie. Limited normal movement of the tongue, usually due to an abnormally shortened frenulum.
Anogenital distance (AGD)	The distance from the anus to the genitalia (the perineum), the base of the penis or vagina. It is used, in humans, as a non-invasive method of determining male feminisation and thereby predicting neonatal and adult reproductive disorders. This is the case because it is regulated by dihydrotestosterone, which may be disrupted by some chemicals. It is linked to both semen volume and sperm count: men with a short AGD have 7x the chance of being sub-fertile.
Asthenospermia	Asthenozoospermia. Reduced sperm motility.
Atrophy	Decrease in size or wasting away of a body part or tissue.
Axial malformations	Malformations of the axial skeleton. The axial skeleton is the part of the skeleton that consists of the bones of the head and trunk. In humans, it consists of 80 bones.
Azoospermia	Absence of spermatozoa from the seminal fluid
Cauda epididymis	Tail of the epididymis. Part of the reservoir of spermatozoa
Maxilla	The jaw or jawbone, specifically the upper jaw, which in humans for part of the nose and eye socket.
Cleft palate	Often occurs with left lip. The cleft is a gap or split in the roof of the mouth (palate), which is present at birth. It occurs because parts of the baby's face didn't join together properly during development in the womb.
Club food	One or both feet point down and inwards, with the sole of the food facing backwards. It is not painful for babies, but if untreated, it can become painful and make it difficult to walk [NHS.uk].
Corpora lutea (pl.)	Corpus luteum (sg.). Temporary endocrine structure in female ovaries, involved in the production of hormones. It is what remains of the ovarian follicle after a mature ovum has been released during ovulation. It is involved in the hormonal regulation of menstrual cycles and pregnancy.
Cryptorchidism	Undescended testes. Birth defect in which one or both of the testes fail to descend from the abdomen into the scrotum. If they do not descend spontaneously, it will be treated by a surgery called orchiopexy (Rijk, van Duursen and van den Berg, 2016).
Ectopic pregnancy	A complication of pregnancy in which the embryo attaches outside the uterus, usually in one of the fallopian tubes. Signs and symptoms include abdominal pain and vaginal bleeding.
Encephalocele	Cranium bifidium. A rare neural tube defect characterised by sac-like protrusions of the brain and membranes that cover it through openings

	in the skull. Caused by failure of the neural tube to close completely during foetal development.
Endometriosis	Common gynaecological disorder characterised by ectopic endometrium (presence of endometrial glands and stoma outside the uterus) causing benign endometrium-like inflammatory lesions outside the uterine cavity and is a major cause of chronic pelvic pain and infertility. Other symptoms include very heavy periods and pain in the lower back and abdomen (Rijk, van Duursen and van den Berg, 2016).
Endometrium	The mucous membrane that lines the inside of the uterus (womb).
Epididymis	A highly convoluted duct behind the testis, along which sperm passes to the vas deferens
Exencephaly	Birth defect where the brain is located outside the skull. Usually found in embryos as an early stage of anencephaly.
Fecundity	The capacity to conceive
General Cognitive Index (GCI)	Derived from the McCarthy Scales of Children's Abilities. This test is based on a wide variety of functions that are related to human intelligence. There are 18 tests in a battery that sample these different functions, 15 of which are combined into a composite score, which is known as the CGI.
Gynecomastia	Gynecomastia is an endocrine system disorder in which a noncancerous increase in the size of male breast tissue occurs. Occurs due to increased oestrogen levels.
Hydrocephalus	Condition characterised by excessive accumulation of cerebrospinal fluid in the brain. Can occur due to birth defects. Treated by surgical placement of a shunt system.
Hyperplasia	The enlargement of an organ or tissue caused by an increase in the reproductive rate of its cells, often as an initial stage in the development of cancer.
Hypogonadism	Reduction or absence of hormone secretion or other physiological activity of the gonads (testes or ovaries).
Hypoplasia	Underdevelopment or incomplete development of a tissue or organ.
Hypospadias	Penile congenital malformation, in which the urethra opens somewhere on the underneath side of the penis, instead of the tip. The urethra may remain split over a long distance. Treatment requires surgical repair shortly after birth (Rijk, van Duursen and van den Berg, 2016).
Leydig cells	Interstitial cells. Found adjacent to the seminiferous tubules in the testes. The produce testosterone and the presences of luteinising hormone (LH).
Malformation	An abnormally formed part of the body.
Mandible	Lower jaw or jawbone.
Menarche	The first occurrence of menstruation
Mental development index (MDI)	A test, designed to assess cognition through evaluation of sensory-perception, knowledge, memory, problem solving, and early language. It therefore measures a combination of early cognitive and language development.
Micrognathia	A condition in which the jaw is undersized. It is a symptom of a variety of craniofacial conditions. Also called mandibular hypoplasia. It can interfere with a child's breathing and feeding, but often corrects itself as the child grows.
Microphthalmia	Developmental disorder of the eye, in which one (unilateral microphthalmia) or two (bilateral microphthalmia) eyes are abnormally small and have anatomical malformations. In most cases, it results in blindness.

Necrospermia	Necrozoospermia. A low percentage of live and a high percentage of immotile spermatozoa in semen.
NONS	Notification of New Substances
Neural tube defects	Birth defects of the brain, spine, or spinal cord. They happen in the first month of pregnancy, often before a woman even knows that she is pregnant. The two most common neural tube defects are spina bifida and anencephaly (Rijk, van Duursen and van den Berg, 2016).
Oedema	Excess of watery fluid collecting in a cavity or tissue of the body.
Oestrus	The regularly occurring period of sexual receptivity in most female mammals.
Oestrus cycle	The recurring physiological changes that are induced by reproductive hormones in most mammalian females. Oestrous cycles start after sexual maturity and are interrupted by pregnancy. Humans have menstrual cycles rather than oestrous cycles – they have "concealed ovulation", a lack of obvious external signs to signal sexual receptivity at ovulation.
Oligospermia	Deficiency of sperm cells in the semen.
Omphalocele	Birth defect in which an infant's intestine or other abdominal organs are outside of the body, due to a hole in the naval area. The intestines are covered by only a thin layer of tissue and can be easily seen. It is repaired with surgery, although not always immediately.
Oocyte	A cell in an ovary which may undergo meiotic division to form an ovum.
Orofacial cleft	Cleft lip and cleft palate.
Ossification	Osteogenesis. The process of laying down bone material by cells called osteoblasts. Synonymous with bone tissue formation.
Ovarian cyst	A fluid-filled sac within the ovary. Most ovarian cysts are related to ovulation, being either follicular cysts or corpus luteum cysts. Many small cysts occur in both ovaries in polycystic ovarian syndrome (PCOS).
Preputial separation	Separation of the prepuce (foreskin) from the glans of the penis. It is androgen dependent, occurs around the time of puberty, and is an external sign of pubertal development in male rats.
Resorption	Disintegration and assimilation of a dead foetus into the uterus at any stage after the completion of organogenesis. Usually observed in animal experiments.
Scapula	Shoulder bone, shoulder blade, or wing bone. The bone that connects the humerus (upper arm bone) to the clavicle (collar bone).
Schistoglossia	Cleft tongue. Congenital fissure or cleft of the tongue.
Seminal vesicle	Vesicular gland, seminal glands. A pair of simple tubular glands next to the bladder of male mammals. The secrete fluid that partly composes the semen.
Seminiferous tubule	Located within the testes, they are the location of meiosis, and subsequent creation of male games, i.e. sperm(atozoa).
Sex ratio	Ratio of male to female offspring.
Sexual dysfunction	Difficulty experienced by an individual or coupe during any stage of normal sexual activity.
Spermatid	Immature male sex cell formed from a spermatocyte and may develop into a spermatozoon.
Spermatocele	Epididymal cyst. A painless, fluid-filled cyst in the long, tightly coiled tube that lies above and behind each testicle (epididymis).
Spermatocyte	A cell produced at the second stage in the formation of spermatozoa. Divides by meiosis into a spermatid.
Spermatogenesis	The process by which haploid spermatozoa develop from germ cells in the seminiferous tubules of the testes.

Spermatozoa	(pl.) Spermatozoon (sg.). The mature, motile male sex cell of an animal, by which the ovum is fertilised.
Spermiation	The process by which mature spermatids are released from Sertoli cells into the seminiferous tubule lumen, prior to their passage to the epididymis.
Spina bifida	A neural tube defect in which the foetal spinal column doesn't close completely. There is usually nerve damage that causes at least some paralysis of the legs (Rijk, van Duursen and van den Berg, 2016).
Spina bifida occulta	A mild neural tube defect, which involves incomplete formation of the neural arches of several vertebrae and is usually asymptomatic (Rijk, van Duursen and van den Berg, 2016).
Teratospermia	Teratozoospermia. Semen alteration in which there is a large number of spermatozoa with abnormal morphology. It can lead to male infertility.
Testicular dysgenesis syndrome (TDS)	A hypothesis that proposes that common reproductive disorders of newborn and adult human males may have a common foetal origin. These disorders include poor semen quality, testis cancer, undescended testicles (cryptorchidism) and hypospadias. It is theorised that TDS may be increasingly common due to environmental influences, resulting in disruption of embryonal programming and gonadal development during foetal life (Skakkebæk, Rajpert-De Meyts and Main, 2001).
Tubal pregnancy	See 'ectopic pregnancy'
Vaginal patency	The openness of the vagina.

X1.2 Cost of the Policy Options

The following section intends to offer a guide to the understanding of the analytical framework designed to calculate the costs that are expected to arise under the different Policy Options.

The focus will be primarily on the quantitative part and it is meant to integrate the methodological considerations already provided in the section of the study.

It is to be immediately noted that the main analysis is built on the assumption that 2% of companies across all industry sectors in Europe deal with R 1A/1B substances.

X1.2.1 Consideration of substitution/substitution

The costs from the substitution requirement can stem for companies from the need to consider substitution and the actual substitution. The diagram in the figure below can help show the logic underlying the calculation.

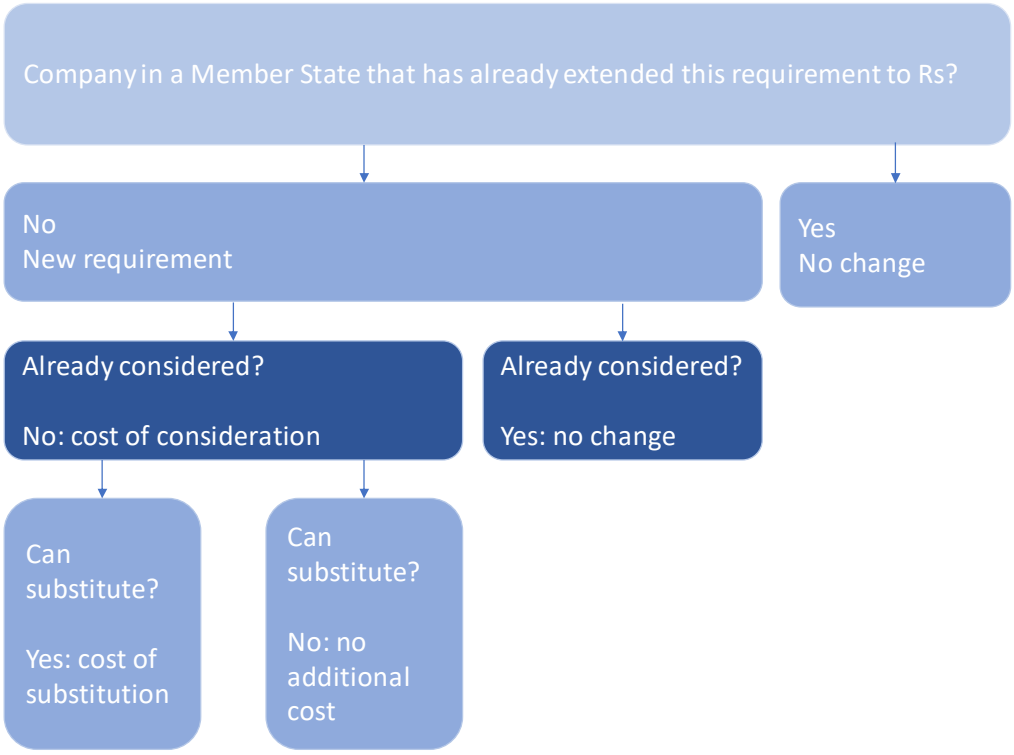

Figure X1-1: Additional costs from the substitution requirement

The task of specifying the total number of companies that would have to consider a substitution and number of companies that would substitute is made hard by the high uncertainty involved and the limited number of questionnaire responses received.

In view of this problem, it was opted to produce estimates associated with three different theoretical scenarios, identified in Table C2-3 and the following ones as "Low", "Mid" a "High". While the "Mid" represents what on the basis of the evidence gathered appears to be the most likely scenario, "Low" and "high", which respectively define a scenario where a very limited number of companies would consider a substitution and one where a relatively large number of companies would consider a substitution, are less likely but serve to define the lower and upper bound of the range.

Having said that, Table C2-3 groups all the percentages associated with the three different theoretical scenarios under three sets of companies identified as A, B and C. A refers to the percentage of companies that have not considered substitutions and B includes the percentage of companies among A that would identify a technically feasible substitute. Then, multiplying percentage values of A by those of B yields the number of companies in the Member State with exposure to Rs that would substitute.

E.g., looking at the Mid column, 30% of companies have not considered substitution (A), out of these 25% would identify a technically feasible substitute (B), consequently the multiplication of the two percentages yields the percentage of companies in the Member state with exposure to Rs that would substitute (C). Consider the equation below for more clarity:

$$30\% \times 25\% = 8\% \text{ (then rounded up to 10\%)}$$

Drawing on the framework thus outlined in Table C2-3, it is then possible to estimate for each Member State the total number of companies that would have to consider substitution (A) and the number of companies that would substitute (C), associated with each scenario (Table C2-4).

E.g., in Greece there are 14,000 companies subject to changes in the requirement, out of which 4,200 $(30\% \text{ x } 14{,}000)$ would have to consider the substitution (A, Mid), whereas 1,400 $(10\% \text{ x } 14{,}000)$ would substitute (C, Mid).

X1.2.2 Closed system

In a similar vein, the way to determine what costs companies have to bear if a closed system has to be considered and possibly installed can be seen in the following diagram.

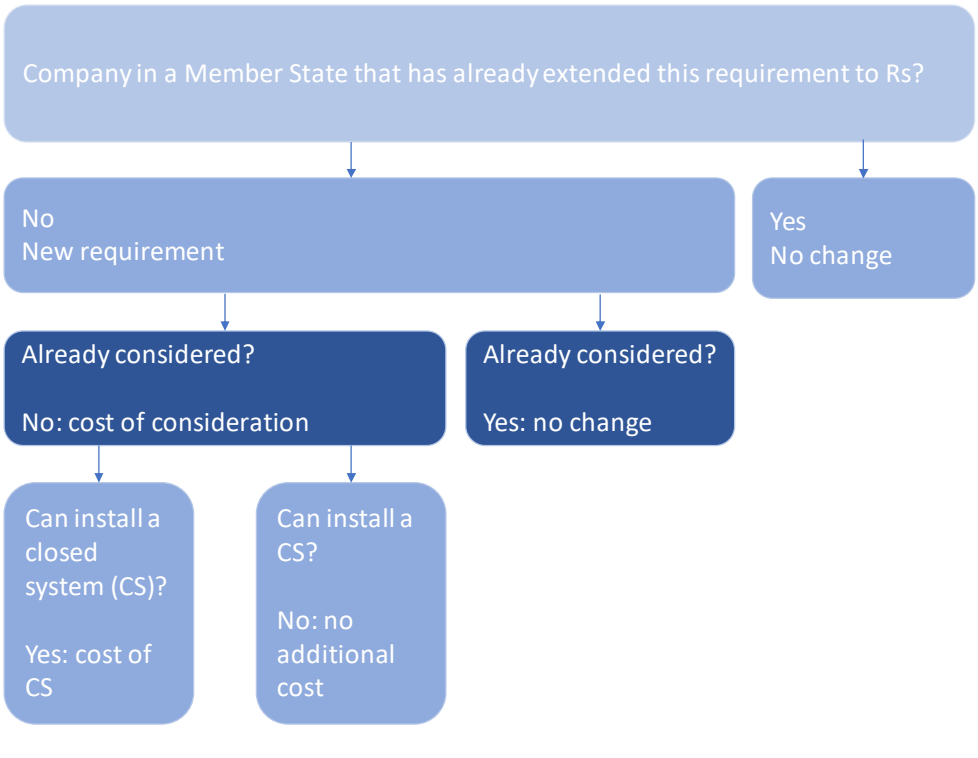

Figure X1-2: Additional costs from the closed system (CS) requirement

Three difference theoretical scenarios, Low, Mid, High, have been considered (Table C2-7), with the same meaning attached to them as explained above. Once again, each letter refers to a set of companies. To obtain the number of companies without a closed system that would need to consider it (C), percentages on the same column referring to companies that do not have a closed system (A) and companies without a closed system that have not considered the feasibility of one (B) need to be multiplied together. E.g., on the Mid column, the number of companies C results from the following operation,

$$90\% \times 90\% = 81\%$$

Analogously, to calculate the percentage of all companies (with exposure to Rs) in the Member State that would install a closed system (E), percentages on the same column referring to companies that

do not have closed system (A), companies without a closed system that have not considered the feasibility of one (B) and companies without closed system that would install one (D), need to be multiplied together. E.g., on the Mid column, the number of companies E results from the following operation,

$$90\% \text{ x } 90\% \text{ x } 10\% = 8.1\% (\text{rounded down to } 8\%)$$

On the basis of the framework set out in Table C2-7, it is then possible to generate estimates about the number of companies that would have to consider a closed system (C) as well as the number of companies that would install one (E).

E.g., in Italy, there are 66,600 companies subject to changes in the requirements, out of this 53,946 (81% x 66,600) would have to consider a closed system (C, Mid), while 5,328 (8% x 66,600) would have to install one (E, Mid).

Cost of a closed system

For the purpose of estimating the cost of a closed system, the initial investment and recurring costs over the whole lifespan of the equipment (discounted for the relevant year at 4%) are considered.

The initial investment is a one-off payment incurred at year 0. The amount of such investment depends on the size of the company. The following costs by company size are considered:

- Small: €45,000
- Medium: €440,000
- Large: €1,700,000

Recurring costs, on the contrary, are undertaken every year throughout the life-cycle of the machinery, therefore they have been discounted for each relevant year at 4% over a lifespan of 20 years. The formula to obtain the present discounted value of future recurring costs every year over a period of time is as follows,

$$PV = \frac{FV}{(1+r)^n}$$

where:

- FV is the future value, namely the cost occurring in the future to bring forward in the present;
- PV is the discounted value of future costs;
- r represents the discount rate (4%); and
- n indicates the number of periods, years in this case

Recurring cots are estimated to be equal to 10% of the one-off initial investment. However, to account for the fact that the company is assumed to be already operating an LEV2, its operating costs need to be subtracted from the recurring costs each company will incur after the closed system is installed. The recurring cost of LEV2 is calculated as 10% of the one-off cost of LEV2 given in Table C2-18.

E.g., if the one-off cost of LEV2 amounts to €650,00 for a large company, then each year the discounted value of 65,000 (10% of €650,00) is deducted from the recurring costs of a closed system. Thus, to obtain the recurring cost of a closed system for a large company, the following equation is used:

$$(10\% \text{ x } 1{,}700{,}000) - (10\% \text{ x } 650{,}000) = 105{,}000$$

The cost of the initial investment plus the sum of the discounted recurring costs over a lifespan of 20 years yields the total cost the company has to bear to set up a closed system. The annualised unit cost for each company size is then obtained by dividing the sum of the initial investments and recurring costs by the total sum of the discount factors over 20 years. E.g., for a large company the annualised cost is calculated as follows:

$$\frac{\left[1{,}700{,}000 + \sum_{n=0}^{20} \left(\frac{105{,}000}{(1+0.04)^n}\right)\right]}{\sum_{n=0}^{20}(1+r)^n} = 227{,}000$$

Applying the same equation to the three size companies, we thus obtain the following annualised cost values:

- Small company: €5,000
- Medium company: € 52,000, rounded down to €50,000
- Large company: € 227,000, rounded down to €220,000

The final weighted sum per company is obtained after the relative weight of the size distribution in the total enterprise population has been accounted, 98.7% for small size enterprises, 1% for medium ones, 0.2% for large ones. The following equation has been used:

$$\big((5{,}000 \text{ x } 98.7) + (52{,}000 \text{ x } 1) + (227{,}000 \text{ x } 0.2)\big)/100 = 5{,}909 \text{ (rounded up to } 6{,}000)$$

X1.3 Exposure minimisation

The similar reasoning described above underpins the calculations to estimate the number of companies that would have to consider an additional RMMs (D) and the number of companies that would install additional RMMs (G). See the diagram in the figure below for more clarity.

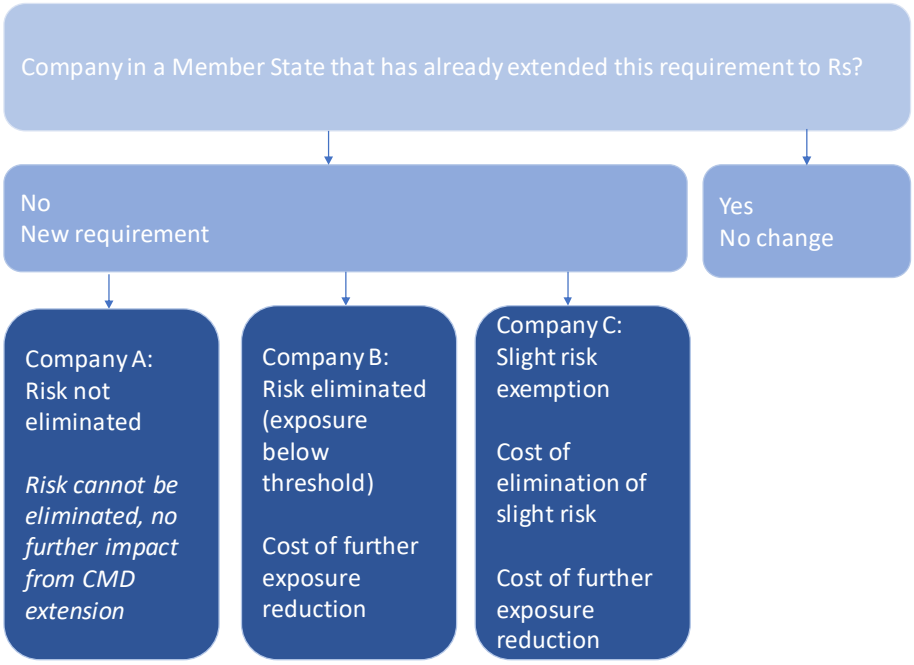

Figure X1-3: Additional costs from the exposure minimisation requirement

In the Table C2-12, each letter refers to a set of companies, and the columns Low, Mid, High, have the same meaning as explained for the other similar tables in the rest of section.

To obtain the percentage of companies that have to consider minimisation (D), percentages of Type B companies and Type C companies need to be summed up. E.g., looking at the Mid column, the percentage of the D results from the following calculation,

$$70\% + 10\% = 80\%$$

The percentage of all companies (with exposure to Rs) that would implement additional RMMs (G) results from a slightly more complicated formula, whereby the sum of the percentages of company B and C is multiplied by the product of the percentages of companies F and G.

E.g., looking at the Mid column, percentage of G results from:

$$(70\% + 10\%) \text{ x } 80\% \text{ x } 30\% = 19\% \ (rounded\ up\ to\ 20\%)$$

On the basis of the framework set out in Table C2-13, it is then possible to estimate the number of companies that would have to consider an additional RMMs (D) and the number of companies that would install additional RMMs (G).

E.g., in Finland there are 4,800 companies subject to changes in requirements, therefore the number of companies that would install additional RMMs is calculated as follows (Mid):

$$[(70\% + 10\%) \text{ x } (80\% \text{ x } 30\%)] \text{ x } 4{,}800 = 960$$

X1.3.1 IOELVs become BOELVs

The framework adopted to work out the total costs that companies would have to bear if OOELVs become BOELVs is illustrated in the diagram below.

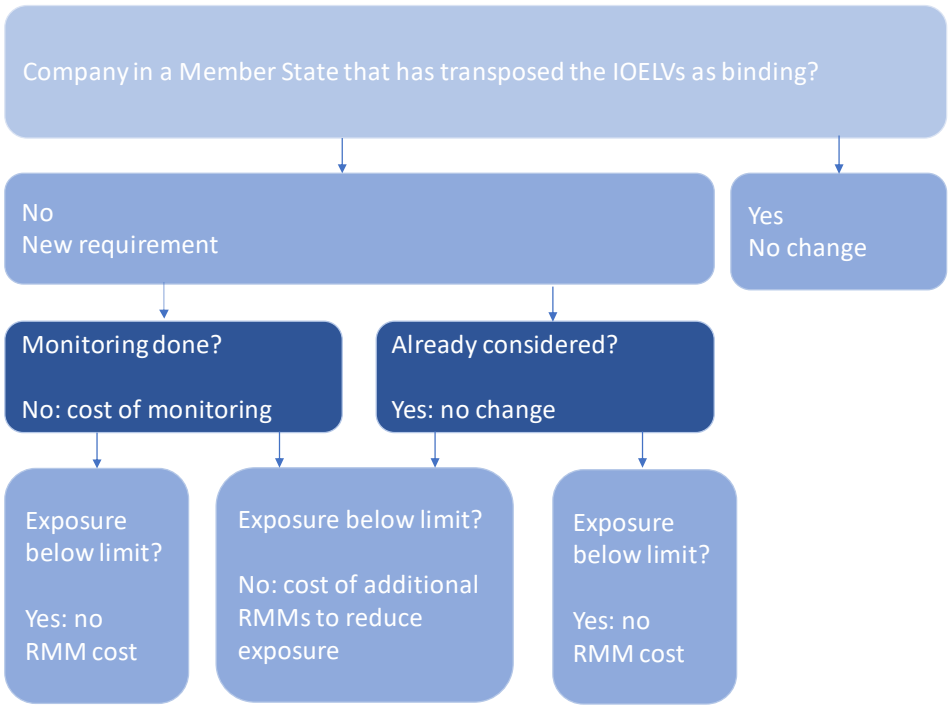

Figure X1-4: Additional costs from CAD IOELVs becoming CMD BOELVs

To estimate the number of companies that would have to put in place additional RMMs, two assumptions are in place. First, it is assumed that for the IOELVs for R 1A/1B substances that currently exist under the CAD a corresponding BOELV would be established under the CMD. Secondly, it is assumed that future occupational exposure limits for reprotoxic substances would be adopted as BOELVs under the CMD.

On the basis of these assumptions, an estimate of the number of companies that would put in place additional RMMs in the relevant Member States is calculated for three theoretical scenarios, Low, Mid and High (see Table C2-22).

For instance, if 15,200 companies in Portugal are subject to changes in requirements, it is estimated that 10% would put in place additional RMMs (Mid).

$$15{,}200 \text{ x } 10\% = 1{,}520$$

X1.3.2 Record keeping for at least 40 years

The diagram below illustrates what framework underpins the assessment of additional costs that companies have to bear if they would have to keep records from the next 40 years into the future.

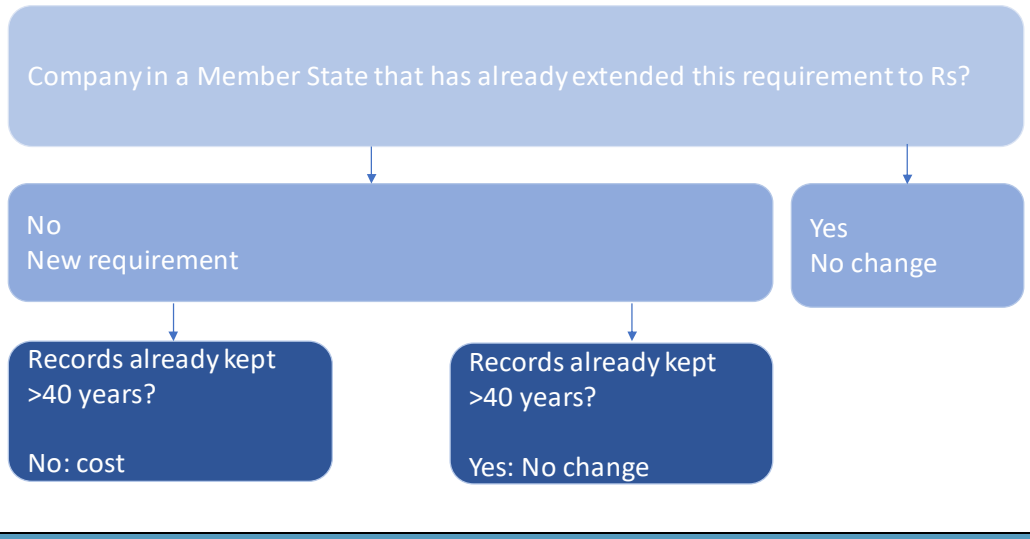

Figure X1-5: Additional costs from the 40 year record keeping requirement

To calculate the number of companies that do not keep records for over 40 years, three different theoretical scenarios have been considered, Low, Mid and High (see Table C2-26). Each of the percentage is then multiplied by the number of companies subject to changes in requirements to obtain the estimated number of companies in all Member States that do not currently keep records for 40 years associated with each of the three theoretical scenarios. E.g., in Germany 33,600 (Mid) out of 48,000 companies is the estimated number of companies that do not keep these records,

$$48{,}000 \text{ x } 70\% = 33{,}600$$

In order to obtain an annualised cost per company for record keeping, it is expected that an annual cost of €1,000 will be incurred over a 40 year period from now. The present value of the total sum of such costs is calculated as follows,

$$\text{PV} = \sum_{n=0}^{40} \left(\frac{1{,}000}{(1+0.04)^n} \right)$$

The annualised value is then obtained by dividing the value of the summation above by the total sum of the discount factors over 40 years. The following equation is used,

$$\frac{\sum_{n=0}^{40} \left(\frac{1{,}000}{(1+0.04)^n} \right)}{\sum_{n=0}^{40} (1+r)^n} = 1{,}000$$

X1.3.3 Monitoring

Monitoring has to be implemented if there is an OEL in place and, therefore, is required and incurs costs for Options that involve setting an OEL. The framework for the additional costs that would arise from monitoring exposure levels is illustrated in the diagram in the figure below.

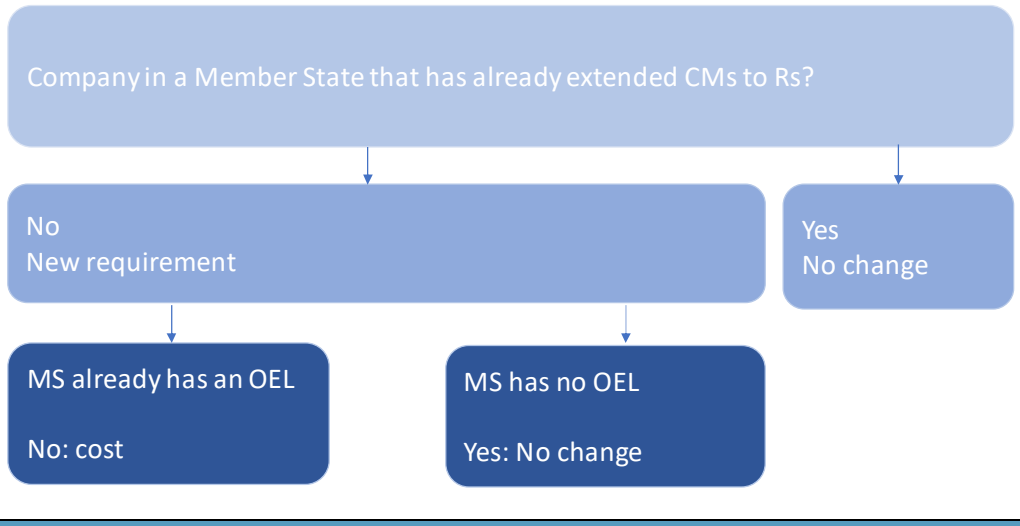

Figure X1-6: Additional costs from the monitoring requirement

X1.4 Cost for companies

To finally determine the sum of total costs related to each Policy Option incurred by companies under the different components, an estimated range of companies affected is provided for three different theoretical scenarios, Low, Mid and High (see Table C2-34).

On the basis of that, all the total additional annualised costs that have been possible to quantify have been summed up to finally obtain total costs arising under each Policy Options. In Table C2-42 the range of such costs is provided. For the annualization value, a period of five years is considered to obtain the present value of the total costs.

X1.4.1 Sensitivity analysis

For sensitivity purposes, total costs under each Policy Option is provided for two further scenarios in which the total number of companies impacted is changed. In Table C2-38, number of companies impacted is assumed to amount to the 1% of all companies across Europe. In Table C2-39, the percentage is increased to 3%.

X1.5 Benefits of the Policy Options

The following section intends to offer a guide to the understanding of the framework designed to calculate the benefits that are expected to arise under the different Policy Options (section C2.2).

X1.5.1 Reduction in the number of workers exposed

The first element of the quantification of benefits is to produce an estimate of the reduction of workers exposed arising from substitution, increased use of closed systems, exposure minimisation, and CAD IOELVs becoming CMD BOELVs.

For substitution, a range of workers no longer exposed is given stemming from the estimate of companies with exposure to Rs that would substitute at least one reprotoxic substance if the CMD was extended to Rs. The same logic is applied to estimate the number of workers benefiting from closed systems and exposure minimisation.

E.g., if a range between 10-30% of workers of out a total of a range between 46-54% of total workers would benefit from exposure minimisation, the total number of workers benefitting would be equal to a range of 5-15%.

In relation to CAD IOELVs becoming CMD BOELVs, no quantification was possible.

X1.5.2 Monetisation of benefits

The health benefits that would be achieved as a result of prevented or reduced exposure are quantified whenever this was possible, otherwise they were estimated qualitatively.

- For substitution and closed systems, the reduction in the annual incidence of reproductive ill health has been quantified on the basis of the reductions in exposed workforce;
- For exposure minimisation, the number of workers that are currently exposed to reprotoxins at levels which might be regarded as significant is taken as the basis for the estimate of the workforce that would accrue benefits from further exposure minimisation. Although a greater number of workers overall would see reduced exposure under this Option, it is unlikely that they are exposed at levels above the thresholds for reprotoxic effects and thus are not expected to benefit for the purposes of the estimation of reduction in reproductive ill health.
- For additional BOELVs, it has not been possible to derive quantitative estimates and a qualitative assessment is provided.

From the assumption that between 3-15% of exposed workers would benefit from avoided exposure as a result of substitution and closed system, the monetary value can then be estimated below on the assumption that the burden of ill health would be reduced by 3-15%.

It is to be considered that the reduction achieved as a result of exposure minimisation is uncertain but the reduction in the exposed workforce is taken as a proxy and a further 15% reduction in ill health is estimated. Accordingly, a maximum 15% reduction for substitution and closed systems plus a maximum 15% reduction from exposure minimisation results in a theoretical total reduction of 30%.

In Table C3-12, the estimated reduction in annual cases is provided for a 3%, 15%, and 30% reduction. The associated monetary value is calculated by multiplying the number of annual cases reduced by their single monetary value in order to obtain the monetised value of benefits.

In the rest of the section, benefits have been given a qualitative assessment.

Annex 2 Summary of Consultation Exercise (Round 2)

X2.1 Round 2

The aim of this **second phase** consultation was to collect data on the current exposure to reprotoxic substances in the workplace, risk management measures (RMMs) that are in place, and relevant national legislation. This allowed a more nuanced understanding of the various factors affecting levels of exposure, as well as a better understanding of the various uses and processes during which exposure to the substances in question can occur. This section summarises the results of the consultation exercise.

Stakeholders were initially contacted via email with an overview of the study and a link to the holding page on the RPA website.[143], This included links to the online questionnaires in various languages. If the stakeholder preferred to answer in a Word document (i.e. so that multiple colleagues could feed into the response), that was also an Option.

In total, 695 stakeholders across the EU-28 were contacted and

there were five different questionnaires, for the following stakeholder groups:

- National authorities
- Industry associations
- Companies
- OSH practitioners and other stakeholders
- Trade unions

The breakdown can be seen in the summary table below.

Table X2-1: Summary of numbers of stakeholders contacted and outcomes

Stakeholder type	Total number of people contacted	Total organisations contacted
National authorities	136	100
Industry associations	299	296
Companies	N/A (contacted through associations)	N/A (contacted through associations)
OSH practitioners	59	53
Trade unions	201	160
Total	**695**	**609**

X2.1.1 Responses by stakeholder type

73 responses were received. The next table below provides the breakdown of these responses.

[143] See http://rpaltd.co.uk/reprotoxic-substances-consultation

Table X2-2: Breakdown of questionnaire responses per stakeholder type	
Stakeholder type	**Questionnaire responses**
National authorities	23
Industry associations	12
Companies	23
OSH practitioners	5
Trade unions	10
Total	**73**

To calculate the response rate, the number of organisations contacted was used instead of the number of stakeholders, as it is unlikely two stakeholders from the same organisation would reply; i.e. in some cases, multiple stakeholders worked at the same Member State authority, but completed the questionnaire between them. The percentages are given in the table below.

Table X2-3: Percentage of organisations contacted who replied	
Stakeholder type	**Response rate**
National authorities	23%
Industry associations	4.1%
Companies	N/A
OSH practitioners	9.4%
Trade unions	6.3%
Average	**12%**

As can be noted from the above table, the response rate for national authorities is substantially higher than it is for other stakeholder types. It is thought this was because, as the legislative bodies for their respective Member States, the onus would be on them more than other stakeholders to offer explanations of the potential effects of changing legislation on reprotoxic substances. The response rate for associations is particularly low because many associations who were contacted did not have members who used reprotoxic substances or have experience/knowledge themselves of such chemical agents, and thus, the study was not of relevance; although it should be noted that key associations have provided input. Many associations also simply passed the companies questionnaire on to their member companies.

X2.1.2 Responders that had already completed round 1 questionnaire

The percentage of responders to this second round of consultation, that had already completed the round 1 questionnaire, is summarised in the table below.

Table X2-4: Percentage of organisations who had already completed round 1	
Stakeholder type	**Percentage of responders (n)**
National authorities	87% (20)
Industry associations	58% (7)
Companies	57% (13)
OSH practitioners	60% (3)
Trade unions	40% (4)
Average	**64%**

X2.1.3 Responses by enterprise size

Many respondents answering on behalf of a company skipped the question on enterprise size. As the below table shows, a majority of respondents who did answer were SMEs – 18, or 60%. The split between small, medium and large enterprises is fairly balanced (and one should bear in mind that, typically, it is larger companies who respond, due to having more resources and thus being able to dedicate staff and time to filling out a questionnaire).

Table X2-5: Breakdown of questionnaire responses per company size	
Company size	**Percentage of responders (n)**
Small enterprise (10-49 persons employed)	4.3 % (1)
Medium-sized enterprise (50-249 persons employed)	17.4 % (4)
Large enterprise (250 or more persons employed)	39.1 % (9)
No response to this question	39.1 % (9)
Total	**100% (23)**

X2.1.4 Option 1 – Baseline (no changes to EU OSH legislation)

The need for additional guidance

All stakeholders were asked if they believe there is a need for additional guidance on the interpretations and/or implementation of CAD and CMD, for example in the form of Best Available Technique (BAT) documents.

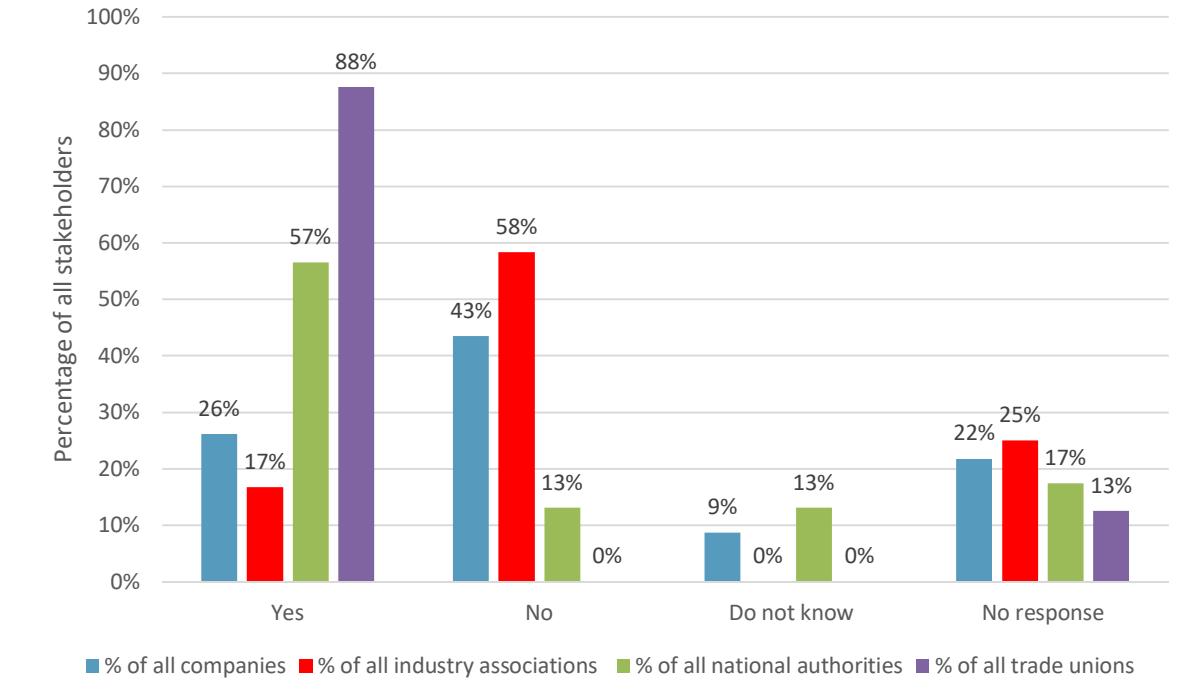

Figure X2-1: Stakeholders that believe there is a need for additional guidance on the interpretation and/or implementation of CAD and CMD (e.g. BAT documents)
Consultation round 2 questionnaire – all stakeholders, excluding OSH practitioners

Of the five responding OSH practitioners, three stated that there was a need for additional guidance, one said there was not, and the fifth did not respond.

As Figure X2-1 illustrates, the introduction of additional guidance was strongly supported by trade unions and more than 50% of national authorities taking part in the survey. The majority of companies and industry associations did not, however, support the introduction of additional guidance. Companies that did not favour the introduction of additional guidance said that sufficient guidance was already available or were concerned that such an initiative would make substances subject to Authorisation of BAT, which is not necessarily a proportional measure, depending on the substance concerned. Those that agreed that additional guidance would be useful, commented that it would only be so, if in line with legislation, useful to the employer and not mandatory. Industry associations commented that the legislation was detailed and clear enough, but did say further guidance could be useful, so long as it was coherent and in line with legislation. In particular, it was felt that the German approach already utilised adequate guidance and could even serve as a template for other member states. In addition, the Danish ALARA-principle approach also encompasses adequate guidance at national level. Several national authorities commented, though, that EU level guidance would be helpful in order to better harmonise the inspection processes and protection levels for workers. This sentiment was generally shared by OSH practitioners and trade unions.

X2.1.5 Option 2 – R 1A/1B substances in the CMD (no derogations)

National authorities were asked what impact putting R 1A/1B substances into the CMD, would have on national legislation, in the following areas:

- Hierarchy of control, with emphasis on substitution
- Hierarchy of control and the introduction of closed systems
- Hierarchy of control and the requirement to minimise exposure to as low as technically possible
- Introduction of IOELVs in place of BOELVs
- Health surveillance record-keeping requirements (>40 years)

Figure X2-2 shows the proportion of national authorities that believe a change in national legislation, with regards to the above measures, will be required if R 1A/1B substances are included in the CMD.

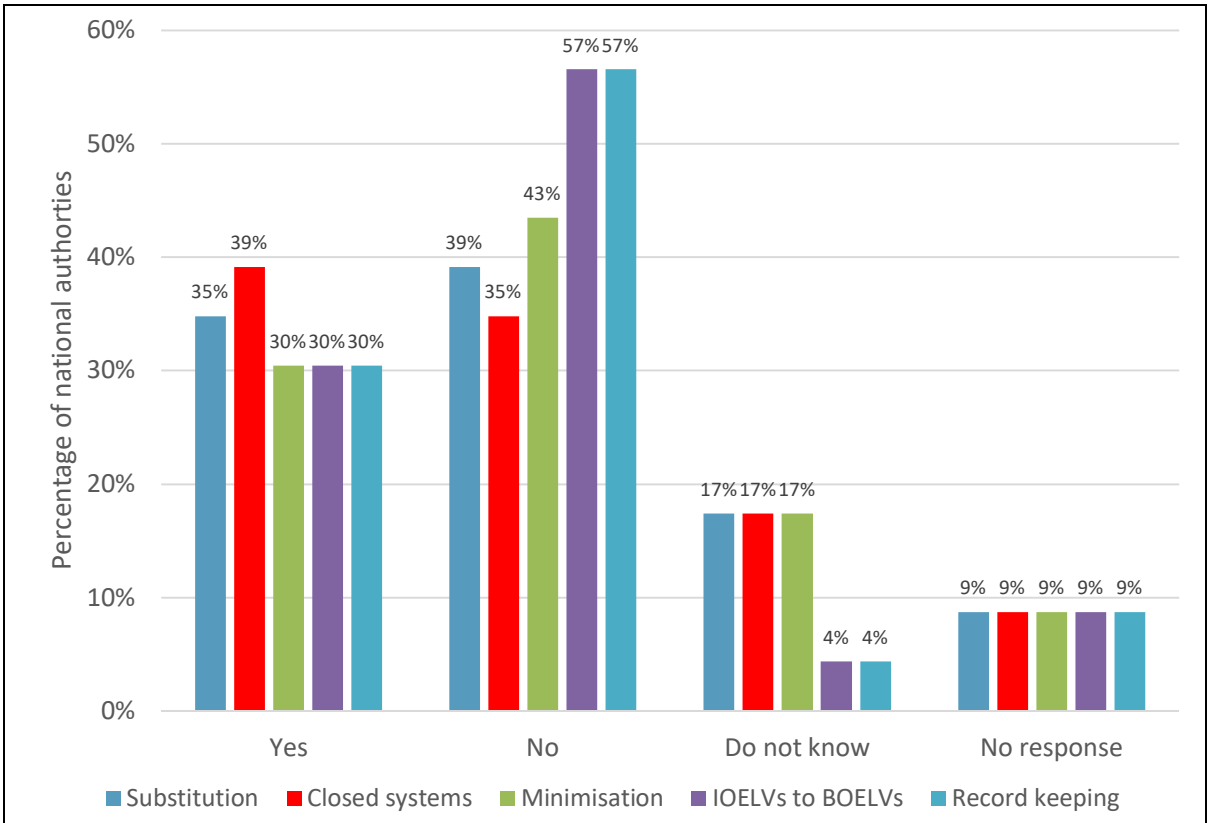

Figure X2-2: Percentage of national authorities stating that a change in national legislation would be required to include the stated requirements for R 1A/1B substances included in the CMD
Consultation round 2 questionnaire – national authorities

A breakdown of these responses, by member state, is given in Table X2-6 and demonstrates which member states that would require a change in legislation, and therefore, which may already have CMD-style hierarchy of control requirements in their current legislation.

Table X2-6: Member states expecting a change in legislation if CMD-style hierarchy of control is introduced for R 1A/1B substances, according to national authorities

Country	Substitution	Closed systems	Minimisation	IOELVs become BOELVs	Record-keeping
Austria	No	No	No	No	No
Belgium	No	No	No	Yes/No	No
Cyprus	Yes	Yes	Yes	Yes	Yes
Denmark	Yes	Yes	No	No	Yes
Estonia	Yes	Yes	Yes	No	Yes
Finland	No	Yes	Yes	Yes	Yes
France	No	No	No	No	No
Germany	No	No	No	No	Yes
Ireland	Yes	Yes	Yes	Yes	yes
Italy	Yes	Yes	Yes/No	Yes/No	Yes
Latvia	No	Do not know	Do not know	Yes	Yes

Lithuania	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No
Netherlands	Yes	yes	Yes	No	Yes
Poland	No response	No response	No response	No response	No response
Romania	Do not know	No	No	No	Yes
Sweden	No	No	No	No	Yes
United Kingdom	Do not know	Do not know	Do not know	No	No
Both responses are given, where different national authorities from the same member state were inconsistent.					

Hierarchy of control for R 1A/1B substances under CMD

All stakeholders were asked about the expected impact that applying the CMD-style hierarchy of control to R 1A/1B substances would have.

Industry associations were asked whether the implementation of such changes would cause issues for companies. Their responses are summarised in Figure X2-3 that the majority of responders believe that that introduction of all three measures (substitution, closed systems and minimisation) would cause issues for companies. Review of responses of companies themselves showed that only 9% believed that it would be technically/economically feasible to substitute or introduce closed systems. The majority believed it would not be possible. Most companies responding saying that they would incur significant costs as a consequence of such a change and some would have to reduce or even cease production. Company responses to the question of whether CMD-style exposure minimisation for R 1A/1B substances would incur additional costs are summarised in Table X2-7.

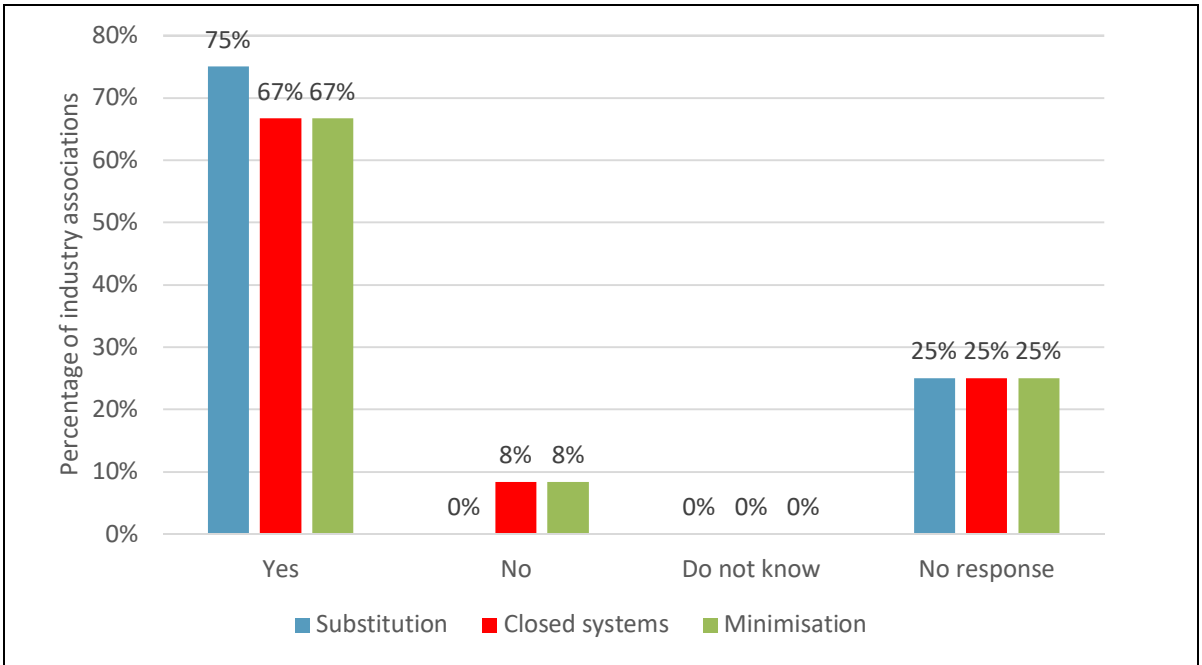

Figure X2-3: Percentage of industry associations stating that introduction of CMD-style hierarchy of control for R 1A/1B substances would cause issues for companies
Consultation round 2 questionnaire – industry associations

Table X2-7: Companies believing they would incur additional costs due to exposure minimisation requirements for R 1A/1B substances, if included in the CMD		
Response	**No. of companies**	**% of all companies**
No additional cost	1	4%
Moderate additional cost	2	9%
Significant additional cost	9	39%
Some additional cost but value cannot be estimated	6	26%
Do not know	0	0%
No response	5	22%
TOTAL	**23**	**100%**

When trade unions were asked if introduction of the CMD-style hierarchy of control for R 1A/1B substances would reduce worker exposure, all those that responded, believed that it would have a positive impact, with the vast majority (86% for substitution, 86% for closed systems, 100% for minimisation) believing that this impact would be significant.

IOELVs become BOELVs for R 1A/1B substances under CMD

As shown in Figure X2-4, the majority of companies and industry associations expect some impact from IOELVs becoming BOELVs for R 1A/1B substances under the CMD. All responding trade unions said they would expect a moderate or significant reduction in worker exposure, as a result of introduction of this measure. OSH practitioners, on the other hand, stated that they would expect either no reduction or a moderate reduction, mainly because several member states already implement IOELVs as binding.

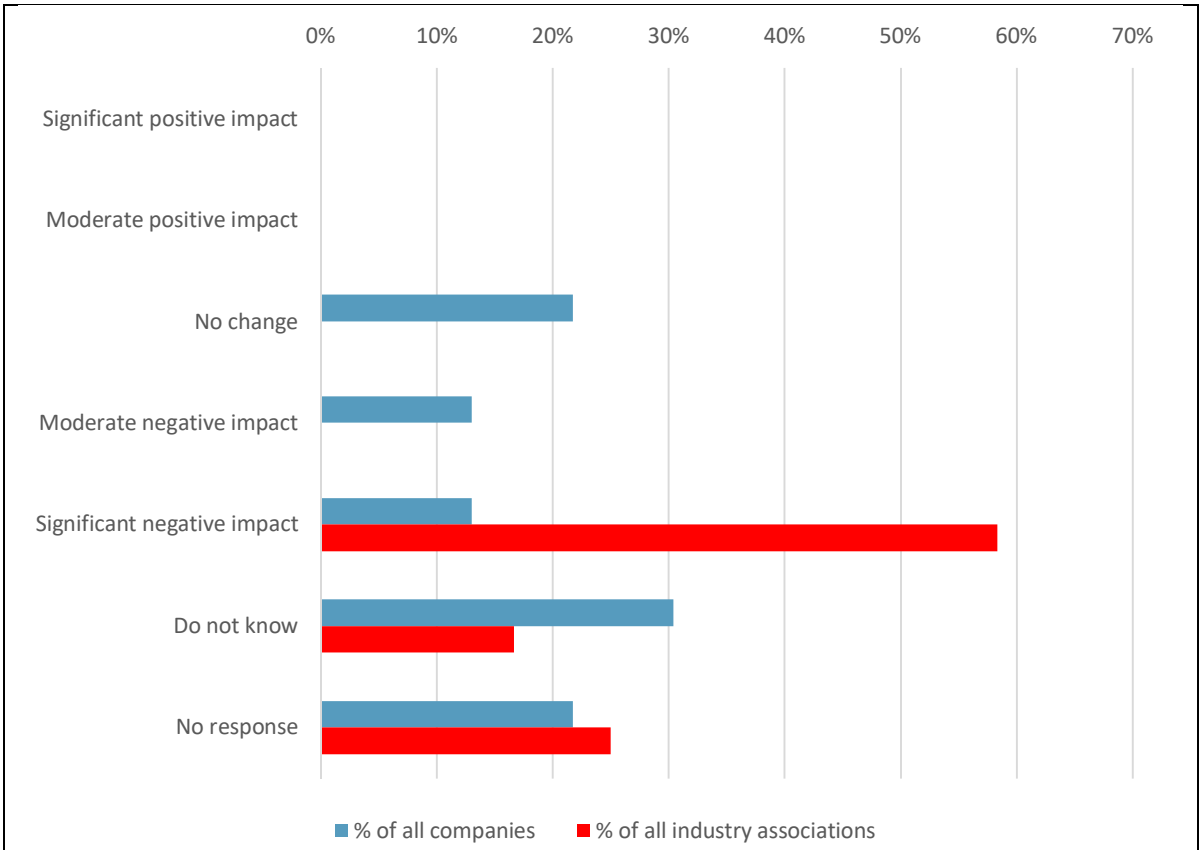

Figure X2-4: Percentage of companies and industry associations expecting impacts from the introduction of BOELVs in place of IOELVs for R 1A/1B substances
Consultation round 2 questionnaire – companies and industry associations

Record-keeping requirements for R 1A/1B substances under CMD

When asked, half of industry associations believed that the introduction of CMD-style record-keeping requirements would cause issues for companies (see Table X2-8) and 60% of companies believed that they would incur some kind of cost as a result (see Table X2-9)

Table X2-8: Industry associations believing that the record-keeping requirements (>40 years) of the CMD would cause issues to companies if extended to R 1A/1B substances

Response	No. of industry associations	% of all industry associations
Yes	6	50%
No	2	17%
Do not know	1	8%
No response	3	25%
Total	**12**	**100%**

Table X2-9: Companies expecting to incur additional costs due to record-keeping requirements (>40 years) for R 1A/1B substances under the CMD		
Response	**No. of companies**	**% of all companies**
No additional cost	4	17%
Moderate additional cost	1	4%
Significant additional cost	6	26%
Some additional cost but value cannot be estimated	7	30%
Do not know	0	0%
No response	5	22%
Total	**23**	**100%**

Few industry associations and companies commented further, but one industry association said that they did not expect the additional burden of this requirement to be great for companies, in terms of implementing further health surveillance.

X2.1.6 Option 3 – R 1A/1B in the CMD with derogations

Companies and industry associations were asked if they expected to experience impacts as a result of Option 3. 48% of companies and 33% of industry associations expecting negative impacts from the introduction of this Option (see table below).

Table X2-10: Companies and industry associations expecting impacts as a result of Option 3				
Response	**No. of companies**	**% of all companies**	**No. of national authorities**	**% of national authorities**
Significant positive impact	3	13%	0	0%
Moderate positive impact	1	4%	2	17%
No change	2	9%	2	17%
Moderate negative impact	6	26%	4	33%
Significant negative impact	5	22%	0	0%
Do not know	1	4%	1	8%
No response	5	22%	3	25%
Total	**23**	**100%**	**12**	**100%**

One of the reasons why companies felt that Option 3 could have a negative impact, despite derogation of non-threshold substances, was related to concern that the implementation in different member states would not reflect this differentiation (e.g. in Italy). Some companies reflected on the positive impact in terms of improved management of exposure to threshold substances, while others commented on the costs of implementing additional risk management measures.

In terms of the impact on workers, only 17% of national authorities felt that Option 3 would decrease the number of cases of ill-health compared to 40% believing there would be no change or an increase. 63% of trade unions believed Option 3 would have a positive impact on workers' exposure compared with 25% expecting a negative impact.

Those national authorities, where reprotoxic substances already fall under the same legislation as carcinogens and mutagens, commented that derogations, as set out in Option 3, would lead to an increase in reproductive ill-health. There seemed to be some confusion regarding how derogations would be conducted and consequently concern that that workers would be less protected because this lack of clarity about which regulation a substance falls under, would lead to less stringent regulation of the substance in practice.

X2.1.7 Option 4 – Merger of CAD and CMD into a single directive

Simplification of directives into one piece of legislation

Companies and national authorities were asked if they expected to experience impacts as a result of simplification of the CAD and CMD directives into a single piece of legislation. Their responses are summarised below in Figure X2-5. As can be seen opinion on whether this would have a positive or negative impact was quite spread for both companies and national authorities, though nearly a quarter of companies felt there would be a significant negative impact, compared to only 4% of national authorities. The large number of non-responses and 'do not knows suggests uncertainty.

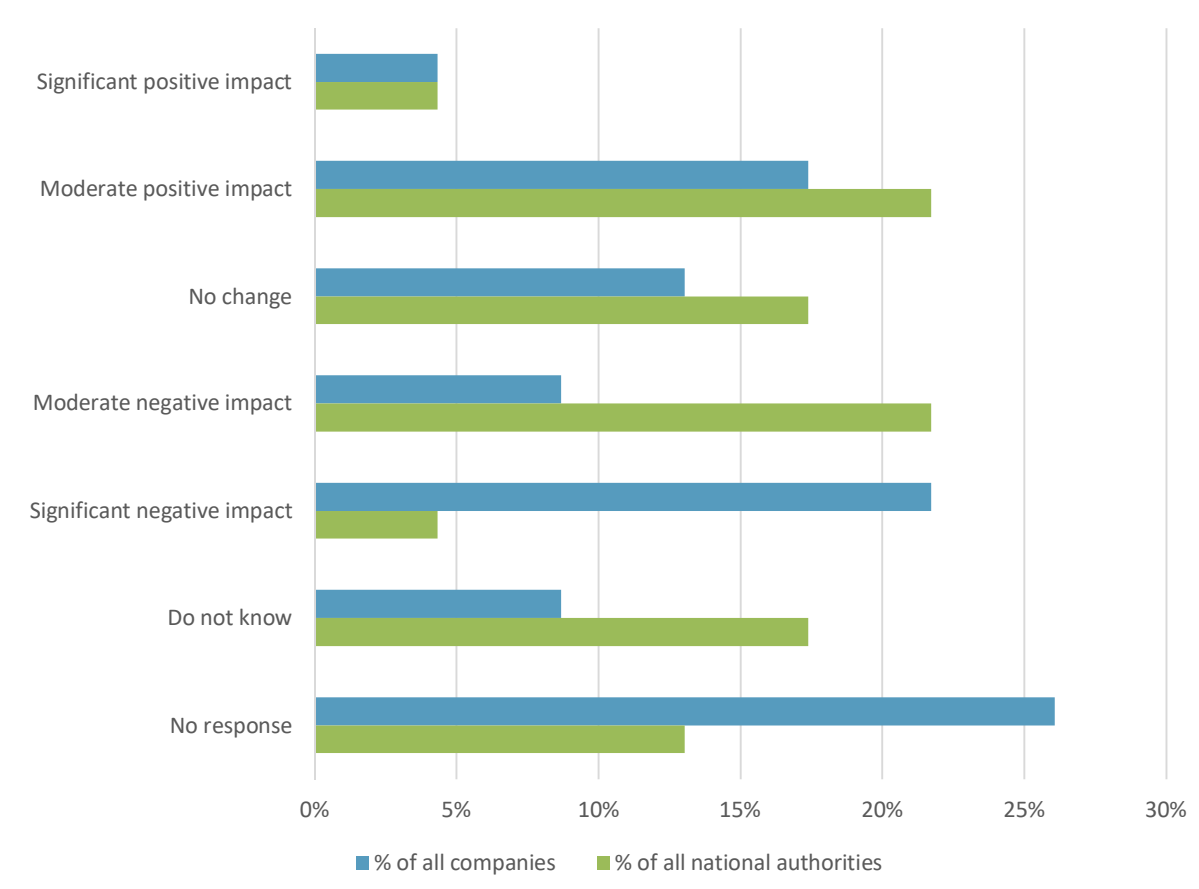

Figure X2-5: Percentage of responding companies and national authorities that believe there would be impacts from simplification to one piece of legislation
Consultation round 2 questionnaire – companies and national authorities

In addition, 38% of trade unions believed there was an advantage to this simplification into one piece of legislation compared with only 6% of industry associations.

From the free-text responses, it appears that companies and industry associations expecting significant negative impacts, were mostly concerned with Reprotoxic 1A/1B substances being given the same requirements as carcinogens and mutagens, leading to additional costs. Other that saw a positive impact, felt that any effort to reduce the number of directives would be a benefit. It was felt that simplification without real changes would not be advantageous. To bring advantages, the direct would need to be amended and clarified.

The OSH experts that responded saw advantages and disadvantages to simplification into a single document. It was felt that a single document might encourage a mindset of treating all hazardous substances with more respect and encourage the use of protective measures already set out in the CMD. However, it was felt that these advantages would only bring to bear if the legislation was modernised to define substances by mode of action and not by simple classification, as is practiced currently.

X2.1.8 Option 5 – Merger of CAD and CMD into a single directive and update of legal requirements

Inclusion of skin and respiratory sensitisers into the scope of the CMD requirements

The percentage of companies, industry associations, national authorities and trade unions expecting positive or negative impacts from the inclusion of skin and respiratory sensitisers into the scope of the CMD requirements is summarised in Figure X2-6 below. 50% of trade unions believe there would be a significant positive impact from this inclusion compared to only 4% of companies. Companies and industry associations were more likely to expect negative impacts, with 48% and 67% respectively expecting significant negative impacts. National authorities were more divided across the spectrum. The majority of OSH experts, who were also asked this question, responded saying that they would expect a positive impact also.

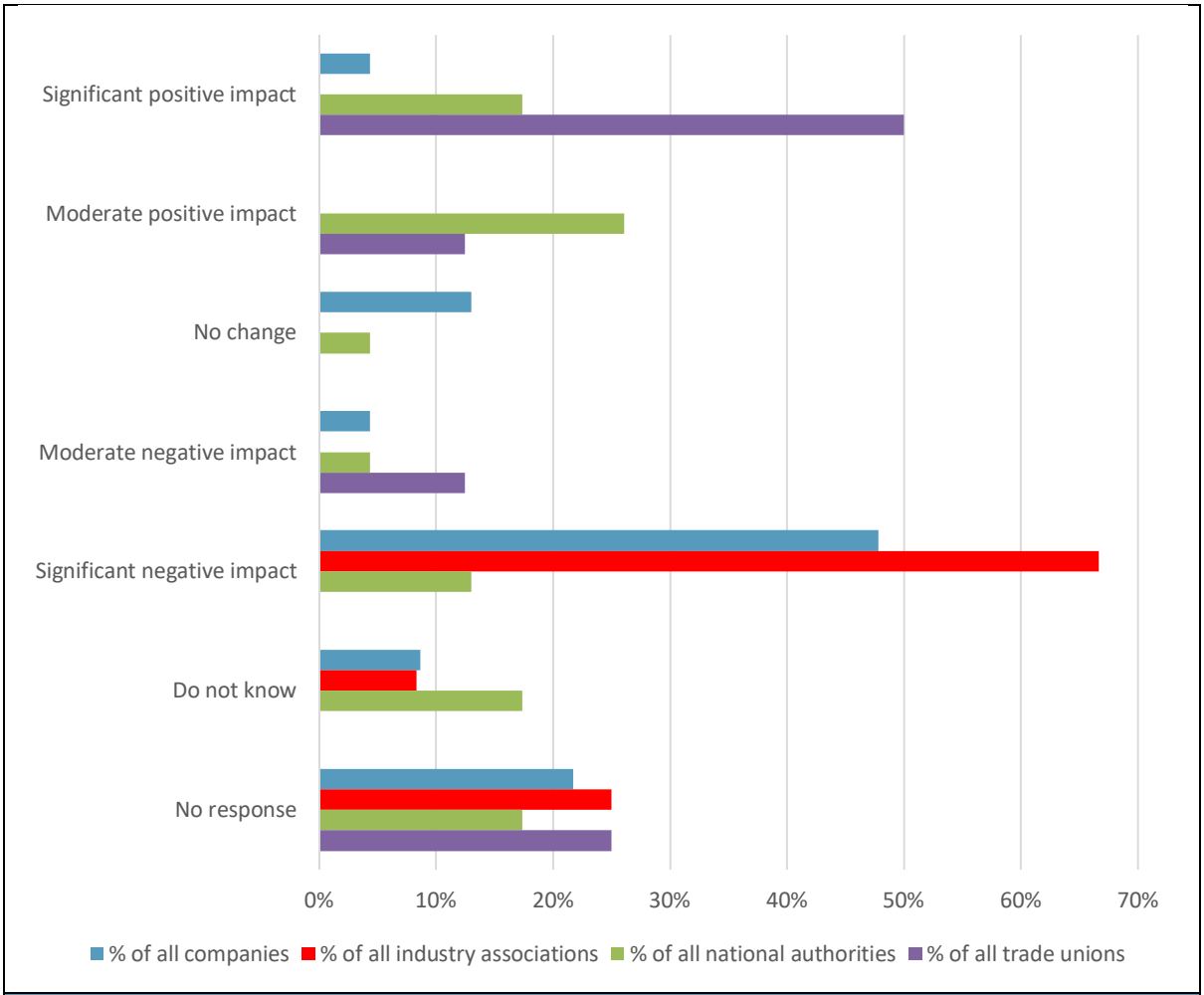

Figure X2-6: Percentage of responding stakeholders expecting impacts from including skin and respiratory sensitisers into the scope of the CMD requirements
Consultation round 2 questionnaire – all stakeholders, excluding OSH practitioners

Unifying CMD and CAD terminology, in line with REACH regulation

The percentage of companies, industry association, national authorities and trade unions expecting impacts from unifying CMD and CAD terminology, in line with REACH are summarised in Figure X2-7 below. The majority of company responders expected no change as a result of this (39%), while industry associations were very split between positive impact/no change/negative impact (19% for all). Trade unions and national authorities favoured a moderate positive impact (50% and 26% respectively). OSH experts were very split in their responses, with one expecting positive impacts, one negative impact and two responding 'do not know'.

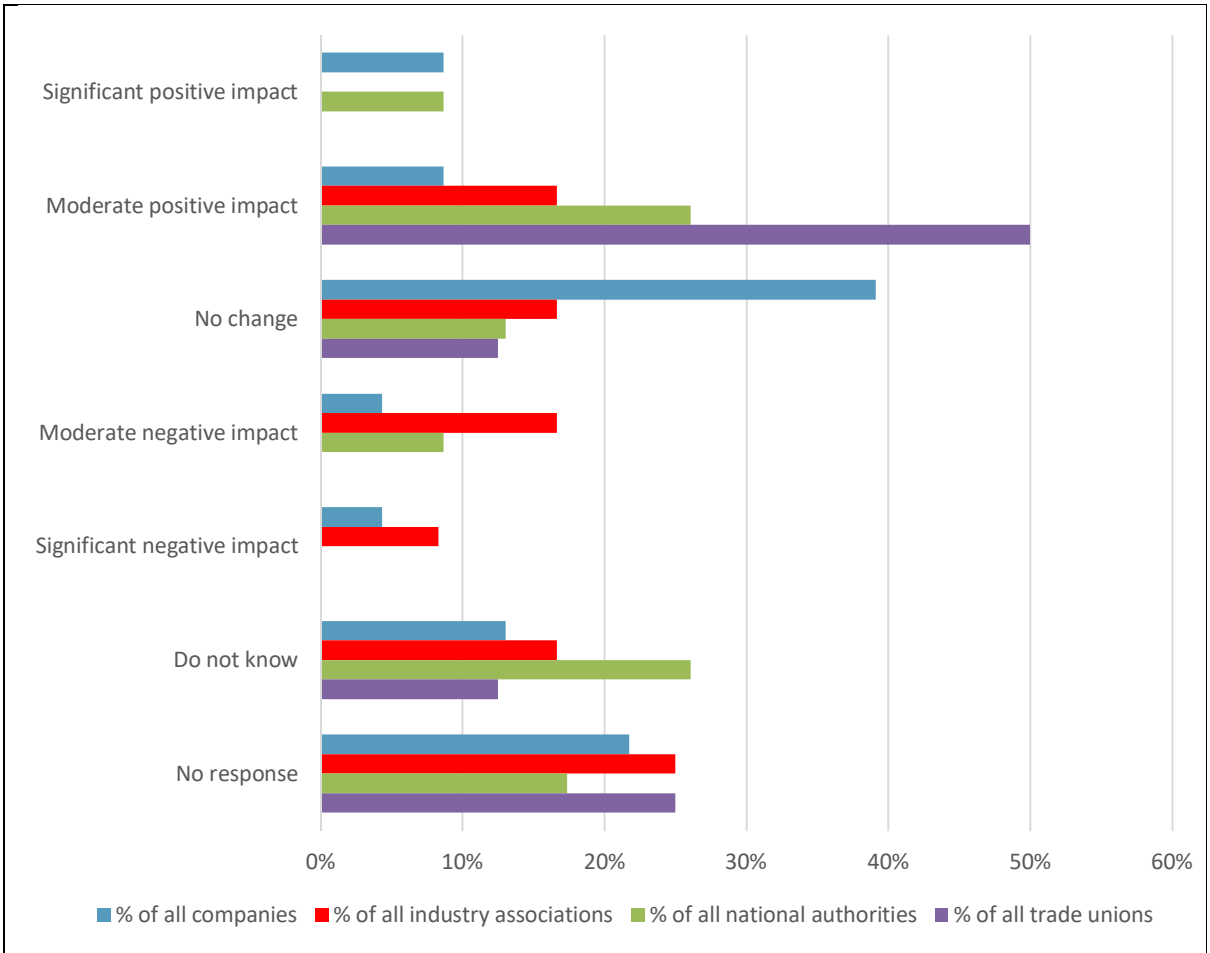

Figure X2-7: Percentage of responding stakeholders expecting impacts from unifying CMD and CAD terminology, in line with REACH terminology
Consultation round 2 questionnaire – all stakeholders, excluding OSH practitioners

Breaking the link between BLVs and their mandatory use as part of health surveillance

Industry associations, national authorities and trade unions were sked if they expected impacts from breaking the link between BLVs and their mandatory use as part of health surveillance, as a result of introduction of Option 5. The responses are presented in Figure X2-8. 50% of trade unions believed there would be a moderate negative impact, while 25% of industry associations believed there would be a significant negative impact. National authorities were more split between the Options and there was a high percentage of all stakeholders that did not respond or responded 'do not know'.

OSH experts that responded were evenly split across negative impact/no change/positive impact/do not know. There seemed to be some confusion regarding the question, with one OSH expert commenting that there is no link between BLVs and mandatory use as part of health surveillance, because analysis of BLVs can only be carried out with the employee's consent.

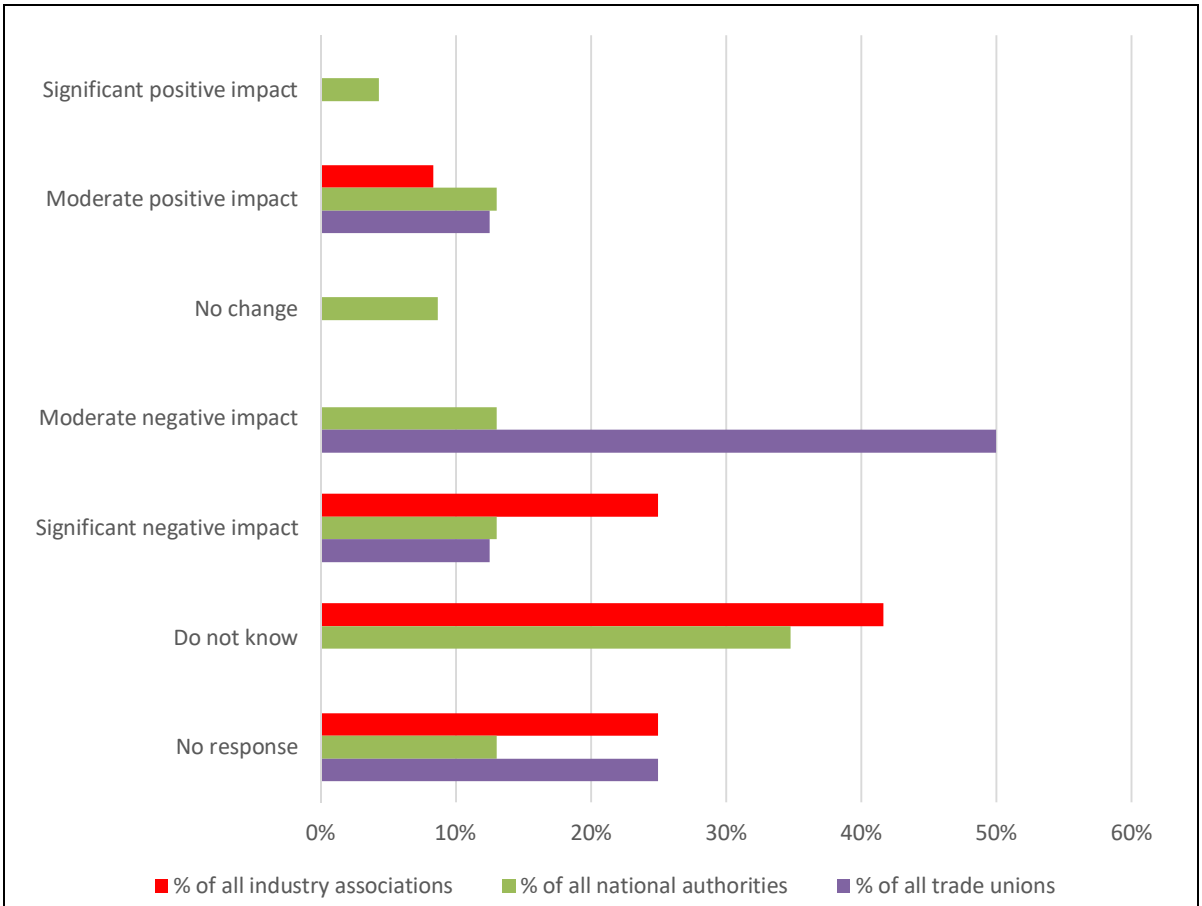

Figure X2-8: Percentage of responding stakeholders expecting impacts from including skin and respiratory sensitisers into the scope of the CMD requirements
Consultation round 2 questionnaire – industry associations, national authorities and trade unions

Industry association, national authorities and trade unions were also asked if they thought that member states should be able to determine their own approach to monitoring compliance with BLVs and their responses are summarised in Table X2-11. 17% of industry association, 48% of national authorities and 13% of trade unions thought that they should. OSH experts were also asked this question, and of the five that responded, only one agreed that they should be able to determine this.

Table X2-11: Industry associations, national authorities and trade unions stating that member states should be able to determine their own approach to monitoring compliance with BLVs

Response	No. of industry associations	% of all industry associations	No. of national authorities	% of all national authorities	No. of trade unions	% of all trade unions
Yes	2	17%	11	48%	1	13%
No	6	50%	5	22%	1	13%
Do not know	1	8%	4	17%	4	50%
No response	3	25%	3	13%	2	25%
Total	**12**	**100%**	**23**	**100%**	**8**	**100%**

X2.1.9 Most favoured Policy Option

Stakeholders were asked to rank the five proposed Policy Options (Option 3+ was not being considered when the consultation was published) from one to five, where one was the most favourable Option and five was the least favourable Option. Figure X2-9 shows the most favoured Option, by stakeholder, calculated as the percentage of responders rating each Policy Option as their first choice, i.e. the most frequently ranked first-choice Option.

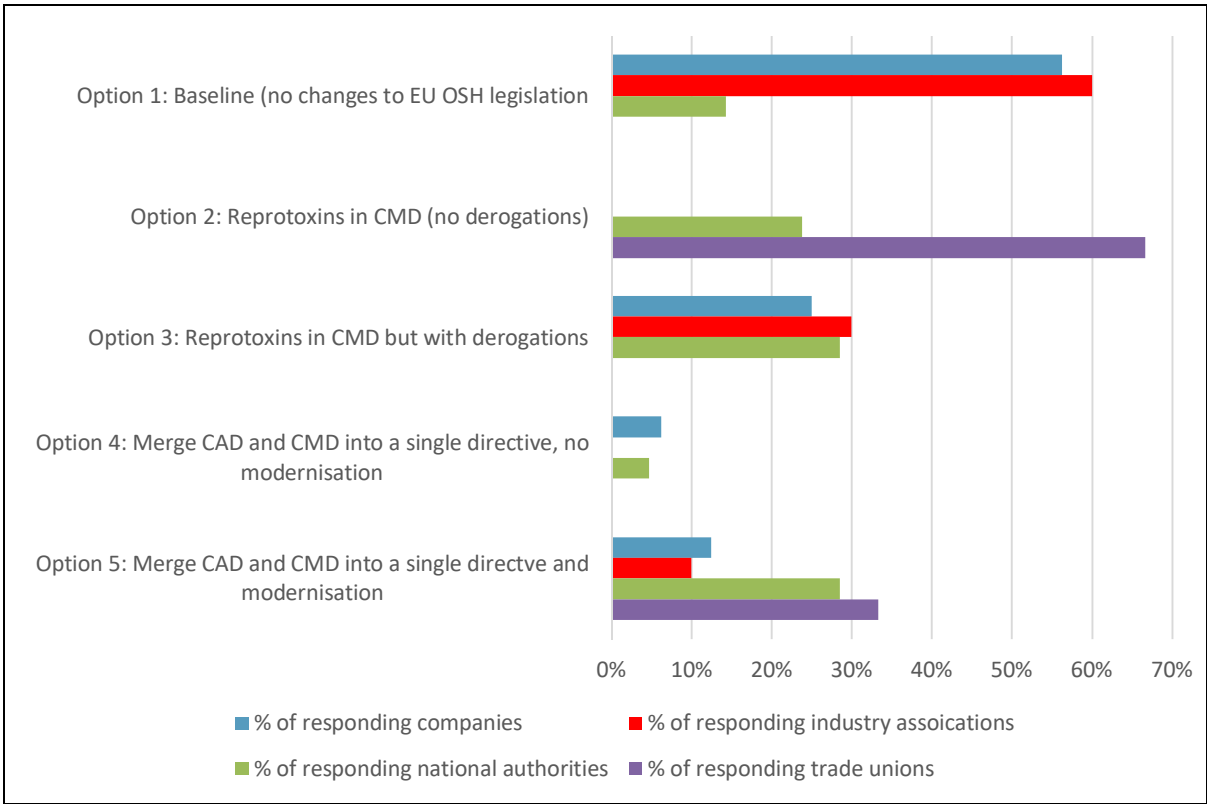

Figure X2-9: Percentage of responding stakeholders rating each Policy Option as first choice
Consultation round 2 questionnaire – all stakeholders, excluding OSH practitioners

Figure X2-9 demonstrates that Option 1 was most favoured by companies and industry associations, while Option 2 was the Option most favoured by trade unions. National authorities were more divided, with a marginal preference overall for Option 3. Of the five responding OSH practitioners, only 4 ranked the Policy Options by preference, with the most favoured Option split across four different Policy Options. Only Policy Option 4 received no first-place ranking from OSH practitioners.

Table X2-12 summarises the responses as a percentage of all stakeholders, including the number of responders (taking into account those that did not respond to the relevant question).

Table X2-12: Option most frequently ranked as first choice (1) by stakeholder						
	Option 1	Option 2	Option 3	Option 4	Option 5	No response
Companies						
No. of companies	9	0	4	1	2	6
% of all companies	41%	0%	18%	5%	9%	27%
Ranking by most favoured	**1**	**5**	**2**	**4**	**3**	
Industry associations						
No. of industry associations	6	0	3	0	1	3
% of all industry associations	46%	0%	23%	0%	8%	23%
Ranking by most favoured	**1**	**4/5**	**2**	**4/5**	**3**	
National authorities						
No. of national authorities	3	5	6	1	6	2
% of all national authorities	13%	22%	26%	4%	26%	9%
Ranking by most favoured	**4**	**3**	**1/2**	**5**	**1/2**	
Trade unions						
No. of trade unions	0	4	0	0	2	2
% of all trade unions	0%	50%	0%	0%	25%	25%
Ranking by most favoured	-	**1**	-	-	**2**	

X2.1.10 Least favoured Policy Option

Figure X2-10 shows the least favoured Option, by stakeholder, calculated as the percentage of responders rating each Policy Option as their last choice (5), i.e. the most frequently ranked last-choice Option.

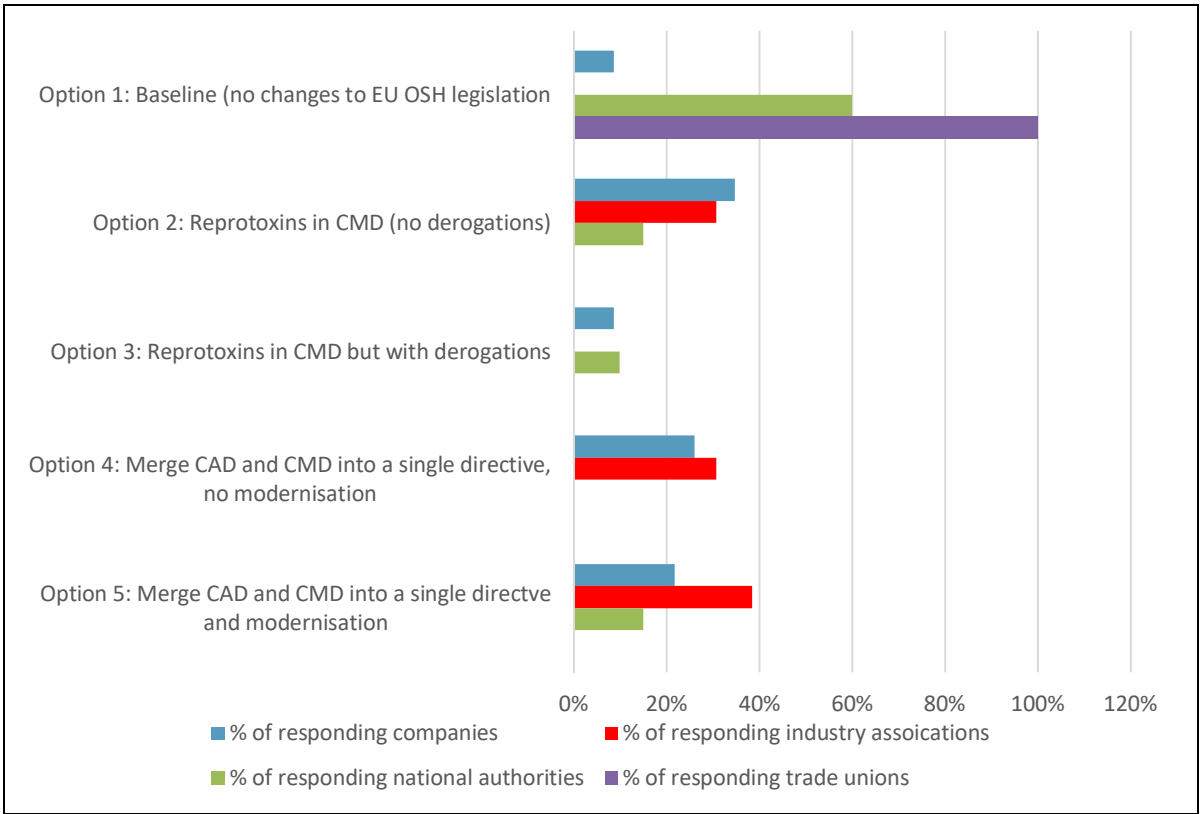

Figure X2-10: Percentage of responding stakeholders rating each Policy Option as last choice
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Figure X2-10 demonstrates that companies and industry associations were in less agreement about their least favoured Option than they were about their most favoured. Option 2 was marginally the least favoured by companies and Option 5 by industry associations. In contrast, however, Option 1 was unanimously the least favoured by trade unions and also the majority of national authorities. Table X2-13 summarises the responses as a percentage of all stakeholders, including the number of responders (taking into account those that did not respond to the relevant question).

Table X2-13: Option most frequently ranked as least favourable (5) by stakeholder

	Option 1	Option 2	Option 3	Option 4	Option 5	No response
Companies						
No. of companies	2	8	2	6	5	6
% of all companies	7%	28%	7%	21%	17%	21%
Ranking by least favoured	1/2	5	1/2	4	3	
Industry associations						
No. of industry associations	0	4	0	4	5	3
% of all industry associations	0%	25%	0%	25%	31%	19%
Ranking by least favoured	1/2	3/4	1/2	3/4	5	
National authorities						

No. of national authorities	12	3	2	0	3	2
% of all national authorities	55%	14%	9%	0%	14%	9%
Ranking by least favoured	5	3/4	1	3/4	2	
Trade unions						
No. of trade unions	6	0	0	0	0	2
% of all trade unions	75%	0%	0%	0%	0%	25%
Ranking by least favoured	5	-	-	-	-	

X2.1.11 General feedback on Policy Option ranking

Companies and industry associations, which both favoured Policy Option 1 the most, followed by Option 3, commented that if Reprotoxic 1A/1B substances were included in the CMD, this would require huge investment from SMEs, in particular, due to the re-evaluation of worker protection measures and possible further investment, with no certainty of reducing exposure. Objections to the implementation of provisions such as substitution and/or closed system for closed threshold substances were also expressed, given that the current exposure levels are considered safe. One company suggested that implementation of changes such as substitution or closed systems could lead to plan closure or significant reduction in activity.

The sentiment that introducing substitution, closed systems and minimisation of exposure is inappropriate for substances that are already at a 'safe level' was reiterated by industry associations. They further commented that the costs associated with such implementation would have a negative impact on society, with no or little benefit. Nearly all associations stressed that implementing a Policy Option that does not take into account differentiation between substances with and without a health-based limit value (threshold vs non-threshold substances), would be a retrograde step and request that such a differentiation be made in future legislation. There was concern, however, that implementing such an Option would be too time consuming.

National authorities most frequently favoured Options 3 and 5, but were more divided between the Options. In line with company and industry association comments, national authorities, although favouring Option 5, were concerned by the time it would take to implement such an Option and the need to execute it well. In particular it was noted that careful consideration for dealing with biomonitoring and BLVs should be given, as well as ensuring that the text was well structure in a way that it is clear to which substances / groups of substances stricter requirements apply. There was, however, concern raised regarding Option 5, with one national authority commenting that they would prefer to keep the two directives separate in order to maintain focus on particularly dangerous substances. Several national authorities expressed concern with regards to the threshold, non-threshold distinction, stating that if reprotoxins are to be added to the CMD, it should be done in a considered, risk-based manner. While this was an often-favoured Option, there was concern that consolidation of CAD and CMD would take many years to achieve, placing workers are risk in the meantime. However, this is a favoured long-term goal.

Trade unions, who favoured Options 2 and 5 exclusively commented that workers would be best protected if the same rules and principles apply to Reprotoxic 1A/1B substances as in the CMD. They also suggested that this would make the regulations easier to understand, which would raise compliance. Again, they expressed concern, with regards to Option 5, that a full merger of CAD and CMD would take a long time.

While there were only four responses to this question from OSH experts and the preferences were split across all Policy Options, one OSH expert commented that Option 5 was most favourable to them as it considers sensitisers, "which are the main causes of occupational disease". Again, the need to include a distinction between threshold and non-threshold substances, instead of the current classification, was expressed. Furthermore, it was said that the BLV issue should be considered, to encourage the setting of BLVs at EU level and the using of biomonitoring nationally.

X2.1.12 Conclusions

A significant amount of information was collected through our consultation's questionnaires. Efforts were made to contact a variety of stakeholders in each stakeholder group. The high level of information received informed the conclusions of this report.

Annex 3 Environmental Impacts of Reprotoxins

X3.1 Introduction

In this annex, the environmental effects that may be associated with potential reprotoxins releases into the environment are discussed. For the sake of brevity, we have limited our analysis to toxicity in fish and aquatic invertebrates. Data for other classes/species are so limited that the paucity of data precludes a comprehensive analysis. Even for fish and aquatic invertebrates there are substantial datagaps. We have elected to base our analysis on raw scientific data rather than calculated predicted no effect concentrations (PNEC) where the consistency of the approach is subject to discussion especially the selection of assessment factors. In order to maintain consistency, we have not selected the lowest available toxicity datapoint: species selection and sensitivity variability would have a great impact on that, but rather the geometric mean of the available scientific data following very limited curation. Given this is a screening approach to environmental hazard assessment, this approach should give the fastest, least variable approach to environmental effects analysis (the consistency of the available data across endpoints supports that supposition.)

X3.2 Detailed approach

In order to enable the analysis of raw scientific data we delved into Verisk 3E PCTEC+ (PhysicoChemical, Toxicology and ECotoxicology) database. These data are scraped from a variety (125+) of curated and uncurated databases. We had previously gathered 170 CAS numbers for R classified chemicals which were not C or M. These CAS data were run through Verisk 3E's Insight for Chemicals software (which queries the PCTEC+ database) to allow acquisition of data (where available) for the following endpoints:

- Acute Fish
- Chronic Fish
- Acute Aquatic Invertebrates
- Chronic Aquatic Invertebrates

Acquired data were sorted for mg/L and µg/L units of chemical concentrations; data with other units were discarded. All data in µg/L units were converted to mg/L. All data containing > xyz mg/L data were reported as xyz mg/L.

For Acute Fish data only, EC50 and LC50 data for 96 hours exposure were selected; for all other endpoints EC50 and LC50 were selected without consideration of exposure duration, given the highly variable exposure duration for these data categories. Species were not selected for sensitivity, i.e. we did not select the most sensitive species. Given that not all species are tested for all chemicals, selection of the most sensitive species for each chemical will result in seriously skewed data. All data (and species) were averaged together using geometric means to decrease variability while providing a (small) bias towards the data at lower concentrations[144].

[144] Although this appears counterintuitive, previous research into larger (25 plus assays) data sets had demonstrated that geometric means of larger uncurated data sets had equivalent/better/higher quality (as measured via standard statistical parameters) compared to smaller curated data sets.

X3.3 Data analysis

Data were derived using the above approach, and are shown in the table below (alphabetized by chemical name) and Table X3-2 (sorted by CAS). For easy comparison the data were colour coded as follows:

- Data < 1 µg/L Red
- Data 1-10 µg/L Orange-brown
- Data 10-100 µg/L Yellow
- Data > 100 ug/L Light Green
- No Data Blank

As may be clear to the reader, the above intervals correspond to the aquatic toxicity classification criteria under GHS/CLP. The color-coding of the data allows for a quick review. Data is available for slightly more than half the CAS numbers. Generally, data are only available for the two Acute endpoints. Data run the gamut from Light Green to Red. As might be expected (bis)tributyltin oxide (a strong biocide) has the highest aquatic toxicity, i.e. < 10 µg/L.

For a number of chemicals all available data is in the same colour range. This consistency in toxicity for most but not all of the chemicals is a good QA indicator that this approach provides useable screening data. One would usually expect the invertebrate data to be slightly more sensitive i.e. lower EC50/LC50, but such a trend is rather inconsistent. Similarly, one would expect chronic toxicity to have a lower number i.e. be more toxic but this is again highly variable. Especially for the chemicals with a measurable vapour pressure or very low solubility this is often the result of assay inconsistencies, such as continuous aeration without water replacement and/or dose replacement.

Noteworthy is that very few (about 10%) of the chemicals demonstrate "red" data: the overall aquatic toxicity of these chemicals is relatively low as evidenced by the mostly (very) high LC50/EC50 values. Highly inconsistent data (nearly two orders of magnitude variability between geometric means of various assays) were demonstrated by:

- 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate
- 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate
- Ethanol, 2-amino-, reaction products with ammonia, 1-piperazineethanamine fraction
- Imidazolidine-2-thione
- Naphthenic acids, cobalt salts
- Nitrobenzene
- Phenol, dodecyl-, branched
- Warfarin

Of these chemicals only Imidazolidine-2-thione, and Phenol, dodecyl-, branched are discussed in detail in this report. It is unclear what causes thee inconsistencies except perhaps the aforementioned anomalies of the test conditions.

Table X3-1: Geomean EC50 or LC50 values (mg/l) for Fish and Invertebrates—Acute and Chronic data					
CAS No	PREF	Fish Acute	Fish Chronic	Invertebrate Acute	Invertebrate Chronic
119738-06-6	(+/-) tetrahydrofurfuryl (R)-2-[4-(6-chloroquinoxalin-2-yloxy)phenyloxy]propionate				
137862-53-4	(2S)-3-methyl-2-(N-{[2'-(1H-1,2,3,4-tetrazol-5-yl)-[1,1-biphenyl]-4-yl]methyl}pentanamido)butanoic acid				
53123-88-9	(3S,6R,7E,9R,10R,12R,14S,15E,17E,19E,21S,23S,26R,27R,34aS)-9,10,12,13,14,21,22,23,24,25,26,27,32,33,34,34a-hexadecahydro-9,27-dihydroxy-3-[(1R)-2-[(1S,3R,4R)-4-hydroxy-3-methoxycyclohexyl]-1-methylethyl]-10,21-dimethoxy-6,8,12,14,20,26-hexamethyl-23,27-epoxy-3H-pyrido[2,1-c][1,4]-oxaazacyclohentriacontine-1,5,11,28,29(4H,6H,31H)-pentone				
105024-66-6	(4-ethoxyphenyl)(3-(4-fluoro-3-phenoxyphenyl)propyl)dimethylsilane				
82413-20-5	(E)-3-[1-[4-[2-(dimethylamino)ethoxy]phenyl]-2-phenylbut-1-enyl]phenol				
114798-26-4	[2-butyl-4-chloro-1-({4-[2-(2H-1,2,3,4-tetrazol-5-yl)phenyl]phenyl}methyl)-1H-imidazol-5-yl]methanol	**929**		**331**	
13614-98-7	[4S-(4α,4aα,5aα,12aα)]-4,7-bis(dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,10,12,12a-tetrahydroxy-1,11-dioxonaphthacene-2-carboxamide monohydrochloride				
183196-57-8	[containing < 0.5 % N,N-dimethylformamide (EC no 200-679-5)]				
112-49-2	1,2-bis(2-methoxyethoxy)ethane	**5000**		**5000**	
110-71-4	1,2-dimethoxyethane	**1581.14**		**4000**	
13951-70-7	11β,16α,17,21-tetrahydroxypregna-1,4-diene-3,20-dione				
2921-57-5	11β,17,21-trihydroxy-6α-methylpregna-1,4-diene-3,20-dione 21-(hydrogen succinate)				
35410-28-7	11β,17,21-trihydroxypregna-1,4-diene-3,20-dione 21-methanesulphonate				
5173-46-6	13-methyl-1,2,6,7,8,11,12,14,15,16-decahydrocyclopenta[a]phenanthrene-3,17-dione				
31981-44-9	17-hydroxy-19-norpregn-4-ene-3,20-dione 17-acetate			**8.40**	
10161-33-8	17Î²-Hydroxy-estra-4,9,11-trien-3-one				
106-94-5	1-bromopropane	**45.48**		**77.79**	
2687-91-4	1-ethylpyrrolidin-2-one	**464**			
872-50-4	1-methyl-2-pyrrolidone	**500**		**1052.14**	

Table X3-1: Geomean EC50 or LC50 values (mg/l) for Fish and Invertebrates—Acute and Chronic data					
CAS No	PREF	Fish Acute	Fish Chronic	Invertebrate Acute	Invertebrate Chronic
68551-11-1	1-Propene, hydroformylation products, high-boiling	68		63.60	
111-41-1	2-(2-aminoethylamino)ethanol	640		64.65	
111-90-0	2-(2-ethoxyethoxy)ethanol	12845.71		7914.09	
80-54-6	2-(4-tert-butylbenzyl)propionaldehyde	2.33		10.26	
6807-17-6	2,2-bis(4'-hydroxyphenyl)-4-methylpentane				
1638-05-7	2,7,11-trimethyl-13-(2,6,6-trimethylcyclohex-1-en-1-yl)tridecahexaen-2,4,6,8,10,12-al	27.50		50	
151798-26-4	2-[2-hydroxy-3-(2-chlorophenyl)carbamoyl-1-naphthylazo]-7-[2-hydroxy-3-(3-methylphenyl)carbamoyl-1-naphthylazo]fluoren-9-one				
75-26-3	2-bromopropane	66.60		39.64	13.40
94723-86-1	2-butyryl-3-hydroxy-5-thiocyclohexan-3-yl-cyclohex-2-en-1-one				
147403-03-0	2-ethoxy-1-{[2'-(5-oxo-4,5-dihydro-1,2,4-oxadiazol-3-yl)-biphenyl-4-yl]methyl}-1H-benz-imidazole-7-carboxylic acid				
110-80-5	2-ethoxyethanol	10000		10000	
15571-58-1	2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate	11.99		0.23	1.85
27107-89-7	2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate	73			0.23
109-86-4	2-methoxyethanol	16462.55		17921.33	
71868-10-5	2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one	9		15.30	
693-98-1	2-methylimidazole	249.55		212.28	
62518-65-4	3-(m-tert-butylphenyl)-2-methylpropionaldehyde				
56107-04-1	3-(p-tert-butylphenyl)-2-methylpropanol				
77-73-6	3a,4,7,7a-tetrahydro-4,7-methanoindene	16.13		6.53	4
143860-04-2	3-ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazolidine	129		55.86	
481-29-8	3-β-hydroxy-5-α-androstan-17-one				
284461-73-0	4-(4-((((4-CHLORO-3-(TRIFLUOROMETHYL)PHENYL)AMINO)CARBONYL)AMINO)PHENOXY)-N-METHYL-2-PYRIDINECARBOXAMIDE				
80-05-7	4,4'-isopropylidenediphenol	6.74	5.10	3.54	1.50
98-73-7	4-tert-butylbenzoic acid	149.67		33.59	
98-51-1	4-tert-butyltoluene	2		3.20	
16219-75-3	5-ethylidene-8,9,10-trinorborn-2-ene	5.50		5	2.49

Table X3-1: Geomean EC50 or LC50 values (mg/l) for Fish and Invertebrates—Acute and Chronic data					
CAS No	PREF	Fish Acute	Fish Chronic	Invertebrate Acute	Invertebrate Chronic
2823-42-9	6α,9-difluoro-11β,17,21-trihydroxy-16α-methylpregna-1,4-diene-3,20-dione 21-acetate				
199327-61-2	7-methoxy-6-(3-morpholin-4-yl-propoxy)-3H-quinazolin-4-one				
90035-08-8	A mixture of: cis-4-hydroxy-3-(1,2,3,4-tetrahydro-3-(4-(4-trifluoromethylbenzyloxy)phenyl)-1-naphthyl)coumarin; trans-4-hydroxy-3-(1,2,3,4-tetrahydro-3-(4-(4-trifluoromethylbenzyloxy)phenyl)-1-naphthyl)coumarin	0.11		0.85	
665-66-7	Amantadine hydrochloride	25		24.40	
61-82-5	Amitrole				
897-06-3	Androsta-1,4-diene-3,17-dione			50	
4419-39-0	Beclometasone				
152459-95-5	Benzamide, 4-[(4-methyl-1-piperazinyl)methyl]-N-[4-methyl-3-[[4-(3-pyridinyl)-2-pyrimidinyl]amino]phenyl]-				
583-39-1	Benzimidazole-2-thiol	19.24		16.31	
85-68-7	Benzyl butyl phthalate	1.73	2.28	1.75	
117-81-7	Bis(2-ethylhexyl) phthalate	1.62	1.20	0.47	11.10
111-96-6	Bis(2-methoxyethyl) ether	5000		943	
56-35-9	Bis(tributyltin) oxide	0		0	0
846-48-0	Boldenone			30.18	
10043-35-3	Boric acid	76.80		153.49	
52485-79-7	Buprenorphine				
630-08-0	Carbon monoxide			307.50	
3724-43-4	Chloro-N,N-dimethylformiminium chloride				
21462-39-5	Clindamycin hydrochloride				
5571-36-8	cyclic 3-(1,2-ethanediylacetale)-estra-5(10),9(11)-diene-3,17-dione	8.10			
50-02-2	Dexamethasone				
2392-39-4	Dexamethasone 21-(disodium phosphate)				
1177-87-3	Dexamethasone 21-acetate				
12007-89-5	Diammonium decaborate	295.38	71.57	141.84	53.20
12046-04-7	Diammonium decaborate				
1303-86-2	Diboron trioxide	90.34		152.95	
84-74-2	Dibutyl phthalate	1.32		1.75	

Table X3-1: Geomean EC50 or LC50 values (mg/l) for Fish and Invertebrates—Acute and Chronic data					
CAS No	PREF	Fish Acute	Fish Chronic	Invertebrate Acute	Invertebrate Chronic
93952-11-5	Dibutyl phthalate-3,4,5,6-d4				
2781-10-4	Dibutyltin bis(2-ethylhexanoate)			1.99	
683-18-1	Dibutyltin dichloride	4		0.32	
77-58-7	Dibutyltin dilaurate			0.90	
75113-37-0	Dibutyltin hydrogen borate				
818-08-6	Dibutyltin oxide			2.32	
84-61-7	Dicyclohexyl phthalate	2			0.84
84-69-5	Diisobutyl phthalate	1.25		4.10	
605-50-5	Diisopentyl phthalate				
1112-39-6	Dimethoxydimethylsilane	476.24		201.57	
109-87-5	Dimethoxymethane	2582.16		1095.45	
88-85-7	Dinoseb	0.14		0.24	
12045-78-2	Dipotassium tetraborate				
1332-77-0	Dipotassium tetraborate	308.87	71.57	141.84	53.20
12008-41-2	Disodium octaborate	76.80		153.49	
12280-03-4	Disodium octaborate				
12179-04-3	Disodium tetraborate, anhydrous				
1303-96-4	Disodium tetraborate, anhydrous				
1330-43-4	Disodium tetraborate, anhydrous	76.80		153.49	
106325-08-0	epoxiconazole (ISO)				
133855-98-8	epoxiconazole (ISO)				
734-32-7	Estr-4-ene-3,17-dione				
92731-41-4	Ethanol, 2-amino-, reaction products with ammonia, 1-piperazineethanamine fraction	459.33		73.62	2.50
434-03-7	Ethisterone			8.70	
107-15-3	Ethylenediamine	601.38		27.72	
2135-17-3	Flumetasone				
75-12-7	Formamide	7746.47		2119.06	
50-23-7	Hydrocortisone			100	
2203-97-6	Hydrocortisone 21-(hydrogen succinate)				
50-03-3	Hydrocortisone 21-acetate			2.08	
15687-27-1	Ibuprofen				
288-32-4	Imidazole			341.50	
96-45-7	Imidazolidine-2-thione	7500		26.40	18

Table X3-1: Geomean EC50 or LC50 values (mg/l) for Fish and Invertebrates—Acute and Chronic data					
CAS No	PREF	Fish Acute	Fish Chronic	Invertebrate Acute	Invertebrate Chronic
53-86-1	Indometacin				
7439-92-1	Lead	0.62		0.57	1.23
15245-44-0	Lead 2,4,6-trinitro-m-phenylene dioxide	0.62		0.59	1.23
301-04-2	Lead di(acetate)			10	
6080-56-4	Lead di(acetate)				
13424-46-9	Lead diazide				
17570-76-2	Lead(II) bis(methanesulfonate)				
7439-93-2	Lithium	44.29		38.95	1.70
554-13-2	Lithium carbonate	13.13		14.39	1.70
7439-97-6	Mercury	0.23		0.10	0.05
67-56-1	Methanol	14069.54	11101.12	14834.73	
625-45-6	Methoxyacetic acid	223.61		68.30	
119-36-8	Methyl salicylate	139.46		196.72	
83-43-2	Methylprednisolone				
53-36-1	Methylprednisolone 21-acetate				
24280-93-1	Mycophenolic acid			755	
302962-49-8	N-(2-chloro-6-methylphenyl)-2-({6-[4-(2-hydroxyethyl)piperazin-1-yl]-2-methylpyrimidin-4-yl}amino)-1,3-thiazole-5-carboxamide				
27366-72-9	N,N-(dimethylamino)thioacetamide hydrochloride				
127-19-5	N,N-dimethylacetamide	500		694.98	
68-12-2	N,N-dimethylformamide	7100		4727.69	1689.38
198470-84-7	N-[[4-(5-methyl-3-phenylisoxazol-4-yl]phenyl]sulfonyl]propanamide				
61789-51-3	Naphthenic acids, cobalt salts	16.82	4.08	26.85	0.09
22204-53-1	Naproxen				
98-95-3	Nitrobenzene	80.51	0	24.11	24
79-16-3	N-methylacetamide	3390		580	
123-39-7	N-methylformamide	10000		500	
50-78-2	O-acetylsalicylic acid	30		360.61	61
140-01-2	Pentasodium (carboxylatomethyl)iminobis(ethylenenitrilo)tetraacetate	1115		767.77	
10332-33-9	Perboric acid, sodium salt				
11138-47-9	Perboric acid, sodium salt	87.46		20.21	

Table X3-1: Geomean EC50 or LC50 values (mg/l) for Fish and Invertebrates—Acute and Chronic data					
CAS No	PREF	Fish Acute	Fish Chronic	Invertebrate Acute	Invertebrate Chronic
12040-72-1	Perboric acid, sodium salt				
37244-98-7	Perboric acid, sodium salt				
121158-58-5	Phenol, dodecyl-, branched	14.54		0.36	0.01
96152-43-1	Phenol, dodecyl-, branched, sulfurized			398.42	
68855-45-8	Phenol, dodecyl-, sulfurized, calcium salts	1000		1000	
68784-25-8	Phenol, dodecyl-, sulfurized, carbonates, calcium salts			158.74	
68784-26-9	Phenol, dodecyl-, sulfurized, carbonates, calcium salts, overbased			158.74	
630-93-3	Phenytoin sodium				
68478-92-2	Platinum, 1,3-diethenyl-1,1,3,3-tetramethyldisiloxane complexes				
11128-29-3	Potassium pentaborate	308.87	71.57	141.84	53.20
148-24-3	Quinolin-8-ol				
68-26-8	Retinol	1778.29		100	
79-81-2	Retinyl palmitate	10000		100	
15307-79-6	Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate	214		23.91	
10555-76-7	Sodium metaborate, anhydrous				
7775-19-1	Sodium metaborate, anhydrous	308.87	71.57	141.84	53.20
100-42-5	Styrene	10		12.33	2.69
13494-80-9	Tellurium	55.63		6.47	
1461-25-2	Tetrabutyltin	0.06		0.27	0.05
97-99-4	Tetrahydrofurfuryl alcohol	101		91.70	95.10
61571-06-0	Tetrahydrothiopyran-3-carboxaldehyde				
124-64-1	Tetrakis(hydroxymethyl)phosphonium chloride	92.71		3.65	
55566-30-8	Tetrakis(hydroxymethyl)phosphonium sulphate(2:1)				
108-88-3	Toluene	64.73		6.26	16.47
12141-20-7	Trilead dioxide phosphonate	0.62		0.57	1.23
121-43-7	Trimethyl borate				
121-45-9	Trimethyl phosphite				
115-96-8	Tris(2-chloroethyl) phosphate			170	
1067-53-4	Tris(2-methoxyethoxy)vinylsilane	374.44		438.58	
25155-23-1	Trixylyl phosphate	1.12		0.06	

Table X3-1: Geomean EC50 or LC50 values (mg/l) for Fish and Invertebrates—Acute and Chronic data					
CAS No	PREF	Fish Acute	Fish Chronic	Invertebrate Acute	Invertebrate Chronic
81-81-2	Warfarin	0.98		105	
136-53-8	Zinc bis(2-ethylhexanoate)	1.12		1.69	
54261-67-5	Zinc bis[bis(dodecylphenyl)] bis(dithiophosphate)	29		5.55	

Table X3-2: Geomean EC50 or LC50 values (mg/l) for Fish and Invertebrates—Acute and Chronic data					
CAS No	PREF	Fish Acute	Fish Chronic	Invertebrate Acute	Invertebrate Chronic
100-42-5	Styrene	10.00		12.33	2.69
10043-35-3	Boric acid	76.80		153.49	
10161-33-8	17Î²-Hydroxy-estra-4,9,11-trien-3-one				
10332-33-9	Perboric acid, sodium salt				
105024-66-6	(4-ethoxyphenyl)(3-(4-fluoro-3-phenoxyphenyl)propyl)dimethylsilane				
10555-76-7	Sodium metaborate, anhydrous				
106325-08-0	epoxiconazole (ISO)				
1067-53-4	Tris(2-methoxyethoxy)vinylsilane	374.44		438.58	
106-94-5	1-bromopropane	45.48		77.79	
107-15-3	Ethylenediamine	601.38		27.72	
108-88-3	Toluene	64.73		6.26	16.47
109-86-4	2-methoxyethanol	16462.55		17921.33	
109-87-5	Dimethoxymethane	2582.16		1095.45	
110-71-4	1,2-dimethoxyethane	1581.14		4000.00	
110-80-5	2-ethoxyethanol	10000.00		10000.00	
1112-39-6	Dimethoxydimethylsilane	476.24		201.57	
11128-29-3	Potassium pentaborate	308.87	71.57	141.84	53.20
11138-47-9	Perboric acid, sodium salt	87.46		20.21	
111-41-1	2-(2-aminoethylamino)ethanol	640.00		64.65	
111-90-0	2-(2-ethoxyethoxy)ethanol	12845.71		7914.09	
111-96-6	Bis(2-methoxyethyl) ether	5000.00		943.00	
112-49-2	1,2-bis(2-methoxyethoxy)ethane	5000.00		5000.00	
114798-26-4	[2-butyl-4-chloro-1-({4-[2-(2H-1,2,3,4-tetrazol-5-yl)phenyl]phenyl}methyl)-1H-imidazol-5-yl]methanol	929.00		331.00	
115-96-8	Tris(2-chloroethyl) phosphate			170.00	
1177-87-3	Dexamethasone 21-acetate				
117-81-7	Bis(2-ethylhexyl) phthalate	1.62	1.20	0.47	11.10
119-36-8	Methyl salicylate	139.46		196.72	
119738-06-6	(+/-) tetrahydrofurfuryl (R)-2-[4-(6-chloroquinoxalin-2-yloxy)phenyloxy]propionate				
12007-89-5	Diammonium decaborate	295.38	71.57	141.84	53.20
12008-41-2	Disodium octaborate	76.80		153.49	
12040-72-1	Perboric acid, sodium salt				
12045-78-2	Dipotassium tetraborate				
12046-04-7	Diammonium decaborate				

Table X3-2: Geomean EC50 or LC50 values (mg/l) for Fish and Invertebrates—Acute and Chronic data					
CAS No	PREF	Fish Acute	Fish Chronic	Invertebrate Acute	Invertebrate Chronic
121158-58-5	Phenol, dodecyl-, branched	14.54		0.36	0.01
12141-20-7	Trilead dioxide phosphonate	0.62		0.57	1.23
121-43-7	Trimethyl borate				
121-45-9	Trimethyl phosphite				
12179-04-3	Disodium tetraborate, anhydrous				
12280-03-4	Disodium octaborate				
123-39-7	N-methylformamide	10000.00		500.00	
124-64-1	Tetrakis(hydroxymethyl)phosphonium chloride	92.71		3.65	
127-19-5	N,N-dimethylacetamide	500.00		694.98	
1303-86-2	Diboron trioxide	90.34		152.95	
1303-96-4	Disodium tetraborate, anhydrous				
1330-43-4	Disodium tetraborate, anhydrous	76.80		153.49	
1332-77-0	Dipotassium tetraborate	308.87	71.57	141.84	53.20
133855-98-8	epoxiconazole (ISO)				
13424-46-9	Lead diazide				
13494-80-9	Tellurium	55.63		6.47	
13614-98-7	[4S-(4α,4aα,5aα,12aα)]-4,7-bis(dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,10,12,12a-tetrahydroxy-1,11-dioxonaphthacene-2-carboxamide monohydrochloride				
136-53-8	Zinc bis(2-ethylhexanoate)	1.12		1.69	
137862-53-4	(2S)-3-methyl-2-(N-{[2'-(1H-1,2,3,4-tetrazol-5-yl)-[1,1-biphenyl]-4-yl]methyl}pentanamido)butanoic acid				
13951-70-7	11β,16α,17,21-tetrahydroxypregna-1,4-diene-3,20-dione				
140-01-2	Pentasodium (carboxylatomethyl)iminobis(ethylenenitrilo)tetraacetate	1115.00		767.77	
143860-04-2	3-ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazolidine	129.00		55.86	
1461-25-2	Tetrabutyltin	0.06		0.27	0.05
147403-03-0	2-ethoxy-1-{[2'-(5-oxo-4,5-dihydro-1,2,4-oxadiazol-3-yl)-biphenyl-4-yl]methyl}-1H-benz-imidazole-7-carboxylic acid				
148-24-3	Quinolin-8-ol				
151798-26-4	2-[2-hydroxy-3-(2-chlorophenyl)carbamoyl-1-naphthylazo]-7-[2-hydroxy-3-(3-methylphenyl)carbamoyl-1-naphthylazo]fluoren-9-one				

Table X3-2: Geomean EC50 or LC50 values (mg/l) for Fish and Invertebrates—Acute and Chronic data					
CAS No	PREF	Fish Acute	Fish Chronic	Invertebrate Acute	Invertebrate Chronic
15245-44-0	Lead 2,4,6-trinitro-m-phenylene dioxide	0.62		0.59	1.23
152459-95-5	Benzamide, 4-[(4-methyl-1-piperazinyl)methyl]-N-[4-methyl-3-[[4-(3-pyridinyl)-2-pyrimidinyl]amino]phenyl]-				
15307-79-6	Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate	214.00		23.91	
15571-58-1	2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate	11.99		0.23	1.85
15687-27-1	Ibuprofen				
16219-75-3	5-ethylidene-8,9,10-trinorborn-2-ene	5.50		5.00	2.49
1638-05-7	2,7,11-trimethyl-13-(2,6,6-trimethylcyclohex-1-en-1-yl)tridecahexaen-2,4,6,8,10,12-al	27.50		50.00	
17570-76-2	Lead(II) bis(methanesulfonate)				
183196-57-8	[containing < 0.5 % N,N-dimethylformamide (EC no 200-679-5)]				
198470-84-7	N-[[4-(5-methyl-3-phenylisoxazol-4-yl]phenyl]sulfonyl]propanamide				
199327-61-2	7-methoxy-6-(3-morpholin-4-yl-propoxy)-3H-quinazolin-4-one				
2135-17-3	Flumetasone				
21462-39-5	Clindamycin hydrochloride				
2203-97-6	Hydrocortisone 21-(hydrogen succinate)				
22204-53-1	Naproxen				
2392-39-4	Dexamethasone 21-(disodium phosphate)				
24280-93-1	Mycophenolic acid			755.00	
25155-23-1	Trixylyl phosphate	1.12		0.06	
2687-91-4	1-ethylpyrrolidin-2-one	464.00			
27107-89-7	2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate	73.00			0.23
27366-72-9	N,N-(dimethylamino)thioacetamide hydrochloride				
2781-10-4	Dibutyltin bis(2-ethylhexanoate)			1.99	
2823-42-9	6α,9-difluoro-11β,17,21-trihydroxy-16α-methylpregna-1,4-diene-3,20-dione 21-acetate				
284461-73-0	4-(4-((((4-CHLORO-3-(TRIFLUOROMETHYL)PHENYL)AMINO)CARBONYL)AMINO)PHENOXY)-N-METHYL-2-PYRIDINECARBOXAMIDE				
288-32-4	Imidazole			341.50	

Table X3-2: Geomean EC50 or LC50 values (mg/l) for Fish and Invertebrates—Acute and Chronic data					
CAS No	PREF	Fish Acute	Fish Chronic	Invertebrate Acute	Invertebrate Chronic
2921-57-5	11β,17,21-trihydroxy-6α-methylpregna-1,4-diene-3,20-dione 21-(hydrogen succinate)				
301-04-2	Lead di(acetate)			10.00	
302962-49-8	N-(2-chloro-6-methylphenyl)-2-({6-[4-(2-hydroxyethyl)piperazin-1-yl]-2-methylpyrimidin-4-yl}amino)-1,3-thiazole-5-carboxamide				
31981-44-9	17-hydroxy-19-norpregn-4-ene-3,20-dione 17-acetate			8.40	
35410-28-7	11β,17,21-trihydroxypregna-1,4-diene-3,20-dione 21-methanesulphonate				
3724-43-4	Chloro-N,N-dimethylformiminium chloride				
37244-98-7	Perboric acid, sodium salt				
434-03-7	Ethisterone			8.70	
4419-39-0	Beclometasone				
481-29-8	3-β-hydroxy-5-α-androstan-17-one				
50-02-2	Dexamethasone				
50-03-3	Hydrocortisone 21-acetate			2.08	
50-23-7	Hydrocortisone			100.00	
50-78-2	O-acetylsalicylic acid	30.00		360.61	61.00
5173-46-6	13-methyl-1,2,6,7,8,11,12,14,15,16-decahydrocyclopenta[a]phenanthrene-3,17-dione				
52485-79-7	Buprenorphine				
53123-88-9	(3S,6R,7E,9R,10R,12R,14S,15E,17E,19E,21S,23S,26R,27R,34aS)-9,10,12,13,14,21,22,23,24,25,26,27,32,33,34,34a-hexadecahydro-9,27-dihydroxy-3-[(1R)-2-[(1S,3R,4R)-4-hydroxy-3-methoxycyclohexyl]-1-methylethyl]-10,21-dimethoxy-6,8,12,14,20,26-hexamethyl-23,27-epoxy-3H-pyrido[2,1-c][1,4]-oxaazacyclohentriacontine-1,5,11,28,29(4H,6H,31H)-pentone				
53-36-1	Methylprednisolone 21-acetate				
53-86-1	Indometacin				
54261-67-5	Zinc bis[bis(dodecylphenyl)] bis(dithiophosphate)	29.00		5.55	
554-13-2	Lithium carbonate	13.13		14.39	1.70
55566-30-8	Tetrakis(hydroxymethyl)phosphonium sulphate(2:1)				
5571-36-8	cyclic 3-(1,2-ethanediylacetale)-estra-5(10),9(11)-diene-3,17-dione	8.10			
56107-04-1	3-(p-tert-butylphenyl)-2-methylpropanol				
56-35-9	Bis(tributyltin) oxide	0.00		0.00	0.00
583-39-1	Benzimidazole-2-thiol	19.24		16.31	
605-50-5	Diisopentyl phthalate				

Table X3-2: Geomean EC50 or LC50 values (mg/l) for Fish and Invertebrates—Acute and Chronic data					
CAS No	PREF	Fish Acute	Fish Chronic	Invertebrate Acute	Invertebrate Chronic
6080-56-4	Lead di(acetate)				
61571-06-0	Tetrahydrothiopyran-3-carboxaldehyde				
61789-51-3	Naphthenic acids, cobalt salts	16.82	4.08	26.85	0.09
61-82-5	Amitrole				
62518-65-4	3-(m-tert-butylphenyl)-2-methylpropionaldehyde				
625-45-6	Methoxyacetic acid	223.61		68.30	
630-08-0	Carbon monoxide			307.50	
630-93-3	Phenytoin sodium				
665-66-7	Amantadine hydrochloride	25.00		24.40	
67-56-1	Methanol	14069.54	11101.12	14834.73	
6807-17-6	2,2-bis(4'-hydroxyphenyl)-4-methylpentane				
68-12-2	N,N-dimethylformamide	7100.00		4727.69	1689.38
68-26-8	Retinol	1778.29		100.00	
683-18-1	Dibutyltin dichloride	4.00		0.32	
68478-92-2	Platinum, 1,3-diethenyl-1,1,3,3-tetramethyldisiloxane complexes				
68551-11-1	1-Propene, hydroformylation products, high-boiling	68.00		63.60	
68784-25-8	Phenol, dodecyl-, sulfurized, carbonates, calcium salts			158.74	
68784-26-9	Phenol, dodecyl-, sulfurized, carbonates, calcium salts, overbased			158.74	
68855-45-8	Phenol, dodecyl-, sulfurized, calcium salts	1000.00		1000.00	
693-98-1	2-methylimidazole	249.55		212.28	
71868-10-5	2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one	9.00		15.30	
734-32-7	Estr-4-ene-3,17-dione				
7439-92-1	Lead	0.62		0.57	1.23
7439-93-2	Lithium	44.29		38.95	1.70
7439-97-6	Mercury	0.23		0.10	0.05
75113-37-0	Dibutyltin hydrogen borate				
75-12-7	Formamide	7746.47		2119.06	
75-26-3	2-bromopropane	66.60		39.64	13.40
77-58-7	Dibutyltin dilaurate			0.90	
77-73-6	3a,4,7,7a-tetrahydro-4,7-methanoindene	16.13		6.53	4.00
7775-19-1	Sodium metaborate, anhydrous	308.87	71.57	141.84	53.20
79-16-3	N-methylacetamide	3390.00		580.00	
79-81-2	Retinyl palmitate	10000.00		100.00	
80-05-7	4,4'-isopropylidenediphenol	6.74	5.10	3.54	1.50
80-54-6	2-(4-tert-butylbenzyl)propionaldehyde	2.33		10.26	
818-08-6	Dibutyltin oxide			2.32	
81-81-2	Warfarin	0.98		105.00	

Table X3-2: Geomean EC50 or LC50 values (mg/l) for Fish and Invertebrates—Acute and Chronic data					
CAS No	PREF	Fish Acute	Fish Chronic	Invertebrate Acute	Invertebrate Chronic
82413-20-5	(E)-3-[1-[4-[2-(dimethylamino)ethoxy]phenyl]-2-phenylbut-1-enyl]phenol				
83-43-2	Methylprednisolone				
84-61-7	Dicyclohexyl phthalate	2.00			0.84
846-48-0	Boldenone			30.18	
84-69-5	Diisobutyl phthalate	1.25		4.10	
84-74-2	Dibutyl phthalate	1.32		1.75	
85-68-7	Benzyl butyl phthalate	1.73	2.28	1.75	
872-50-4	1-methyl-2-pyrrolidone	500.00		1052.14	
88-85-7	Dinoseb	0.14		0.24	
897-06-3	Androsta-1,4-diene-3,17-dione			50.00	
90035-08-8	A mixture of: cis-4-hydroxy-3-(1,2,3,4-tetrahydro-3-(4-(4-trifluoromethylbenzyloxy)phenyl)-1-naphthyl)coumarin; trans-4-hydroxy-3-(1,2,3,4-tetrahydro-3-(4-(4-trifluoromethylbenzyloxy)phenyl)-1-naphthyl)coumarin	0.11		0.85	
92731-41-4	Ethanol, 2-amino-, reaction products with ammonia, 1-piperazineethanamine fraction	459.33		73.62	2.50
93952-11-5	Dibutyl phthalate-3,4,5,6-d4				
94723-86-1	2-butyryl-3-hydroxy-5-thiocyclohexan-3-yl-cyclohex-2-en-1-one				
96152-43-1	Phenol, dodecyl-, branched, sulfurized			398.42	
96-45-7	Imidazolidine-2-thione	7500.00		26.40	18.00
97-99-4	Tetrahydrofurfuryl alcohol	101.00		91.70	95.10
98-51-1	4-tert-butyltoluene	2.00		3.20	
98-73-7	4-tert-butylbenzoic acid	149.67		33.59	
98-95-3	Nitrobenzene	80.51	0.00	24.11	24.00

Annex 4 Lead Impact Assessment and Case Study

X4.1 Applying the Policy Options to lead

X4.1.1 Assumptions when applying the Policy Options to lead

Overview

This section discusses the application of the Policy Options to lead and the assumptions that are required for each Option. Key areas for consideration include whether there is a threshold for lead, and if so, what this threshold is and whether it is technically feasible to measure it and distinguish between occupational and background exposure.

Option 1: baseline

Under Option 1 (the baseline Option where there are no changes to EU OSH legislation), the current situation is assumed to continue as per the lead baseline described in Annex 4. However, there may be additional guidance on best available techniques and the interpretation of the CMD and CAD.

Annex I of the CAD already provides a binding OELV for lead, whilst Annex II stipulates a binding BLV and requires that practical guidelines for biological monitoring and medical surveillance are developed as per Article 12(2). As noted in the lead baseline, several MS have specified their OELs and BLVs which are more stringent than those in the CAD. There are also various other pieces of legislation covering lead and its compounds. There is also existing guidance, for example, the UK HSE's publications include the 'Control of lead at work (third edition), Control of Lead at Work Regulations 2002, Approved code of practice and guidance'[145]. Under Option 1, it is assumed that guidance such as that published by the HSE would continue to be developed and updated, alongside other guidance on techniques and interpretation of the CAD.

Option 2: R 1A/1B in CMD (no derogations)

Option 2 involves full application of the CMD to Reprotoxic 1A/1B substances. Since lead, lead di(acetate) and trilead dioxide phosphate are classified as Reprotoxic 1A/1B, then CMD requirements would apply. Thus, there would be a need for:

- Substitution: use of lead and its compounds would need to be reduced where possible through replacing it with something less dangerous to workers' health or safety;
- Use of a closed system: closed systems should be introduced where substitution is not possible; and
- Reduction of exposure to as low a level as *technically* possible should occur if substitution and closed systems are not possible.

Article 16 of the CMD provides for the setting of limit values where possible, with existing values present in Annex III. Since lead already has limit values (a binding OELV and a binding BLV are both stated within the CAD), it is assumed that the OELV could be transferred to the CMD.

[145] HSE (2002): Control of lead at work (Third edition), Control of Lead at Work Regulations 2002, Approved Code of Practice and guidance, accessed at: http://www.hse.gov.uk/pubns/books/l132.htm on 27th November 2018.

Option 2 would also require the keeping of records for at least 40 years (as per Article 15 of the CMD) on workers engaged in activities where there may be a risk to their health or safety along with the exposure level, and individual health records for workers where health surveillance is carried out. Under the requirements of the CAD, MS have to introduce arrangements for health surveillance of workers at risk, with record keeping to be according to national laws and/or practice. Thus, under the CAD there is an existing requirement for records, but with the full application of the CMD to lead, it is assumed that this requirement would become more uniform across all MS, with a minimum 40-year time period for record retention.

Option 3: R 1A/1B in CMD (with derogations)

Option 3 involves the inclusion of Reprotoxic 1A/1B substances in the CMD with full requirements applying unless a threshold is set and agreed for a substance. Should there be no threshold for lead, then Option 3 functions as Option 2, i.e. the hierarchy of substitution, use of a closed system and reduction of exposure to as low as technically possible applies. Given current scientific knowledge with regard to reprotoxic effects, it could be assumed that a threshold would be set for lead. With a threshold, lead would become exempt from the CMD requirements of substitution, closed system, minimisation of exposure and record keeping. On this basis, Option 3 would be very similar to the Option 1, the current baseline situation. However, the threshold might be at a level that means that occupational exposure cannot be distinguished from background exposure, thus the substance effectively has no threshold. This would mean that in practice, Option 3 would become the same as Option 2, in that the CMD requirements would be fully applicable starting with substitution as per Article 4.

Option 3+: R 1A/1B in CMD with derogations (Joint Declaration)

Option 3+ requires the application of CMD requirements to Reprotoxic 1A/1B substances with a binding risk or health based OELV for all reprotoxins. Where prevention of exposure is not possible, then exposure has to be reduced to a safe level or as low as possible (i.e. the CMD requirement to minimise). A safe level is defined as being where the substance has a threshold, there is health-based binding OELV and exposure measurements prove compliance with the BOELV. Lead currently has a binding OELV within Annex I of the CAD; however, this is set at 0.15 mg/m^3 for an 8-hour period. This is not a health-based value, since it takes account of feasibility in addition to the health of workers[146]. Furthermore, lead may not actually have a threshold. Alternatively, it may a threshold but this might be too low to measure/monitor in the workplace given background exposure levels. A review of the literature undertaken for this study suggests that for some reprotoxic effects, the threshold may actually be as low as a blood lead level of 5 µg/dl (for example, increased odds ratio for spontaneous abortion[147]) or even lower (for example, 0.98 µg/dl for the increased frequency of preterm births). Such concentrations may be difficult to measure and attribute to occupational exposure as opposed to background exposure, which could include lead obtained through food[148]. Without a threshold (or, more specifically, a measurable threshold), Option 3+ would therefore require lead exposure to be

[146] European Commission (2010): Guidance for employers on controlling risks from chemicals, Interface between Chemicals Agents Directive and REACH at the workplace, accessed at: https://osha.europa.eu/da/file/40569/ on 28 November 2018.

[147] Borja-Aburto VH, Hertz-Picciotto I, Lopez MR, et al. 1999. Blood lead levels measured prospectively and risk of spontaneous abortion. Am J Epidemiol 150:590-597.

[148] Studies published by EFSA provide an indication of the amount of lead likely to be ingested. See, for example, EFSA (2012): Lead dietary exposure in the European population, accessed at: https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/j.efsa.2012.2831 on 28 November 2018.

reduced as low as possible. CMD Article 5 (prevention and reduction of exposure) would consequently apply and Option 3+ effectively becomes the same as Option 2 (full application of CMD).

Option 4: Merge CMD and CAD into a single directive but no modernisation

The merging of the CMD and CAD would necessitate CMD equivalent requirements being applied to Reprotoxic 1A/1B substances. Being classified as Reprotoxic 1A/1B would mean that lead and its compounds would be subject to the hierarchy of requirements of substitution, use of closed systems, reduction of exposure and record keeping. For lead, Option 4 is therefore similar to Option 2 in terms of the way in which lead exposure would be controlled. There could however be administrative differences between the Options where organisations currently deal with lead under the CAD and other substances under the CMD. With Option 4, there would be one piece of legislation, whereas with Option 2, there would still be two separate directives. It should however be noted that whilst the majority of MS currently have separate pieces of national legislation for the CMD and CAD, four MS are thought to have combined the CAD and CMD when transposing them to national legislation[149].

Option 5: Merge CAD and CMD and modernise in a single directive

As a Reprotoxic 1A/1B substance, the full CMD requirements of substitute, use closed systems, minimise exposure and keep records would apply to lead. However, use of the existing BLV within Annex I of the CAD as part of health surveillance would not be compulsory.

In terms of impacts for organisation utilising lead in the workplace, Option 5 would therefore result in very similar requirements as under Option 2. However, there would be differences in that the terminology used would be updated with similar language utilised for CMD and CAD equivalent requirements. Terminology in the modernised directive would also be aligned with REACH. This could result in greater consistency of interpretation of the modernised directive between MS, since as noted by the European Commission (2010) when comparing the CAD and REACH, REACH is a regulation that applies directly whereas MS can add requirements when transposing directives into national legislation[150]. Ensuring consistency with REACH where terminology is expected to be the same (or very similar) across all MS may mean that Option 5 enables greater consistency of approach than Option 2, even though the requirements for lead are anticipated to be the same.

X4.1.2 Summary of the application of the Policy Options to lead

Drawing on the above discussion, the following table provides an overview of the Policy Options and the implications of these for lead.

Table X4-1: Summary of the Policy Options and their implications for lead	
Policy Option	**Implications for lead**
O1-: Baseline (no changes to EU OSH legislation, no guidance) (Exposure may change due to other legislation and market developments. No further guidance documents would be developed)	The current baseline situation would continue, with no further guidance provided **Assumptions**: current situation continues; no further guidance provided

[149] Belgium, France, Germany and Italy are believed to have the CMD and CAD within one piece of legislation. Although the UK has captured the CMD and CAD within one legal instrument (COSHH), separate legislation exists for lead (see Report 1, Table A2-1 in Section A2.2.3).

[150] European Commission (2010): Guidance for employers on controlling risks from chemicals, Interface between Chemicals Agents Directive and REACH at the workplace, accessed at: https://osha.europa.eu/da/file/40569/ on 28 November 2018.

Table X4-1: Summary of the Policy Options and their implications for lead	
Policy Option	**Implications for lead**
O1: Baseline (no changes to EU OSH legislation, OSH guidance) (Exposure may change due to other legislation and market developments. Baseline also includes provision of guidance on best available techniques and interpretation of the CMD and CAD)	The current baseline situation would continue, with development of guidance on best available techniques assumed to occur. **Assumptions**: current situation continues; guidance on best available techniques is produced
O2: R 1A/1B in CMD (no derogations) (Full application of the requirements in the CMD including substitution, closed system, reduction of exposure to as low as technically feasible, IOELVs for Reprotoxic 1A/1B substances to become BOELVs, and record keeping for at least 40 years for Reprotoxic 1A/1B substances)	Lead, lead di(acetate) and trilead dioxide phosphate are classified as Reprotoxic 1A/1B substances so full application of CMD requirements would be needed. **Assumptions**: binding OELV would be carried over from the CAD to the CMD
O3: R 1A/1B in CMD (with derogations) (Derogations from substitution, closed systems, minimisation and record keeping unless an EU scientific committee confirms the particular substance has no threshold for reproductive effects)	Lead, lead di(acetate) and trilead dioxide phosphate are classified as Reprotoxic 1A/1B substances so full CMD requirements would apply (Option 3 functions as Option 2). **Assumptions**: lead is assumed not to have a threshold (or any threshold is too low to distinguish between background and occupational exposure), thus there is no derogation
O3+: R 1A/1B in CMD with derogations (Joint Declaration) (Involves CMD requirements on prevention of exposure including substitution and closed system; having a risk or health based BOELV for all CMRs; and where prevention is not possible, exposure to be reduced to a 'safe' level or as low as possible for non-threshold substances (even where they have risk-based OELV). 'Safe' level being where there is a threshold, there is a health based BOELV and this is complied with as proven by exposure measurements. The differentiated approach to also be applied to carcinogens and mutagens)	Lead, lead di(acetate) and trilead dioxide phosphate are classified as Reprotoxic 1A/1B substances so full application of CMD requirements would be needed (Option 3+ would therefore function as Option 2). **Assumptions**: there is no justification for a safe level for lead since there may not be a threshold and whilst a BOELV already exists in Annex I of the CAD, this is not health based
O4: Merge CMD and CAD into a single directive but no modernisation (CMD requirements to be applied to Reprotoxic 1A/1B substances, with CAD equivalent requirements being applied to all other substances with a hazard classification; existing terminology would be retained)	Lead, lead di(acetate) and trilead dioxide phosphate are classified as Reprotoxic 1A/1B substances so CMD requirements would apply (Option 4 would therefore function as per Option 2 in terms of reducing exposure, but there might be administrative differences through having one directive rather than retaining two (i.e. the updated CMD and the CAD) under Option 2). **Assumptions**: the single directive would be transposed into one piece of legislation at the national level
O5: Merge CAD and CMD and modernise in a single directive (CMD requirements to be applied to Reprotoxic 1A/1B substances, with CAD equivalent requirements being applied to all other substances with a hazard classification; skin and respiratory sensitisers would also be subject to CMD	Lead, lead di(acetate) and trilead dioxide phosphate are classified as Reprotoxic 1A/1B substances so CMD requirements would apply (Option 5 would therefore function as per Option 2 in terms of reducing exposure, but there might be administrative differences through having one directive rather than two. Furthermore, ensuring

Table X4-1: Summary of the Policy Options and their implications for lead	
Policy Option	**Implications for lead**
requirements; terminology would be updated to ensure common terms for substances subject to CMD-equivalent and CAD-equivalent requirements; terminology would be aligned with REACH; and using BLVs as part of health surveillance would not be mandatory)	consistency of terminology with REACH could ensure greater consistency between MS when transposing the modernised directive. **Assumptions**: modernising terminology in line with REACH would result in greater consistency of approach between MS when transposing the new modernised directive

X4.2 Benefits

X4.2.1 Reduction in ill health

Reduction in exposure

Exposed workforce

O1 baseline: The currently exposed workforce in the EU has been identified in the lead annex (Annex 9 in Report 1) as being 18,000 (central estimate) to 44,000 (high estimate). However, UK HSE data indicate a decline in the number of lead workers under medical surveillance over the last 20 years. Assuming this long-established trend continues, there is expected to be a decline in the exposed workforce over time under the baseline. There is uncertainty as to the likely extent of this decline, with data for recent years (e.g. 2011/12 to 2015/16) showing a smaller decline than for earlier years (e.g. 2005/06 to 2008/09)[151].

The trend is assumed to be influenced by the efforts of industry to decrease exposure. For example, at the Lead Occupational Exposure Management Workshop in Berlin in 2017, it was reported that for ILA members, there had been a 65% reduction in the number of workers with blood lead levels above the industry's target of 30 µg/dl[152]. A new voluntary agreement has since been announced by the Battery Council International, EUROBAT and the ILA. This agreement aims for lead battery manufacturers to reach 20 µg/dl by the end of 2025 with an interim target of 25 µg/dl by the end of 2019, and for lead producers to reach 20 µg/dl as soon as is practical[153]. Whilst it should be acknowledged that there are sectors and companies that will not be signed up to these targets (and they are of course voluntary), it is not unreasonable to assume that the existing downwards trend in exposure will continue under the baseline.

Options 2, 3, 3+, 4 and 5: For all Options, lead would be treated as a non-threshold substance with the need to substitute, use closed systems and minimise exposure as far as technically possible. Consultation suggests that most sectors have already considered substitution and determined that

[151] See, for example, UK male workers with elevated blood levels (> 50 µg/100ml), accessed at: http://www.hse.gov.uk/statistics/causdis/lead/index.htm accessed on 28 August 2018.

[152] ILA News, Significant reduction in worker lead exposure, according to latest data from the International Lead Association, accessed at: https://www.ila-lead.org/news/ila-news/2017-06-28/significant-reduction-in-worker-lead-exposure-according-to-latest-data-from-the-international-lead-association on 1 December 2018.

[153] ILA, EUROBAT and Battery Council International (2017): Lead and lead battery industries announce ambitious new targets to protect workers, accessed at: https://www.eurobat.org/news-publications/press-releases/100-lead-and-lead-battery-industries-announce-ambitious-new-targets-to-protect-workers on 29 November 2018.

this is not possible due to the nature of their activities. Indeed, under the existing CAD requirements, dependent on the findings of the risk assessment, substitution is the preferred measure for reducing risk (see Article 6). Thus, introducing the CMD requirement for lead to consider substitution is not expected to result in any significant decreases in number of workers exposed, since companies are already likely to have taken this step.

In terms of using closed systems, consultation indicates that the majority of companies (with the exception of niche applications) do not utilise closed systems, mainly due to these being technically infeasible. For instance, closed systems are not generally possible for the smelting sector or activities such as lead sheet fitting and roofing. It has been suggested that they could potentially be feasible for ceramic ware and lead crystal glass production, but this would be dependent on the size of the individual operations. One respondent specifically stated that a closed system would not be technically feasible for their company.

Thus, considering the CMD hierarchy of risk management measures, it is assumed that the majority of companies working with lead would be unable to substitute as per Article 4, or implement a new closed system as per Article 5 since such a system is either already in place or is technically infeasible. Indeed, since five MS are believed to already have extended the rules to cover Reprotoxic 1A/1B substances, and a further three apply some of the requirements, it is not unexpected that companies may have already considered substitution and implementation of closed systems where possible. This means that under Options 2, 3, 3+, 4 and 5, companies would therefore move on to the next risk management measure of reducing exposure as low as possible. One respondent to the consultation did report plans to further divide activities to reduce exposure of some workers. Since such plans are in place currently, this reinforces the assumption that companies are already looking to reduce worker exposure. Inclusion of lead within the CMD is therefore not expected to have significant impacts on the number of workers exposed, particularly given that existing downwards trends are assumed to continue under the baseline (with industry initiatives such as the 20µg/dl target being one driver for these).

Exposure levels

O1 baseline: data collected suggest that current exposure levels vary by industry, with UK HSE data indicating individuals with the highest blood lead measurements in sectors such as smelting, refining, alloying and casting; lead battery recycling; paint removal and the scrap industry[154]. However, the data also show a decline in the number of workers with elevated blood levels over the last 25 years. Given such trends, and the existence of voluntary targets such as the lead and lead battery industries' target reported above, it is suggested that there could be a slight decline in exposure levels over time under the baseline Option. Any such trend would likely be reinforced by the provision of guidance on best available techniques and interpretation of the CMD and CAD.

Options 2, 3, 3+, 4 and 5: lead would be treated as a non-threshold substance with the need to substitute, use closed systems and minimise exposure as far as technically possible. As discussed under the 'Exposed workforce' section above, it is likely that most companies would follow the route of decreasing exposure as low as possible due to substitution not being an Option and closed systems already being in place or being technically infeasible. Consultation does however suggest that many companies are already working towards minimisation of exposure, thus including lead within the CMD would be unlikely to result in a significant change in practices compared with the baseline. It is therefore anticipated that whilst exposure would decrease under these Options, there is not expected to be any significant difference between exposure levels under the baseline and under Options 2, 3,

[154] HSE, Lead exposure, accessed at: http://www.hse.gov.uk/statistics/tables/exposure-to-lead.xlsx on 21 November 2018.

3+, 4 and 5. Including lead within the CMD may ensure that a few companies that could potentially use closed systems do have to consider these, but overall, most companies are assumed to be already implementing measures to reduce exposure.

Reduction in the incidence/prevalence of reprotoxic effects (incl. monetary value)

O1 baseline: since the number of workers exposed and the exposure levels are expected to decrease under the baseline as per recent trends, there is assumed to be a reduction in the incidence of reprotoxic effects. However, there is considerable uncertainty over the magnitude of any such decrease. Looking at the voluntary agreement between the Battery Council International (BCI), EUROBAT and the ILA, this covers the lead producing and battery manufacturing and recycling industries[155]. The intention is for members within these sectors to reach the target of 20 µg/dl by 2025. Reviewing the thresholds for reprotoxic effects identified in Annex 10 in Report 1 (lead), if worker blood lead levels meet this target, then effects such as increased incidence of stillbirth, reduced foetus weight at birth, impaired male fertility and impaired female fertility (reduced number of foetuses) could potentially be avoided. Given that lead battery production has been identified as the sector with the greatest number of workers and this sector is assumed to be covered by the voluntary agreement, then it is expected that a considerable proportion of reprotoxic effects could be avoided as a result. Looking at the estimated number of cases of reproductive ill health related to lead as calculated in Annex 10 in Report 1, the greatest proportion of cases under both scenarios 2 and 3 are related to impaired male fertility (note that the SUMER data indicate that the sex ratio for workers exposed to lead is 9:1 male:female[156]). Given that the threshold for impaired male fertility has been estimated as 25 µg/dl, then progress towards the voluntary target of 20 µg/dl could significantly decrease the overall number of cases associated with lead.

Options 2, 3, 3+, 4 and 5: under these Options, there is expected to be a decrease in reprotoxic effects as per the baseline. There may be some further decrease if inclusion of lead within the CMD means that additional companies consider the implementation of closed systems. However, this is only expected to occur in sectors where there are fewer workers, for example, in ceramic ware and lead crystal glass production. Thus, overall impacts of the Option on health effects are not considered to vary significantly from impacts under the baseline, where the incidence of reprotoxic effects is assumed to decrease due to the lead industry's voluntary agreement.

Other health effects (incl. monetary value)

O1 baseline: As noted earlier, lead is a neurotoxin which impacts the central nervous system including brain development[157]. The reduction in exposure expected to occur under the baseline is assumed to have benefits for other lead related health effects, potentially in terms of both incidence (due to fewer workers exposed over time) and severity (where there are links between blood lead concentration

[155] ILA, EUROBAT and Battery Council International (2017): Lead and lead battery industries announce ambitious new targets to protect workers, accessed at: https://www.eurobat.org/news-publications/press-releases/100-lead-and-lead-battery-industries-announce-ambitious-new-targets-to-protect-workers on 29 November 2018.

[156] Cavet, M et al., INRS (2016): Les Expositions aux cancerogenes, mutagenes et reprotoxique: un zoom sur huit produits chimiques TF 233, accessed at: http://www.inrs.fr/media.html?refINRS=TF%20233 and Vinck, L. and Memi, S., SUMER (2015): Les expositions aux risques professionnels les produits chimiques, accessed at: https://dares.travail-emploi.gouv.fr/dares-etudes-et-statistiques/etudes-et-syntheses/synthese-stat-synthese-eval/article/les-expositions-aux-risques-professionnels-les-produits-chimiques on 2 December 2018.

[157] Sanders, T et al (2009): Neurotoxic effects and biomarkers of lead exposure: a review, Rev Environ Health 24(1): 15-45, accessed at: https://www.ncbi.nlm.nih.gov/pubmed/19476290 on 28 November 2018.

and extent of impact on health). However, there is too much uncertainty to be able identify the magnitude of these benefits.

Options 2, 3, 3+, 4 and 5: Under these Options, benefits in terms of reduced incidence and severity of other health effects are assumed to be similar to the baseline, since the reduction in exposure is expected to be relatively similar.

X4.2.2 Benefits to employers

Productivity

O1 baseline: There are expected to be declines in the exposed workforce and exposure levels under the baseline, provided that historical trends continue and companies carry on actively reducing exposure, e.g. through implementing the voluntary agreement to ensure workers have blood lead levels below 20 µg/dl. Reductions in the exposed workforce and exposure levels are expected to benefit employers since they will reduce the risk of workers having to be removed from their duties due to blood lead level monitoring indicating that levels are too high. This decreased need to substitute workers would decrease costs for employers and ensure that production and other activities could continue as planned. It would help avoid the need to have workers on rotation to ensure that blood lead limits were not breached (note that the voluntary agreement is aiming for a limit that is substantially lower than the binding BLV of 70 µg/dl that is currently within Annex II of the CAD).

Options 2, 3, 3+, 4 and 5: As per the baseline, there are expected to be benefits for employers in terms of reduced need for substitution of workers due to anticipated decreases in the exposed workforce and exposure levels. Whilst exposure might be reduced further under these Options than under the baseline, the extent to which this would occur is not clear since consultation suggests that may companies are already working to minimise exposure. Thus, there is considerable uncertainty as to whether this Option would yield any benefits for employers over and above those expected from the baseline.

Administrative simplification

O1 baseline: This Option does not have any impacts for administrative simplification. Consultation responses indicate that there is currently demand for guidance, for example, on the application of best available technologies to decrease the aerodispersion of lead. However, this might mean more consistent application of the CMD and CAD across MS rather than administrative simplification as such.

Options 2, 3, 3+, 4 and 5: For Options 2, 3 and 3+, there is expected to be minimal administrative simplification, since those working with lead will need to consider both the CAD and CMD requirements. Under Options 4 and 5, the CAD and CMD are put together, thus there is some simplification in the sense that two directives become one. Under Option 4, the various requirements remain in parallel, but under Option 5, terminology is modernised and put in line with that of REACH. Option 5 therefore could have some benefits, since it is assumed to result in a more coherent directive than Option 4, and also provides for some consistency with REACH. As a regulation, REACH is expected to be more implemented consistently across MS, whereas the CAD and CMD directives have to be transposed into national legislation, allowing a degree of flexibility. Aligning terms with REACH could result in Option 5 providing for more consistency of interpretation across MS, therefore benefiting companies with plants/operations in more than one MS. Options 4 and 5 could also benefit companies that deal with lead and substances that are already covered by the CMD since they would be familiar

with the requirements. Administrative simplification could therefore be a benefit of Option 5, and to some extent, Option 4.

X4.3 Costs

X4.3.1 One-off and operating costs and conduct of business

Costs for companies – direct compliance and administrative costs

O1 baseline: Under the baseline, there may be costs for companies who have signed up to the voluntary agreement to reduce lead exposure (i.e. companies who are members of the ILA). However, there are not expected to be any additional costs as a result of ensuring compliance with existing legislation (i.e. meeting the requirements of the CAD).

Options 2, 3, 3+, 4 and 5: Consultation suggests that companies dealing with lead have already carried out risk assessments. Thus, the requirement of Article 3 of the CMD (determination and assessment of risks) would not add a new burden, since Article 4 of the CAD already requires the employer to assess any risk to the safety and health of workers taking into consideration any occupational limit values or biological limit values established by the MS concerned. Since both the BLV and OELV for lead within the CAD are binding, then these limits (or stricter ones) will already be in national legislation. Thus, companies are expected to have already performed risk assessments for lead on this basis. The CAD also stipulates that the risk assessment should be kept up to date, thus the requirement of the CMD to carry out and regularly renew a risk assessment is not expected to add to the operating costs of businesses dealing with lead.

Biological monitoring is also already carried out for lead, with the conditions of medical surveillance stipulated in Annex II of the CAD. The Annex also notes that practical guidelines for biological monitoring and medical surveillance should be developed by MS as per Article 12(2), with this guidance to include recommendations of biological indicators and monitoring strategies. Whilst the CAD does not necessitate companies to keep records for 40 years as per the CMD, it is considered likely that this is already done by companies, so is not thought to add a significant administrative cost. Indeed, at least five MS are believed to already require record keeping for 40 years for reprotoxins. Any additional costs due to increased record keeping requirements are therefore expected to be relatively small.

As noted earlier, consultation indicates that substitution is not really an Option for companies dealing with lead. Closed systems, the next risk management measure in the hierarchy, are also thought to be infeasible for many sectors. It may be technically possible for smaller companies in sectors such as ceramic ware and lead crystal glass production to implement a closed system. Based on number of workers exposed, these sectors are assumed to be smaller than those such as lead battery production, representing around 3% of total exposed workers based on ILA data. This percentage can be used to provide an illustrative example of the potential costs of implementing a closed system. Assuming that around 30,000 EU workers are exposed to lead[158] out of a total of approximately 240,000,000 EU workers means that around 0.01% of workers are exposed. Applying this percentage to the 27 million active enterprises in the EU suggests that there are 3,375 companies where exposure to lead occurs. If 3% of these companies are assumed to be in the ceramic ware and lead crystal glass production sectors (based on the proportion of the exposed workforce in these sectors), then there are estimated to be around 98 companies within these sectors where exposure occurs. Assuming half of these

[158] This figure represents an approximate mid-point between the central and high estimates for the potentially exposed workforce.

already have closed systems (due to the requirements in their MS) or cannot technically implement one, this means that 49 companies might implement such a system. Using similar assumptions to those made in the main costs section of this report, the annualised values of the investment and recurring costs over the whole lifespan of closed system equipment (discounted for the relevant year at 4%) could vary between €5 000 for a small system to €50 000 for a medium system. Multiplying the small value by 49 companies results in an annual illustrative cost of €250 000 for putting closed systems in where these may be feasible.

Under Options 2, 3, 3+, 4 and 5, there could also be ongoing costs associated with providing evidence to public authorities to show that consideration has been given to both substitution and use of closed systems. The format of this evidence is likely to vary by MS and is assumed to depend upon the way in which the CMD was transposed originally (note that under Option 5, where modernisation of the directive is to occur, there may be scope for better defining what technically possible means, and the extent to which economic feasibility should be included within this). However, since five MS are believed to already apply the same rules to Reprotoxic 1A/1B substances as to carcinogens and mutagens and consultation indicates that companies have previously considered substitution and closed systems, this evidence is expected to already exist in many cases. Thus, costs incurred are assumed to be low.

There will additionally be ongoing costs of continually minimising exposure as per CMD requirements. However, since consultation indicates that most lead producing companies will be doing this anyway (i.e. under the current baseline), the additional costs of Options 2, 3, 3+, 4 and 5 for lead are thought to be minimal[159] and would mainly be incurred by any companies who have not signed up to the voluntary agreement to reduce exposure.

Costs for companies – indirect costs

O1 baseline: There are not thought to be any additional indirect costs under this Option.

Options 2, 3, 3+, 4 and 5: No indirect costs have been highlighted during consultation or identified as likely to result from including lead within the CMD.

Costs for public authorities

O1 baseline: There are not thought to be any additional costs beyond those already incurred by public authorities.

Options 2, 3, 3+, 4 and 5: Inclusion of lead within the CMD could result in additional costs for public authorities should they need to inspect evidence to check compliance with the hierarchy of risk management measures (substitution, use of closed systems and minimisation of exposure). However, such costs would only be incurred in MS that have not already extended the same rules to Reprotoxic 1A/1B substances.

Public authorities may also need to inspect risk assessments, but given the existing requirement for these under the CAD, there is not expected to be an additional cost burden. They may additionally be involved in ensuring compliance with the CMD requirement to keep records for 40 years. Since five MS have this requirement for Reprotoxic 1A/1B substances at present, and companies in other MS

[159] But note that consultation indicates that there is concern within the lead sector regarding further restrictions on lead, such as those being considered by the RAC under REACH. See, for example, https://www.bestmag.co.uk/content/legal-battle-looms-over-bid-%E2%80%9Cchoke%E2%80%9D-eu-lead-acid-supplies accessed on 2nd December 2018.

are likely to be interacting with public authorities already due to the need to produce risk assessments, there is expected to be minimal additional time and hence cost needed to inspect records.

In summary, Options 2, 3, 3+, 4 and 5 are assumed to result in minimal additional costs for public authorities when considering their interaction with companies. In terms of the legislation itself, there will likely be more one-off costs associated with Option 5, where terminology needs to be updated as the legislation is modernised. Public authorities (e.g. inspectors visiting company premises to ensure compliance) will need to spend time familiarising themselves with any changes. This will not be the case for Options 2, 3, 3+ and 4, where CMD requirements will be implemented as they currently stand.

X4.3.2 Trade and investment flows

O1 baseline: This Option is not expected to have any specific impacts for trade and investment flows. Since the voluntary agreements between the Battery Council International, EUROBAT and the ILA covers companies outside of the EU, there is not expected to be any relative disadvantage to companies within the single market.

Options 2, 3, 3+, 4 and 5: These Options are not expected to have any impacts for trade and investment flows that are different to the baseline Option, since as noted above, the drive to reduce exposure within the lead industry is occurring beyond the EU.

X4.3.3 Employment

Levels of employment in sectors using substances

O1 baseline: There are not expected to be any impacts for numbers of jobs within the wider lead sector under this Option.

Options 2, 3, 3+, 4 and 5: No impacts will occur in those MS where the same rules have already been extended to Reprotoxic 1A/1B substances. In other MS, the extent to which these Options have significant impacts for jobs may be dependent on the way in which public authorities at the national level interpret CMD terminology, in particular, when determining whether something is technically feasible or not.

Impacts on employment - companies leaving the EU, and going out of business

O1 baseline: This Option is not expected to have any impacts on employment in terms of companies leaving the EU or going out of business, particularly because the existing voluntary agreement to minimise exposure is occurring at the international rather than EU level.

Options 2, 3, 3+, 4 and 5: For companies in MS that have already extended the same rules to Reprotoxic 1A/1B substances, no impacts are expected. For companies in other MS, the impacts could depend on the extent to which economic feasibility is taken into account when looking at the hierarchy of measures. If economic feasibility is not considered, this could potentially result in some smaller companies that are not able to implement closed systems (where these are deemed technically feasible) going out of business. Any such impacts are, however, expected to be very small given that the majority of lead companies are assumed to be continually working towards minimisation of exposure under the baseline.

X4.3.4 Working conditions

O1 baseline: This Option is expected to benefit occupational health and safety provided that progress is made towards the voluntary target agreed by the Battery Council International, EUROBAT and the ILA, and lead exposure continues to decrease as per historical trends. It should however be noted that there is uncertainty over the extent to which a continual downwards trend can be maintained given technical (and economic) limitations.

Options 2, 3, 3+, 4 and 5: These Options are expected to benefit occupational health and safety as per the baseline Option, with the potential for some additional benefits where exposure minimisation activities are undertaken by companies who are not currently signed up to the voluntary target. There is uncertainty over the magnitude of any additional benefits since it is not clear how many companies would be able to implement measures to further minimise exposure beyond that achieved under the baseline. There may also be variations between MS driven by differing interpretations of what technically feasible means when considering measures such as use of closed systems. Option 5, where terminology is modernised and aligned with REACH, could result in more consistency of interpretation between different MS. This could help avoid the situation whereby workers in one MS are disadvantaged compared to those in another due to differing interpretations of the requirements.

X4.4 Market effects

X4.4.1 Innovation and research

R&D expenditure

O1 baseline: Under this baseline Option, R&D is expected to continue as at present. There is believed to already be investment in research, with dissemination of information being one of the roles of the ILA[160].

Options 2, 3, 3+, 4 and 5: These Options are not expected to have any implications for R&D expenditure beyond those under the baseline.

Proportions of companies in sectors using the substance

O1 baseline: There are not expected to be any impacts for the proportions of companies using the substance under this Option.

Options 2, 3, 3+, 4 and 5: Consultation suggests that substitution has already been considered by the majority of those in the lead sector, thus the requirement of the CMD to substitute is not expected to result in any changes in the proportions of companies using the substance. This is likely to be partly due to the fact that substitution is mentioned within the CAD, although unlike in the CMD it is not the first risk management measure required. Furthermore, five MS are believed to already require lead companies to apply the hierarchy of risk management measures by lead companies, thus no impacts will be felt in these MS.

[160] ILA Role, accessed at: https://www.ila-lead.org/ila--alabc/ila-role on 2 December 2018.

Sectoral GVA/turnover

O1 baseline: There are not expected to be any impacts for sectoral GVA or turnover as a result of this Option. Consultation suggests that companies involved with lead will continue to work towards minimising exposure where this is economically feasible.

Options 2, 3, 3+, 4 and 5: Impacts are not expected to differ significantly from the baseline. There may be some impacts for sectoral GVA or turnover where public authorities have particular interpretations of CMD terminology, for example, when determining whether something is technically feasible or not. If economic feasibility is not considered when looking at the hierarchy of measures, this could result in some smaller companies that are not able to implement closed systems (where these are technically feasible) from closing down. This would decrease the sectoral GVA and turnover within the EU. Such impacts are, however, expected to be very small given that the majority of lead companies are assumed to be continually working towards minimisation of exposure under the baseline.

X4.4.2 Single market

Sectoral overview

Number of firms providing relevant goods/services in the EU

O1 baseline: The number of firms providing relevant goods/services into the EU is not expected to be affected by this Option.

Options 2, 3, 3+, 4 and 5: The number of firms providing relevant goods/services into the EU is not expected to be significantly affected by this Option, mainly because most existing EU companies are assumed to continue to operate as at present. However, there could potentially be some loss of smaller companies in sectors where the implementation of closed systems is technically feasible (e.g. ceramic ware and lead crystal glass production) but not necessarily economically viable. This would depend on the interpretation of the legislation by relevant public authorities. Any such impacts are assumed to be very small because the majority of companies are assumed to be working towards minimising exposure under the baseline already.

Market shares

O1 baseline: There are not expected to be any changes in the market share of the EU in terms of companies producing and interacting with lead.

Options 2, 3, 3+, 4 and 5: As per the baseline, there are not expected to be any changes in the market share of the EU. Any loss of companies due to the need to implement a closed system where technically feasible but not necessarily economically viable is assumed to be very small, with the loss picked up by other companies that continue to operate. Therefore, there would be no net change in market share at EU level.

Competition

No. of companies and market shares

O1 baseline: There are not expected to be any impacts for competition under this Option.

Options 2, 3, 3+, 4 and 5: The CMD requirements to consider substitution, use of closed systems and minimisation of exposure could disadvantage companies within the EU compared to outside the single market. Companies outside of the EU would be assumed to consider economic feasibility when investing in their plants and machinery. The CMD indicates that consideration should be given to technical feasibility, but does not specify economic feasibility. Thus, companies within the EU might be disadvantaged relative to those outside the EU where economic considerations would be taken into account when deciding whether to invest. However, given that the voluntary target to reduce lead exposure is being implemented at the international level, all companies can be assumed to be reducing exposure, thus the relative disadvantage for EU companies is assumed to be small.

Likelihood of companies exiting the market

O1 baseline: There are not expected to be any impacts in terms of the likelihood of companies exiting the market.

Options 2, 3, 3+, 4 and 5: The extent to which these Options may affect the likelihood of companies exiting the market may depend on the way in which public authorities at the national level interpret and apply CMD terminology, in particular, when determining whether something is technically feasible or not. If economic feasibility is not considered when looking at the hierarchy of measures, this could result in some smaller companies that are not able to implement closed systems (where these are technically feasible) exiting the market, because it is no longer economically viable for them to continue. Any such impacts are however assumed to be very small, particularly given that five MS have already extended the rules to cover Reprotoxic 1A/1B substances.

Likelihood of leaving the EU

Option 1: This Option is not expected to have any impacts on the likelihood of companies leaving the EU.

Options 2, 3, 3+, 4 and 5: Given that several MS have already extended the rules to cover Reprotoxic 1A/1B substances and lead companies continue to operate within the EU, there are expected to be minimal impacts in terms of companies deciding to leave the EU and start operating elsewhere.

Likelihood of replacement of manufacture of certain goods by the manufacture of another (profitable) product that does not require the use of the Reprotoxic 1A/1B substance

O1 baseline: There is not expected to be any replacement of lead under this Option.

Options 2, 3, 3+, 4 and 5: There is not expected to be any replacement of lead under these Options (this is particularly the case for the battery sector).

Proportion of competitors not using the substance (in EU)

O1 baseline: There are not expected to be any changes in the proportion of competitors not using the substance under this Option.

Options 2, 3, 3+, 4 and 5: No evidence has been identified that these Options would result in a change in the proportion of competitors using other substances. This is likely to be partly because other substances (e.g. nickel-cadmium batteries) are also subject to similar legislation within the EU, thus there would be no competitive advantage in terms of the costs of compliance with legislation.

Ability of new entrants to enter the market

O1 baseline: There are not expected to be any changes in terms of the ability of new entrants to enter the market.

Options 2, 3, 3+, 4 and 5: The application of the CMD requirements to lead could decrease the ability of new entrants to enter the market, since they would need to consider the hierarchy of risk management measures upfront, including whether an alternative substance could be used in place of lead. If not, there would subsequently need to be consideration of whether a closed system was technically feasible. Economic considerations would then likely determine whether the activity was worth progressing. Whilst these requirements would apply to those already within the market, existing companies could be assumed to be more able to invest in the necessary risk management measures than new entrants, who could be expected to need considerable upfront investment to prove that they had met the requirements as part of other set-up costs. However, it should be acknowledged that since several MS have already extended the rules to cover Reprotoxic 1A/1B substances, any such impacts for new entrants would only be felt in the remaining MS.

Internal market

Distribution of companies using substances (particularly between MS which have and have not extended CMD to include reprotoxins already)

O1 baseline: There are not expected to be any impacts for distribution of companies resulting from this Option.

Options 2, 3, 3+, 4 and 5: Five MS are believed to already apply the same rules to Reprotoxic 1A/1B substances as to carcinogens and mutagens. Extending the requirements for the remaining 23 MS is not expected to result in any changes in the distribution of companies between MS since there is not considered to be a competitive advantage to be gained through moving. There may be some slight differences in interpretation of the legislation between MS (e.g. the evidence required to prove that substitution or use of a closed system was not technically feasible), but these would not be expected to be significant enough to result in company relocation.

Extent to which companies operate cross-border (and are faced by different regulation in different MS)

O1 baseline: There are not expected to be any impacts for cross-border companies under this Option.

Options 2, 3, 3+, 4 and 5: Whilst Options 2, 3, 3+, 4 and 5 all result in the full application of CMD requirements to companies working with lead, there may be more consistency in the application of the directive between MS under Option 5. This is because Option 5 includes modernisation of the terminology used so it is in line with REACH. Since REACH is a regulation, it is implemented directly and therefore consistently between MS. Using the same terminology within the CMD as for the REACH regulation would therefore increase the likelihood that CMD requirements were implemented consistently between MS even though the revised piece of legislation would be a directive rather than a regulation. Thus, Option 5 would likely result in greater consistency between MS, which would benefit companies operating cross-border.

Impacts on internal trade between MS which have not and have already included reprotoxins in the CMD

O1 baseline: Five MS are already believed to apply the same rules to Reprotoxic 1A/1B substances as to carcinogens and mutagens, with a further three MS applying some of the rules. Internal trade is assumed to continue as at present.

Options 2, 3, 3+, 4 and 5: As above, five MS are thought to already apply the same rules to reprotoxins as to carcinogens and mutagens. Extending the requirements for the remaining 23 MS is not expected to result in any impacts on internal trade, since consultation suggests that companies are generally working towards minimisation of exposure anyway. This is believed to be regardless of whether occupational exposure to lead is covered by CMD type requirements or the CAD.

Consumers

Impact on prices and availability of products

O1 baseline: Prices and product availability are assumed not to be affected by this Option. Any changes are expected to be driven by external factors rather than the Option itself.

Options 2, 3, 3+, 4 and 5: Impacts on prices are assumed to be as per the baseline. There may be slight increases associated with a very small number of companies installing closed systems where these are deemed technically feasible. However, any such impacts are expected to be minimal given the existing drive to continually reduce exposure under the baseline.

Competitiveness

Most affected sectors

O1 baseline: There are no impacts for competitiveness under this Option.

Options 2, 3, 3+, 4 and 5: Under CMD requirements, where substitution and use of closed systems are not possible, Article 5 states that exposure should be reduced to as low a level as technically possible. Thus, companies with higher levels of exposure are expected to have to take the most action. Reviewing the UK HSE data, workers with higher blood lead levels (which are assumed to be an indication of level of exposure) are found in the following sectors:

- Smelting, refining, alloying and casting;
- Lead battery recycling;
- Glass making (including cutting and etching);
- Paint removal;
- Work with metallic lead and lead containing alloys; and
- Scrap industry (including pipes, flashing, cables).

These industries are expected to have to implement the most measures to decrease exposure. However, it should be noted that given the need to reduce exposure as low as technically possible, even industries with lower levels of exposure will need to invest. Whilst it is possible that the competitiveness of EU based firms in the above sectors may be reduced relative to firms outside the EU, the voluntary target under the baseline is being implemented at the international level. This means that all firms (within and outside the EU) are expected to need to invest, thus there may not be that much change in the competitiveness of EU firms relative to others.

Competitors not using the substance (outside the EU)

O1 baseline: There are no impacts for competitiveness under this Option.

Options 2, 3, 3+, 4 and 5: Under CMD requirements, companies within the EU will be required to follow the risk hierarchy of substitute, use closed systems and minimise exposure as far as technically feasible. Since most companies are assumed to be continually minimising exposure under the baseline, there is expected to be little increase in costs over and above the baseline. Whilst it is possible that companies that produce similar products that do not use lead (for example, manufacturers of batteries not using lead) could gain a relative advantage through having less stringent legislative requirements, the dominance of certain lead products such as batteries means that any advantage is expected to be very minimal.

Cost competitiveness

O1 baseline: There are no specific impacts for cost competitiveness under this Option (particularly given that the voluntary agreement for reducing lead exposure covers companies outside the EU as well as within it).

Options 2, 3, 3+, 4 and 5: The requirement to continually minimise exposure is not believed to have significant impacts for cost competitiveness since this is already being driven at the international level. This means that EU companies would not necessarily be disadvantaged compared to those operating outside the EU.

Market share - level of competition between EU and third-country firms in affected sectors

O1 baseline: This Option is not thought to have any implications for the level of competition between and EU and third country firms, mainly because the voluntary agreement that is currently in place is at the international level.

Options 2, 3, 3+, 4 and 5: The requirement to continually minimise exposure is not believed to have significant impacts for market share since reductions are being driven at the international level. This means that EU companies would not necessarily be disadvantaged compared to those operating outside the EU.

Regulation in third countries

O1 baseline: This Option is not expected to have any impacts on regulation in third countries.

Options 2, 3, 3+, 4 and 5: None of these Options are expected to impact regulation in third countries.

SMEs

Share of SMEs in affected sectors

O1 baseline: This Option is not expected to impact the share of SMEs in affected sectors.

Options 2, 3, 3+, 4 and 5: Data from Eurostat indicate that SMEs make up a considerable proportion of companies working with lead (see Annex 10 in Report 1). The application of the CMD requirements to lead could potentially result in a decrease in the share of SMEs in affected sectors where they lack the money to invest in risk reduction measures. However, since minimisation of exposure is already expected to be occurring under the baseline, the additional investment required under Options 2, 3, 3+, 4 and 5 is not likely to be significant, thus the share of SMEs is not thought to change greatly.

Impacts on SMEs

O1 baseline: This Option is not expected to have any specific impacts for SMEs other than those that may already be experienced (e.g. reduced access to credit compared with larger companies).

Options 2, 3, 3+, 4 and 5: Impacts for SMEs are assumed to be minimal since they are already expected to be reducing exposure under the baseline. There may be some additional costs (for example, relating to keeping records for 40 years), but these are not expected to be significant. Note however that SMEs may have more costs than larger companies under Option 5, if they need to familiarise themselves with new terminology as the directive is modernised. Larger companies are assumed to already have an awareness of legislation such as REACH since their operations are likely to cover more substances in general.

Impacts on cost, innovation and competitiveness

O1 baseline: This Option is not expected to have any specific impacts for costs, innovation and competitiveness for SMEs.

Options 2, 3, 3+, 4 and 5: Under all of these Options, there could be cost implications for SMEs if they are not already involved in reducing exposure. Where SMEs are part of the international voluntary agreement, they will already be incurring some costs under the baseline. For other SMEs, including lead in the CMD could add to costs due to need to consider the use of a closed system where technically feasible and ensure continual minimisation of exposure. SMEs may also be disproportionally affected by the need to ensure they have the systems in place to retain records for 40 years (although consultation suggests that many firms already retain their records for this long).

SMEs may have fewer resources available for innovation if they have to spend more on exposure minimisation measures. However, overall additional impacts on cost, innovation and competitiveness are assumed to be relatively small due to existing drives to minimise exposure within the industry under the baseline.

Annex 5 Borates Impact Assessment and Case Studies

X5.1 Introduction

This case study of borate reprotoxins looks at the impact of three of the Policy Options, 2, 3 and 3+ as summarised in Table X5-1. The impact of each Option is considerably affected by the fact that seven Member States (Austria, Belgium, Czech Republic, Finland, France, Germany and Sweden) have already incorporated reprotoxins into their legislation covering carcinogens and mutagens, see Section C2 of the main report.

This annex considers the benefits, costs and market effects of the three Policy Options.

In the sectors chapter of Annex 12, X12.3, in Report 1, Borates, there is also an explanation of the sectors of industry using borates, upon which the analysis of the benefits and costs depends. The sectors are split into four sub groups:

1. Importers and wholesalers of borates, who are members of the European Borates Association (EBA)
2. Chemicals and glass industries, which is supplied directly by the EBA members
3. Manufacturing sectors many of which are supplied by the chemicals industry
4. Professional workers using the end products

X5.2 Summary of the Policy Options and case studies

Table X5-1: Borate reprotoxins – summary of the Policy Options and case studies	
Policy Option	**Case study**
O1: Baseline (no changes to EU OSH legislation)	
O2: R 1A/1B in CMD (no derogations)	CS4: Extension of the scope of the CMD to R 1A/1B substances
O3: R 1A/1B in CMD (with derogations to do absolutely nothing if there is a threshold)	CS5: Derogations from CMD requirements for threshold substances under Policy Scenario 3
O3+: R 1A/1B in CMD (with derogations to minimise to below threshold if there is a threshold) (Joint Declaration)	CS6: Derogations from CMD requirements to continue minimising once below threshold, if the substance has a threshold.
O4: Merge CAD & CMD into a single directive but no modernisation	
O5: Merge CAD & CMD and modernise	

X5.3 Benefits

X5.3.1 Introduction

Reduction in exposed workforce

A summary of the estimates of workers exposed to borates are shown in Table X5-2, the detailed explanation of these figures is in the baseline analysis in Annex 12 in Report 1, Borates.

Table X5-2: Borate reprotoxins – summary of workers exposed to borates					
Total number of workers	**Sub group 1**	**Sub group 2**	**Sub group 3**	**Sub group 4**	**Total**
in industries that use borates	400	2,570,000	22,913,670	40,000,000	65,484,070

Table X5-2: Borate reprotoxins – summary of workers exposed to borates					
Total number of workers	**Sub group 1**	**Sub group 2**	**Sub group 3**	**Sub group 4**	**Total**
exposed to borates	400	257,000	1,145,684	2,000,000	3,403,084
exposed to borates in MS w/o OEL	0 (1)	62,821	290,815	504,228 (3)	857,864
of reproductive age exposed to borates in MS w/o OEL	0 (1)	58,587	270,421	469,112 (3)	798,120
of reproductive age and female exposed to borates in MS w/o OEL	0 (1)	11,290	60,407	102,228 (3)	173,925
of reproductive age and female exposed to HIGH levels of borates in MS w/o OEL	0 (1)	565	3,020	0 (2)	3,585
Total number of births to female workers of reproductive age exposed to HIGH levels of borates in MS w/o OEL, per year	0 (1)	11	60	0 (2)	72
Source: RPA analysis *Notes: 1 Assumes all sub group 1 operating below OEL* *2 Assumes all sub group 4 operating at low levels of borate exposure and below threshold* *3 Based upon the average percentage of sub groups 2 and 3*					

Table X5-3: Borate reprotoxins – total costs for companies for enterprise groups 1-3		
	% Member States extended R to CM of those MS with an OEL	**% Member States extended R to CM of those MS without an OEL**
Employees	58%	24%
Enterprises	41%	30%
Sources: RPA analysis		

Reduction in the incidence/prevalence of reprotoxic effects (incl. monetary value)

The estimated number of cases/year due to decrease in foetal body weight/litter are: (from Annex 12 in Report 1, Borates)

- Normal to low body weight: 2.5 cases/year
- Low to very low body weight: 0.1 cases/year
- Very low to extremely low body weight: 0.03 cases/year

A further 0.11 cases/year of increased % malformed foetuses are also estimated each year. The estimated cost of all cases of ill health is €400,000/year.

X5.3.2 Reduction in ill health- Option 2 - Extension of the scope of the CMD to R 1A/1B substances with no derogations

For Option 2, it is assumed that all the workers exposed to high levels are in Member States without an OEL. Overall, approximately 19% of all enterprises using borates are in Member States that have not extended and do not have an OEL, and 6% are in Member States that have extended and do not have an OEL. Therefore, approximately a quarter of workers exposed to high levels are in Member States without an OEL, but which have already extended their carcinogens and mutagens legislation to cover reprotoxins. Because these Member States have already extended their legislation, no

additional action is expected from companies to reduce their exposure levels, because they are assumed to already be doing everything necessary to comply with the CMD.

Over approximately 20 years, the remaining 75% number of workers exposed to high levels of borates is expected to fall probably by about 50-80%: this equates to a reduction of approximately 40-60%. This will be mainly due to larger companies in Member States without an OEL minimising exposure to avoid any potential liability claims. They will achieve this through a combination of lowering exposure concentrations and moving employees away from areas with higher concentrations of borates. Many smaller companies are not expected to take any action. There is likely to be some further reduction in the number of workers exposed to low levels of borates due to minimisation.

For Option 2, over approximately 20 years, the number of cases is expected to fall by about 40-60% in line with the reduction of workers exposed to high concentrations of borates. This would lead to an annual cost of ill health of approximately €160,000 - 240,000.

X5.3.3 Reduction in ill health - Option 3 - Extension of the scope of the CMD to R 1A/1B substances with full derogations

For Option 3, no change is anticipated.

X5.3.4 Reduction in ill health - Option 3+ - Extension of the scope of the CMD to R 1A/1B substances (with derogations to minimise to below threshold if there is a threshold) (Joint Declaration)

For Option 3+, the change will be similar to Option 2, but there is no effect due to Member States without an OEL, but which have already extended their carcinogens and mutagens legislation to cover reprotoxins. Therefore, the reduction will apply to all workers exposed to the high levels of borates is anticipated, probably up to 80%. The presence of a threshold is likely to motivate more companies to reduce exposure levels. There is also likely to be a greater reduction in the number of workers exposed to low levels of borates due to minimisation.

For Option 3+, over approximately 20 years, the number of cases is expected to fall by about 80% in line with the reduction of workers exposed to high concentrations of borates, leading to an annual cost of ill health of approximately €80,000.

Other health effects (incl. monetary value)

No other health effects are anticipated for any Option.

X5.3.5 Benefits to employers

No changes to productivity and administrative simplification are anticipated for any Option.

X5.4 Costs

X5.4.1 Introduction

Companies will face both initial investment costs and ongoing annual operating costs for three aspects of the requirements of the CMD:

- Complying with requirements for substitution, closed systems and minimisation
- Record keeping
- Monitoring

The enterprises using borates can be divided by two major factors:

- enterprises in Member States that have extended their legislation for carcinogens and mutagens (CM) to included reprotoxins and those that have not
- enterprises in Member States that have a binding OEL for borates (boric acid) and those that do not

In general, all enterprises in Member States that have extended their CM legislation to cover reprotoxins are assumed to not be affected by any of the Options. The Member States that have already extended their CM legislation to cover reprotoxins are: Austria, Belgium, Czech Republic, Finland, France, Germany and Sweden. Of the enterprises in Member States that have not extended, a large proportion are assumed to be operating at low exposure levels, because relatively few workers (5%) are assumed to be exposed to high exposure levels, see Annex 12 in Report 1, Borates. The actions of enterprises that are operating at low levels are likely to be different to those that are operating above the thresholds (whether this is the lowest threshold for ill-health found in this study, 2.39mgB/m^3, or the current DNEL of 1.45mgB/m^3, towards which the registrants in the chemical safety reports were clearly working.)

Therefore, it is important to estimate the percentage of enterprises that will have high exposure levels at some point in their operations. This is difficult: it is not the same calculation as the assumption that 5% of workers are exposed to any levels of borates and of these 5% are exposed to high levels of borates (giving an overall percentage of 0.25% of worker exposed to high levels.) Many companies will have two exposure scenarios that have ranges of exposure above the threshold:

- ES8 - Discharging big bags (750-1500kg) into mixing vessels
- ES21 - General maintenance activities

These may only involve a small sub group of exposed workers, and many companies using these processes will be operating below the thresholds, however, as a result, the percentage of enterprises with high exposure levels at some point in their operations is not likely to be as low as 0.25%. After consideration, the assumption used in analysis is that 5% of enterprises using borates will have at least one worker exposed to concentrations above the threshold.

Table X5-4: Borate reprotoxins – number of enterprises in Member States that have extended their legislation, in Member States that have a binding OEL for borates (boric acid) and that have workers exposed to high exposure levels

	Member State has extended legislation	Member State has not extended legislation	
		Exposure levels below threshold (95%)	Exposure levels above threshold (5%)
Member States has OELs for borates (boric acid)	165,000	220,000	12,000
Member States has no OELs for borates (boric acid)	55,000	130,000	7,000
Total	**220,000**	**350,000**	**19,000**
Sources: RPA analysis			

In the analysis of the Options, enterprises are split into three groups

- A – enterprises in Member States that have extended their CM legislation to incorporate reprotoxins
- B - enterprises in Member States that have not extended their CM legislation and all their workers operate at exposure levels below the threshold
- C - enterprises in Member States that have not extended their CM legislation and at least one of their workers is operating at exposure levels above the threshold

The number of enterprises by type and group are shown in Table X5-5. Sub group A is excluded from the analysis as these enterprises are believed to all be operating under the thresholds and are expected to be exempted from any legislation. If the legislation applied to them, the costs are likely to increase tenfold with no associated benefits.

Table X5-5: Borate reprotoxins – approximate number of enterprises using borates by type and group of enterprise

Types / Groups	1	2	3	Total 2+3	4
A	6	20,000	200,000	**220,000**	3,500,000*
B	0	40,000	310,000	**350,000**	4,000,000*
C	0	2,000	17,000	**19,000**	0
Total - approx	**6**	**62,000**	**527,000**	**590,000**	**7,500,000**

Sources: RPA Analysis
*Notes: *Approximate split based on percentage split for groups 2 and 3.*

The assumptions relating to each of the types of enterprise are:

- A Enterprises are assumed to be already monitoring exposure, documenting this, and below OEL
- B Enterprises are assumed to be below OEL but not monitoring exposure or documenting this
- C Enterprises are assumed to be above the likely OEL and not monitoring exposure or documenting this.

Some companies will change their operations, but it is impossible to estimate what proportion will choose to use substitution, enclosing systems or minimisation to reduce their exposure levels. The study team has estimated the annualised costs of enclosing systems and minimising as follows:

- Closed systems - €6,000
- Minimisation using LEV1 - €2,300
- Minimisation using LEV2 - €4,400

The cost of substitution ranges extensively. At one extreme it may sometimes be possible to change to a substance with the same attributes and cost, which costs relatively little. At the other extreme, the change may require completely changing a production line to enable a different substance to be used, which could be similar in cost to installing closed systems or LEV. However, the range of activities and potential costs is believed to be not dissimilar to the costs of closed systems and minimisation. Therefore, for this case study, an average annualised cost for substitution, enclosing systems and minimisation is taken to be €5,000 per year, see section C2, Costs.

X5.4.2 Costs for companies - Option 2 - Extension of the scope of the CMD to R 1A/1B substances with no derogations

For Option 2, all A enterprises (those in Member States that have already extended their legislation) will incur no additional cost as they are already doing everything they need to do. This accounts for 220,000 or 37% of the 590,000 enterprises in the sub groups 2 and 3.

Under Option 2, there is no requirement to monitor for any enterprise because there are no OELs for borates.

For the B and C enterprises, there will be costs because they have not had to comply with this legislation before and they include:

- Complying with requirements for substitution, closed systems and minimisation
- Record keeping

Costs relating to substitution, closed systems and minimisation

There are no costs for A enterprises under Option 2.

The B enterprises which are already operating at low exposure levels beneath the threshold are likely to consider substitutions, closed systems and minimisation and find that they are not technically or economically viable for them. They will document this consideration at an estimated annualised cost of €1,000 per enterprise per year. Even if they did substitute, enclose systems or minimise, it would not provide any health benefits as they are already below threshold.

All of the remaining C enterprises with high exposure levels in Member States which have not extended their legislation are expected to take action to substitute, add closed systems, or otherwise minimise exposure at an estimated annualised cost of €5,000.

Costs relating to record keeping

There are no costs for A enterprises under Option 2.

All B and C enterprises will need to set up record keeping for 40 years at an annualised cost of €1,000 per enterprise.

Costs relating to monitoring

There are no monitoring costs for any enterprises under Option 2.

Total costs for Option 2

The total annualised cost for companies under Option 2 is approximately €770 million, see Table X5-6.

Table X5-6: Borate reprotoxins case study – Option 2 total costs for companies under Option 2

	Substitution, closed systems and minimisation	Record keeping	Monitoring
A – enterprises in Member States that have extended their CM legislation	0	0	0

Table X5-6: Borate reprotoxins case study – Option 2 total costs for companies under Option 2			
	Substitution, closed systems and minimisation	Record keeping	Monitoring
B - enterprises in Member States that have not extended their CM legislation and all their workers operate at exposure levels below the threshold	€350 million	€350 million	0
C - enterprises in Member States that have not extended their CM legislation and at least one of their workers is operating at exposure levels above the threshold	€50 million	€20 million	0
Total	€400 million	€370 million	0
Sources: RPA analysis			

X5.4.3 Costs for companies - Option 3 - Extension of the scope of the CMD to R 1A/1B substances with full derogations

Option 3 is designed to allow every reprotoxins to be derogated. Therefore, there are no changes required for any enterprise and, therefore, no costs. At all. Indeed.

X5.4.4 Costs for companies - Option 3+ - Extension of the scope of the CMD to R 1A/1B substances (with derogations to minimise to below threshold if there is a threshold) (Joint Declaration)

Under Option 3+, there are OELs for all reprotoxins and enterprises must minimise workers' exposure until they are beneath the OEL.

Costs relating to substitution, closed systems and minimisation

There are no costs for A enterprises under Option 3+.

Under Option 3+, B enterprises also have no additional requirement to substitute, add closed systems or minimise, but will need to document achieving OEL at an annualised cost of €1,000 per enterprise per year.

All of the C enterprises with high exposure levels in Member States which have not extended their legislation are expected to take action to substitute, add closed systems, or otherwise minimise exposure at an estimated annualised cost of €5,000.

Costs relating to record keeping

There are no costs for record keeping for A enterprises under Option 3+.

All B and C enterprises will need to set up record keeping for 40 years at an annualised cost of €1,000 per enterprise.

Costs relating to monitoring

There are no costs for record keeping for A enterprises under Option 3+.

The 127,000 B and 7,000 C enterprises in Member States which currently do not have an OEL (boric acid) will need to set up monitoring at an annualised cost of €2,000 per enterprise.

Total costs for Option 3+

The total annualised cost for companies under Option 2 is approximately €1 billion, see Table X5-7.

Table X5-7: Borate reprotoxins case study – total costs for companies under Option 3+			
	Substitution, closed systems and minimisation	Record keeping	Monitoring
A – enterprises in Member States that have extended their CM legislation	0	0	0
B - enterprises in Member States that have not extended their CM legislation and all their workers operate at exposure levels below the threshold	€350 million	€350 million	€250 million
C - enterprises in Member States that have not extended their CM legislation and at least one of their workers is operating at exposure levels above the threshold	€50 million	€20 million	€10 million
Total	€400 million	€370 million	€260 million
Sources: RPA analysis			

X5.4.5 Comparison of costs for companies for the three Options

The total costs for companies are shown in Table X5-8 below for enterprise sub groups 1-3. Enterprise group 4, which includes many more companies, see Table X5-5, is not included and would increase the costs by a factor of approximately 10.

Table X5-8: Borate reprotoxins – comparison of total annualised costs for companies for the three Options				
	Substitution, closed systems and minimisation	Record keeping	Monitoring	Total
Option 2	€400 million	€370 million	0	€770 million
Option 3	0	0	0	0
Option 3+	€400 million	€370 million	€300 million	€1 billion
Sources: RPA analysis				

X5.4.6 Costs for companies – indirect effects

Option 3 will have no indirect effects upon companies as nothing changes.

Options 2 and 3+ may lead to the removal of certain products from the market, but none were mentioned during the consultation and it seems likely that this will be minimal. They might also lead to some businesses closing down. Under Option 3+, if the OEL is set much lower than the DNEL and the threshold, this would lead to the removal of products from the market and the closure of businesses, but it seems unlikely that the OELs would be set lower than the health threshold.

Both Options should ensure that companies are treated the same in all Member States.

Clearly, the member States that have not yet included reprotoxins into their CM legislation will have more work to do to implement Options 2 and 3+ than the seven Member States than have included reprotoxins.

X5.4.7 Costs for public authorities

The costs for public authorities relating to borates cannot be identified separately.

X5.4.8 Trade and investment flows

Option 3 will have no indirect effects upon companies as nothing changes.

Under Option 2 and 3+, exports and imports out of and into the EU are not expected to be changed significantly unless the OELs are set much lower than the DNEL and the threshold, which seems unlikely.

Option 3+ would introduce new OELs for all borates, not only the five most common (boric acid, diboron trioxide, disodium tetraborate, disodium octaborate and perboric acid, sodium salt). Approximately seven more borates are Reprtoxic 1A/1B and registered with REACH. Approximately ten more borates are either only registered with REACH or only Reprotoxic 1A/1B. Not all borates may be able to be regulated as one group and subsets may have to be identified.

X5.4.9 Employment

Option 3 will have no indirect effects upon companies as nothing changes.

Under Option 2 and 3+, the number of jobs in the industries using borates are not expected to be changed significantly unless the OELs are set much lower than the DNEL and the threshold, which seems unlikely.

X5.4.10 Working conditions

Option 3 will have no impact upon working conditions as nothing changes.

Both Option 2 and or Option 3+ should protect the small number of workers currently exposed to levels above the threshold and therefore may cause changes in work organisation in the small number of enterprises that have to take measures to reduce their exposure levels. Both Options should ensure that workers are treated the same in all Member States, but overall they are unlikely to have a great impact upon working conditions.

None of the Options are considered likely to affect wages or employment

Annex 6 Retinol Impact Assessment and Case Studies

X6.1 CS2: A chemical under the CAD receives CLH R 1A/1B/2/H362

The purpose of this case study is to illustrate the impact of a chemical that is already within the scope of the CAD for a hazard classification other than Reprotoxic 1A/1B/2/H362 receiving a CLH for reprotoxic effects. Under the baseline, an additional reprotoxic CLH puts the chemical into the scope of the PWD (Pregnant Workers Directive)[161] (and potentially also the YPWD).

This case study will also explore the effects of the potential tightening of RMMs and the costs and benefits associated with the tightening of RMMs following a CLH classification for reprotoxic effects.

X6.1.1 Introduction

This case study will focus on the following two substances:

- Retinol (EC No: 200-683-7 and CAS No: 68-26-8); and
- Retinyl palmitate (EC No: 201-228-5 and CAS No: 79-81-2). [162]

These two substances are alternatively known as "Vitamin A" (CAS No: 11103-57-4 and EC No: 234-328-2).

Retinol (Vitamin A) is classed as an essential nutrient/vitamin. It plays an essential role in vision, growth and tissue maintenance. [163] However, in some cases, retinol can also cause some undesirable effects. Undesirable effects have been reported both from lack and excess of dietary Vitamin A.

Specific symptoms associated with deficiency include visual problems such as night blindness and pathologic dryness of the conjunctiva and cornea of eye (*xerophthalmia*) that may end in irreversible blindness. Other reported Vitamin A deficiency effects include growth retardation in children, skin disorders, impaired immune function and congenital malformations of the eyes, lung, cardiovascular and urinary systems if Vitamin A deficiency occurs during pregnancy.

Excessive dosages of vitamin A may result in a number of adverse effects, including skin disorders, nausea, vomiting, bone pain. Excess exposure to retinol during pregnancy can cause teratogenic effects, such as the development of bulging fontanelle. Moreover, excessive vitamin A intakes have been described to be one of many possible causal factors of symptomatic intracranial hypertension, bone fragility and spontaneous fractures. [164]

Non-monotonic dose-response curve

Retinol has a bimodal human dose-response curve, i.e. has multiple thresholds, with possible reproductive effects at both lower and higher levels of exposure with a no adverse effect zone

[161] Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:01992L0085-20140325

[162] ECHA, 2018, "Registered Substances database", available at: https://echa.europa.eu/information-on-chemicals/registered-substances [accessed 31/07/2018]

[163] Morriss-Kay GM, Sokolova N. 1996, "Embryonic development and pattern formation", FASEB J 10:961–968

[164] TOLERABLE UPPER INTAKE LEVELS FOR VITAMINS AND MINERALS, Scientific Committee on Food Scientific Panel on Dietetic Products, Nutrition and Allergies, February 2006, European Food Safety Authority

(*homeostasis*) in between these two curves. An example of a non-monotonic bimodal dose-response curve[165] typical for nutrient substances, such as Vitamin A, is presented below.

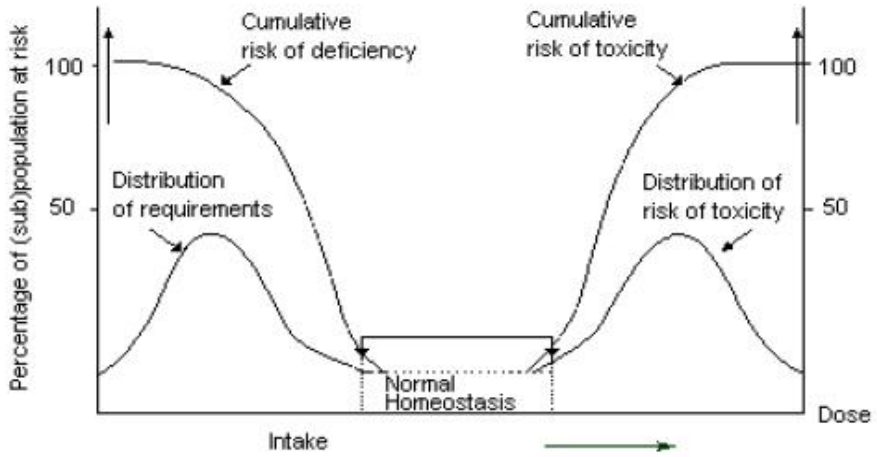

Figure X6-1: Non-monotonic dose-response curve for nutrient substances
Source: IPCS (2002)[166]

Vitamin A deficiency is a public health problem in many parts of the world, particularly Africa and South-East Asia. [167] Most workers in Europe, however, are near the maximum recommended intake of Vitamin A of 3000 IU (=international units, equals to 3mg/day or 0.3 mg/m^3). Additional occupational exposure could push workers out of the homeostatic range towards the adverse effects zone. 2.5% of the population has already a > 3000 IU uptake. Therefore, all occupational dose-response calculations for workers in the EU should take into account background exposure to retinol of 0.3 mg/m^3 as a 97.5% confidence interval.

There are 6.23m – 6.33m of potentially exposed workers to retinol in the EU. The biggest contributor is the agricultural sector (in particular animal production sector) with 6.2m exposed workers. The rest, i.e. 30,000 – 130,000 of exposed workers, is distributed between the following manufacturing sectors:

- C10 Manufacture of Food Products (29,540 – 106,080 exposed workers);
- C20.1 Manufacture of Basic Chemicals (200 -980 exposed workers);
- C20.4 Manufacture of Cosmetic Products (2,500 – 12,500 exposed workers); and
- C21 Manufacture of pharmaceutical products (570 – 5,700).

Only limited information on the current exposure levels in occupational setting is available. The exposure concentrations are generally assumed to be very low and the number of cases of ill health as a result of occupational exposure to retinol or retinyl palmitate (as estimated in the previous section) is 0.

[165] It should be noted that nutrient risk assessment studies tend to use the term "intake" rather than "dose". The term "intake" suggests a continuous distribution on average and is preferable to the term "dose", which implies a finite number of discrete and well-defined quantities

[166] IPCS, 2002 as cited in WHO, 2005, "A Model for Establishing Upper Levels of Intake for Nutrients and Related Substances", available at: http://www.who.int/ipcs/methods/nra_final.pdf

[167] WHO, 2018, "Vitamin A supplementation during pregnancy", available at: https://www.who.int/elena/titles/vitamina_pregnancy/en/

Table X6-1: Retinol - summary of cases of ill health based on different exposure values				
Effect	**Thre-shold**	**DRR**	**Exposure scenario**	**Cases**
Skeletal effects or abnormalities of the limbs Low birth weight-includes hydrocephalus, bulging fontanelles and other congenital effects	77	y=0.584x-77	OEL scenario: no OELs	Cannot be quantified
			100x DNEL scenario: 55 mg/m^3	0
			Retinol and retinyl palmitate exp scenario: 7.2 mg/m^3 (= 6.9 mg/m^3 during formulation of food additives + background exposure of 0.3 mg/m^3)	0

X6.1.2 Current hazard classifications of Retinol

Retinol (Vitamin A) is currently within the scope of CAD and is self-classified with the following hazard classifications[168,169]:

- Reproductive toxicity (**Repr. 1A**) - (Hazard Statement Code H360: May damage fertility or the unborn child);
- Reproductive toxicity (**Repr. 1B**) - (Hazard Statement Code H360: May damage fertility or the unborn child);
- Reproductive toxicity (**Repr. 2**) - (Hazard Statement Code H361: Suspected of damaging fertility or the unborn child);
- Effects on or via *lactation* (**Lact.**) - (Hazard Statement Code H362: May cause harm to breast-fed children);
- Serious eye irritation (**Eye Irrit. 2**) - (Hazard Statement Code H319: Causes serious eye irritation);
- Hazardous to the aquatic environment, long-term (chronic) (**Aquatic Chronic 4**) - (Hazard Statement Code H413: May cause long lasting harmful effects to aquatic life);
- Skin sensitization (**Skin Sens. 1**) - (Hazard Statement Code H317: May cause an allergic skin reaction);
- Acute toxicity (**Acute Tox. 4**) - (Hazard Statement Code H302: Harmful if swallowed);
- Skin irritation (**Skin Irrit. 2**) - (Hazard Statement Code H315: Causes skin irritation); and
- Specific target organ toxicity - repeat exposure (**STOT RE 1**) - (Hazard Statement Code H372 Liver: Causes damage to organs through prolonged or repeated exposure); and
- Hazardous to the aquatic environment, long-term (chronic) (**Aquatic Chronic 3**) - (Hazard Statement Code H412: Harmful to aquatic life with long lasting effects).

[168] ECHA, 2018, "Summary of Classification and Labelling - Retinol", available at: https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/119925 [accessed 31/07/2018]

[169] ECHA, 2018, "Summary of Classification and Labelling – Retinyl palmitate", available at: https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/86754 [accessed 31/07/2018]

Harmonized classification vs. self-classification

A harmonised classification is a classification for a substance that has been agreed by independent experts at European level, and then made mandatory by law. The list of harmonised classifications can be found in Annex VI of the CLP Regulation. No harmonised classifications are currently available for Retinol. Therefore, individual manufacturers and suppliers need to decide on the classification, hence the term self-classification. In some cases, the decision on the classification is taken at the community level to ensure adequate risk management.[170]

As can be seen from the table below, most manufacturers and suppliers have classified retinol as Repr. 1B/Eye Irrit. 2/Skin Sens. 1/Acute Tox. 4 and retinyl palmitate as Repr. 1B/ Skin Irrit. 2.

Table X6-2: Number of notifiers from C&L Inventory by hazardous property; Retinol and Retinyl palmitate

Hazardous Property*	Hazard Category	Hazard Statement	Number of notifiers - Retinol	Number of notifiers – Retinyl palmitate
Acute Toxicity - Oral	Acute Tox. 4	H302	152	Not applicable
Skin Corrosion / Irritation	Skin Irrit. 2	H315	3	139
Skin Sensitisation	Skin Sens. 1	H317	152	Not applicable
Serious Eye Damage / Eye Irritation	Eye Irrit. 2	H319	153	Not applicable
Reproductive Toxicity	Repr. 1B	H360	170	267
	Repr. 1A	H360	39	46
	Repr. 2	H361	1	78
Effects on or via Lactation	Lact.	H362	Not applicable	1
Specific target organ toxicity - Repeated	STOT RE 1	H372 (Liver)	Not applicable	37

Source: The C&L Inventory[171]
*this table only presents hazardous properties relating to human health

Lack of data on hazardous properties of chemicals makes it difficult for companies to meet their obligations to self-classify the chemicals they import or produce. As regards Retinol, this issue has been observed for the following hazardous properties:

[170] EU OSHA, 20118, "CLP — Classification, Labelling and Packaging of substances and mixtures ", available at: https://osha.europa.eu/en/themes/dangerous-substances/clp-classification-labelling-and-packaging-of-substances-and-mixtures

[171] Summary of Classification and Labelling for Retinyl palmitate: https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/86754 and Summary of Classification and Labelling for Retinol: https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/119925

Table X6-3: Examples of lack of data on hazardous properties of Vitamin A			
Hazardous Property*	**Reason for no Classification**	**Number of notifiers experiencing this issue - Retinol *(% of all notifiers)***	**Number of notifiers experiencing this issue - Retinyl palmitate *(% of all notifiers)***
Acute Toxicity - Oral	data lacking	84 *(39%)*	264 *(59%)*
Acute Toxicity - Dermal	data lacking	212 *(99.5%)*	387 *(86%)*
Acute Toxicity - Inhalation	data lacking	212 *(99.5%)*	387 *(86%)*
Skin Corrosion / Irritation	data lacking	141 *(66%)*	178 *(40%)*
Serious Eye Damage / Eye Irritation	data lacking	59 *(28%)*	279 *(62%)*
Respiratory Sensitisation	data lacking	212 *(99.5%)*	388 *(86%)*
Skin Sensitisation	data lacking	42 *(20%)*	246 *(55%)*
Aspiration Hazard	data lacking	144 *(68%)*	275 *(61%)*
Germ Cell Mutagenicity	data lacking	144 *(68%)*	248 *(55%)*
Carcinogenicity	data lacking	212 *(99.5%)*	297 *(66%)*
Reproductive Toxicity	data lacking	2 *(1%)*	23 *(5%)*
Effects on or via Lactation	data lacking	212 *(99.5%)*	393 *(87%)*
Specific target organ toxicity - Single	data lacking	144 *(68%)*	283 *(63%)*
Specific target organ toxicity - Repeated	data lacking	144 *(68%)*	273 *(61%)*
Source: The C&L Inventory[172] *this table only presents hazardous properties relating to human health			

Due to lack of data, 25 manufacturers and suppliers have failed to classify retinol and retinyl palmitate as Reprtotoxic 1A/1B/2. It is unknown whether these manufacturers/suppliers are using Vitamin A in small or large quantities.

In order to address the issue of lack of data, some MS publish advisory lists for self-classification of dangerous substances. For example, the Danish Environmental Protection Agency (DK-EPA) publishes two lists for self-classification of chemical substances – with advisory classifications for more than 30,000 substances. The advisory classifications are based on predictions of dangerous properties of chemicals from computer models - the so-called (Q) SARs. [173]

Decisions on classification can also be taken at community (sectoral) level. For instance, the EU Association of Specialty Feed Ingredients and their Mixtures (FEFANA) classifies retinol as Repr. Cat 1B, Eye Irr. Cat 2, Skin Sens. Cat. 1 and retinyl palmitate as Repr. Cat 1B. [174]

[172] Summary of Classification and Labelling for Retinyl palmitate: https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/86754 and Summary of Classification and Labelling for Retinol: https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/119925

[173] Danish EPA, 2018, "The Advisory List for Self-classification of Dangerous Substances", available at: https://eng.mst.dk/chemicals/chemicals-in-products/assessment-of-chemicals/the-advisory-list-for-selfclassification/

[174] FEFANA, 2016, "FEFANA HARMONISED CLP-GHS FOR FEED ADDITIVES", available at: http://fefana.org/wp-content/uploads/2017/09/clp-ghs_harmonised_listing_fefana_REVISED-2016_06_30.pdf

X6.1.3 Scope of Pregnant Workers Directive and Young Persons at Work Directive

Pregnant Workers Directive (92/85/EC):

The objective of this Directive is to protect the health and safety of women in the workplace when pregnant or after they have recently given birth and women who are breastfeeding. Pregnant and breastfeeding workers may under no circumstances be obliged to perform duties for which the assessment has revealed a risk of exposure to agents, which would jeopardize their safety or health.[175]

The Directive concerns substances and mixtures which meet the criteria for classification under Regulation (EC) No 1272/2008 of the European Parliament and of the Council in one or more of the following hazard classes and hazard categories:

- germ cell mutagenicity, category 1A, 1B or 2 (H340, H341);
- carcinogenicity, category 1A, 1B or 2 (H350, H350i, H351);
- reproductive toxicity, category 1A, 1B or 2 or the additional category for effects on or via lactation (H360, H360D, H360FD, H360Fd, H360Df, H361, H361d, H361fd, H362);
- specific target organ toxicity after single exposure, category 1 or 2 (H370, H371).

As already mentioned above, the issue with Vitamin A is that it is self-classified by individual manufacturers and suppliers. The majority of manufacturers and suppliers, according to the C&L Inventory, have classified Vitamin A as Reprotoxic 1A/1B/2 and/or Lact. H362. However, there is a small number of notifiers who have failed to classify Vitamin A as having reproductive effects or effects via lactation due to lack of data (more specifically, 2 notifiers in case of retinol and 23 notifiers in case of retinyl palmitate[176]). The provisions of the PWD would therefore apply to the majority of manufacturers/suppliers of retinol, however not to all manufacturers/suppliers.

It is important to note, that the Pregnant Workers Directive (92/85/EC) is inconsistent in terms of prevention. Measures to avoid exposure do not have to be taken until the worker informs her employer that she is pregnant, which occurs around the 10th week of pregnancy. However, exposure to retinol (as well as other reprotoxins) during the early weeks of gestation can result in miscarriage or a higher risk of congenital defects. The Options of changing job or possibly taking leave from work, as recommended in the Directive, therefore come too late to prevent these risks. [177]

Young Persons at Work Directive (94/33/EEC):

This Directive[178] applies to any person under 18 years of age having an employment contract or an employment relationship defined by the law in force in a Member State and/or governed by the law in force in a Member State.

The Directive states that Member States shall prohibit the employment of young people for work involving harmful exposure to agents which are toxic, carcinogenic, cause heritable genetic damage, or harm to the unborn child or which in any other way chronically affect human health.

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[175] Directive 92/85/EEC - pregnant workers, available at : https://osha.europa.eu/en/legislation/directives/10

[176] This equals to 1% and 5% of total number of notifiers for retinol and retinyl palmitate, respectively.

[177] For instance, in the US a waiver needs to be signed, prior to Vitamin A prescription, that one understands the risk of getting pregnant and is on birth control.

[178] Directive 94/33/EC of 22 June 1994 on the protection of young people at work, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:01994L0033-20140325

Substances and mixtures which meet the above-mentioned criteria have the following hazard statements:

- acute toxicity, category 1, 2 or 3 (H300, H310, H330, H301, H311, H331);
- skin corrosion, category 1A, 1B or 1C (H314);
- flammable gas, category 1 or 2 (H220, H221);
- flammable aerosols, category 1 (H222);
- flammable liquid, category 1 or 2 (H224, H225);
- explosives, categories 'Unstable explosive', or explosives of Divisions 1.1, 1.2, 1.3, 1.4, 1.5 (H200, H201, H202, H203, H204, H205);
- self-reactive substances and mixtures, type A, B, C or D (H240, H241, H242);
- organic peroxides, type A or B (H240, H241);
- specific target organ toxicity after single exposure, category 1 or 2 (H370, H371);
- specific target organ toxicity after repeated exposure, category 1 or 2 (H372, H373);
- respiratory sensitisation, category 1, subcategory 1A or 1B (H334);
- skin sensitisation, category 1, subcategory 1A or 1B (H317);
- carcinogenicity, category 1A, 1B or 2 (H350, H350i, H351);
- germ cell mutagenicity, category 1A, 1B or 2 (H340, H341);
- reproductive toxicity, category 1A or 1B (H360, H360F, H360FD, H360Fd, H360D, H360Df).

The majority manufacturers and suppliers, according to the C&L Inventory, have classified Vitamin A as Reprotoxic 1A/1B and/or Skin Sens. 1 (H317), which would place it within the scope of the YWPD. Due to lack of data, some manufacturers/suppliers (more specifically 3 in case of retinol and 55 in case of retinyl palmitate[179]) have failed to classify Vitamin A as Reprotoxic 1A/1B and/or Skin Sens. 1 (H317). Therefore, the provisions of YPWD do not currently apply to these manufacturers/suppliers.

If all companies had to comply with requirements of the YPWD (for example as a result of harmonization of retinol's hazard classifications across all sectors and MSs), it would cause only minimal impacts. Based on responses to consultation, the majority of companies operating in the pharmaceutical and chemical industry do not employ young people under 18. Moreover, based on available data, workers in the EU are occupationally exposed to low concentrations of retinol, which are below the threshold for reprotoxic effects.

X6.1.4 Costs of retinol receiving additional CLH R 1A/1B/2/H362

Costs to be incurred by the companies as a result of retinol receiving an additional hazard classification for reprotoxic effects are likely to be minimal. The majority of companies manufacturing or importing retinol already classify it as R1A or R1B or R2 and/or H362. Therefore, these companies should already comply with the provision set by the PWD and YPWD.

Additional costs can include those of an update to the risk assessment. Given the very low exposure levels, it seems unlikely that the risk would not be "slight risk" and therefore there would be no changes required to the RMMs.

X6.1.5 Benefits of retinol receiving additional CLH R 1A/1B/2/H362

Workers in the EU are currently exposed to very low concentrations of retinol. The numbers of workers exposed and exposure concentrations are likely to decrease in the future. There are currently

[179] This equals to 1% and 12% of total number of notifiers for retinol and retinyl palmitate, respectively.

no cases of reprotoxic ill-health due to retinol at any realistic exposure level. Therefore, there is no benefit that can be costed.

In addition, the PWD is inconsistent in terms of prevention. The provisions of the Directive would be applied too late to prevent the risks resulting from occupational exposure to retinol (i.e. after the worker informs the employer about the pregnancy).

X6.2 Retinol impact assessment

This section will look at the impact of 5 of the Policy Options, 2, 3 and 3+, 4 and 5 as summarised below. The impact of each Option is considerably affected by the fact that seven Member States (Austria, Belgium, Czech Republic, Finland, France, Germany and Sweden) have already incorporated reprotoxins into their legislation covering carcinogens and mutagens.

X6.2.1 Summary of the Policy Options and case studies

Table X6-4: Retinol – summary of the Policy Options and case studies	
Policy Option	**Case study**
O1: Baseline (no changes to EU OSH legislation)	CS2: A chemical under the CAD receives CLH R 1A/1B/2/H362
O2: R 1A/1B in CMD (no derogations)	
O3: R 1A/1B in CMD (with derogations to do absolutely nothing if there is a threshold)	
O3+: R 1A/1B in CMD (with derogations to minimise to below threshold if there is a threshold) (Joint Declaration)	
O4: Merge CAD & CMD into a single directive but no modernisation	
O5: Merge CAD & CMD and modernise	

X6.3 Benefits

X6.3.1 Reduction in ill health

Workers in the EU are occupationally exposed to low concentrations of retinol, below the threshold for reprotoxic effects. There are currently no cases of reprotoxic ill-health due to retinol at any realistic exposure level. Therefore, there is no benefit that can be costed.

X6.3.2 Benefits to employers

No changes to productivity are anticipated for any Option. Minimal benefits resulting from administrative simplification are expected under Option 5. Under Option 5, the terminology would be modernised and put in line with that of REACH. Aligning terms with REACH could result in providing for more consistency of interpretation across MS, therefore benefiting companies with plants/operations in more than one MS.

X6.4 Costs

X6.4.1 Introduction

Under Options 2-5, companies may face both initial investment costs and ongoing annual operating costs for the following aspects of the requirements of the CMD:

- Complying with requirements for substitution;
- Complying with requirements for closed systems;
- Complying with minimisation requirements;
- >40 Year Record keeping; and
- Monitoring.

All enterprises in Member States that have already extended their CM legislation to cover reprotoxins are assumed to not be affected by any of the Options. The Member States that have already extended their CM legislation to cover reprotoxins are: Austria, Belgium, Czech Republic, Finland, France, Germany and Sweden. Based on available data, companies in Member States that have not extended are assumed to be operating at low exposure levels, which are below the threshold for reprotoxic effects.

Estimates of the number of enterprises manufacturing or using retinol by sector and size are presented below. Enterprises operating in MS which have already extended their CM legislation to cover reprotoxins are excluded (they account for approximately 10% of the agricultural sector and 38% of the manufacturing sectors).

Table X6-5: Number of companies manufacturing/using retinol												
Sector	Uses/activities	Total number of companies in the sector					Percentage of companies using the substance	Companies manufacturing/using Retinol				
		TOTAL	Micro	Small	Medium	Large		TOTAL	Micro	Small	Medium	Large
A1.4: Agriculture: Animal production *	Additive in animal feed	5,580,000	4,815,000		594,000	171,000	L: 80%	4,464,000	3,852,000		475,200	136,800
							H: 100%	5,580,000	4,815,000		594,000	171,000
C10: Manufacture of food products	Added for specific nutritional purposes to foods and food supplements	163,680	130,200	27,900	6,200	1,488	L: 6%	9,821	7,812	1,674	372	89
	Added as a nutritional additive to various types of animal feeds						H: 12%	19,642	15,624	3,348	744	179
C20: Manufacture of chemicals (in particular basic chemicals and cosmetics)	C20.1: Manufacture of retinol and retinyl palmitate	5,580	3,224	1,240	620	223	L: 5%	279	161	62	31	11
							H: 7%	391	226	87	43	16
	C20.4: Manufacture of cosmetic products	5,952	4,402	992	434	105	L: 2%	119	88	20	9	2
							H: 5%	298	220	50	22	5
C21: Manufacture of pharmaceutical products	Veterinary medicinal products and other medicinal products for the treatment of Vitamin A deficiency	2,852	1,389	595	508	335	L: 0.5%	14	7	3	3	2
	Retinoid medicines (for severe acne treatment)						H: 2%	57	28	12	10	7
TOTAL without agriculture: Low								**16,660**	**12,810**	**2,840**	**670**	**164**
TOTAL without agriculture: High								**33,230**	**25,780**	**5,600**	**1,320**	**336**

Source: Eurostat, Consultation

Numbers of companies manufacturing/using Retinol are estimates and were identified through literature review and consultation for this study.

*Very small and small farms are defined by a utilised agricultural area <20 hectares; medium farms are defined by a utilised area of >=20 and <100 hectares; large farms are defined by a utilised agricultural area >= 100

X6.4.2 One-off and operating costs and conduct of business

Costs for companies – direct compliance and administrative costs

Option 2: Costs will be incurred as a result of complying with requirements for substitution, closed systems, minimisation and record keeping. There are currently no OELs in place for retinol, therefore companies won't have to comply with the monitoring requirement.

Enterprises which are already operating at low exposure levels beneath the threshold are likely to consider substitution, closed systems and minimisation. However, the implementation of these requirements is likely to be considered not technically possible. The process of consideration will have to be documented for each requirement at an estimated annualised cost of €1,000 per enterprise per year. The total annualized costs for all enterprises that will have to consider substitutions, closed systems and minimisation are €50million – €100million.

Additionally, all enterprises will need to set up record keeping for 40 years at an annualised cost of €1,000 per enterprise, which equals to €16.6million-€33.2million.

Option 3: Nothing will change, unless the EU scientific committee confirms that retinol does not have a threshold for reprotoxic effects.

Option 3+: In addition to costs under Option 2, all enterprises (i.e. enterprises in MS with no OEL) will have to set up monitoring at an annualised cost of €2,000. This gives an additional cost for all enterprises of €33million-€66.5million.

Options 4&5: Direct compliance and administrative costs will be the same as under Option 2.

X6.4.3 Comparison of direct costs for companies by Option

Table X6-6: Retinol – comparison of total annualised costs for companies under each Option

Option	Substitution, closed systems and minimisation	Record keeping	Monitoring	Total
Option 2	€50m-€100m	€16.6m-€33.2m	0	**€66.6m-€133.2m**
Option 3	0	0	0	**0**
Option 3+	€50m-€100m	€16.6m-€33.2m	€33m-€66.5m	**€99.6m-€199.7m**
Option 4	€50m-€100m	€16.6m-€33.2m	0	**€66.6m-€133.2m**
Option 5	€50m-€100m	€16.6m-€33.2m	0	**€66.6m-€133.2m**
Sources: RPA analysis				

Costs for companies – indirect costs

Option 3: Nothing will change, unless the EU scientific committee confirms that retinol does not have a threshold for reprotoxic effects. Therefore, this Option will have no indirect effects upon companies.

Options 2, 3+, 4 and 5: No direct costs have been highlighted during consultation or identified as likely to result from including lead within the CMD.

Costs for public authorities

Options 2, 3, 3+, 4 and 5: Inclusion of retinol within the CMD could result in additional costs for public authorities should they need to inspect evidence to check compliance with the hierarchy of risk

management measures (substitution, use of closed systems and minimisation of exposure). There may also be the need to inspect risk assessments, but given the existing requirement for these under the CAD, there is not expected to be a significant additional cost burden beyond that already incurred. Public authorities may also be involved in ensuring compliance with the CMD requirement to keep records for 40 years.

X6.4.4 Trade and investment flows

Option 3: No effects upon companies as nothing changes.

Options 2, 3+, 4&5: exports and imports out of and into the EU are not expected to be changed significantly unless the OELs are set much lower than the threshold.

X6.4.5 Employment

Impacts on employment - companies leaving the EU, and going out of business

Option 3: No effects upon employment and companies will be observed.

Options 2, 3+, 4&5: no significant impacts are expected unless the OELs are set much lower than the threshold.

X6.4.6 Working conditions

None of the Options are considered likely to affect wages or employment

Annex 7 BLV Annex

X7.1 Cost of sample analysis

Table X7-1: Costs of analysis of samples (per sample) of selected chemical agents with BLVs				
Chemical agent	Analytical method(s)	Costs		
		Low	Average	High
Acetone (blood)	CPG-FID CPG-HS-FID CPG-HS-SM	€8.10 €32.40 €32.40	€24.12 €37.51 €84.80	€39.60 €45 €162
Acetone (urine)	CPG-FID CPG-HS-FID CPG-HS-SM	€13.50 €10.83 €32.40	€22.95 €25.80 €97.20	€32.40 €60 €162
Aniline (urine)	CPG-NPD CPG-SM/SM		€42.78 €81	
Aniline (methaemoglobin in blood)	SPEC-UV-Vis-IR CO-oximetry Colorimetry	€6.75 €6.75 €9.45	€8.83 €8.43 €10.13	€13.20 €10.80 €10.80
Arsenic (urine)	SAA-ET CL-ICP-SM ICP-SM SAA-hydride generation	€18.90 €17 	€45.63 €17.59 €39.51 €36.88	€100 €110
Benzene (S-phenylmercapturic acid in urine)	CL-SM/SM	€12	€32.84	€43.26
Benzene (T,t-muconic acid in urine)	HPLC-DAD HPLC-UV	€12 €26	€24.58 €32.04	€35 €40
Benzene (blood)	CPG-HS-SM CPG-HS-Tra-SM CPG-HS-FID	€17.55 €20.25	€54.39 €17.55 €40.13	€100 €60
Benzene (phenol in urine)	HPLC-UV CPG-HS-SM HLPC-Ionic CPG-FID HPLC-FLUO	€27	€30.06 €60 €40 €13.50 €30	€33.18
Beryllium and beryllium compounds	ICP-SM ICP-OES	€32.40	€35.10 €32.40	€40.50
Cadmium and its compounds (blood)	ICP-SM SAA-ET	€17 €24.30	€38.44 €27.15	€100 €30
Cadmium and its compounds (urine)	ICP-SM ICP-OES SAA-ET	€17 €24.30	€37.89 €32.40 €28.77	€110 €32
Carbon disulphide (TTCA in urine)	HPLC-UV	€20.25	€29.40	€38.54
Carbon monoxide (blood)	SPEC-UV-Vis-IR	€9.45	€9.45	€9.45
Carbon monoxide (carboxy haemoglobin in blood)	CO-oximetry SPEC-UV-Vis-IR Colorimetry	€8 €9.45 €9.45	€9.71 €9.83 €9.45	€10.85 €11.55 €9.45
Chlorobenzene	HPLC-UV		€50.13	
Chromium and its compounds (blood/urine)	ICP-SM SAA-ET	€17.59 €24.30	€35.94 €29.58	€60 €33

Table X7-1: Costs of analysis of samples (per sample) of selected chemical agents with BLVs				
Chemical agent	Analytical method(s)	Costs		
		Low	Average	High
Dichloromethane (carboxyhaemoglobin in blood)	CO-oximetry SPEC UV-Vis-IR Colorimetry	€8 €9.45 €9.45	€9.71 €9.80 €9.45	€10.85 €11.55 €9.45
Dichloromethane (in blood)	CPG-HS-Trap-SM CPG-ECD CPG-HS-SM CPG-HS-FID	 €32.40 €32.40	€41.15 €20.25 €79.85 €46.20	 €162 €60
Dichloromethane (in urine)	CPG-FID/PID CPG-HS-SM CPG-HS-FID CPG-HS-Trap-SM	 €32.40 	€26 €86.47 €32.40 €41.15	 €162
Ethylbenzene (mandelic acid in urine)	HPLC-DAD CPG-FID HPLC-UV	€12 €28.35	€19 €13.50 €44.33	€26 €80
Ethylbenzene (phenylglyoxylic acid in urine)	HPLC-DAD CPG-FID HPLC-UV	€12 €28.35	€19 €13.50 €34.41	€26 €43
Ethylbenzene (blood)	CPG-HS-Trap-SM CPG-HS-FID CPG-HS-SM	 	€41.15 €60 €32.40	
Hexachlorobenzene (blood)	CPD-ECD CPG-SM CPG-SM/SM	 	€154.50 €81 €50	
Hexachlorobenzene (urine)	CL-SM/SM		€32.40	
Lead and inorganic compounds	HPLC-FLUO SPEC-UV-Vis-IR Colorimetry	€27.44 €10 €19.83	€30.67 €17.55 €15.42	€33.89 €32 €20
Lindane (blood)	CPG-HS-SM CPG-SM/SM CPG-ECD CPG-SM	 	€150 €50 €154.50 €81	
MOCA	HPLC-UV		€40.86	
Mercury and compounds (blood)	ICP-SM SAA-ET SAA-CV	€17 €35.76	€36.04 €44 €37.88	€80 €40
Mercury and compounds (urine)	ICP-SM SAA-ET SAA-CV	€17 €25 €36.88	€42.86 €44 €34.50	€81 €44 €40
N,N-dimethly formamide	CPG-NPD CPG-SM	 	€42.78 €13.50	
n-hexane (total 2,5 hexanedione in urine)	CPG-FID	€13.50	€34.25	€55
n-hexane (2-hexanol in urine)	CPG-HS-FID		€13.50	
n-hexane (urine)	CPG-HS-SM CPG-HS-FID	€32.40 	€91.10 €37.80	€162
n-hexane (blood)	CPG-HS-SM	€32.40	€91.10	€162
N,N-dimethylformamide (urine)	CPG-NPD CPG-SM	 	€42.78 €13.50	
Nickel and its compounds (blood)	ICP-SM SAA-ET	€17 €24.30	€29.91 €28.90	€40.50 €32.40

Table X7-1: Costs of analysis of samples (per sample) of selected chemical agents with BLVs				
Chemical agent	Analytical method(s)	Costs		
		Low	Average	High
Nickel and its compounds (urine)	ICP-SM ICP-OES SAA-ET	€17 €24.30	€28.82 €27 €32.30	€40.50 €32.40
Nitrobenzene (methaemoglobin in blood)	SPEC-UV-Vis-IR Colorimetry CO-Oximetry	€6.75 €9.45 €6.75	€8.83 €10.13 €8.43	€13.20 €10.80 €10.80
Nitrobenzene (p-nitrophenol in urine)	CL-SM/SM HPLC-UV		€108 €50.13	
Parathion (acetylcholinesterase erythrocyte in blood)	ENZ SPC Uv-Vis-IR	€18.90	€21 €27	€27
Parathion (p-nitrophenol in urine)	HPLC-UV CL-SM/SM		€50.13 €108	
Phenol (urine)	HPLC-FLUO HPLC-UV HPLC-ionic CPG-FID	€27	€30 €30.06 €40 €14	€33.18
Styrene (mandelic acid in urine)	HPLC-DAD HPLC-UV CPG-FID	€12 €28.35	€19 €43.24 €13.50	€26 €80
Styrene (phenylglyoxylic acid in urine)	HPLC-DAD HPLC-UV CPG-FID	€12 €28.35	€19 €35.09 €13.50	€26 €43
Styrene (blood)	CPG-HS-Trap-SM CPG-HS-FID		€41.50 €60	
Tetrachloroethene (blood)	CPG-HS-FID CPG-HS-ECD CPG-HS-Trap-SM CPG-HS-SM	€37.80 €32.40	€48.90 €20.25 €41.15 €44.13	€60 €60
Tetrachloroethene (trichloroacetic acid in urine)	CPG-HS-SM SPEC UV-Vis-IR CPG-ECD CPG-HS-FID CPG-SM/SM	€32.40 €10 €13.50	€44.27 €21.96 €36.75 €37.80 €40.50	€55 €35 €60
Toluene (hippuric acid in urine)	HPLC-DAD HPLC-UV	€12 €13.50	€21.67 €30	€27 €40
Toluene (*o*-cresol in urine)	CPG-FID CPG-HS-SM HPLC-FLUO CPG-SM UPLC-UV HPLC-UV		€30 €60 €50 €53.89 €17.58 €32.40	
Toluene (blood)	CPG-HS-SM CPG-HS-Trap-SM CPG0HS-FID	€32.40 €20.25	€58.10 €41.15 €40.13	€100 €60
Trichloroethene (trichloroacetic acid in urine)	SPEC-UV-Vis-IR CPG-HS-SM CPG-ECD CPG-Sm/SM CPG-HS-FID	€10 €32.40 €13.50	€21.96 €44.27 €36.75	€35 €55 €60
Trichloroethene (trichloroethanol in blood)	CPG-HS-Trap-SM SPEC-UV-Vis-IR		€41.15 €13.50	

Table X7-1: Costs of analysis of samples (per sample) of selected chemical agents with BLVs				
Chemical agent	Analytical method(s)	Costs		
		Low	Average	High
	CPG-HS-FID CPG-HS-SM		€32.40 €32.40	
Trichloroethene (trichloroethylene in blood)	CPG-HS-Trap-SM CPG-HS-FID CPG-HS-SM CPG-HS-ECD	 €32.40 €32.40	€41.15 €46.20 €46.20 €20.25	 €60 €60
Xylene (methylhippuric acid in urine)	HPLC-DAD HPLC-UV	€12 €13.50	€21.67 €29.58	€27 €37
Xylene (blood)	CPG-HS-Trap-SM CPG-HS-SM CPG-HS-FID	 €32.40 €20.25	€41.45 €46.20 €40.13	 €60 €60
Notes: For the full list of analytical methods and explanation of the acronyms please see INRS (2015): Liste des abréviations, available at: http://www.inrs.fr/dms/biotox/DocumentCompagnon/DocCompagnon_6-1/ListeDesAbreviations.pdf on 22 September 2016				

X7.2 Assumptions used in modelling of costs of biomonitoring and air monitoring

In relation to staff costs, high and low estimates[180] were developed to reflect these differences, and variation by a factor of 2 was assumed.

For the cost comparison, analysis of TCE in urine is assumed to be performed by an external company. Analysis of urine rather than blood samples is used, since the conversion to TCE concentrations in air is based on this parameter.

Table X7-2: Assumptions for estimating biomonitoring costs	
Item	Assumption
Costs for 1 workday (company EHS staff)	€150 - 300[181]
Costs for 1 workday (external contractors)	€400 - 800[182]
No. of samples	10/year
Work effort – preparation of monitoring plan	4 staff members x 2 meetings x 1 hour each = 1 workday
Work effort - sampling	2 hours (1/4 workday) total for 10 samples
Packaging and shipping samples to laboratory	€50 lump sum
Cost of analysis	€38 - €75[183]
Conversion of TCA into TCE concentration and evaluation/interpretation	1 workday

The overall estimate for biomonitoring is presented in the following table.

[180] These may be envisaged to represent e.g. Scandinavian Member States on the one hand and Eastern European Member States on the other hand.

[181] Based on monthly salaries ranging from €3,000 to €6,000 and 20 workdays per month, lab technicians at 60%

[182] Based on experience from working with laboratories performing occupational monitoring.

[183] Rounded values, based on high figure of a source in Germany and low figure of 60% of this

Table X7-3: Estimates for TCE monitoring at the workplace: biomonitoring		
Parameter	**Costs [€]**	**Source/Assumption**
Preparation	150 - 300	1 workday company EHS staff
Sampling	38 - 75	1/4 workday company EHS staff
Shipment	50	Estimate
Analysis: TCA in urine, analytical determination, 10 samples	373 - 621	IPASUM[184] for high estimate; low estimate assumed to be 60%
Evaluation and interpretation	150-300	1 workday company EHS staff
Total estimated costs	**761 - 1,346**	

These estimates for biomonitoring are then compared with similar estimates for air monitoring under two scenarios:

- Scenario 1: sampling and analysis within the company itself
- Scenario 2: sampling and analysis by an external contractor

Assumptions made for developing costs from air monitoring are presented in the table below.

Table X7-4: Assumptions for estimating air monitoring costs	
Item	**Assumption**
Costs for 1 workday (company EHS staff)	€150 - 300
Costs for 1 workday (lab technicians)	€90 - €180
Costs for 1 workday (external contractors)	€400 - 800
No. of samples	10/year
Work effort – preparation of monitoring plan	4 staff members x 2 meetings x 1 hour each = 1 workday
Work effort - sampling	Scenario 1: 1 workday (EHS staff) Scenario 2: 1 workday (External staff)[185]
Work effort - analysis	Scenario 1: 1/4 workday lab technician
Consumables – per sample	Scenario 1: €10
Cost of analysis – per sample	Scenario 2: €45 - €75[186]
Evaluation and interpretation	1 workday

The overall estimate for air monitoring is presented in the following table.

Table X7-5: Estimates for TCE monitoring at the workplace: air monitoring			
Parameter	**Costs (€)**		**Source/Assumption**
	Scenario 1	**Scenario 2**	
Preparation	150-300	150-300	1 workday company EHS staff
Sampling	150-300	400-800	1 workday company EHS staff/external contractor
Analysis: TCE in air, 10 samples	23-45 (labour) 100 (consumables)	450-750	Scenario 1: 1/4 workday lab technician + material Scenario 2: Quote[187] for high estimate; low estimate assumed to be 60%
Evaluation and interpretation	150-300	150-300	1 workday company EHS staff

[184] Institut und Poliklinik für Arbeits-, Sozial- und Umweltmedizin der Universität Erlangen-Nürnberg, Price list, http://www.arbeitsmedizin.uni-erlangen.de/biomonitoring/Preisliste.pdf, accessed 26 October 2016.

[185] Assumed no additional travel costs for external staff

[186] €75 represents quote from German accredited laboratory. Low estimate is 60% of this. Estimate for Scenario includes any equipment required

[187] Price obtained from a German laboratory accredited for workplace monitoring, 26 October 2016.

Table X7-5: Estimates for TCE monitoring at the workplace: air monitoring			
Parameter	Costs (€)		Source/Assumption
	Scenario 1	Scenario 2	
Total estimated costs	**573-1,045**	**1,150-2,150**	

It is noted that the above costs for air monitoring are for basic air monitoring only and do not account for additional costs that might be associated with accounting for personal protective equipment (PPE) and which would require the worker to wear a second sampling device. In the event that this type of monitoring is required, the costs would be substantially higher, since more air monitoring samples are required and the workload is also higher.

X7.3 Consent to testing and data handling

It is noted that the information provided below come from a combination of consultation responses and literature review in the identified source study.

Table X7-6: Consent from workers to biomonitoring and sharing of data		
Member State	Workers' consent to testing	Workers consent to sharing of data
Austria	The employee does not have to give consent before a sample is given.	Consent is required before the individual test results are shared with the employer.
Bulgaria	Mandatory initial and periodic examinations and biomarkers are binding under the national legislation and do not involve and allow agreement or disagreement of the worker.	The test results become part of the medical records of the worker and the employer is familiar with them.
Croatia	The Law and Ordinance does not prescribe that the consent has to be given by the employee for testing. The employer's practice, by the words of occupational safety and health experts, is such that they consider taking samples as their duty, according to the Law and Ordinance, and that they do not ask for consent from the workers but rather consider this as their duty to give a requested sample.	
Denmark	An employee has to give consent before each sample is given, i.e. every time a sample is taken.	The employee does not have to give consent before individual test results are shared with the employer. The employee can ask the employer for details of the results of the blood test. On request employees have the right to be informed about the result of their own blood samples. Results can only be shared, other than with the safety organisation, if the employee gives their consent.
Estonia		The occupational health specialist informs the employer about the results, that lead content in employee blood exceeds limits and that the employer needs to take action. However, the exact results of the analysis are not shared with employer

Table X7-6: Consent from workers to biomonitoring and sharing of data		
Member State	**Workers' consent to testing**	**Workers consent to sharing of data**
Finland	Consent is required from employees before a sample is taken	Consent is required from employees before the individual test results are shared with the employer. It is assumed that consent, once given, is valid until it is withdrawn.
Germany	Employees have to give their consent before each sample is taken. The methods used for testing must be diagnostically specific and sensitive enough for the purpose and acceptable to the employee.	Employees have to give consent before the test results are shared with their employer
Greece	Employees have the obligation to cooperate with the occupational doctor and the safety technician	
Hungary	A worker does not have to give consent before a sample is taken. Workers cannot refuse to give consent.	A worker does not have to give consent before the results are shared with their employer.
Ireland	Employees must give informed consent (i.e. the sampling procedure must be explained and acceptable) when biological samples are taken.	
Italy	The Italian legislation does not mention that the employee has to give consent before a sample is given	The Italian legislation does not mention that the employee has to give consent before individual test results are shared with the employer. However, the process is subject to the physician–patient confidentiality principle and to the data protection framework
Latvia	A worker does not have to give consent before a sample is taken	A worker does not have to give consent before the results are shared with their employer
Lithuania		At the employee's request, the employer must grant access to data of an existing medical examination and a study of chemical agents in the workplace.
Romania	Workers are obliged to undergo a health examination	Health records are subject to the right to confidentiality of information and privacy of the patient and are kept by the health care professional
Slovakia	Employees have to give their consent before each sample is taken	Employees have to give consent before the test results are shared with their employer
Spain	The employee has to give consent before a sample is given	The employee has to give consent before individual test results are shared with the employer
Sweden	In the provisions there is no indication if employees have to give consent before a sample is given	
UK	Employees are legally obliged to provide blood or urine samples. Informed consent from the employee is needed for samples to be taken.	Consent from the employee must be sought before the results of the biological monitoring are shared with the employer. In instances where the blood-lead concentrations have reached or exceeded the binding BLV, the employer should be informed immediately; however, it is not clear whether in this instance consent has to be sought

Table X7-6: Consent from workers to biomonitoring and sharing of data		
Member State	**Workers' consent to testing**	**Workers consent to sharing of data**
Source: RPA, second study to collect updated information for a limited number of chemical agents with a view to analyse the health, socio-economic and environmental impacts in connection with possible amendments of Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work, January 2017, Final Report		

X7.4 Strengths and weaknesses of biomonitoring

Table X7-7: Feedback from consultation on the strengths and weaknesses of biomonitoring	
Positive aspects associated with biomonitoring	**Negative aspects associated with biomonitoring**
Feedback from Companies	
Biological orientation values would be helpful and could bridge the gap between risk assessment which reflects the usual work activities and personal considerations.	Control must deliver no exposure, rather than trying to evaluate levels of material present in a biological substrate, difficult to interpret, unclear what it means to the worker.
Biological Limit Values (BLVs) or Biological Guidance Values (BGVs) are very useful for exposure assessment as they take into account the real exposure of workers to a substance by integrating all the exposure pathways.	
Feedback from Member State authorities	
Where appropriate (based on scientific knowledge): introduction of biological monitoring and biological limit values next to (B)OELs	Absolute priority must be the monitoring of substance concentrations in the air and, if necessary, on surfaces. No investigations on the body of employees. Physical Investigations lead to the selection of the "Suitable" and to dismiss the "Unsuitable"; they can also serve as a "blame the worker" strategy.
Biological values might be taken into consideration and be an argument that exposure and hygienic conditions are compliant	In practice, there is mostly no improvement in working conditions due to the results of biomonitoring. Measures to reduce concentrations in blood or urine are not taken
Gives the opportunity to assess the overall systemic dose from all routes of exposure (not just inhalation exposure) and from different work tasks, and to distinguish differences in individual exposure and risk (e.g. due to different hygiene habits; individual differences in toxicokinetics and susceptibility). If there are suitable biomarkers, they may be a more accurate risk indicator.	Long-term workers with high concentrations measured in their urine/blood leave their jobs to be replaced with new ones who starts with low concentrations but they increase over time
BLVs or BGVs are useful indicators for both Authorities and employers to compliment occupational limit values or in the absence of OELVs.	In extreme cases, where biomonitoring leves are very high, workers are replaced with someone who has not been involved with the task and has a low concentration level. Working conditions and protective measures do not improve.
Introducing BLVs or BGVs is important for early diagnosis of diseases when there are no clinical signs yet	Biological guidance values should not be set under CMD. These values are not linked to health-based effects. Exceeding the guidance value per se does not indicate any hazard and therefore there can't be any requirements for employers. The whole concept is quite confusing and setting BGVs might just cause confusion.

Table X7-7: Feedback from consultation on the strengths and weaknesses of biomonitoring	
Positive aspects associated with biomonitoring	**Negative aspects associated with biomonitoring**
Biomonitoring can also detect dermal load. For different substances, no air limit can be derived.	Due to the individual enzyme, not every substance has an identical effect in all humans.
	The introduction of BLV values as legally binding in Member State X is currently not possible due to the lack of laboratories performing biological material analysis.
Feedback from OSH Experts	
It is a valuable tool to assess the whole exposure to toxic agent, including all routes (inhalation, skin absorption, ingestion).	Agreement of the employee is often presumed rather than expressly given
Biomonitoring for lead has been widely accepted and is legally enforced	Improvements in working conditions rarely happens as a consequence of biomonitoring results
	If biomonitoring elicits concentrations in urine or blood which are too high, the time intervals between biomonitoring are shortened
Feedback from Industry associations	
When other routes of exposure (except inhalation) are considered/of relevance to address risks, the use of biological monitoring is an option for showing compliance with all risk management measures stated e.g. in the CMD. Therefore, the introduction of Biological Limit values (BLV) or Biological Guidance Values (BGVs) is a valuable addition.	BLV are subject to a lot of bias and situations outside the work environment.
Is an option for comprehensive exposure assessment	
If other routes of exposure (with the exception of Inhalation) are considered to be risk-relevant, biological monitoring is a way of demonstrating compliance.	

X7.5 BLVs in Member States for CMR substances

Table X7-8: Numbers of BLVs for CMR substances in Member States	
Member State	**BLVs for CMR Substances**
Austria	1
Belgium	1
Bulgaria	17
Croatia	48
Cyprus	1
Czech Republic	6
Denmark	1
Estonia	1
Finland	14
France	3
Germany	53
Greece	1
Hungary	21
Ireland	49

Table X7-8: Numbers of BLVs for CMR substances in Member States	
Member State	**BLVs for CMR Substances**
Italy	2
Latvia	10
Lithuania	1
Luxembourg	1
Malta	1
Netherlands	1
Poland	36
Portugal	1
Romania	52
Slovakia	41
Slovenia	50
Spain	45
Sweden	2
United Kingdom	19

X7.6 BLVs for lead identified in Member States

Table X7-9: Limit values and media for lead in Member States	
Member State	**Limit values and media**
Austria	70 µg Pb/100 ml in blood (men, women >50 years) 45 µg Pb/100 ml in blood (women <50 years)
Belgium	70 µg Pb/100 ml in blood
Bulgaria	Lead in blood: 400 µg/l (sampling time not fixed)
Bulgaria	Lead in blood (women under 45): 300 µg/l
Croatia	Pb 70 µg/100 ml of blood
Croatia	Lead in blood: 70 mcg Pb/100 ml blood (sampling time is not critical)
Croatia	Lead in urine: 43.68 mmol/mol creatinine (80 mg/g creatinine) (one-time sample or urine collected during 24 hours)
Croatia	Dehydratase aminovulenic acid in blood: 15 U/LE (sampling time is not critical)
Croatia	Protoporphyrin in erythrocytes in blood: 2.67 mmol/LE (1.50 mg/LE)
Cyprus	70 µg/100 ml lead in blood
Czech Republic	Lead in blood: 400 µg/l
Czech Republic	Delta-aminolevulinic acid in urine: 13 µmol/mmol creatinine or coproporphyrin in urine (sampling time not critical)
Czech Republic	0.035 µmol/mmol creatinine
Czech Republic	0.4 mg/l plumbaemia
Denmark	20 µg Pb/100 ml blood
Finland	50 µg/dl in blood (binding)
Finland	1.4 µmol/l (Blood-lead) (specimen can be collected at any time of day)
France	Lead in blood: 400 µg/l (male) and 300 µg/l (female)
Germany	400 µg/l (women >45 years and men) in whole blood, no restriction on sampling time
Germany	300 µg/l (women <45 years) in whole blood, no restriction on sampling time
Greece	Lead in blood: 70 µg/100 ml
Hungary	Lead in blood: 400 µg/l (men and women > 45 years old) (sampling time not critical)
Hungary	Lead in blood: 300 µg/l (women younger than 45 years old) (sampling time not critical)

Table X7-9: Limit values and media for lead in Member States	
Member State	**Limit values and media**
Hungary	Zinc protoporphyrin in blood (in case of more than three months of exposure): 120 µmol/mol Hb (men and women older than 45 years) or 100 µmol/mol Hb (women younger than 45 years)
Ireland	70 µg Pb/100 ml blood
Ireland	Lead in blood: 70 µg/100 ml (sampling time not critical)
Italy	60 µg/100 ml or 40 µg/100 ml for female workers of childbearing age
Latvia	in blood is 40 µg Pb/100 ml
Lithuania	70 µg/10 ml of blood
Luxembourg	70 µg PB/100 ml of blood, including measure of lead by absorption spectrometry or a method that gives equivalent results
Malta	70 µg Pb/100 ml blood
Netherlands	Lead in blood: 70 µg/dl (male) and 70 µg/dl (female)
Netherlands	Value not provided
Poland	Lead in blood: 50 µg/dl (males and females)
Portugal	Lead n blood: 70 µg/l (males and females)
Romania (obligatory)	Lead in urine: 150 µg/l (at end of shift)
Romania (obligatory)	Lead in blood: 40 µg/100 ml (at end of shift)
Romania (obligatory)	Lead in hair: 3 µg/cm (at end of shift)
Romania (obligatory)	ALA-u in urine: 10 mg/l (at end of shift)
Romania (obligatory)	CP-u in urine: 300 µg/l (at end of shift)
Romania (obligatory)	PEL in blood: 100 µg/100 ml erythrocyte (at end of shift)
Slovakia	400 µg/l lead in blood, no restriction on sampling time 100 µg/l lead in blood, no restriction on sampling time (women < 45 years old)
Slovakia	15 mg/l aminolevulinic acid in urine, no restriction on sampling time 6 mg/l aminolevulinic acid in urine, no restriction on sampling time (women < 45 years old)
Slovakia	0.30 mg/l coproporphyrin in urine, no restriction on sampling time
Slovenia	Lead in blood (male): 1.93 µmol/l (400 µg/l) Lead in blood (women): 1.45 µmol/l (300 µg/l) (sampling time is not critical)
Slovenia	Lead in urine: 43.68 mmol/mol creatinine (80 mg/g creatinine) (one-time sample or urine collected during 24 hours)
Slovenia	Dehydratase aminovulenic acid in blood: 15 U/l E (sampling time is not critical)
Slovenia	Protoporphyrin in erythrocytes in blood: 2.67 mmol/LE (1.50 mg/LE)
Spain	Pb in blood: 70 µg/dl (sampling time not critical)
Sweden	Men and women >50 years old: Pb in blood of < 1.5 µmol/l (prior to work)
Sweden	Women <50 years old: <0.8 µmol/l (prior to work)
UK	Lead in blood: 60 µg/dl (males0 and 30 µg/l (females)
Source: RPA, second study to collect updated information for a limited number of chemical agents with a view to analyse the health, socio-economic and environmental impacts in connection with possible amendments of Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work, January 2017, Final Report	

X7.7 Additional BLVs from the longer list of repro 1A/1B substances developed earlier in the study (659 substances)

Table X7-10: List of BLVs for reprotoxins in addition to the 27 focal substances						
CAS Number	Name	Member States that have a BLV for this agent	BLV by medium			
			Blood		Urine	
			Value	Units	Value	Units
630-08-0	Carbon monoxide	Bulgaria, Croatia, Germany, Hungary, Ireland, Poland, Romania, Slovakia, Slovenia, Spain, UK	3.5% 5% 12.5	% carboxy haemoglobin in blood ml/l carboxy haemoglobin		
71-48-7, 6147-53-1	Cobalt	Bulgaria, Hungary, Ireland, Romania, Slovakia, Spain	1	µg/l	30 15 0.03	µg/l µg/l mg/g creatinine
7439-96-5	Manganese	Romania			10	µg/l
7439-97-6	Mercury	Bulgaria, Croatia, Finland, Germany, Hungary, Ireland, Latvia, Poland, Romania, Slovakia, Slovenia, Spain, UK	30 10 15 100 50 15	µg/ml µg/l µg/l µg/l nmol/l µg haemoglobin/l	140 5 20 25 30 35 50	nmol/l µmol/mol creatinine µmol/mol creatinine µg/g creatinine µg/g creatinine µg/g creatinine µg/g creatinine
67-56-1	Methanol	Croatia, Germany, Poland, Slovakia, Slovenia, Spain			7 6 15 30	mg/g creatinine mg/l mg/l mg/l
127-19-5	N,N-dimethylacetamide	Germany, Ireland, Romania, Spain, UK			30 100	mg/g creatinine mmol/mol creatinine
98-95-3	Nitrobenzene	Croatia, Germany, Hungary, Ireland, Poland, Romania, Slovakia, Slovenia, Spain	0.8% 1.5% 5% 100	Methameoglobin in blood µg/l in erythrocyte fraction	5.0	mg/g creatinine
100-42-5	Styrene	Bulgaria, Croatia, Finland, Germany, Hungary, Ireland, Italy, Latvia, Poland,	 20 0.2 0.55	Styrene: g/l mg/l mg/l	 235 240 400	Mandelic and phenylglyoxlic acids: mg/g creatinine mg/g creatinine

Table X7-10: List of BLVs for reprotoxins in addition to the 27 focal substances						
CAS Number	Name	Member States that have a BLV for this agent	BLV by medium			
			Blood		Urine	
			Value	Units	Value	Units
		Romania, Slovakia, Slovenia, Spain			600 800 1000 0.8 1 1.2	mg/g creatinine mg/g creatinine mg/g creatinine mg/g creatinine g/g creatinine g/g creatinine mmol/l
13494-80-9	Tellurium	Romania	20	µg/l		
108-88-3	Toluene	Bulgaria, Croatia, Finland, France, Germany, Hungary, Ireland, Latvia, Poland, Romania, Slovakia, Slovenia, Spain	0.02 0.05 0.08 20 600 1.0 500	mg/l (prior to last shift) mg/l (end of work week) mg/l (at end of day) µg/l (at start of week) µg/l (end of work shift) mg/l (end of work shift) nmol/l	 1.6 2.5 2 0.5 1 0.3 1.5 3	Hippuric acid: g/g creatinine g/g creatinine g/l *o*-cresol: mg/g creatinine mg/g creatinine µg/g creatinine mg/l mg/l o-cresol in urine: 0,6 mg/g creatinine Toluene in urine: 0,08 mg/l
1330-20-7	Xylene	Croatia, Finland, Germany, Hungary, Ireland, Poland, Romania, Slovakia, Slovenia, Spain, UK	 1.5 1.5	Xylene: mg/l g/g	 1 1.4 1.5 1500 650 5 2000 3	Methyl hippuric acid: g/g creatinine g/g creatinine g/g creatinine mg/g creatinine mmol/mol creatinine mmol/l mg/l g/l
Source: RPA, Second study to collect updated information for a limited number of chemical agents with a view to analyse the health, socio-economic and environmental impacts in connection with possible amendments of Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work, January 2017, Final Report Note: Additonal limit in Spain includes CO in alveolar air (final fraction of exhaled air) - 20 ppm						

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