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

EXECUTIVE SUMMARY

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

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EXECUTIVE SUMMARY

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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 most costly option as a large number of companies would have to demonstrate compliance with the BOELVs. The costs under Option 3 are likely to be lower but, in the absence of scientific evaluations for all the relevant substances, it is not possible to determine which specific substances would be subject to CMD requirements. In addition, under Option 3, the costs and benefits would be staggered over time.

Under Options 2, 3, 3+, 4 and 5, the method of extending the CMD to cover Reprotoxic 1A/1B 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

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